A Non Invasively Extendible 
Endo-prosthetic Replacement

A thesis submitted to the University of London for the degree of 
Doctor of Philosophy in the Faculty of Engineering by:

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ABSTRACT

An endo-prosthetic replacement (EPR) has been developed that can be lengthened under control from outside the body. This EPR is for use with child bone tumour cases and is to be surgically implanted to replace a section of bone, usually including a joint, which has been resected as part of the treatment for a bone tumour occurring in one of the long bones of a limb. The EPR includes an extendible module that can be adapted for individual patients by the addition of alternative types of artificial joint to suit various tumour sites. The extendible module may be lengthened at frequent intervals during the child’s growth years to maintain limb length symmetry. The non-invasive method of lengthening is considered to be a marked improvement on current methods that require a surgical operation each time an extendible EPR requires to be lengthened.

Placing the limb into a rotating magnetic field actuates extension. This field acts on a small magnet sealed within the extendible module of the EPR and induced rotation of this magnet drives reduction gearing that turns a power screw to extend telescopic sections. The extension force is sufficient to overcome the expected resistance of body tissues and the extension may be in sufficiently small increments to avoid pain or excessive joint stiffness. Extension can be reversed if necessary.

This study considers alternative extension methods and details the reasons for the final selection of the magnetic drive. The study then covers the detailed design of the various elements of the system including a compact and robust gearing mechanism and the equipment that generates the rotating magnetic field.

The complete system has been constructed in prototype form and the study is concluded with tests demonstrating that the magnetic drive is capable of reliably extending the telescopic sections of the EPR against simulated in-vivo loading.
ACKNOWLEDGEMENTS

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North Parade
Horsham
West Sussex
RH12 2DP

**Wishbone Trust**
British Orthopaedic Association
34-35 Lincoln's Inn Fields
London
WC2A 3PN

I am grateful to the late Professor David Broome and to Dr Alistair Greig, both of the Mechanical Engineering Department of University College London, who have given advice in the preparation of this thesis. I also acknowledge the foresight of Professor John Scales, former Head of Department at the Centre for Biomedical Engineering, Stanmore, who identified the medical requirement for a non-invasively extendible endo-prosthetic replacement for use with bone tumour patients and who initiated the first feasibility study for such a device.
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**ABRIEVIATIONS**

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<th>Abbreviation</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>ADC</td>
<td>Analogue to digital converter</td>
</tr>
<tr>
<td>EPR</td>
<td>Endo-prosthetic replacement</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and drugs administration</td>
</tr>
<tr>
<td>FEA</td>
<td>Finite element analysis</td>
</tr>
<tr>
<td>GRP</td>
<td>Glass reinforced plastic</td>
</tr>
<tr>
<td>HA</td>
<td>Hydroxyapatite (a bio-active ceramic used to coat orthopaedic implants)</td>
</tr>
<tr>
<td>IM</td>
<td>Intra-medulary (located within the intra-medulary canal)</td>
</tr>
<tr>
<td>PC</td>
<td>Personal computer</td>
</tr>
<tr>
<td>PMMA</td>
<td>Poly-methyl-methacrylate (a principle constituent of the bone cement most commonly used in orthopaedic surgery)</td>
</tr>
<tr>
<td>NRPB</td>
<td>National Radiological Protection Board</td>
</tr>
<tr>
<td>RMS</td>
<td>Root mean square</td>
</tr>
<tr>
<td>THR</td>
<td>Total hip replacement</td>
</tr>
<tr>
<td>TKR</td>
<td>Total knee replacement</td>
</tr>
<tr>
<td>UHMWP</td>
<td>Ultra high molecular weight polyethylene</td>
</tr>
</tbody>
</table>
# MEDICAL TERMINOLOGY

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior</td>
<td>Located towards the front of the body, ie. the toes are anterior to the ankle.</td>
</tr>
<tr>
<td>Condyle</td>
<td>Curved surface at the distal end of the femur. The two condyles of the femur carry the load transmitted through the knee from the tibia.</td>
</tr>
<tr>
<td>Distal</td>
<td>Located away from the heart – i.e. the distal femur is the lower part of the femur.</td>
</tr>
<tr>
<td>Femur</td>
<td>The main bone of the thigh</td>
</tr>
<tr>
<td>Humerus</td>
<td>The main bone of the upper arm</td>
</tr>
<tr>
<td>Intra-medulary canal</td>
<td>The region in the centre of the large bones of the limbs, these regions containing soft non-structural material.</td>
</tr>
<tr>
<td>Lateral</td>
<td>Located away from a vertical plane passing centrally through the body in a back to front direction – i.e. the little toe is lateral to the big toe.</td>
</tr>
<tr>
<td>Medial</td>
<td>Located towards a vertical plane passing centrally through the body in a back to front direction - i.e. the big toe is medial to the little toe.</td>
</tr>
<tr>
<td>Metastasis</td>
<td>Secondary tumours caused by the spread of cancer through the body.</td>
</tr>
<tr>
<td>Posterior</td>
<td>Located towards the rear of the body, ie. the ankle is posterior to the toes.</td>
</tr>
<tr>
<td>Proximal</td>
<td>Located towards the heart – i.e. the proximal tibia is the upper part of the tibia.</td>
</tr>
<tr>
<td>Tibia</td>
<td>The main bone of the leg below the knee</td>
</tr>
<tr>
<td>Resect</td>
<td>Cut away by surgery</td>
</tr>
</tbody>
</table>
Section 1 MEDICAL BACKGROUND

This section outlines the application of endo-prosthetic replacements (EPRs) in bone tumour treatment for children, gives a brief history of development to date and describes some of the main features that are applicable to both the extendible and non-extendible versions of these devices.

1.1 The application for extendible Endo-prosthetic replacements

An endo-prosthetic replacement (EPR) is an artificial structure that is surgically implanted in the body to replace natural bone. The implant of an EPR is one of the main methods of salvaging limb function following surgical resection of a malignant bone tumour. For adult patients, a fixed length EPR is used, but for child patients an extendible EPR is required so as to maintain limb length symmetry as the child grows. The great majority of extendible EPRs currently in use are extended by means of periodic surgical operations that are traumatic for the patient and can lead to infection and other complications as well as being costly for the health services. This project is the development of a non-invasively extendible EPR, that is an EPR that having been implanted can be extended in length from outside the body without the need for further surgery. There is a compelling medical requirement for such a device, the availability of which could potentially eliminate the need for a considerable number of surgical operations. The advantages of non-invasive extension of bone tumour EPRs are further discussed in section 1.11.

Although the immediate application for the methods considered in this study is in the treatment of bone tumours in children there may be further medical applications for comparable devices. The method of extension could be applicable wherever an implanted device is occasionally required to produce a slow movement against substantial loading.
1.2 Bone tumours

Bone tumours are a form of cancer and can be malignant. Malignant bone tumours grow invasively and if untreated can catastrophically disrupt the structure of the bone and can also form metastases leading to further cancer elsewhere in the body, particularly in the lungs.

In the UK, treatment for bone tumours is available at two specialist centres:

- London Bone Tumour Service, based at the Royal National Orthopaedic Hospital, Stanmore.
- Birmingham Bone Tumour Service, based at the Royal Orthopaedic Hospital, Birmingham.

Prior to about 1975 the treatment of malignant bone tumours affecting one of the main bones of a limb was generally by amputation of the affected limb. The overall five-year survival rate in this era was reported to be less than 20% for both osteosarcoma cases [Bramwell et al, 1992 #2] and Ewing's sarcoma cases [Jaffe et al, 1976 #27] [Nesbit et al, 1990 #41].

In recent years there has been great advance in cancer treatment. The majority of bone tumour cases in the western world can now be successfully treated using radiotherapy and chemotherapy. It is then necessary either to amputate the affected limb or to resect the tumour and adjacent bone and to attempt to salvage at least partial function of the affected limb. The five-year survival rates for such treatments have been reported to be 64% for osteo-sarcoma cases [Bramwell et al, 1992 #2] and 77% for Ewing's sarcoma [Burgert et al, 1990 #4].

The limitations of the available methods for salvaging limb function are such that many centres worldwide still advocate amputation [Finn, Simon, 1991 #16] but the preference at the two UK centres for bone tumour treatment is to attempt limb salvage where feasible, both for adult and for growing child cases. There is no significant difference in overall survival rate between bone tumour patients receiving limb salvage and those receiving amputation. [Rougraff et al, 1992 #44][Simon et al, 1986 #51]
Table 1-1 categorises a sample of 282 extendible EPRs according to the type of bone tumour or other condition for which the EPRs were required to be implanted.

[Meswania JM et al, 1998 # 38] All the extendible EPRs in this sample were manufactured at the Centre for Biomedical Engineering at Stanmore and were implanted at one of the two treatment centres noted above.

<table>
<thead>
<tr>
<th>Reason for surgery and implant of extendible EPR</th>
<th>Number of cases</th>
<th>% of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osteosarcoma</td>
<td>190</td>
<td>67</td>
</tr>
<tr>
<td>Ewing's Sarcoma</td>
<td>42</td>
<td>15</td>
</tr>
<tr>
<td>*Others</td>
<td>17</td>
<td>6</td>
</tr>
</tbody>
</table>

**Reason for surgery and implant of extendible EPR**

<table>
<thead>
<tr>
<th>Reason</th>
<th>Number of cases</th>
<th>% of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>Loosening/bone fracture</td>
<td>10</td>
<td>4</td>
</tr>
<tr>
<td>Mechanical failure</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>Other complications</td>
<td>7</td>
<td>2</td>
</tr>
</tbody>
</table>

* Others - includes Periosteal Sarcoma, Radionecrosis, Malignant Fibrous Histiocytoma, Lymphangioma, Osteolysis, Chondrosarcoma

**Revisions due to:**

**Revisions are cases for which an existing EPR has to be removed and replaced due to one of the causes listed.

Table 1-1: Application of extendible EPRs manufactured at Stanmore

It is seen from Table 1-1 that 79% of tumours requiring implant of an extendible EPR are either osteosarcoma or Ewing's sarcoma. These two types of tumour are briefly described as follows, for further information see medical references. [Glass, 1970 #20][Huvos, 1991 #25]

1.2.1 Osteosarcoma

An Osteosarcoma is a malignant tumour of bone in which the malignant proliferating spindle cell stroma directly produces osteoid or immature bone. The mean annual incidence in the UK is 2.3 per million of population [Huvos, 1991 #25]. This tumour can affect persons of any age but most commonly affects children and adolescents, 56% of cases are in the age range 10 to 20 years. Male cases outnumber female in an approximately 3 to 2 ratio. The tumour tends to be associated with bone growth and so
is prevalent in the long bones of children including the femur, tibia and humerus. 44% of all cases involve the femur. Where the femur or tibia are affected the tumour is most frequently sited in the knee region, in the humerus it is most frequently sited in the proximal region. Modern treatment is by chemotherapy followed by surgical resection of the tumour followed by further chemotherapy to treat metastases, which generally occur in the lungs.

1.2.2 Ewing's Sarcoma

A Ewing's sarcoma is a primitive malignant tumour of bone characterised by uniform densely packed small cells with round nuclei but without distinct cytoplasmic borders or prominent nucleoli. The mean annual incidence in the UK is 0.6 per million of population [Huvos, 1991 #25]. This tumour principally affects persons in the age range 5 to 25 years and only rarely affects persons over 30 years. An analysis of 482 American cases showed a peak incidence in girls between 5 and 9 years of age and in boys from 10 to 14 years. Male cases outnumber female in an approximately 3 to 2 ratio. The long tubular bones are most often affected, particularly the femur. Treatment is by chemotherapy and radiotherapy followed by surgical resection of the tumour.
1.3 Alternative approaches to limb salvage following bone tumour resection

Surgery to resect a bone tumour usually leads to a large bone loss and restoration of limb function requires this loss to be made good. Four approaches to limb salvage following bone tumour surgery are:

- Implant of an Endo-prosthetic replacement (EPR) [Eckardt et al, 1991 #6].
- Allografts and composite allografts [Gebhardt et al, 1991 #17][Gitelis et al, 1991 #19]. This is the use of suitably prepared cadaveric bone in the reconstruction of the patient’s bone. Composite allografts combine cadaveric bone with some form of EPR. These are relatively new techniques, developed principally in the USA.
- Arthrodesis [Capanna et al, 1991 #5]. This is the joining of the bones on each side of a joint. Where a tumour is associated with a joint this can enable the limb to be salvaged but with much reduced mobility.
- Van Nes rotationplasty [Gotsauner-Wolf et al, 1991 #21][Kotz and Salzer, 1982 #31][Van Nes CP, 1950 #67]. This is the removal of the knee joint and rotation of the ankle joint so that this can function as a knee joint in conjunction with a special endo-prosthesis (artificial limb). This extensive surgery can offer the patient some limited mobility.

Implant of an EPR is the most widely used of the four approaches listed above and is the preferred method at the UK centres for bone tumour treatment. For growing children it is feasible to manufacture an EPR that can be extended in length so that limb length equality can be maintained. The three other approaches listed above cater less well for child cases, although allograft methods have been described [Gebhardt et al, 1991 #17], [Gitelis and Piasecki, 1991 #19] for use with children that are at near full growth.

It should be noted that there is expected to be loss of limb functionality following tumour resection and limb salvage by implant of an EPR. With growing children there is a higher risk of complications than with adults and so for many patients the implant of the EPR will postpone rather than avoid the amputation of the limb. Even if the EPR
remains effective until adulthood, further surgery will be required at this point to replace the extendible EPR with a stronger fixed length version.

### 1.4 Customisation of EPRs for various tumour sites.

EPRs are not standard products, each one is customised for a particular patient according to the site of the tumour and the dimensions of the patient’s bones as determined from X-ray images. Bone tumours most frequently occur in the long bones of the lower limb and so the great majority of extendible EPRs are used to replace part of the femur or part of the tibia. There is an occasional requirement for humeral replacement in an upper limb.

A survey of 125 child bone tumour cases receiving extendible EPRs [Cool et al, 1996 #10] was categorised by tumour site to produce Table 1-2.

<table>
<thead>
<tr>
<th>Tumour Site</th>
<th>% of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distal Femur</td>
<td>63.6</td>
</tr>
<tr>
<td>Proximal Tibia</td>
<td>15.7</td>
</tr>
<tr>
<td>Proximal Femur</td>
<td>8.3</td>
</tr>
<tr>
<td>Proximal Humerus</td>
<td>5.8</td>
</tr>
<tr>
<td>Mid Humerus</td>
<td>5.0</td>
</tr>
<tr>
<td>Mid Femur</td>
<td>0.8</td>
</tr>
<tr>
<td>Distal Humerus</td>
<td>0.8</td>
</tr>
</tbody>
</table>

**Table 1-2 – Child bone tumour cases categorised by tumour site**

The most frequently treated tumour site is the distal femur, the next most frequent is the proximal tibia. Both these tumour sites are adjacent to the knee and normally require the natural knee to be replaced with an artificial knee joint that is integrated into the EPR as discussed in section 1.7. The proximal femur is the third most frequent tumour site and this normally requires the natural hip to be replaced with an artificial hip joint as discussed in section 1.8. Similarly, the proximal humerus and distal humerus tumour sites, which are comparatively rare cases, require the replacement of the natural shoulder and elbow joints respectively. The mid humerus and mid femur tumour sites are usually treated with an EPR that replaces the whole of the natural bone and incorporates artificial joints at both ends.
1.5 **Role of the Centre for Biomedical Engineering in bone tumour treatment.**

The Centre for Biomedical Engineering at Stanmore has played a significant part in the development of EPRs for use in bone tumour treatment, including the extendible EPRs required for child cases. The Centre for Biomedical Engineering is located at the Royal National Orthopaedic Hospital Trust at Stanmore, Middlesex and is a Department within the Faculty of Clinical Sciences at University College London. The author of this thesis is currently employed at this centre. In recent years, the EPRs developed at Stanmore have been manufactured by Stanmore Implants World-wide Ltd. (SIW) this being a company working in close liaison with the Centre for Biomedical Engineering and sharing the same premises on the campus of the Royal National Orthopaedic Hospital Trust.

The first extendible EPR manufactured at Stanmore was implanted at the Royal Orthopaedic Hospital, Birmingham in 1976 [Scales et al, 1987 #46][Scales and Sneath, 1987 #47]. To the end of 1998, approximately 290 extendible EPRs manufactured at Stanmore have been used with child cases, the great majority of the implant operations being performed at the Royal Orthopaedic Hospital in Birmingham and the Royal National Orthopaedic Hospital at Stanmore. Approximately 25 extendible EPRs are manufactured at Stanmore each year. This number is likely to remain fairly constant since it is linked to the occurrence of bone tumours for which, unfortunately, there is no foreseeable preventative measure.
1.6 Active and passive accommodation of growth

The longitudinal growth of the limb bones such as the femur and tibia originates in two regions, the distal and proximal physes, or growth plates, which are located near the ends of the bones, see figure 1.1(a). If bone tumour treatment requires the loss of one of these growth plates then future growth of the bone is limited to that growth initiated at the remaining growth plate at the opposite end of the bone. It is then appropriate to implant an extendible EPR having a telescopic section to make up the loss of growth and preserve limb length equality with the opposite limb that was not affected by the tumour. The use of an extendible EPR in this way is known as active accommodation of growth [Scales et al, 1987 #46][Scales and Sneath, 1987 #47]. Current designs of extendible EPR do suffer the limitation that extension can only be achieved with a surgical operation that is repeated at intervals through the patient’s growth years. The system developed under this project is intended to eliminate the need for these operations.

In many cases, bone tumours are resected in the knee region and regardless of whether the tumour site is in the femur or the tibia the EPR will then include an artificial knee joint with both femoral and tibial components. To implant this joint replacement it is necessary to resect part of both the femur and the tibia although the tumour directly affected only one of these bones. It is normally possible to preserve most of the growth plate in the adjoining end of the bone that did not contain the tumour and so this bone will grow at near normal rate. Fixation of the artificial joint component to this bone would normally be by an intra-medulary stem (IM stem) passing through the growth plate into the IM canal, this being the cavity along the centre of the bone that is filled with relatively soft tissue. For growing bones it has been found unsatisfactory to fix an IM stem using PMMA bone cement since the bone growth can exert sufficient force to fracture the cement [Safran et al, 1992 #45]. The fixation of the stem needs to be designed so that it will remain secure even although the bone is growing. The technique used to achieve this is known as passive accommodation of growth and is described with reference to Figure 1-1.

Figure 1-1(a) shows a tumour sited in the distal femur, although the procedure discussed is also applicable to tumours sited in the proximal tibia.
Figure 1-1(b) shows the situation after the tumour site has been resected and an extendible EPR has been fitted. The shaft of the femur normally has to be resected 50mm clear of the boundary of the tumour site to ensure removal of all cancer cells and at this point the extendible section of the EPR is fixed to the remaining bone using an IM stem. The natural knee joint is replaced with an artificial joint having femoral and tibial components. The tibial component of this knee joint is fixed to the tibia by means of an IM stem, which penetrates clear through the growth plate in the proximal tibia. This IM stem is supported at two levels by polymer sleeves, the more distal of these sleeves being below the level of the proximal tibial growth plate. These sleeves are machined from ultra high molecular weight polyethylene (UHMWP). The distal part of the tibial IM stem is non-tapered and is a sliding fit in the distal sleeve, this sleeve being externally tapered so that it is a firm press fit into the reamed bore of the tibial IM canal. The tibial stem is thus free to move partially out of the distal sleeve so as to accommodate the tibial growth initiated at the proximal tibial growth plate.
Figure 1-1: Active and passive accommodation of growth

Femoral head
Femur
Tumor site
Distal femoral physis
Tibia
Femoral head — Femoral head
Femoral intra medullary canal
Femoral intramedullary stem of EPR
Hydroxyapatite collar
Extendible section of EPR
Artificial knee joint - femoral component
Artificial knee joint - femoral component
Tibial stem of EPR fits in UHMWP sleeve which is press fit in tibial intra medullary canal

Note: UHMWP sleeves shown solid shaded.

Femoral stem may loosen in bone canal due to diametral growth of femur

Boney pedical forms, particularly on medial side and should ideally form bond to hydroxyapatite collar

Due to growth, tibial stem of EPR slides partway out of UHMWP sleeve

Extendible section elongated to maintain leg length equality

Proximal tibial physis
Fibula
Femoral intramedullary stem of EPR
Hydroxyapatite collar
Extendible section of EPR
Artificial knee joint - femoral component
Artificial knee joint - tibial component
Tibial stem of EPR fits in UHMWP sleeve which is press fit in tibial intra medullary canal

(a) (b) (c)
Figure 1-1(c) shows the situation after the extendible EPR has been implanted for some time. The patient has undergone a number of minor operations by which the extendible section in the femoral part of the EPR has been lengthened, typically by 6mm at each lengthening. The tibia has grown at near normal rate causing the tibial IM stem of the EPR to partially retract out of the distal sleeve but this sleeve continues to support the stem against side loading. At the interface between the extendible EPR and the femur there is a likelihood of loosening of the femoral IM stem since the remaining natural femur has grown in diameter as well as in length. The additional fixation provided by a Hydroxyapatite collar, as discussed in Section 1.9, may compensate for this effect. Once the patient has reached adult stature it is expected that the EPR will be at least partially loosened and normal practice would be to remove the EPR at this stage and replace it with a non-extendible adult size version.

For resection of a tumour in the proximal tibia, the EPR would have an extendible tibial section for active accommodation of growth and a femoral component with a stem that slides in a femoral polymeric sleeve for passive accommodation of growth. This arrangement is an inversion of that shown in Figure 1-1(b).

Bone growth at a growth plate that has been penetrated by an IM stem and polymeric sleeve is usually less than at the corresponding growth plate in the patient's opposite limb that is not affected by surgery. It has been thought that this loss of growth is directly due to the loss of that part of the growth plate that is cut away when the tibia is bored and reamed to accept the tibial stem and sleeve. The lost area of the growth plate is relatively small, in a survey [Cool et al, 1996 #10] of 44 cases the area destroyed was determined as a percentage of the original area using MRI scans and was not more than 13% in any patient. An attempt was made to correlate the retardation of growth with the percentage area of the growth plate destroyed by penetration but the results were inconclusive suggesting that some factor(s) other than the loss of growth plate area may be responsible for the observed growth retardation.
1.7 Artificial knee joints incorporated in EPRs

As discussed in Section 1.6 above, the majority of EPRs used in bone tumour treatment of both children and of adults incorporate artificial knee joints. The design of these knee joints differs from that of the standard total knee replacements (TKRs) which are now manufactured in large numbers mainly for use with elderly osteo-arthritis patients. Most TKR designs for osteo-arthritis patients aim to replace damaged joint articulating surfaces whilst retaining, as far as is possible, the motion of the natural knee and it is generally considered that this gives optimum comfort and functionality for the patient. In the natural knee the relative motion between the tibia and the femur can include minor translations and rotations for degrees-of-freedom other than that of the main hinge action of the joint. These minor movements are guided and limited by the various ligaments and muscle attachments surrounding the knee.

Surgery to resect a tumour is more invasive than that to implant a TKR alone. Such surgery usually requires the destruction of many of the ligaments and muscle attachments surrounding the natural knee so that an artificial knee joint that simply mimicked the motion constraint of the natural knee would not give adequate support to the joint. The artificial joints for EPR application need to be stable with little or no support from the surrounding tissue structures and this generally requires the use of a hinge type of artificial knee joint such as the Stanmore Modular Lower Extremity System (SMILES).

Figure 1-2 shows the SMILES configured for use with a growing child patient having a tumour site in the distal femur. The SMILES is manufactured by Stanmore Implants World Wide Ltd., see Section 1.5, and the design is customised for individual patients having tumour sites in either the distal femur or the proximal tibia. It is basically a hinge joint but with a secondary axis of rotation allowing some restricted rotation of the tibial component about the longitudinal axis of the tibia. This secondary axis of rotation is intended to reduce the torque transferred from the tibia onto the femur [Walker et al, 1982 #69], hence reducing the torque loading on the relatively weak mid-shaft fixation between the EPR and the resected bone. Although the secondary rotation axis is likely to provide motion constraint closer to that of the natural knee, the limited clinical
experience to date has shown no significant reduction in loosening attributable to the provision of the secondary rotation axis [Unwin et al, 1995 #62,63,64,65].

With reference to Figure 1-2, the lugs (a) are cast integral with the metallic tibial component (b). These lugs support axle (c), which runs in UHMWP bushes (j) fitted into the femoral part (d). One end of the axle is formed into an eccentric head (e) that fits in an eccentric counter-bore in the lug of the tibial component. An internal circlip (k) is fitted by the surgeon into this eccentric counter-bore to retain the axle after assembly of the joint in-situ in the patient. The eccentricity of the head of the axle ensures that the axle rotates relative to the bushed femoral component rather than relative to the tibial component. The lugs of the tibial component are symmetrically featured so that the axle can be inserted and retained from either side of the assembly.

At full knee extension, i.e. the straight knee position, the surface of the femoral component comes into contact with a UHMWP pad (f) to provide a robust stop to prevent hyperextension. The tibial stem (g) is supported in two UHMWP sleeves fitted into the drilled and reamed tibial IM canal as discussed in Section 1.6. The tibial stem can rotate in these sleeves providing a secondary axis of rotation as discussed above. Rotation of the tibial component about this secondary rotation axis is restricted by a cam action between the concave part cylindrical surface of the UHMWP part (h) and the convex part cylindrical surface of the tibial part (b). As part (b) rotates relative to (h) it 'rides up' the curved surface of part (h) and since there is normally an axial force compressing these parts together this produces a 'damping' torque that opposes and limits the rotary motion. The small webs (l) machined integral with component (h) key this component to the tibial bone preventing rotation in the bone.

As discussed in Section 1.6, the distal part of the stem (g) is non-tapered and is a sliding fit in the distal UHMWP sleeve (i) so as to allow the stem to slide partway out of the sleeve as the bone grows. The internal bore of this sleeve is nominally 0.30mm diametric clearance with the stem for a free sliding fit. The external surface of this sleeve is a taper press fit in the reamed bore of the bone, the included angle of taper being normally 1:40 (1.43 degrees). The external surface of the sleeve is provided with both longitudinal and circumferential grooves to grip the bone surface. Earlier designs of these sleeves had a non tapered external surface provided with a coarse male screw thread that was intended to have a self tapping action with the bone.
Figure 1-2: Knee replacement EPR for use with distal femoral tumour site
At the proximal end of the assembly shown in Figure 1-2, the femoral component (d) is bored for shrink fit onto the femoral shaft (m). For a growing child patient this femoral shaft would incorporate a telescopic section.

The materials used in the assembly shown in Figure 1-2 are UHMWP for parts (f),(h),(i),(j) and cast cobalt chrome alloy for the metallic parts other than the femoral shaft section, which is normally titanium. All the metal parts are polished to a mirror finish and in recent years the titanium femoral shaft has usually been nitride coated to resist abrasion by surrounding tissues.

The SMILES is adapted for use with both adult and child bone tumour cases [Walker et al, 1982 #69]. The arrangement for an adult case is generally similar to that shown in Figure 1-2 except that for an adult the two UHMWP parts (h) and (i) would be a single component since passive growth accommodation is not required.
1.8 Artificial hip joints incorporated in EPRs.

Figure 1-3 shows a bone tumour EPR customised for a tumour site in the proximal femur. The natural knee joint and distal part of the femur are retained and the proximal part of the femur and the natural hip joint are removed by surgery. The EPR includes an artificial hip joint incorporating a cobalt chrome ball and an UHMWP acetabular socket, these being standardised components as manufactured in large numbers for total hip replacements used in the treatment of arthritis.

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**Figure 1-3: EPR for proximal femoral tumour site**
1.9  **Fixation of EPRs to natural bone**

Most EPRs used in bone tumour treatment replace only a part of a natural bone and so an attachment is required between the natural bone and the EPR, this attachment being commonly referred to as the fixation of the EPR to the bone. The exception is a small minority of cases for which it is necessary to replace a whole bone including the joints at each end, for example replacement femurs occasionally incorporate both an artificial hip joint and an artificial knee joint.

Surgical resection of a bone tumour often falls in the mid shaft region of a long bone such as the tibia, femur or humerus where the diameter of the bone is relatively small and the bone is highly stressed, particularly by bending moment. Because of these factors, a mid shaft fixation between bone and an EPR is an inherent weak point.

The most usual method for mid shaft fixation between a bone tumour EPR and one of the long bones is by an IM stem, see Figure 1-4, which spigots into the bone canal. The IM stem is usually cemented in place with polymethyl-methacrylate cement (PMMA cement), the thickness of the cement layer being typically 1mm.

![Figure 1-4: Typical fixation between EPR and mid shaft bone](image)

The diameter of the IM canal restricts the diameter of the stem and there can be high stresses at the root of this stem when there is bending load on the assembly. The root diameter of femoral IM stems is rarely more than 16mm for large adults and ranges down to 8mm or occasionally less for children.
The IM stem must be designed for fatigue loading and Figure 1-4 shows a typical method of attaching the stem to the EPR using a heat fitted interference fit with a rivet as a backup. Heavy bending load will cause small movement at the metal to metal interface where the root of the stem enters the socket in the EPR. These small movements relieve the high stress concentration that would occur if the stem were machined integral with the body of the EPR.

![Diagram](image)

(a) - Cross section showing fixation with cement between stem and bone

(b) - Cross section showing fixation without cement and with cutting flutes directly engaging bone.

Figure 1-5: Fixation of IM stem with and without bone cement.

The necessarily small diameter of the stem makes this type of fixation inherently weak against torque load transmitted between bone and EPR, even if the strength against bending is adequate. An IM stem is usually slightly curved to match the curvature of the bone of a particular patient and this curvature does strengthen the fixation against torque loading. The curvature is usually achieved by cold setting the stem after machining. The stem may also be provided with flutes keying the metal into the PMMA cement to resist rotation between stem and cement - see Figure 1-5 (a). An alternative approach applied at Stanmore in recent years is omit the cement layer and to provide the stem with much more pronounced cutting flutes that engage the bone directly to resist torque loading - see Figure 1-5 (b).
For further resistance to torque loading the shoulder of the EPR that buts against the resected bone may be provided with an 'anti-rotation lug', see Figure 1-6. This lug fits into a groove that the surgeon cuts in the resected end of the bone.

**Figure 1-6: Anti-rotation lug**

Pedicai grows on medial side of prosthesis where bone remains under compression  
Bone recaeds on lateral side of stem

**Figure 1-7: Femoral shaft bone remodelling**

After an EPR has been implanted for a period of months or longer several effects may weaken the fixation. The stress pattern in the bone changes dramatically after implant of the EPR since the bending stresses are transferred from the outer part of the bone to the metal. The living bone reacts to this change in stress pattern by resorbtion in regions of reduced cyclic stress. The interface between the cut end of the bone and the shoulder of the EPR cannot sustain tensile stress caused by bending and so the bone adjacent to this interface is lightly stressed and is subject to resorption – see Figure 1-7. A second effect is believed to be caused by joint wear particles. Bone tumour EPRs normally include artificial joint components and these shed UHMWP wear particles. It has been found possible for such wear particles to migrate into the interface between the bone and the PMMA cement layer around the stem. The wear particles then elicit a phagocytic response stimulating osteoclastic resorption of bone from the immediate vicinity of the cement layer so causing a loosening effect [Murray et al, 1990 #39][Schmalzried et al, 1992 #50].
Thirdly, in child cases, the overall growth in bone diameter may directly cause loosening of IM stem fixation. Figure 1-7 shows typical re-modelling seen after a femoral resection and implant of an EPR. A gap develops between bone and metal, particularly on the lateral side, hence the location for an anti-rotation lug should be on the medial side. On the medial side, a bony pedicle often develops but this will not bond to non-coated metal and does not appear to add strength to the fixation of the EPR.

![Diagram of HA coated collar](image)

**Figure 1-8: HA coated collar**

Over the last few years the majority of bone tumour EPR’s manufactured at Stanmore have been provided with a Hydroxyapatite coated ‘collar’ adjacent to a mid shaft resection, as shown in Figure 1-8 [Unwin et al, 1993 #66][Unwin et al, 1995 #61]. Hydroxyapatite (HA) is a biologically active synthetic ceramic that living bone can grow in contact with, forming an adhesive bond. In at least a proportion of bone tumour patients having a mid-femoral resection, a bony pedicle grows as shown in Figure 1-7 and with HA coating this pedical can bond to the EPR providing a bony bridge to strengthen the fixation, particularly against the effect of torque loading. Over a period of years, the HA may become detached from the underlying metal surface of the EPR and it may also be absorbed by the bone tissue. However, the HA collar is machined with a deeply grooved surface as shown in Figure 1-8, so that a mechanical key with the bone remains even if the bond between HA and metal fails or if the HA is absorbed. A further possible advantage of having a bony bridge between bone and EPR is that it may prevent or restrict the ingress of joint wear particles into the stem bone interface so as to reduce or eliminate bone resorption triggered by the presence of wear particles. There is research in progress at Stanmore into the use of an artificial membrane at the bone resection point to further seal the stem bone interface against particle ingress.
Section 1: Medical Background

Figure 1-9: External fixation

A further development in the fixation of bone tumour EPRs at mid shaft resections is the use of 'external fixation', by which the bone becomes a spigot fitted into a metallic cage or an array of metallic fingers, known as extra-cortical plates, which project from the end of the EPR. Figure 1-9 shows a typical scheme with three extra-cortical plates spaced around the bone shaft and fixed with bone screws. The extra-cortical plates are perforated to encourage bone to encapsulate the metal parts and are flexible enough to bend with the bone and this reduces concentrations in the stress transfer between metal and bone. This approach has been tried in the past and has become more promising now that HA coatings are available to bond the bone to the metal parts. The screw fixings are necessary for fixation in the short term following implant but ideally the long-term durability of the fixation is by bone encapsulating and bonding with the metal parts. The surgery to implant an EPR in this way causes more damage to tissue external to the bone but against this there is less loss of tissue within the IM canal. For child patients, IM tissue is responsible for blood regeneration.

Extra-cortical fixation appears particularly attractive for growing child patients since growth in bone diameter would seem likely to make the fixation firmer rather than causing loosening as happens when the metal component is an internal spigot. The Howmedica Modular Reconstruction System is intended for use with child patients and includes external fixation with three extra-cortical plates [Kotz et al, 1986 #30][Kotz et al 1991 #32][Schiller et al, 1995 #48].

Animal experiments at Stanmore have shown strong bonding between live resected goat femurs and various prototype designs of extra-cortical plates. The more flexible designs of extra-cortical plates were those that more rapidly became encapsulated by bone [Cobb et al, 1995 #8].
1.10 The design evolution of extendible sections for bone tumour EPRs

The method of extension of the telescopic sections of the extendible EPRs manufactured at Stanmore has evolved through five stages. The most recently used extension method is basically similar to the method used in the very first extendible EPR but between these first and fifth stages three other methods of extension have been tried and abandoned. If a non-invasive method of extension is to be adopted in future, then this would be a sixth stage of development.

The development of the artificial joints for integration into EPRs and of methods for fixation of EPRs to bone have progressed simultaneously with the development of extension methods for child patients. These two lines of development have been largely independent since EPRs are designed by combining interchangeable modules, hence various joint designs have been used with various extension methods.

The first extendible EPR ever used in bone tumour treatment was the Stanmore Mk1 design [Scales et al, 1987 #46] as shown in Figure 1-10. This EPR was intended only for distal femoral replacement and was fitted with plastic condyles ('Delrin' acetate material) articulating against the proximal end of the patient's natural tibia, the use of an artificial joint for passive growth accommodation not having been developed at that time. The telescopic section could be lengthened by surgical operations repeated at intervals of typically 6 months according to the growth rate of the patient. These lengthening operations required the surgeon to insert a key transversely into the side of the EPR to turn a worm engaging a worm wheel. This worm wheel was axially located within the body of the EPR and a power screw connected to the inner telescopic section passed through a central threaded hole in the worm wheel so that rotation of the worm wheel extended the telescopic sections. A key and key-way prevented relative rotation between the inner and the outer telescopic sections.

Four of the Mark 1 design were implanted between 1976 and 1981. It was found that the plastic knee condyles bearing on the patient's natural tibia did not provide an adequately stable joint for a patient that had lost much of the soft tissue structure that maintains the stability of the natural knee. There were also some difficulties in operating the extension mechanism due to excessive friction and binding between rotating parts.
The next design stage, the Stanmore Mark II, included a knee joint replacement with both femoral and tibial components, the tibial component being the first to be adapted for 'passive' growth accommodation as discussed in Section 1.6. This knee joint was a hinge type to provide inherent stability. A novel extension method was adopted, this being intended to be less prone to seizing between moving parts than the screw mechanism had been. Extension was by the surgeon using a special tool to force balls into a cavity within the telescopic section of the EPR. The arrangement is shown diagrammatically in Figure 1-11.

Figure 1-11: Extension by ball insertion
At implant, the EPR contained two balls and the first extension operation forced one or more additional balls between these to extend the EPR in increments of one ball diameter. The balls were 6.35mm (1/4") diameter and were initially of cobalt chrome alloy, then later of tungsten carbide. A difficulty with this design was the high contact stresses at the points of contact between adjacent balls resulting in the fracture of balls in some of the EPRs and difficulty in providing sufficient force to insert the balls for those patients having stiff scar tissue surrounding the EPR. To overcome the latter difficulty the next design, the Stanmore Mark III, [Scales et al, 1987 #46] was extended by the surgeon applying a special tool engaging circumferential grooves in the inner and outer telescopic sections of the EPR. This tool is referred to as a distraction tool and resembles a pair of tongs with jaws moving apart to lengthen the EPR. The column of balls was retained but was used only to maintain the length, the ball(s) being easily inserted once the correct length was achieved by use of the distraction tool. A total of 59 mark II and mark III EPRs were manufactured and implanted over a period of ten years. The balls used to lock the length of both these types of EPRs continued to be prone to fracture.

Figure 1-12: C-ring extension locking – diagrammatic
To overcome the problem of ball fracture in the Mark II and Mark III designs, a Mark IV design was introduced in 1988. This is referred to as a 'C' ring EPR and is shown diagrammatically in Figure 1-12. As with the ball extended EPR, extension was in increments governed by the dimensions of a spacing element but in this case the spacing element was a 'C' shaped component, the 'C' ring. To extend the 'C' ring EPR, a distraction tool similar to that used with the Mark III design was fitted into external grooves in the EPR and used to open the telescopic sections so that the required 'C' ring, or rings, could be positioned externally over the inner telescopic section. Each 'C' ring was locked into position by a quarter turn allowing a lug on the end of the 'C' ring to engage a recess when the distraction tool was closed and withdrawn, as shown in the figure. The 'C' rings maintain the length of the EPR positively without the high contact stresses encountered with ball spacers. A total of 208 'C' ring EPRs were implanted and generally performed satisfactorily from a mechanical point of view although in two cases a C ring became detached from the EPR during service. The disadvantage of the 'C' ring EPR is the relatively invasive nature of the surgery required to insert the distraction tool and to fit the rings in position. The Mark I, II and III designs were better in this respect.

To reduce the extent of surgery required for extension operations, a development project was started in 1990 to develop a 'minimally invasive' extendible EPR, the Stanmore Mark V design which is shown in Figure 1-13 and Figure 1-14. The Mark V design is based on the original screw and worm extension principle as used for the Mark I design, but with attention to design features to make for easier manufacture and to reduce frictional losses. The worm wheel is an integral part of the power screw rather than being a nut rotating on the power screw as for the Mark I design. Thrust on the power screw is reacted on the small diameter end of the screw rather than on the larger diameter of the worm wheel. This must considerably reduce friction loss. Figure 1-13 shows how a 'T' handle, having hexagonal section end similar to an 'Allen' key, is inserted by the surgeon into a matching hexagonal section recess in the worm that engages the worm wheel. This Mark V extendible EPR came into production in 1995 and at the time of writing it is the EPR used for the great majority of Stanmore patients requiring an extendible EPR.
The first manufactured Mark V extendible EPRs retained the 'C' ring extension method as a back up method of extension to be used in the event of failure of the worm and screw mechanism. The grooves for the 'C' ring distraction tool are visible in Figure 1-13 and Figure 1-14. The worm and screw mechanism has now proved to be reliable and the Mark V EPRs are now manufactured without the external grooves required for the 'C' ring back up extension system.

One difficulty encountered with the early manufactured Mark V EPRs was the worm occasionally working loose from the side of the EPR, the worm being retained only by engagement with the thread of the worm wheel. This required a minor design modification to include an 'O' ring in a groove on the worm so as to increase friction to prevent unintentional rotation of the worm.

In addition to the extendible EPRs manufactured at Stanmore, some other extendible EPRs have been developed for use with child bone tumour patients, but these have been implanted in smaller numbers than the Stanmore extendible EPRs.

The Lewis Expandable Adjustable Prosthesis (LEAP) was manufactured by Dow Corning Wright and included a telescopic section with power screw for extension [Eckardt et al, 1991 #12][Kenan et al, 1991 #28][Kenan et al 1995 #29][Lewis et al, 1991 #34][Lewis et al 1987 #35]. For distal femoral and proximal tibial tumour sites this EPR included a knee joint, the earlier versions having a hinge action only then a second rotation axis was introduced, as for the Stanmore SMILES. For distal femoral tumours the tibial component of the artificial knee joint was fixed with an IM stem cemented through the proximal tibial growth plate without provision for bone growth and this was reported to lead to cement fracture [Safran et al 1992 #45].

The Howmedica Modular Reconstruction (HMR) system [Kotz et al, 1986 #30][Kotz et al, 1991 #32] also includes a telescopic section extendible by a power screw. For distal femoral tumours the tibial knee component is fixed with a smooth non-cemented IM stem that accommodates bone growth by sliding directly in the bone without the polymeric sleeves used in the Stanmore EPRs. Fixation of the HMR system to mid shaft bone is by extra-cortical plates, see Section 1.9 above.
Figure 1-13: Extendible section of minimally invasive extendible EPR with femoral component of SMILES knee joint attached

Figure 1-14: Extendible section of minimally invasive extendible EPR shown dismantled.
1.11 The need for a non-invasive extension method

The Stanmore Mark V extension method has proved to be reliable but the need for access by surgery in order to lengthen the EPR is an inherent drawback. The surgical operation required to insert a key into the EPR is less invasive than with previous designs, particularly the 'C'-ring type, but a general anaesthetic is still required.

On average each patient receives two lengthening operations each year during the period that the patient is growing. The total number of lengthening operations varies widely between patients and depends on the duration for which the extendible implant remains implanted. This in turn depends on the patient age at initial implant and on any subsequent complications leading to amputation or death of the patient. In January 1993 a clinical review was made at Stanmore with 35 distal femoral cases and 14 proximal tibial cases and at the time of this review these patients had had a total of 344 lengthening operations, an average of 7.02 operations per patient. The maximum number of lengthening operations for one patient was 20.

Each lengthening operation exposes the patient to a 2% risk of infection [Cool et al, 1996 #10], such infection being likely to lead to amputation. Each operation on average requires the patient to be away from school for five days. To keep the number of lengthening operations to a minimum, the extensions are normally in increments of 6mm and this often leaves the limb initially stiff and there can be pain requiring post-operative physiotherapy.
A totally non-invasive extension method would offer the following advantages:

- Elimination of lengthening operations together with the associated risk of infection, scar tissue formation, trauma and lost schooling.
- Lengthening could be by more stages with smaller increments, avoiding pain and stiffness. The patient would be conscious during lengthening and so the lengthening could be stopped if pain occurs. If the extension mechanism can be made reversible then such over extension could be promptly corrected.
- There is a likelihood of reduced demand on the resources of the health services. The cost of the non-invasively extendible EPR and associated equipment will be greater than for an EPR extended by surgery but this is likely to be more than offset by elimination of the cost of a number of surgical operations and associated post operative care including physiotherapy.

The advantages summarised above make a compelling case for the development of a non invasively extendible EPR. If this EPR is designed so that it can also be lengthened by surgery using the C-ring method then the risk to patients associated with this development is minimal. If for some unforeseen reason a non-invasively extendible prosthesis should fail to extend non-invasively then it would be possible to revert to the C-ring extension method which is well proven although it does have the disadvantage of requiring more extensive surgery for extension than does the key operated EPR.
1.12 Previous work on non-invasive extension

At the time that the project described in this thesis was initiated, no non-invasive extension system for bone tumour EPRs had been developed to the stage of being ready for clinical use although two projects to develop such an EPR were already started, these being at the University of Twente, Netherlands and at the Department of Orthopaedics, University of Vienna, Austria - see Sections 1.12.1 and 1.12.2 below. At the time of writing these are two of four projects that have progressed to limited clinical application whereas the project at Stanmore has not yet reached this stage due to delay caused by lack of funding.

The four projects that at the time of writing are believed to have lead to clinical use are discussed in Sections 1.12.1 to 1.12.4 below. At present these developments are commercially confidential and little technical information is published.

1.12.1 Research Projects at the University of Twente, Enshede, Netherlands.

A series of research projects [Verkerke et al, 1991 #68] initially considered a wide range of basic approaches to drive an extension mechanism from outside the body and then developed two of these to produce several prototypes. The two basic approaches that were selected for development to prototype stage were:

1) A small permanent magnet inside the EPR is turned on bearings by rotating a large D.C. energised electro-magnet around the limb. The internal permanent magnet provides a low torque input to a high ratio epicyclical gear train that turns a screw mechanism to extend the EPR.

2) An A.C. energised coil positioned around the limb transfers power by electromagnetic induction to a small coil positioned in the limb. The transferred power is used to drive a small D.C. electric motor to provide the input torque to a gear and screw mechanism similar to that for approach 1) above.

Prototypes were implanted and tested in calf limbs and some extension was achieved in one such test. The diameter of the extendible section of these prototypes was 38mm and this would severely limit the application to human implant. In the calf limb tests there
was difficulty in achieving sufficient extension force to overcome restriction from bone that grew to partially encapsulate the moving parts of the EPR. No such encapsulation has occurred with the various designs of Stanmore extendible EPRs in human implant and so testing in a calf limb may be an unnecessarily severe test of the prototype extension method.

It is understood that a single non-invasively extendible EPR produced at Twente has now been used in human implant but details have not been reported in the literature. Recent correspondence indicates that there are no definite plans for further clinical use of this system.

1.12.2 Research Project at the University of Vienna.

An EPR actuated by knee joint movement has been developed at the Department of Orthopaedics, University of Vienna, Austria [Windhager and Kotz, 1995 #71][Windhager et al, 1993 #72] and has now been used with three patients. This EPR is only for use with distal femoral and proximal tibial tumour sites and it includes an artificial knee joint as an essential component. Each time the knee is bent to an angle exceeding a fixed point, typically 62 degrees from the straight limb position, a ratchet is rotated by one tooth increment driving a screw to extend a telescopic section by a small (0.056 mm) non-reversible increment. Accidental over extension may occur but the extension produced by the device tends to be self limiting. This is because extension increases tension in the tissues of the limb such that the knee becomes less mobile until it is not possible for the patient to reach the knee flexion angle at which the ratchet mechanism operates.

1.12.3 Souberain-Delphine Mk.II & Mk.III EPR (Phoenix Medical, France)

The Mark II EPR is extendible by percutaneous manipulation, the Mark III by an electromagnetic device [Soubeiran, 1995 #54]. Little information on the construction is currently available. A small number are understood to have been implanted but no clinical follow up is reported to date.
1.12.4 Fabroni's 'Non Conventional Endoprosthesis'

This EPR includes a telescopic section with a one way mechanism allowing only an increase in length. The device is intended to be extended by stretching the limb with considerable tension whilst the patient is under general anaesthetic [Fabroni et al, 1995 #15]. At least one such device has been implanted but no clinical follow up is reported to date.
Section 2  PROJECT HISTORY

The history of this project is considered to fall into four stages as outlined in subsections 2.1 to 2.4 below. The key events for the whole project are summarised in the timeline diagram, Figure 2-1.

2.1 November 1989 to December 1991

This period covered an initial study, prior to the author’s involvement in the project.

In November 1989 the Department of Biomedical Engineering at Stanmore submitted a proposal to the medical charity Action Research for a two-year feasibility study of a non-invasive system for extension of an EPR to be used with child bone tumour cases. This was the first proposal for such a system from Stanmore. A slightly later proposal was made to a second charity, the Wishbone Trust of the British Orthopaedic Association. These proposals considered that the most likely method of extension would utilise an electric motor or solenoid powered by inductive transmission between a coil external to the limb and an in-vivo coil. Such a system of inductive power transfer was already under development at Stanmore at that time and was subsequently successful in powering EPRs containing electronic instrumentation for force measurement. The proposals considered three methods of electrically driving the extension, these being an electric motor with gearing and power screw, an electric motor with hydraulic pump and actuator using body fluid as a working medium and finally an electric solenoid extending the EPR in small steps through a ratchet mechanism. The proposals for a two-year feasibility study were accepted by both Action Research and the Wishbone Trust. These two charities jointly funded both the initial two-year study and the subsequent work to 30 April 1994.

Part way through the initial two year feasibility study it was decided that although a totally non-invasive extension system was a worthwhile long term goal the technical difficulties would be formidable and hence the greatest benefit to patients could be gained by improving the currently available systems for extension by surgery. Consequently, with the agreement of the funding charities, the main work carried out during this period was a new design of extendible EPR that was designed to be
Section 2: Project History

2000

1999

Project re-instated

1998

Project cancelled

1997

1996

1995

1994

Second field generator system constructed but not commissioned

Work started on specialist fatigue testing machine

Prototype EPR first extended against realistic loading using magnetic field

Complete EPR first bench tested using external mechanical drive to gear input

1993

Started construction of windings for field generator

Prototype gear system first bench tested

Construction work started on prototype gearing - design work started on field generator

Second feasibility study completed, design work started on prototype gearing

Author of this thesis first involved in project - second feasibility study started

1992

1991

1990

First proposal for project funding submitted

Work started on first feasibility study

Jan 1 - 1989

Project re-instated

Project cancelled

Second field generator system constructed but not commissioned

Work started on specialist fatigue testing machine

Prototype EPR first extended against realistic loading using magnetic field

Complete EPR first bench tested using external mechanical drive to gear input

Started construction of windings for field generator

Prototype gear system first bench tested

Construction work started on prototype gearing - design work started on field generator

Second feasibility study completed, design work started on prototype gearing

Author of this thesis first involved in project - second feasibility study started

Work started on first feasibility study

First proposal for project funding submitted

Figure 2-1: Principle events in the development of a non-invasively extendible EPR at Stanmore.
extendible with less invasive surgery than that required for the current ‘C’ ring extension method. This ‘minimally invasive’ extendible EPR came into clinical use in 1992 and is described in Section 1.10 of this thesis.

Little further consideration was given to non-invasively extendible designs and no prototypes were constructed nor were any detailed drawings produced.

The other work carried out under this first feasibility study was a series of measurements of the force required to extend an extendible EPR. These measurements were made in the operating theatre during the extension of ‘C ring’ extendible EPRs, as described in Section 3.1. The purpose of taking these measurements was to establish reliable design data for any future work on non-invasive extension.

2.2 January 1992 to April 1994

The great bulk of the development work was carried out during this period of two years and three months. The author of this thesis was the sole person working on the project during this period, apart from the staff of companies subcontracted to manufacture some of the parts required for testing. Action Research and the Wishbone Trust jointly provided funding. The aim was to produce a working prototype system within two years and this was accomplished. Prototype construction and testing was then curtailed due to the need to use the resources of the project to build new fatigue testing equipment to supplement that currently available at Stanmore.

The first work carried out by the author on this project was a second feasibility study and this occupied the first three months of 1992. The aim was to make a fresh appraisal of the design options and this lead to the final choice of an EPR including a magnet, gearing and power screw, the magnet being turned by a rotating magnetic field generated by an assembly of windings placed around the limb.

Work on the first prototype non-invasively extendible EPR started with the design of the gearing since this was considered to be critical to the success of the project. During April 1992 a novel gear configuration was envisaged and working drawings were produced. Since the Centre for Biomedical Engineering had no facilities for manufacture of the small precision gear parts a specialist machining company was required. After visits to several companies a contract was placed and manufacturing
work on parts for a prototype gear system commenced at the end of April 1992. This gearing was designed to utilise the body of the EPR as a housing and this alone saved significant space by comparison with the installation of an off-the-shelf gear unit within the EPR. The gearing was designed for a nominal housing inner diameter of 17mm, the outer diameter of the EPR being envisaged at that time to be 21mm rather than 24mm as was adopted for the later prototypes.

While the gear parts were being manufactured, a test rig was designed and built for use in bench testing the gearing, this test rig also being suitable for later testing the whole drive train within the EPR. Software was written in Pascal to data log and process readings from this test rig. The first prototype for the gear system was a single reduction stage as shown in Figure 2-2. This single stage of gearing was first bench tested in September 1992 using a small motor to turn the gearing. Figure 2-3 shows the test rig, including a precision electronic balance to measure the torque reaction on the drive motor and weights suspended from a cord round a drum to load the output. These measurements indicated that the gearing was capable of meeting the predicted requirements for torque amplification and for torque output.

During October 1992, subcontractors were contracted to produce the telescopic body for a first prototype EPR and the remaining EPR parts, including magnet and shaft seal, were sourced and placed on order. Also at that time, the design of the field windings to generate the rotating magnetic field was finalised using purpose written design software. Construction of the field windings started in December 1992. Due to a lack of technician availability at the Centre for Biomedical Engineering this work was carried out by the author of this thesis using workshop facilities owned by the author and located in Hampshire. The work initially concentrated on making the windings and the liquid sealed housing to contain these, these being shown in Figure 2-4 and Figure 2-5. A temporary field generator system was then assembled for test purposes, this consisting of the field windings assembly together with a three phase inverter, liquid cooler and pump mounted on a wooden support structure as shown in Figure 2-6. The housing for the field windings is to the left of the photograph, this housing being connected to the rest of the equipment by a flexible trunking carrying cooling oil pipes, power cables and wiring to temperature sensors within the windings. On the right of the photograph an inverter is seen to be temporarily attached to the outside of the unit. This particular inverter was one on loan for evaluation purposes and was found to be
unsuitable for the application, it is not the same type of inverter as was later used to extend the EPR. The fins of the forced air oil cooler are just visible to the extreme right of the photograph.

The first prototype of the extendible EPR with gearing and power screw installed was completed in March 1993. This prototype was initially tested with the magnet removed and using a small motor to turn the input to the gearing in the EPR whilst the telescopic sections were loaded with axial load and bending moment using a system of pulleys and dead weights. The test arrangement is shown in Fig. 7. This test confirmed that the required input torque to the gearing was within that which it was predicted could be generated by the rotating magnet.

The field generator system was first operated in April 1993. The inverter used to energise the field windings was manufactured and custom modified by a small company based near Cambridge, this unit appearing to be more suitable for the particular requirements of the project than those manufactured by the main suppliers of motor drive electronics. The magnetic field strength was measured using a hand held gauss meter and was initially close to that which had been theoretically predicted. After a short period of operation a fault occurred in the inverter causing the over-current protection system to function in an erratic manner. Because of this fault, the unit would not operate continuously for more than half a minute or so and would not operate at more than approximately 25% of the rated current output at any time. This reduction in the current to the field windings gave a proportionate reduction in magnetic field strength. This fault was never repaired since the manufacturer of the inverter was unable to provide a satisfactory after sales service or to supply a circuit diagram or other technical information. Since the design field strength was intended to include a generous margin it was decided to continue testing with the reduced field strength and intermittent operation whilst sourcing an alternative inverter.

A landmark in this project was reached during July 1993 when the field generator system was first used to extend the prototype EPR against loading comparable to that expected in in-vivo use. The prototype extendible EPR was mounted in a frame with a spring loading the telescopic sections and a dial gauge to detect the extension as shown in Fig. 8. The spring had a measured spring rate of 71N/mm, this being a similar stiffness to that measured for the limb tissues during surgical extension. The EPR was placed with
the magnet close to the centre of the field windings and the field generator was operated with the maximum field strength then available, this being reduced to approximately 25% of the design value due to the fault in the inverter. Operation was intermittent, again due to this fault. Despite the reduced field strength and intermittent operation, the field generator was able to turn the magnet within the EPR and the spring was compressed in a number of stages by a total of 10mm to exceed the design distraction force of 700N. This test was repeated several times and conclusively demonstrated the feasibility of the magnetic drive system. At a later stage in the project this test was successfully repeated a further ten times over using this same prototype EPR, thus demonstrating reliability.

At this stage the project was ahead of schedule. One extendible EPR was functional and parts were available to assemble a second one. The field generator system had been shown to function but it was a temporary and not very elegant arrangement that was unreliable due to the fault in the inverter. Eight months funding remained, after which the proposed system was expected to be ready for submission to the local medical ethics committee prior to clinical use.

At that point it was suggested that the medical ethics committee would require the extendible EPR to be fatigue tested under simulated in-vivo loading using more complex equipment than that available at Stanmore at that time. The fatigue testing facilities at the Centre for Biomedical Engineering then consisted of two six station hydraulic loading machines, these machines having six hydraulic cylinders each capable of loading a specimen with sinusoidal cyclic force at frequencies of up to about 5Hz. It was understood that the medical ethics committee might not accept the results of a fatigue test carried out with only a single force actuator loading each specimen since such an arrangement cannot reproduce the out of phase cyclic load components which occur in-vivo. Accordingly, the main part of the remaining eight months duration and funding for the project was allocated to the design and construction of a special purpose fatigue testing machine having three independently controlled hydraulic actuators acting on a single specimen. The other work completed during this period was an improved field generator system, as shown in Figure 10-14 and Figure 10-15 and as described in Section 10.5. This unit was constructed by the author with assistance with welding and sheet metal work given by a small local engineering company.
The special purpose fatigue testing machine designed and partly constructed as part of this project was based on a rectilinear space frame with the specimen located within this frame and with three hydraulic cylinders mounted in various alternative positions between the frame members and the specimen. Additionally, tension and compression members with ball jointed end fittings were connected between the frame members and the specimen in sufficient number that the specimen was restrained in all degrees of freedom but without over constraint, hence the system was statically determinate when loads were applied by the actuators. The aim was to produce a very adaptable system that could provide a wide range of loading conditions applicable to EPRs configured for various tumour sites. The three hydraulic cylinders were to be connected to fast acting pressure control valves, the signals to control these being independently generated for each actuator and of any waveform within the limitations of the frequency response of the hydraulic system.

It was envisaged that the first fatigue test to be carried out using this machine would be on the extendible EPR configured for a proximal tumour site. In this configuration the EPR would be fitted with an artificial hip joint and it was required to use the three actuators of the fatigue machine to simulate in-vivo loading on the femoral head of the artificial hip. Measurements had recently been published for the in-vivo loading on the head of standard total hip replacements [Bergmann et al, 1993 #1] and it was intended to use this data to control the actuators of the fatigue machine, accepting that the loading on the head of a bone tumour EPR may differ slightly from that on a standard total hip replacement. These measurements showed that the direction as well as the magnitude of the total load vector on the femoral head varies over a typical walking cycle, so three actuators are needed if a precise simulation is required. A custom made three axis load cell was designed, constructed and calibrated to monitor the three load components acting on the femoral head and to provide a feed back signal for the three axis hydraulic control system. This load cell included a mounting for a standard acetabular cup to locate on the femoral head of the EPR under test.

Purpose written software was produced for generating control signals for the three axis hydraulic control systems using a DAC card fitted in a PC and for monitoring the forces acting on the three axis load cell through an ADC card. A feature of this software was a graphical display of the programmed and the measured resultant load vectors on the femoral head.
The hydraulic actuators for the fatigue testing machine were designed in collaboration with a company specialising in long life hydraulic components for fatigue test applications. These actuators were designed without any high pressure sliding elastomeric seals, the piston and rod sealing being by fine clearances between steel and bronze parts, the leakage through these clearances being collected and returned by a scavenge pump.

At the end April 1994, shortly before funding from Action Research and Wishbone Trust terminated, the frame of the fatigue test machine was assembled with the hydraulic actuators, load cell and specimen mounting components. Orders for the remaining parts, including the high cost hydraulic control system, had been held back due to the uncertainty of future funding. On termination of funding, this fatigue test machine was dismantled and the parts placed in storage together with the field generator unit and other parts constructed for the project. Unfortunately most of the parts for the fatigue test machine together with some of the parts of the field generator and the various test rigs were subsequently damaged or lost during a re-arrangement of the laboratory and workshop space at the Centre for Biomedical Engineering.
2.3 May 1994 to May 1998

During this period relatively little progress was made since the author was primarily involved with other projects including the following:

- Wear testing equipment for total knee replacements
- Orthopaedic implants having internal force measuring systems.
- Software for generating the geometry of hip replacements by digitising X-ray images
- A profilometer for measuring UHMWP wear test specimens – joint development with the National Physical Laboratory.

The non-invasively extendible EPR project was funded for part of this period from research funds generated within the Royal National Orthopaedic Hospital at Stanmore and the following work was carried out:

1. Improved quality shaft seals were made and were satisfactorily tested.
2. Drawings for the EPR were updated to allow for an outer diameter of 24mm at the end containing the drive mechanism, rather than 21mm as for the first prototype.
3. The requirements for fatigue testing the EPR were reconsidered and a simple fatigue test arrangement was built and tested.
4. Analytical work, including some structural analysis by FEA.
5. Construction started on four further EPR prototypes, based on the revised drawings.

With regard to item 2 in the above list, the larger diameter was chosen to be consistent with the dimensions of the currently used minimally invasive design as configured for a distal tumour site. The standard diameter of the socket in the femoral component of the SMILES knee joint is nominally 24mm, this socket being a heat shrink fit onto the extendible module. The larger outside diameter allowed an increase in the diameter of the gearing in the EPR and this was expected to make for easier gear cutting. It is now seen that in the longer term the standard diameter of 24mm should not be regarded as
fixed and there will certainly be applications where it would be of benefit to return to
the original diameter of 21mm, or an even smaller diameter if this is feasible.

With regard to item 3 in the above list, the requirement to have more than a single
actuator for each station of the fatigue testing machine was reviewed and was
considered to be superfluous. A simpler and lower cost fatigue testing apparatus was
constructed as shown in Figure 13-1 and was used in a student project to study fretting
at taper fits between EPR shaft sections. For this project the apparatus performed
satisfactorily over 10 million cycles applying 2.2kN axial force and 100Nm bending
moment.

At the end of November 1997 the extendible EPR project was unexpectedly cancelled, it
being stated that the benefits of the project were no longer considered to be worthwhile.
A contract for the manufacture of four prototype EPRs was in progress at the time and
this contract was cancelled, the work to date being paid for.

During December 1997 a meeting was held with surgeons of the London bone tumour
service and the Birmingham bone tumour service and these surgeons strongly expressed
a view that the project would be beneficial to patients and that the project should be re-
instated with renewed funding. The project was then re-instated in late May 1998.

2.4 **June 98 to date of issue of this thesis.**

Immediately following the reinstatement of the project the contract for the manufacture
of four prototype EPRs was also re-instated. Various parts for the field generator system
that had been lost or damaged during storage from April 1994 were remade and the
wiring was completed. The frequency inverter in the field generator unit was
commissioned with the assistance of the manufacturer during November 1998. In
January 1999 the field generator system was used to extend the original prototype
extendible EPR ten times against simulated in-vivo load as described in 0.

The feasibility of the magnetic drive system for an extendible EPR is now considered to
be proven as far as is practical prior to actual implant. Further work is as outlined in
Section 13 of this thesis.
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Section 2: Project History

Figure 2-2: Single stage of gearing

Figure 2-3: Test rig for measuring gearing efficiency.

Figure 2-4: Field windings with housing part completed.
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Section 2: Project History

Figure 2-5: Field windings assembly completed.

Figure 2-6: Temporary field generator system.

Figure 2-7: (Left) Test rig for power screw and telescopic sections.

Figure 2-8: (Below) Prototype extendible EPR with spring for loading and dial gauge to detect extension
**Section 3  DESIGN REQUIREMENTS**

This section outlines the requirements constraining the design of the non-invasively extendible EPR system.

**3.1 Distraction force**

To extend the telescopic section of the extendible EPR it is necessary for the extension mechanism to apply sufficient force to overcome the resistance of the tissues of the limb together with friction between the telescopic parts. This force is referred to as the distraction force. To minimise the distraction force it is advantageous to carry out the extension procedure with the patient in a comfortable position and the limb not load bearing. The muscles of the limb are then relaxed and the distraction force is much less than the compression loading that the EPR experiences during vigorous activities.

The distraction force for EPRs extended by a surgical procedure has been determined by previous work at the Centre for Biomedical Engineering at Stanmore, this work being carried out shortly before the author joined the Centre [Meswania et al, 1998 #38]. The aim was to establish a design distraction force for a future non-invasively extendible EPR system, although at that time there was no definite proposal for the form that such a system might take. Force measurements were made during a number of extension operations with 'C' ring extendible EPRs - see Section 1.10. These measurements provide directly relevant design data for the extension mechanism of the non-invasively extendible EPR. The measurements were made in the operating theatre as the 'C' ring EPRs were extended with the patients under general anaesthetic. A special tool was used to extend the telescopic sections of the EPR, this tool having strain gauge bridges sensing the force on one of two jaws engaging the grooves in the telescopic sections. The strain gauges were bonded to the internal surface of a sealed tubular arm carrying the jaw. The whole assembly was washable and suitable for autoclaving at up to 130 degrees C.

A total of 76 distraction force measurements were made on 34 patients. The number of measurements made on individual patients ranged from one to five. The patients were grouped according to whether the tumour sites were femoral, tibial or humeral.
For each measurement, the telescopic sections were initially extended just 0.1mm to determine the force acting on the EPR with the patient anaesthetised. For both the femoral and tibial patient groups this initial force averaged 140N, for the humeral group it was near zero. Following this initial measurement, the EPR was extended 9mm in steps of 1mm, force measurements being taken at each step and the measurements being at approximately 10 second time intervals. This 9mm extension was required in order to insert a 'C' ring spacer of 6mm thickness, giving a real extension of 6mm, the 'lost motion' of 3mm being required for clearance and to accommodate the lug locating the 'C' ring. Additionally, to investigate possible visco-elastic behaviour of the tissues, a single set of measurements was taken on one patient with the extension rate reduced by allowing a 30 second delay after each one millimetre increment.

Plotting the force measurements against extension for any one patient indicated that the increment in force above the initial force was approximately proportional to extension, but the rate of increase with extension varied quite widely from patient to patient as shown in Figure 3-1, Figure 3-2 and Figure 3-3 below. Those patients that had above average rates of increase in force with extension were those which had much scar tissue resulting from previous surgery, including previous extension operations. For both the femoral and tibial groups the mean increase in force with extension was approximately 70N per mm, for the humeral group it was approximately 50 N/mm.

![Figure 3-1: Femoral distraction force vs. Extension: 52 curves from 22 cases](image)
Figure 3-2: Tibial distraction force vs. Extension: 18 curves from 8 cases

Figure 3-3: Humeral distraction force vs. Extension: 6 curves from 4 cases

The force measurements described above were made at a mean extension rate of approximately 0.1 mm per second. It is anticipated that the non-invasive extension mechanism will operate at a lower rate, possibly in the region of 0.003 mm per second, although with most of the mechanisms considered this speed could be adjusted as required. For the one extension operation where a 30-second delay was allowed after each 1 mm extension increment, the distraction force was seen to fall slightly during each delay period. This suggested that the tissues have a visco-elastic behaviour and so the distraction forces can be expected to be slightly reduced with a lower extension rate. However, this has not been taken into account in determining the design distraction force since the effect cannot be reliably quantified from the limited data available.
A non-invasively extendible EPR may be extended more frequently in smaller increments than when a general anaesthetic and surgery are required at each extension. Medical staff have suggested that a reduction of the extension increment from 6mm, as is the normal practice with extension by surgery, down to 2mm would avoid pain and greatly reduce joint stiffness following the extension procedure. As indicated by the graphs shown above, reducing the extension increment also reduces the distraction force which the extension mechanism is required to generate.

The distal femoral growth plate is the growth plate exhibiting the most rapid growth [Tupman, 1962 #60] this being typically 12mm per annum. Hence extension increments of 2mm would require extension procedures at two monthly intervals which would fit in with current schedules for outpatient visits. Patients for which growth plates other than in the distal femur have been replaced would have slower growth and smaller increments. A small minority of patients having total femoral replacement with two growth plates removed would require additional outpatient visits purely for extension procedures.

Some of the possible extension mechanisms would permit both an extension and retraction of the EPR and this would be advantageous since it would allow the extension to be adjusted up and down until a maximum increment which is comfortable for an individual patient is achieved. Experience with the system in clinical use will ultimately determine the most appropriate extension increment for a typical patient but prior to this experience a 2mm increment is believed to be appropriate for design purposes.

Inspection of the measured distraction force data for the femoral and tibial patient groups indicates that an extension mechanism capable of providing 700N distraction force would achieve at least 2 mm extension in a single extension procedure with all but one of the patients measured. The one exceptional case had considerable scar tissue and this required abnormal distraction force for just one particular extension operation. Even in this one case, 700N distraction force would achieve approximately 1.5mm extension.

Based on the above, the design distraction force for the non-invasive extension system is taken to be 700N. It is considered acceptable that for the small minority of patients having tissue stiffness increased by an abnormal amount of scar tissue the extension increment might need to be reduced below the nominal design value of 2mm. It is also
taken into account that the 'C' ring extension system would be retained to provide a backup should the non-invasive system fail due to inadequate distraction force being available.

3.2 Extension allowance

The maximum extension to be allowed for in the design of an individual extendible EPR depends on the anticipated growth potential of a particular patient. The design of the extendible section of the EPR should be such that it can readily be adapted to suit the anticipated growth of individual patients. For example, if the EPR is to include telescopic sections then it is advantageous if these are designed so that batches can be manufactured having length sufficient for any patient and then later shortened as required for individual patients.

Generally the youngest patients place the greatest demand on the design of the extendible EPR since these patients are both the shortest and are those with the greatest potential growth. Designing to suit such patients requires maximum extension capability for a given initial length of the extendible section.

The procedure for estimating potential bone growth, as currently used at the UK centres for bone tumour treatment, requires the ‘bone age’ to be determined for the patient [Greulich and Pyle, 1966 #23]. Data for the expected growth at the various growth plates is available as a function of bone age for males and females [Tupman GS, 1962 #60].

Taking the minimum bone age for an EPR patient to be 7 years, Tupman gives the anticipated growth at the different growth plates as Table 3-1 below.
<table>
<thead>
<tr>
<th>Growth plate</th>
<th>Expected growth from 7 years ‘bone age’ to adulthood -mm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Boys</td>
</tr>
<tr>
<td>Distal femoral</td>
<td>100</td>
</tr>
<tr>
<td>Proximal femoral</td>
<td>45</td>
</tr>
<tr>
<td>Distal tibial</td>
<td>60</td>
</tr>
<tr>
<td>Proximal tibial</td>
<td>75</td>
</tr>
</tbody>
</table>

Table 3-1: Expected growth at the lower limb growth plates

The above data indicates the maximum extension required of an extendible EPR to be 100mm, this being for a young male patient having a bone age of 7 years at implant and requiring resection of the distal femoral growth plate. A greater extension would be required only rarely, for example for an exceptionally young patient at time of implant or for cases where growth plates are destroyed at both ends of the bone. In the later case the expected growth is the sum of that for the proximal and distal growth plates.

Current practice at the UK centres for bone tumour treatment is to implant an extendible EPR only if the potential growth for the growth plate to be destroyed by implant of the EPR exceeds 30mm. For lower potential growth a fixed length EPR is used since the potential complications associated with current designs of extendible EPRs outweigh the disadvantage of a small limb length discrepancy. The availability of a reliable non-invasively extendible EPR at reasonable cost might result in a downward revision of this threshold for selection of an extendible EPR.

### 3.3 Constraint on overall diameter

The current design of extendible EPR manufactured at Stanmore has a manually driven worm and gear driving a power screw – see Section 1.10. The cross section at the position of the worm and gear is slightly oval, the major diameter of this oval section being 24 mm. For the distal femoral tumour site, which is the largest patient group, the section containing the worm and gear blends into a 24mm diameter spigot which is an interference fit in a socket bored in the femoral component of the SMILES artificial knee joint.
It is considered desirable that the non-invasively extendible module for the distal femoral tumour site should initially retain the 24mm outer spigot diameter so as to be interchangeable with the current extendible module without modification to the design of the SMILES femoral component.

For future development it would be an advantage for smaller patients and for patients having humeral bone tumour sites if a smaller diameter non-invasively extendible EPR could be achieved, subject to meeting appropriate strength and distraction force requirements. Also, there may in future be orthopaedic applications outside the field of bone tumour treatment where it would be required to develop smaller diameter extendible devices. A possible example could be an extendible IM nail and this may require the outside diameter to be reduced to about 10mm.

3.4 Loading during the activities of daily living.

The loading on the extendible EPR during normal activity of the patient is significantly higher than the loading during the extension procedures for which the patient is at rest. Once implanted, the extendible EPR will become part of the structure of the patient's skeleton and hence must be designed to have sufficient strength to resist axial compression loading, bending moment and torque under fatigue loading conditions. Of these three load components it is the bending moment which in practice is found to be the most significant.

The loads on bone tumour EPRs for various patient activities have been directly measured at the Centre for Biomedical Engineering at Stanmore using EPRs specially modified to provide electronic force sensing. The author of this thesis was responsible for the mechanical engineering work associated with these projects.

The first version of force sensing EPR constructed at Stanmore [Taylor et al, 1997 #56] was customised for a proximal femoral tumour site and included an artificial hip joint, see Section 1.8. Figure 3-4 shows the general arrangement. The instrumentation within the EPR was capable of measuring only the axial load on the EPR, that is the component of the total force parallel to the longitudinal axis of the device.
The axial load was measured both in the body of the EPR and at a cross section close to the tip of the IM stem, the later measurement being relevant to the study of loosening of the stem. The second version of force measuring EPR Stanmore [Taylor et al, 1999 #56] was customised for a distal femoral tumour site, see Section 1.7 above, and in addition to axial force measurement the bending moment was measured in two perpendicular planes and torque was measured about the longitudinal axis. The general arrangement is shown in Figure 3-5.

Both versions of force measuring EPR had a hermetically sealed cavity within the shaft, this cavity containing strain gauges and electronic circuits. The first version used epoxy bonded foil strain gauges, the second version used thin film strain gauges. The thin film gauges were chosen for low power consumption, small size and long term stability of the zero force reading, the latter being an important property for a force measuring system which cannot be recalibrated once implanted in the body. Thin film strain gauges are made by laser etching a thin metallic film which overlays a thin alumina film, these films being deposited by sputtering directly onto the load bearing substrate the strain of which is to be measured. The use of laser etching required the strain gauges to be on the outer surface of the strained component and this lead to a double walled construction at the strain gauged section, the two walls sharing the loading on the EPR. The strain gauges were deposited on the outer surface of the inner wall and then the outer wall was in welded in place by electron beam welding. Electron beam welding produces minimal heat distortion and avoids thermal damage to electrical circuits.

For both versions of force measuring EPR, a single core metal in glass feed through provided a hermetically sealed connection between the electronic circuit within the EPR and a small coil of gold wire encapsulated in silicon rubber. For the first version, this coil was located in the IM canal adjacent to the tip of the stem. For the second version the coil was wound around a necked region in the shaft of the EPR. This was a more robust arrangement and was easier to handle in the operating theatre.
Section 3: Design Requirements

Femoral head

Electronics cavity

Pair of foil strain gauges bonded to inner wall of cavity, similar pair diametrically opposite. Strain gauges wired to measure axial force.

Anti-rotation lug

Hollow stem carries wiring between main electronics cavity and tip of stem

Strain gauges to measure axial force on stem tip - configuration as for strain gauges in main electronics cavity

Metal in glass feed-through

Gold wire coil wound on small ferrite core and encapsulated in silicon rubber

Remaining natural bone

Figure 3-4: First version of force sensing EPR
Proximal femur

Strain gauges on strut welded into tip measure axial loading on tip of IM stem.

Intra-medulary stem cemented into femur

HA Coated grooved collar

Double walled section with array of thin film strain gauges on outer surface of inner wall to measure axial force, bending moments and torque.

Electronics Cavity

Metal in glass feed through connects pick up coil to circuit housed in electronics cavity

Pick up coil of gold wire wound on half torroidal ferrite sections and encapsulated with silicon rubber.

Pick up coil protected by outer sleeve of UHMWP

Distal Shaft

Rotating hinge knee

Figure 3-5: Second version of force sensing EPR
When it is required to take measurements from the force measuring EPR a second external coil is placed around the limb of the patient and energised at 1.4MHz to transfer power to the internal coil and electronic circuits by electromagnetic coupling. This avoids the need to have batteries in the body of the patient. The coupling between the internal and external coils is also used to transfer data from the instrumentation in the EPR. Momentarily short circuiting the internal coil by a solid state switch induces a pulse detectable at the external coil. The electronics which energises the external coil and interprets the signals transmitted from the EPR is contained in a small pack carried by the subject and a short range radio telemetry system is used to transfer data from this pack to a computer based data logging system. The use of the radio telemetry link allows the equipment carried by the subject to be compact and lightweight so that the subject's movement is not impeded.

Two subjects, referred to as A and B, received the first version of instrumented EPR which measured only axial force. Also, two other subjects received the second version that included bending moment and torque measurement but one of these later two subjects had very limited mobility since the implant surgery rendered the patella tendon ineffective. Hence there were three subjects having mobility which could be considered appropriate in setting design force levels. Bending and torque measurements were available for only one of these three, this subject being referred to as C.

The range of forces and moments, taken over a gait cycle, is used as the basis for predicting the fatigue life of an EPR in the lower limb, the force or moment range being the maximum minus the minimum over a typical cycle.

During the first few months post operation the subjects were recovering from the implant operation and walking speed and force or moment measurements were increasing steadily from one measurement session to another. At two years post operation the measurements were relatively consistent from one measurement session to another.

Measurements with subjects A, B and C indicated that the axial force range at two years post operation and over an averaged gait cycle of level walking at comfortable speed was generally 2.5 to 3.0 times the body weight of the subject. This is in good agreement with various theoretical predictions for the axial force in the femur during slow level
walking. [Morrison, 1970 #10] Figure 3-6 shows typical axial force data from the telemetry system.

Individual cycles shown dotted, average shown solid.

**Figure 3-6: Axial force on EPR for six typical walk cycles**

Measurements were also taken with the subjects stair climbing, stair descending and pedalling an exercise bicycle. None of these activities produced significantly higher force or moment ranges than level walking. Measurements for jogging, at very slow pace, were taken only with patient C and produced axial force range up to 3.5 body weights.

The range of bending moment in the EPR, measured for patient C and for level walking at comfortable pace at two years post operation, was in the region of 0.11 body weight metres in the plane in which the peak bending moment was highest. The corresponding torque about the long axis of the EPR was in the region of 0.015 body weight metres. Stair climbing and descending did not produce significantly higher peaks than level walking, but slow jogging did increase bending moment to around 0.13 body weight metres and torque to about 0.016 body weight metres. The peaks of bending moment about an anterior posterior axis were generally rather higher than about a medial lateral axis but since the total bending vector was continually varying in both direction and
magnitude this data is not considered to justify constructing the EPR with higher bending strength for one axis than another. The cyclic variation of direct stress resulting from the bending moment would be better approximated by a tensile fatigue test with zero minimum load rather than the Wohler rotating beam test in which direct stresses are fully reversed from tension to compression.

Based on the measurements for patient C and assuming a patient body mass of 75kg, the design value of bending moment for the purpose of fatigue life prediction for the EPR is taken to be 100Nm and that for torque loading about the long axis is taken to be 10Nm. 75kg is a typical body mass for adult patients and is conservatively assumed for child patients on the grounds that an extendible EPR will ideally remain implanted until the child reaches adult stature.

The number of load cycles accumulated per annum varies according to patient activity. An active patient might accumulate $10^6$ cycles per annum, this being the equivalent of walking approximately 5km every day. Since an extendible EPR for child patients would be removed from the body at adulthood the design life for the purpose of fatigue prediction is taken to be $2\times10^7$ walking cycles.

In setting design strength requirements for EPRs it should be remembered that if an IM stem is used for fixing to the natural bone as is current practice, see Section 1.9 above, this stem is likely to be the weakest part of the EPR assembly. There is no advantage in designing the remainder of the EPR structure to have strength much greater than that of the IM stem. There is limited scope for increasing the strength of an IM stem since this normally approximates to a smooth solid rod having a diameter fixed by the geometry of the patient’s bone. Stem diameters for child patients do not normally exceed 12mm. For $2\times10^7$ cycles of zero minimum loading and based on the material data for a smooth titanium specimen as discussed in Section 5.6, the bending strength for a 12mm diameter is 120Nm. There is some stress concentration at the root of the stem and applying a stress concentration factor from standard data [Peterson, 1953 #42], the bending strength of the stem is reduced to approximately 100Nm. The factor of safety is then approximately unity, based on the bending moment measurements taken with subject C as discussed above. Despite this apparently inadequate factor of safety the incidence of mechanical failures of bone tumour EPRs is small and is considered acceptable given that for most cases the alternative treatment is amputation of the limb.
The data measured with patients A, B and C above is the only directly measured force data currently available for bone tumour cases. It is accepted that these three cases may not be typical and also that these are adult rather than child cases.

The above has considered cyclic loading which may cause failure through a fatigue mechanism. The structure of the EPR will also be subjected to occasional higher loads due, for example, to the patient falling, stumbling or using exceptional muscle force. This situation has never occurred during telemetric force measurements at Stanmore but two patients in Germany happened to suffer stumbles while hip loading was being monitored by a force sensing total hip replacement. [Bergmann et al, 1993 #1] The highest force on the femoral head during these stumbles was 8.7 body weights compared with a force range of 3.0 to 3.5 body weights for level walking. In the absence of further measured data 7kN (9.3 body weights) is taken as a design axial load for occasional peak loading of the EPR.
3.5 **Suitability for sterilisation**

It is essential that the complete extendible EPR assembly be sterilised prior to implant. The most widely used sterilisation methods require elevated temperature and this should be taken into consideration in the design of a non invasively extendible EPR, particularly if the device contains a permanent magnet which may be demagnetised by temperature. Magnetisation after sterilisation may be possible but would be inconvenient.

The duration required for dry heat and steam sterilisation depends on temperature, a higher temperature allowing a shorter time period. Typical peak temperatures and durations are:

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dry heat</td>
<td>0.5 to 2 Hours</td>
</tr>
<tr>
<td>Steam</td>
<td>2 to 15 minutes</td>
</tr>
<tr>
<td>160-175 C</td>
<td>120-130 C</td>
</tr>
</tbody>
</table>

Sterilisation methods that do not require high temperature include ethylene oxide, gas plasma and irradiation. These methods all require equipment which is only available in a minority of hospitals and which is not available at the Royal National Orthopaedic Hospital (Stanmore) or the Royal Orthopaedic Hospital in Birmingham, these being the main centres for bone tumour treatment in the UK. The need to send out EPRs for a special sterilisation procedure would be an inconvenience and would make it more difficult to meet scheduled times for surgical procedures.
3.6 **Restriction on the choice of materials**

All implanted materials in contact with body tissues must have minimal toxicity and must have a high resistance to corrosion in the saline in-vivo environment. This limits the choice of materials for this project to those materials that are currently used in orthopaedic implants. Selection of alternative materials to be in contact with body tissues would require thorough testing for bio-compatibility which could not easily be justified for the small volume manufacture envisaged.

The list of materials successfully used in orthopaedic implant manufacture is short and includes the following:

**Metals:**

**Titanium alloy** - Type 318 containing 6% aluminium and 4% vanadium (ASTM standard specification F136). Supplied as bar stock annealed at 700 degrees C. Good specific yield strength and exceptional specific fatigue strength. Nitriding the surface produces a hard coating of TiN and Ti2N which reduces abrasion by adjacent tissues in-vivo. Modulus of elasticity approximately half that of steel.

**CoCr Alloy (cast)** – A non ferrous alloy primarily of cobalt with typically chromium 28% and Molybdenum 6%. (ASTM specification F75). Used as castings in the manufacture of mass produced standard designs of total hip and total knee replacements. Widely used as highly polished components in combination with UHMW polyethylene in sliding joints for orthopaedic implants.

**CoCr Alloy (wrought)** – ASTM specifications for CoCr wrought alloys for implant use include F799, F562, F90 and F563. F799 and F562 are the more widely used. The composition for F799 is similar to cast F75 as above, the composition of F562 is cobalt with typically 20% chromium, 35% nickel and 10% molybdenum. These wrought alloys can be supplied with greater yield and ultimate strength than cast CoCr alloy. The alloys are not easily machined but can be worked using carbide cutters and by grinding and polishing.
Stainless Steel 316L – An austenitic stainless steel with typically 17% chromium, 12% nickel, 2% molybdenum and a maximum of 0.03% carbon. This is a non-magnetic stainless steel. Specification 316L requires a lower carbon content than 316 and this gives improved corrosion resistance in a saline environment. Used as an alternative to cobalt chrome alloy but more sensitive to crevice corrosion, for example corrosion may be seen where oxygen is depleted such as beneath the heads of screws securing plates to bone. Should not be used in combination with titanium where an electrolyte is present.

The strength properties of the metallic materials listed above are summarised in Table 3-2 which is based on published data. [Bronzino (Ed), 1995 #7]

<table>
<thead>
<tr>
<th>Material</th>
<th>Ultimate Tensile strength MPa</th>
<th>0.2% Yield strength MPa</th>
<th>Youngs Modulus GPa</th>
</tr>
</thead>
<tbody>
<tr>
<td>Titanium 318</td>
<td>860</td>
<td>795</td>
<td>106</td>
</tr>
<tr>
<td>Cast CoCr (F75)</td>
<td>655</td>
<td>450</td>
<td>225</td>
</tr>
<tr>
<td>Wrought CoCr (F562) cold worked and aged</td>
<td>1793</td>
<td>1585</td>
<td>225</td>
</tr>
<tr>
<td>Stainless steel 316L cold worked</td>
<td>860</td>
<td>690</td>
<td>200</td>
</tr>
</tbody>
</table>

Table 3-2: Mechanical properties of metals used in orthopaedic implants

Polymers:

Ultra-high molecular weight polyethylene (UHMWP) – Widely used with polished stainless steel or cobalt chrome counter-faces in sliding bearings for joint replacements. The material cannot be injection moulded. Components can be machined from bar stock or mass produced components can be produced by a specialised pressure moulding process. The material is suitable for most sterilisation processes although special precautions are required to avoid the material being degraded if it is sterilised by irradiation.

Silicon&rubbers - Elastomeric materials suitable for sealing elements etc. The use of silicon rubber for certain in-vivo applications not related to orthopaedics has lead to costly litigation in the USA as a result of which the main suppliers of these materials now refuse to supply any material for medical applications. However, there are some small suppliers specialising in medical applications and material can be certified as suitable for implant use by the Food and Drugs Administration (FDA) of the USA.
Silicon rubbers are more resistant than other elastomers to degradation by elevated temperature and they are suitable for all sterilisation processes.

### 3.7 Rate and control of extension

It is known from work on limb lengthening that the application of longitudinal strain to a partially healed bone fracture may cause the muscles of the limb to go into spasm. This can be painful and could cause the required distraction force to exceed the design value discussed in Section 3.1, this design value being based on measurements made with an anaesthetised patient. To avoid muscle spasm it is required to extend the EPR at a slow steady rate. It is required that the extension procedure can be halted promptly should pain or excessive stiffness occur in the limb and it is desirable, but not essential, to be able to reverse extension so that excessive extension can be corrected.

A suitable extension rate can best be determined by experience of using the system with patients and hence it is desirable to be able to adjust the extension rate once the system is in clinical use. For design purposes, medical staff have suggested that an extension rate of 1mm in five minutes should be suitable. A very slow extension rate would give an excessively long extension procedure but provided that the patient can relax and perhaps read or watch television during the procedure, a duration of say 60 minutes for a two millimetre extension would be acceptable.

### 3.8 Equipment external to the patient

The extension procedure may require equipment external to the patient, although some of the possible extension methods offer the advantage of not requiring such equipment, for example see Section 1.12.2. It is the opinion of the medical staff involved that the extension procedure should be under trained supervision and so even if the equipment could be sufficiently inexpensive to issue to each individual patient it would not be acceptable for the patients or their parents to operate it. It would be of some advantage for the equipment to be sufficiently portable to be taken to the patient's home or school as an alternative to carrying out extension procedures at a medical centre. However, this is not essential since the patients do in any case need to visit an outpatient clinic at regular intervals and extension could be included in these visits. Even if some outpatient visits are required only for extension procedures, it is still less expensive to the health service for the patients to travel to a central clinic than for medical staff to visit the
patients at home. Hence it is acceptable for the extension equipment to be non-portable and to be permanently installed in those outpatient clinics visited by bone tumour patients. At the present time this would require the equipment to be duplicated at two centres, one at Stanmore in Middlesex and the other in Birmingham. It may also be required to have one backup system available to provide cover for both centres in case of breakdown. Further installations would be required if the system became used internationally.

### 3.9 Regulatory Requirements

Volume produced implanted devices for orthopaedic surgery, for example total knee and hip replacements, require to be CE marked under European legislation. However, non-invasively extendible EPRs are devices that are customised for individual patients and as such they are not required to be CE marked.

Any equipment which might be necessary for use with non-invasively extendible EPRs in order to carry out extension procedures would require to be CE marked if it were to be manufactured to be sold. At the present stage there is no intention to sell such equipment. It is envisaged that the equipment would be manufactured in a quantity not more than three off and would be available for use only by the two bone tumour services within the UK.

Although a non-invasively extendible EPR and any associated equipment does not require to be CE marked, under European Directive 93/42/EEC, both the EPR and the associated equipment would require a risk assessment to be carried out and a device master document to be produced. The device master document would be audited both in-house and externally to verify conformity with all current requirements for electrical and mechanical safety and for non-interference with other equipment in the area of use.
Section 4  METHOD OF EXTENSION

An early stage of this project considered a number of alternative methods for non-invasive extension of a bone tumour EPR for children, these methods being briefly described under sub sections 4.1.1 to 4.1.6. Sections 4.2 and 4.3 contain a more detailed examination of important design features of the more likely methods of extension. Finally, Section 4.4 assesses the various methods against the design requirements set out in Section 3 and draws a conclusion as to the most suitable method for further development.

4.1 Alternative methods of extension

4.1.1 Actuation by tensioning the limb under externally applied force.

This method has been used, see Section 1.12.4. The extending sections of the EPR need to include a ratchet mechanism to lock the extension and reversing the extension is not possible unless an additional mechanism is included. A general anaesthetic has been found to be necessary for the extension procedure, partially negating the advantages of non-invasive extension. To extend the telescopic sections of the EPR by applying limb tension force through the skin, a greater volume of tissue would come under tension than for extension by a mechanism within the EPR. Hence the strain energy input and the force applied would be higher than the distraction force discussed in Section 3.1 above. After discussion with surgeons it was agreed that this was not an ideal approach, although it does offer a simpler and lower cost mechanism within the EPR than any of the other methods considered.

4.1.2 Actuation by joint movement

Extendible EPRs generally include an artificial joint as discussed in 1.7 and 1.8 above and energy drawn from the motion of this joint could be used to extend the EPR. A mechanical linkage is the most probable means to transfer energy from the joint to the extendible section, although a fluid power system might just be considered. All human joints have an oscillatory motion and so a ratchet mechanism is likely, the ratchet possibly also being used to lock the extension on completion of an extension procedure. Additional mechanism would be required if the extension were to be reversible.
Because the number of joint movement cycles is unpredictable, it is necessary to have control over the coupling of joint movement to extension movement. Two methods of control are envisaged. Either the extension mechanism can be enabled and disabled by some external signal or the mechanism can be designed so that it only operates when the patient performs some abnormal activity that is unlikely to occur inadvertently. An example of the later method is the extendible EPR that extends at a knee flexion angle exceeding 62 degrees, see Section 1.12.2 above. Another example might be a gravity operated device that enables the extension mechanism only when the limb is inverted. Damping such a device could possibly prevent unwanted operation during brief periods of downward acceleration of the limb. An example of control by an external signal would be a mechanism linking the motion of the joint to the extension of the EPR through a clutch, this clutch being engaged when an external magnet is placed close to the limb. There are other signalling methods that could be considered, e.g. radio signals, acoustic signals or mechanical force applied through the skin and soft tissues onto a moving part attached to the EPR. The magnetic method is simple and requires no electrical devices in the body. Also it is reasonably secure against accidental triggering provided that the magnetic field strength required for triggering extension is considerably greater than the earth’s magnetic field and other magnetic fields encountered in everyday life.

A disadvantage of linking joint movement to extension of the EPR is that the design of the extension system becomes specific to particular types of artificial joint. As discussed in Section 1.4 above, extendible EPRs are used with several different types of artificial joint and each of these types are manufactured in a range of sizes according to patient stature. Manufacturing the extension system in a number of different versions to match these alternative joints would increase the cost and would also increase manufacturing lead-time making it more difficult to meet schedules for surgical procedures.

4.1.3 Actuation by percutaneous manipulation

The power to actuate extension could possibly be transferred from outside the limb by manipulation of the skin and soft tissues. This method differs from that discussed in 4.1.1 above in that the force applied through the skin would be relatively small but would be amplified by a mechanism within the EPR to provide the distraction force discussed under Section 3.1 above. Certainly, the shaft of a tibial EPR lies close to the skin surface in the region of the shin and so a moveable part(s) on the side of the EPR
could be repeatedly depressed through the skin to both power and control the extension. This approach is less attractive for other tumour sites. There is also concern that a young child could rather too easily operate such a device. The complexity of the mechanism required within the EPR is likely to be comparable to using joint movement to actuate extension.

4.1.4 Magnetic drive

Section 4.1.2 above has considered the use of a magnetic field to control an extension mechanism powered by joint movements. Alternatively and more directly, a rotating magnetic field could be used to provide the power for extension and control would then be by starting, stopping or reversing the field rotation. A rotating magnetic field generated externally to the limb could spin a small permanent magnet mounted on a spindle within the EPR. The torque generated by the magnet would be small but could be mechanically amplified by gearing to drive a mechanism such as a power screw. An alternative might be a pulsed magnetic field that oscillates a magnet within the EPR but this is not so convenient for mechanical amplification of the force generated, nor is it so straightforward to reverse the output motion. The extension mechanism including the magnet and gearing could be a standard module common to all extendible EPRs.

4.1.5 Electric motor drive

The in-vivo force measurement project discussed in Section 3.4 above has demonstrated that an electrically energised coil placed temporarily around a limb can transfer electrical power to a smaller coil permanently implanted in the limb. The equipment already used for this project transfers about 1 Watt to energise a number of strain gauges. This system could readily be developed to transfer several watts at radio frequency. This output could be rectified and would certainly be sufficient to power a small electric motor that could be suitably geared to actuate extension of the EPR. The external coil and associated electronic equipment could be briefcase sized, easily portable and operated from mains supply. As for the magnetic drive discussed above, the internal coil, motor, gearing and other mechanisms for extension could become a standard extendible module common to all extendible EPRs customised for various tumour sites and size of patient. The transfer of electrical power via external and internal coils requires less bulky internal components than an in-vivo battery and avoids the limitation of battery life. The extension could be made reversible by incorporating some additional electronics both within the EPR and externally. For example, solid state
switching could reverse direction of a dc motor under control of signals superimposed on the field that transfers power to the EPR.

The most likely type of motor to be used with this system would be an ironless rotor dc motor with commutator and precious metal brushes. A motor with an iron core armature might also be suitable since rapid acceleration is not required for this application, but in small sizes iron cored motors tend to be of low quality construction being manufactured for high volume low cost applications such as children's toys. A further possibility is an ultrasonic motor. An ultrasonic motor consists of a ring of piezoelectric ceramic blocks which generates a circular travelling wave in an elastomeric annulus and this induces rotation in a metal ring pressed against this annulus by a spring. The drive electronics are often integrated into the construction of the motor. Such motors offer a high ratio of torque to volume of space envelope although they are usually designed to minimise axial length rather than diameter. They are used for the motorised functions of products such as automatic cameras. Output speed and power efficiency are low but this is not a great disadvantage for the EPR application. The difficulty of using an ultrasonic motor for the EPR application is that such motors are custom designed as an integral part of high volume products, the cost of developing such a motor for a low volume application is expected to be prohibitive.

An inductive power transfer system can be arranged to transfer electrical energy to almost any part of the body. It is advantageous for the internal coil to be fairly close to the body surface, but if necessary this coil can be linked by an internal power cable to a device implanted deep in the body. Such a system has powered electrical stimulation for activating the muscles of paraplegic patients. This makes the system readily adaptable for the various possible tumour sites and could offer an advantage over the magnetic drive should there be future applications where an extendible device needs to be implanted in the trunk of the body rather than in a limb.
4.1.6 Some further alternatives for actuation

For completeness, some other possibilities for actuation of extension are noted below, but are considered to have more obvious drawbacks than those previously discussed.

- The motion of the limb during normal activities could provide a power source, as for the use of wrist movement to rewind watches prior to the era of electronic watches. A separate control system would be required to enable and disable the system.

- Power could be transferred from outside the limb by an inductive heating coil or microwave transmitter which intermittently heats an expanding element, for example a wax filled capsule as used to actuate water flow regulating valves in most car engine coolant systems. An alternative expanding element might be made using TiN shape memory alloy, as used for switching the power to automatic electric kettles. A shape memory alloy offers a relatively large dimensional change for a small temperature change, this temperature change causing a transition in the material crystal structure. Thermal actuation systems may require bulky insulation to avoid damage to adjacent tissue, unless the temperature variation can be limited to a few degrees above and below normal body temperature.

- Strain energy could be stored in the EPR at the time of manufacture and later used to activate extension with control by one of the methods previously discussed. Such a clockwork motor system is likely to have a relatively poor energy storage density. Also it would be necessary to ensure that failure of the control system could not cause violent over extension. Storing the energy as a compressed gas, or as compounds that can later be made to react to generate gas under pressure, offers a better energy storage density but control and application of this energy may be even more difficult.
4.2 A preliminary design for knee joint actuation of extension

Figure 4-1, Figure 4-2 and Figure 4-3 show a design for an extendible EPR actuated by knee joint action as discussed in Section 4.1.2 above. This study was carried out by the author of this thesis in order to gain some insight into the complexity of the mechanism required, so as to allow comparison with alternative methods.

With reference to Figure 4-3, as the knee joint reaches full extension, a push rod (a) protruding from the femoral component contacts the tibial component. Repeatedly extending and flexing the joint imparts an oscillating linear motion to this push rod and this motion is used to drive a mechanism to extend the EPR. The extension mechanism is enabled only when an external magnet is suitably positioned in close proximity to the limb.

It may be a disadvantage that the push rod (a) is oscillating whenever the patient is active, subjecting the push rod guide surfaces and seal to wear and subjecting the spring that extends the push rod to fatigue loading. A modification to reduce the amplitude of this oscillatory motion is discussed below. Alternatively, a push rod actuated at full knee flexion rather than full knee extension might be considered since the knee only occasionally reaches full flexion during most human activity. Walking, for example, requires flexion angles only up to about 15 degrees. However, a disadvantage of operating extension at full flexion is that bone tumour patients often have knee stiffness resulting in reduction in the maximum flexion angle they can achieve. Since the maximum flexion varies between patients and may also vary over time with any one patient there would be difficulty in determining a suitable flexion angle at which to initiate the extension motion.

Figure 4-1 shows a possible method to enable and disable the extension by use of the external magnet. The oscillating motion derived from joint action is applied to push rod (a) and the output motion to drive extension is from push rod (b). The disc shaped permanent magnet (c) is magnetised across a diameter and mounted on a central spindle. The pin (d) attached to this magnet engages a slot in the link (e) that pivots on the end of the output push rod. A spiral hairspring behind the magnet, shown in Figure 4-3 but not in Figure 4-1, applies a continuous torque to rotate the magnet clockwise in Figure
4-1. Under the action of this spring, the link (e) is held clear of the input push rod so that oscillating movement of this push rod is not transferred to the output push rod. Suitably manipulating a second permanent magnet externally to the limb causes the internal magnet (c) to rotate anticlockwise against the action of the hairspring as shown in the right hand view. Pin (d) then moves the link (e) into line with the input rod enabling motion transfer between input and output. Stops limit rotation of magnet (c) so that link (e) is accurately aligned with the input and output rods when the mechanism is enabled.

![Mechanism diagram showing enabled and disabled states](image)

**Figure 4-1: Mechanism to enable/disable transfer of oscillating motion**

The second pin (f) attached to the magnet is optionally included to hold the input rod (a) in a near fully retracted position when the motion transfer is disabled, thus reducing wear on the guides and seals which bear on this rod. The first upward motion of rod (a) following the setting of the mechanism to disabled state causes pin (f) to snap into a recess in the side of the input rod (a) so locking rod (a) in a position close to fully retracted. It is desirable for rod (a) not to be fully retracted when locked so that a small further upward motion is possible, this allowing free disengagement of pin (f) under the limited torque available from the magnet.

The permanent magnet (c) is arranged to rotate rather than translate under the influence of the external field. Rotation of a magnet potentially generates more mechanical energy for a given volume of space envelope around the magnet than does a translation movement of a magnet. The rotating magnet is pivoted about an axis through the centre...
of gravity so that it is balanced and will not tend to rotate when the limb is under acceleration.

The oscillating motion of the push rod marked (b) in Figure 4-1 needs to be converted to a continuous extension of the EPR. The most obvious mechanism is a linear ratchet with a pawl(s) attached to the push rod driving the extension and a pawl(s) attached to the body of the EPR locking the extension against reverse motion. It might be feasible to link the driving pawl(s) directly to the movement of the magnet to avoid the need for the mechanism shown in Figure 4-1. The ratchet and the locking pawl(s) would need to be quite robustly constructed to withstand loading during patient activity.

A preferred alternative to a linear ratchet mechanism is shown in Figure 4-2. This mechanism uses the oscillatory motion of push rod (d) to rotate a nut engaging a thread.

Figure 4-2: Mechanism to convert oscillating motion to reduced speed unidirectional motion
With this mechanism, the loading on the EPR is transferred through a screw thread rather than through a ratchet pawl(s). Ratchet pawls are unlikely to be as robust as a thread and may possibly fail to engage properly. A further advantage is that the screw thread gives a mechanical advantage with consequent velocity reduction. The reduced speed output reduces the chance of inadvertent over extension and this is important since a reverse extension capability cannot be provided without considerable increase in complexity.

With reference to Figure 4-2, an internally threaded outer telescopic section (a) fits over an inner telescopic section (b). The assembly extends by rotation of part (c), which has an external thread engaging the internal thread of the outer telescopic section. This configuration gives minimum length in the contracted position since, apart from the axial length of (c); the inner telescopic section can be completely retracted into the outer. The input motion is applied to push rod (d) that is fastened to the serrated head (e) by cross pin (f). This pin also engages slots in the end of the inner telescopic section so as to prevent rotation of push rod (d). Serrations on the face of part (g) match those on (e). Part (g) has a coarse external multi-start thread engaging a matching internal thread in part (c). A light conical compression spring (h) applies a downward force on part (g). To save axial length this spring could possibly be fully recessed into part (g).

Upward motion of rod (d) raises parts (e) and (g), closing the matching serrations and rotating part (c) to extend the EPR. Downward motion of rod (b) disengages the serrations between parts (e) and (g) so that as part (g) falls under the effect of spring (h) it also rotates and does not reverse the previous rotation of part (c). By making the internal thread for part (c) much coarser than the external thread of part (c) a large mechanical advantage can be achieved.

Figure 4-3 shows how the mechanisms detailed in Figure 4-1 and Figure 4-2 might be assembled within a knee joint EPR based on the SMILES design, see Section 1.7 above. The permanent magnet is contained in a thin walled titanium 'can' that could be sealed by electron beam welding so that the magnet cannot come into contact with body fluids. Apart from the magnet, all the materials of the assembly could be selected to be bio-compatible. Although sealing of the assembly is then not critical to patient safety,
Figure 4-3: A preliminary design for an EPR extended by knee joint motion
elastomeric seals are expected to be necessary to prevent accumulation of solid or semi-solid material which might impede movement of the mechanical parts. The final assembly of the EPR would be by electron beam welding to produce defect free welds with negligible heat distortion.

The arrangement shown in Figure 4-3 is a preliminary study and some details are incomplete, also alternative mechanisms could certainly be developed to perform the same function. However, the design shown is considered to be sufficiently detailed for the purpose of cost and reliability comparison with alternative methods of extension.
4.3 Magnet torque compared with small motor

The magnet drive, as briefly described in Section 4.1.4 above, is a form of electric motor and considered as such it would be classed as a permanent magnet synchronous machine, the field windings being outside the limb and the armature within the EPR. Having only the armature of the motor within the EPR might be expected to save space compared with having a whole motor within the EPR. On the other hand, the 'air gap' between the field windings and the armature is very large compared to usual electric motor designs giving very low overall power efficiency. This low efficiency has been found to require relatively high electrical power input using bulky power electronics and cooling systems for the external field generator.

To compare the space requirement for an electric motor with that of the permanent magnet used with the magnetic drive, a survey was made of commercially available electric motors having diameters up to 18mm and data for a selection of these is given in Table 4-1 below. Since the speed of extension of the EPR is not expected to be critical, maximum continuous torque rather than maximum continuous power is an appropriate factor of merit. Higher motor torque reduces the torque amplification required of the gearing and so reduces the size and cost of gearing.

The motor torque must be sufficient to overcome the starting friction in the first stage of a multi-stage gear system otherwise no output can be produced. This is true regardless of the torque amplification that the gear system can achieve once the gears are rotating. The very small motors listed may not be able to produce the necessary minimum starting torque.

All but one of the motors tabulated are conventionally commutated direct current ironless rotor designs, mostly with precious metal brushes. The one exception, marked *, is an electronically commutated motor which claims improved long-term reliability but the torque is similar to conventionally commutated motors of comparable dimensions. The cost of the conventionally commutated motors in this survey is typically in the region of £30 to £80. This cost is comparable with the unit cost of having a high strength permanent magnet custom made to specified dimensions in small batches, say 50 off.
<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Catalogue ref.</th>
<th>Dia. x Length mm x mm</th>
<th>Maximum cont. Torque N x mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Portescap SA (Switzerland)</td>
<td>17N78-216E</td>
<td>17x30</td>
<td>5.26</td>
</tr>
<tr>
<td></td>
<td>16C18-210</td>
<td>16x19</td>
<td>1.13</td>
</tr>
<tr>
<td></td>
<td>13N88-216E</td>
<td>13x31</td>
<td>3.4</td>
</tr>
<tr>
<td></td>
<td>707L61-205</td>
<td>10x20</td>
<td>0.46</td>
</tr>
<tr>
<td>Maxon SA (Switzerland)</td>
<td>2017-941</td>
<td>17x30</td>
<td>2.0</td>
</tr>
<tr>
<td></td>
<td>25-15-989</td>
<td>15x38</td>
<td>3.1</td>
</tr>
<tr>
<td></td>
<td>23-12-910</td>
<td>12x17</td>
<td>0.49</td>
</tr>
<tr>
<td>Norcroft Dynamics (USA)</td>
<td>08DM200</td>
<td>16x47</td>
<td>6.0</td>
</tr>
<tr>
<td>Minimotor SA (Switzerland)</td>
<td>1727-006C</td>
<td>17x29</td>
<td>5.0</td>
</tr>
<tr>
<td></td>
<td>1717-006S</td>
<td>17x19</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>1616-006S</td>
<td>16x18</td>
<td>0.5</td>
</tr>
<tr>
<td></td>
<td>*1628-012B</td>
<td>16x29</td>
<td>2.5</td>
</tr>
<tr>
<td></td>
<td>1331-006S</td>
<td>13x34</td>
<td>2.5</td>
</tr>
<tr>
<td></td>
<td>1319-006S</td>
<td>13x21</td>
<td>1.2</td>
</tr>
<tr>
<td></td>
<td>1016-006G</td>
<td>10x18</td>
<td>0.5</td>
</tr>
<tr>
<td></td>
<td>0816-006S</td>
<td>8x20</td>
<td>0.15</td>
</tr>
</tbody>
</table>

Note:
The length dimension (L) is measured axially and does not include the output shaft or protruding power connection solder tags which could if necessary be shortened.

Table 4-1: Comparison of motor dimensions and torque output

Figure 4-4: Torque vs. Volume for a selection of small electric motors

Figure 4-4, which plots maximum continuous motor torque against the volume of the motor space envelope, indicates that torque increases approximately in proportion to motor volume. The plot shows considerable scatter and the smallest motors have much inferior torque to volume ratio, probably because there is a minimum practical size for components such as bearings and commutator. The slope of the best-fit straight line shown is 670 Nm². Part of the scatter may be due to variation in housing design and in the criteria which different manufacturers use to determine maximum continuous
torque. Comparison of data sheets also suggests that larger diameter motors tend to give higher torque than smaller diameter but longer motors of the same volume.

For the magnetic drive system, preliminary calculations based on the principles summarised in Section 9.1, 9.3.5 and 9.3.7 suggest that the windings should be capable of continuously producing a field strength of 16,000 A/m, corresponding to a magnetic flux density in free space of 20mT (200 gauze). The effect of resistive heating in the windings is expected to limit the field strength possible and higher field strengths may be achieved intermittently. The torque per unit volume of magnet is calculated as the magnetisation of the magnet multiplied by the field strength – see Section 9.1. The magnetisation for a rare earth magnet material can be in the region of 120mT (1200 gauze) and so the torque per unit volume of magnet material can be expected to be around $2 \times 10^4 \text{Nm}^{-2}$. Comparing this value with the slope of the best fit line in Figure 4-4 suggests that the magnet can produce in the region of 30 times more torque than a small electric motor of similar dimensions. This factor will be reduced by perhaps 15% if the space taken up by the spindle and bearings for the magnet is taken into account.

The torque produced by the magnet is proportional to the volume of magnetic material regardless of the geometric form of the magnet. This allows flexibility to design the magnet with geometry to best suit the space available in the shaft of the EPR, whereas a motor would have to be selected from a limited range of dimensions. Also, the relationship between torque and volume for the permanent magnet remains linear for the smallest magnet and this could give the magnetic drive a significant advantage in the future development of smaller extendible EPRs.
4.4 The choice of system for development

Option 4.1.1 above was eliminated on the advice of medical specialists in the field, leaving options 4.1.2 to 4.1.5 to be matched against appropriate selection criteria as tabulated below (* = low, ***** = high).

<table>
<thead>
<tr>
<th></th>
<th>OPTION A Joint movement actuation</th>
<th>OPTION B Percutaneous manipulation</th>
<th>OPTION C Electric motor drive</th>
<th>OPTION D Magnetic drive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Portability and cost of equipment external to the limb</td>
<td>****</td>
<td>*****</td>
<td>***</td>
<td>*</td>
</tr>
<tr>
<td>Compactness of the extension mechanism within the EPR</td>
<td>*****</td>
<td>****</td>
<td>***</td>
<td>*****</td>
</tr>
<tr>
<td>Cost of the extension mechanism within the EPR</td>
<td>***</td>
<td>***</td>
<td>****</td>
<td>****</td>
</tr>
<tr>
<td>Adaptability to suit EPRs for different tumour sites</td>
<td>*</td>
<td>**</td>
<td>*****</td>
<td>*****</td>
</tr>
<tr>
<td>Ease of making extension reversible</td>
<td>*</td>
<td>***</td>
<td>****</td>
<td>*****</td>
</tr>
</tbody>
</table>

Table 4-2

In comparing the systems, the compactness of the mechanism within the EPR was given a high priority. A more longitudinally compact mechanism allows a greater extension distance for a given contracted length and this allows the system to be used with more patients, including the younger patients which combine short stature with large growth potential. A more laterally compact mechanism is also more suitable for use with younger patients and may open up further applications for the technology, for example as an IM extending 'nail'.

The cost of the mechanism within the EPR is inevitably of some importance but there is no large disparity in cost between the alternative systems. The magnetic drive and the motor drive are similar in cost, the difference being that a small motor is substituted for a custom made permanent magnet and these items are of roughly similar cost. The cost
of a mechanism for extension by percutaneous manipulation is likely to be comparable with that for actuation by joint movement, both mechanisms requiring force amplification from a small oscillatory motion to a one way linear extension. Comparing the complexity of manufacture of a typical scheme for extension by joint movement, see Figure 4-3, with the complexity of a magnet or motor driving a custom made epicyclic gear train and power screw it is considered that the number of parts required is roughly similar for both schemes, but for the schemes including a multi-stage gear train there is scope for use of a number of identical parts. Certainly, if it were possible to utilise an 'off-the-shelf' gearbox then the magnetic drive or the electric motor drive would offer a clear cost saving over the alternatives, but at present it has not been possible to source a suitably compact gearbox.

Adaptability to suit different tumour sites was also considered important and can be considered to offset the disadvantage of a more complex extension mechanism. If the extension mechanism can be standardised to suit any tumour site then the components can be manufactured in greater volume and cost may well be reduced even if the design becomes more complex.

A moderate priority was given to the ease with which extension can be made reversible. It is not essential for extension to be reversible but a simple means for retraction of the EPR would be beneficial in that it would make it easier to adjust the EPR to optimum length for limb length symmetry without excessive limb stiffness. For EPRs extended by surgery, as are currently implanted, retraction would be unlikely to be considered worthwhile due to the trauma and risk of complications associated with each operation the patient undergoes.

Lesser priority was given to the compactness and cost of the external equipment since it is envisaged that only three units of this equipment need be constructed to serve the UK, this including one reserve unit, and these units do not need to be hand portable.

Some attempt was made to weight and then sum the advantages of the alternative systems so as to produce a quantitative assessment and the systems were also briefly discussed with a group of surgeons at the Birmingham bone tumour service. The conclusion of this assessment was that a magnetic drive was the most suitable approach for future development. Both the magnetic drive and the motor drive could be designed
as a standard module to suit EPRs for all tumour sites. The motor drive and the
magnetic drive would share many components within the EPR, but the magnetic drive
has a permanent magnet in place of a complete electric motor and this is simpler and
more compact.
Section 5  TELESCOPIC BODY AND POWER SCREW

5.1 Configuration of the extending parts

A mechanical assembly of rigid parts which is extendible in length would be expected to include parts which overlap in length when the assembly is contracted, the overlap reducing as the length of the assembly is increased. An alternative could be an assembly of pivoted parts which extends by rotation at the pivots, but this is less suitable for an assembly which needs to carry bending moment with a minimal cross section envelope. Given that the assembly will consist of overlapping sliding parts, then these parts can be arranged so that one part envelopes the other either completely or partially at the overlap region, these two options being shown diagrammatically in Figure 5-1 (a) and (b).

![Figure 5-1](image)

Figure 5-1: Possible cross sections for an extendible assembly

With reference to Figure 5-1(a), for ease of manufacture to close tolerances and for uniformity of bending strength in all directions it is advantageous for the parts to be basically cylindrical in which case a feature such as a key way is required to resist relative rotation.

Figure 5-1(b) is typical of numerous options for interlocking sections where one part does not completely enclose the other in cross section. Generally, the part which partially encloses the other, this being the left hand part in the diagram, is prone to distortion when the assembly is loaded in bending with only a short overlap between the parts. If the overlap will always be adequate to avoid this, then arrangement (b) can be designed to be as strong, or possibly stronger, in bending about some preferred axis than can arrangement (a) but it is unlikely to be as strong in all bending directions as is (a).

The sections shown in Figure 5-1 (a) and (b) are drawn with the same total cross section area and without calculation it would seem probable that (b) has a slightly greater...
bending strength for moment about a horizontal axis but is weaker for bending about the vertical axis.

For the extendible EPR application, the telescopic sections were made cylindrical following the basic configuration shown in Figure 5-1(a) rather than (b), the reasons being:

- The outer cylindrical component can be conveniently extended at one end of the assembly to form a cylindrical housing which suits the proposed gearing configuration.
- The cylindrical form of the main components approximately matches the cross section of the large human bones.
- Ease of manufacturing – the main parts can be made as turned parts.
- Uniform bending strength in all directions, although this bending strength may be less than that possible in the 'preferred' direction with arrangement (b).
- Resistance to distortion of the sections under bending when the overlap between sections is small.

5.2 Actuation of extension

Given that the body of the EPR is to consist of telescopic sections extended by a driving device having a rotary output then the following are amongst the means which might be considered to convert this rotary output into a linear extension of the telescopic sections:

1. Power screw, i.e. screw driving nut attached to linearly guided component (or vice versa) - alternatively known as a 'lead screw'. May be plane threaded or may include balls or rollers providing rolling contact between loaded parts.

2. Worm or pinion driving a rack.

3. Sprocket with chain attached to linearly guided component (or pulley and belt etc.).

4. Reciprocating mechanisms incorporating a ratchet action.

5. Linkage (e.g. Crank and link(s)) between shaft and linearly guided component.

6. Fluid power system including an actuating cylinder and piston.
For the application under consideration, the power screw, listed 1 above, has clear advantages over the alternatives listed 2 to 6. A linkage arrangement is likely to be bulky since the extent of linear motion tends to require long links moving through large angles. A fluid power system would require many more individual parts than the other alternatives. A further disadvantage is the possibility of seal leakage causing external contamination and/or allowing the EPR to collapse under load unless a secondary locking mechanism is included. The load carrying ability of a power screw for a given overall envelope is likely to be greater than for a rack and pinion since the contact between the main moving parts carries load over a greater cross section of material. Also the input shaft to a power screw has its axis aligned with the direction of output motion which suits the convenient orientation of gearing within the cylindrical body of the EPR. A power screw with a suitably fine pitch offers a higher mechanical advantage than can be easily achieved with options 2, 3 or 4. This reduces the mechanical advantage required of the gearbox and in the presence of friction it ensures that the rotary to linear motion conversion cannot be back driven so providing a means to lock the length of the EPR without having constant torque on the gearbox output shaft.

5.3 Alternatives to a plane threaded power screw

Ball screws and roller screws are alternatives to plane threaded power screws and offer rolling rather than sliding contact between loaded components. In general, these devices offer much improved power efficiency and may have lower backlash than is possible with plain threads. However, for a given axial load carrying ability the assembly is bulkier in overall diameter than a plain screw and nut and manufacture requires precise machining of hard materials which would be expensive for small volume production. Considering a typical ball screw arrangement, additional diameter is due to the need to provide space for balls to roll between male and female thread forms and also due to the need for balls which have rolled through the load bearing part of the thread to be recirculated along a guide external to the female threaded part. For the EPR application it might be feasible to avoid the need to recirculate the balls by making the male and female threads similar in length. The minimum practical pitch for a ball screw is greater than for a similar diameter plain screw since the thread form has to be large enough to accommodate the balls. The rolling contacts wear less than plane screws at moderate loading but at high loading may suffer surface damage due to high Hertzian contact stresses.
For the extendible EPR application, the ratio of axial output force to input torque is more important than power efficiency. A ball screw typically has a power efficiency in the region of 90% whereas the power efficiency of a plain threaded screw is likely to be less than half this. However a plain threaded screw can have a considerably finer pitch than the ball screw resulting in a comparable or better ratio between output force and input torque.

In summary, the reasons for adopting a plain threaded power screw rather than a more efficient rolling contact power screw were:

- Smaller overall diameter of the assembly for a given screw diameter and axial force capacity.
- Higher ratio of output force to input torque.
- Ease of manufacture and assembly.
- Avoidance of small moving parts which may possibly be impeded by accumulation of biological material.

One device that was briefly considered as an alternative to a threaded screw is the 'Ballnut' marketed by Ransom Hoffman and Pollard Ltd. This is a 'nut' which is similar in construction to a deep grooved ball-race except that the outer race is slightly helical over a 340 degree segment and the diameter of the race is also slightly reduced over this segment causing the balls in the helical part of the race to be an interference fit on a smooth ground shaft. As the shaft turns it advances with potentially a very fine pitch giving a high ratio of output force to input torque. For the EPR application the reduction in input torque could possibly avoid the need for multiple stages of gearing. A limitation is that the axial force available is limited to that which can be carried by friction between balls and shaft. For example, for 12.5 mm shaft diameter the maximum axial load for a single Ballnut is quoted as being 300N and so an impractically large number of these devices would need to be ganged together to meet the design loading.
5.4 Arrangement of the screw and drive within the telescopic sections

A principle aim in designing the extendible EPR is to minimise the retracted length required for a given extension distance. This makes the EPR adaptable for use with a wider range of patients, including those patients that combine small stature with large growth potential. In general, the younger patients are those which place the greatest demand on the design of the EPR since it is the young patients which have the shortest bone length at the time of implant and also require the largest provision for future growth. At the same time, the younger patients also have generally the smallest diameter bones at time of implant, requiring the overall diameter of the EPR to be small whilst retaining sufficient strength to support the loading which will be imposed when the patient reaches adult body weight.

Several basic arrangements for the telescopic components are shown in Figure 5-2 and are evaluated against the requirement for minimum retracted length, indicated \( LIN \) in the diagrams, for a given extension, indicated \( EXT \) in the diagrams.

With reference to Figure 5-2, for configuration (a) the drive unit is installed within the outer telescopic section whereas for (b) and (c) it is within the inner telescopic section. In configuration (c) a large diameter screw thread is employed, the male part of this thread being cut in a disc attached to the output of the drive unit and the female part being cut in the wall of the outer telescopic component. This large diameter thread is less efficient as a power screw than the smaller diameter threads used in (a) and (b). The female thread form for (c) would be cut with a flat-topped thread section to act as one of the telescopic sliding surfaces. Suitable tolerances for the threaded components could ensure that side loads due to bending of the assembly do not act on the output shaft of the drive unit.
Figure 5-2: Alternative configurations for telescopic assembly and power screw

<table>
<thead>
<tr>
<th>Key</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>LIN</td>
<td>Length fully retracted</td>
</tr>
<tr>
<td>LOUT</td>
<td>Length fully extended</td>
</tr>
<tr>
<td>EXT</td>
<td>Extension</td>
</tr>
<tr>
<td>OLP</td>
<td>Overlap between sections at full extension</td>
</tr>
<tr>
<td>ENG</td>
<td>Engagement length of screw thread</td>
</tr>
<tr>
<td>DRV</td>
<td>Length available to accommodate drive unit</td>
</tr>
<tr>
<td>END</td>
<td>Length required for continuation of assembly</td>
</tr>
</tbody>
</table>

Drive unit - assumed to include magnet, gearing and any seals required on output shaft.
There is a minimum overlap, indicated $OLP$ on the diagrams, between the fully extended sections which must be maintained to avoid excessive sliding friction and excessive hoop stresses when the assembly is subjected to bending load and this is taken to be the same for each configuration. It is also required to have a minimum engagement length, indicated $ENG$ on the diagrams, between the male and female threads of the power screw. For arrangements (b) and (c), the assemblies require a solid region, indicated $END$ on the diagrams, to be included at the end of the outer telescopic section in order to provide material to hold the assembly together in the case of (b) and to allow continuation of the assembly to complete the EPR with both (b) and (c). For arrangement (c), but not for (b), it might be possible to omit the length $END$ if the EPR were to be terminated with an extra-cortical fixation, see Section 1.9, rather than with an intra-medulary stem.

For comparison, all the diagrams in Figure 5-2 are drawn with the same $EXT$, $OLP$, $ENG$, $END$ and the same outside diameter of the assembly. Judged on the basis of minimum $LIN$ for a given $EXT$, by inspection of the diagrams the configurations can clearly be rated (b) best and (a) worst. However, this does not take account of the need to provide an appropriately dimensioned space for the drive mechanism that turns the power screw. Each diagram indicates the space available for the drive mechanism and this differs in both volume and aspect ratio.

For configuration (a) the length of the drive space is directly added to both the retracted and extended lengths according to:

$$LIN = DRV - EXT - OLP$$
$$LOUT = DRV - 2EXT - OLP$$

The length of the drive space directly affects the length of the assembly however short the drive space may be.

For configuration (b) the length of the drive space does not affect the length of the assembly provided that the length of the drive space is less than a limit determined by:

$$DRV = LIN - ENG - EXT - END$$  (see left hand sub figure)

Where:

$$LIN = EXT - OLP - END$$  (see right hand sub figure)

Hence:

$$DRV = OLP - ENG$$
For configuration (c) the length of the drive space does not affect the length of the EPR provided that the length of the drive space is less than a limit determined by:

\[ \text{DRV} := \text{LIN} - \text{ENG} - \text{END} \]  
(see left hand sub figure)

Where:

\[ \text{LIN} = \text{EXT} - \text{OLP} - \text{ENG} + \text{END} \]  
(see right hand sub figure)

Hence:

\[ \text{DRV} < = \text{EXT} - \text{OLP} \]

In practice, it is unlikely that the drive mechanism can be made sufficiently compact not to affect the length of the assembly with configuration (b) and so part of the length of the drive space will need to be added to the minimum retracted length of assembly (b). Taking this into account, the order of merit changes, configuration (c) rather than (b) becoming the shortest of the three configurations.

However, configurations (b) and (c) both have a significant disadvantage when compared to (a), this being that the diameter of the space available for the drive mechanism is reduced due to the need to provide adequate wall thickness to the inner telescopic component. The diameter available for the drive mechanism, rather than the volume available, may prove to be crucial since it is the available diameter that largely determines the maximum output torque available from a gear mechanism.

Taking the above into account, configuration (a) was selected in preference to (b) or (c). It is understood that the group which developed a magnetically extended EPR at the University of Twente [Verkerke et al, 1991 #68] chose to use a configuration similar to that shown in (c). This choice may have contributed to difficulty experienced in achieving sufficient output torque from the drive mechanism whilst maintaining a suitable overall diameter for the EPR.
5.5 Backup method of extension

It is considered essential to provide a backup extension method by which a surgeon may extend and lock the telescopic section in the event that the non-invasive extension mechanism fails to operate satisfactorily. The backup method selected is the 'C' ring system which was used as the sole means of extending and locking extendible EPRs in the period between the use of ball extension and the current worm and screw driven method, as is discussed in Section 1.10. The 'C' ring system requires grooves in the two telescopic sections into which a surgeon inserts a special tool to force the sections apart prior to locking the length by inserting 'C' rings. The dimensions of both the grooves and the 'C' rings for the prototype non-invasively extendible EPRs have been kept identical to those of the earlier 'C' ring system since surgeons are still familiar with this system and are equipped with the necessary tools to operate it. Adopting these standard dimensions results in a design for the telescopic sections which is externally similar to that of the current extendible EPR with worm and screw for extension by surgery, as shown in Figure 5-3. If the extension system for the non-invasively extendible EPR proves to be fully reliable in clinical use then it is envisaged that the 'C' ring extension system could in due course be omitted from the design.
Figure 5.3: Telescopic body showing grooves for C-ring system and socket for IM stem.

Note:
Dimensions marked 'D' and 'L' may take the following values to suit alternative stems according to patient bone size.

<table>
<thead>
<tr>
<th>'D' Max</th>
<th>'D' Min</th>
<th>'L'</th>
</tr>
</thead>
<tbody>
<tr>
<td>16.030</td>
<td>16.000</td>
<td>25</td>
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<tr>
<td>14.030</td>
<td>14.000</td>
<td>20</td>
</tr>
<tr>
<td>12.030</td>
<td>12.000</td>
<td>20</td>
</tr>
</tbody>
</table>

Grooves for distraction tool
Female thread for power screw
Compartment for drive mechanism
Cavity for power screw
Inner telescopic section
Point 'A' (refer to text)
Outer telescopic section
Socket for IM stem
Section 5: Telescopic Body and Power Screw

5.6 Selection of materials for the telescopic sections

As discussed in Section 3.6, just three metallic materials are in regular use for load carrying application in orthopaedic implants. These are titanium alloy, cobalt chrome alloy and stainless steel, typically grade 316L. The use of metallic materials other than these would be abnormal and hence would require testing which could not be justified unless for some reason none of these three proven materials are suitable for the particular application.

Titanium was selected for the main parts of the telescopic body on account of its superior machinability to cobalt-chrome. The power screw which engages a titanium female thread to drive the extension motion was in cobalt chrome which incurred the cost of a thread grinding operation but this was considered necessary since titanium on titanium thread combinations are prone to galling and seizure. The use of dissimilar metals at a sliding contact generally gives lower friction coefficient and this will improve the efficiency of the power screw. The Machinery Handbook [Green, 1996 #22] lists friction coefficients for contact between various substances. Although specific data for titanium or cobalt chrome alloy is not included it is clear that friction coefficients for dissimilar metal combinations are lower than for identical metals. For example, the friction coefficient quoted for steel sliding on various other metals listed is not more than half that for steel sliding on steel. The use of cobalt chrome for the power screw was also advantageous in that its modulus of elasticity being higher than that of titanium significantly increases the column buckling strength - see Section 5.10 below.

Stainless steel was not used for any parts other than those sealed within the drive mechanism compartment. An assembly of stainless steel and titanium parts will suffer electrolytic corrosion in-vivo whereas experience with existing designs of EPR at Stanmore indicates that electrolytic corrosion is not significant when combinations of cobalt chrome alloy and titanium are used in-vivo. Even if dissimilar metals were avoided by use of stainless steel throughout the extendible module there would still be potential difficulty should it be required to assemble an EPR consisting of this extendible module together with other titanium components.

The titanium alloy used was type 318, the usual grade for orthopaedic applications. The relevant room temperature mechanical properties are given in data sheets published by
the supplier [IMI Trade Literature #26] and data from this source is summarised in Table 5-1.

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Young's modulus</td>
<td>106 GPa</td>
</tr>
<tr>
<td>Poisson's ratio</td>
<td>0.33</td>
</tr>
<tr>
<td>0.2% proof stress in tensile test</td>
<td>885 MPa</td>
</tr>
<tr>
<td>Yield strength in tensile test</td>
<td>985 MPa</td>
</tr>
</tbody>
</table>

Table 5-1: Mechanical properties of Titanium 318

Titanium is a relatively ductile material and hence the Von Mises shear strain energy criterion can be used in applying the results of a direct stress test (e.g. a tensile or bending test) to assess the possibility of failure of a structure having an arbitrary stress field [Timoshenko, 1968 #58][Case and Chilver, 1993 #59]. The principle on which this failure criterion is based is that to avoid failure, the shear strain energy per unit volume predicted for the arbitrary stress field under investigation should not exceed that which was present in the direct stress test on the material at the point of failure. Considering failure by yield of a ductile material under a single application of a load, this criterion can be expressed:

\[
\left(\sigma_1 - \sigma_2\right)^2 + \left(\sigma_2 - \sigma_3\right)^2 + \left(\sigma_3 - \sigma_1\right)^2 \leq 2\sigma_y^2
\]

Equation 5-1

Where \(\sigma_1, \sigma_2\) and \(\sigma_3\) are the principal stresses for the arbitrary stress field under investigation and \(\sigma_y\) is the yield stress determined by a tension test on the material. If fatigue loading is under consideration then \(\sigma_y\) in this equation is replaced by the maximum cyclic direct stress as determined by a fatigue test for an appropriate number of cycles and with a specimen having appropriate stress concentration factor.

As discussed in Section 3.4, a design life of \(2 \times 10^7\) walking load cycles is taken as an appropriate basis for fatigue prediction of an extendible EPR located in a lower limb. Fatigue tests applying cyclic direct stress are usually rotating beam (Wohler) tests or unidirectional (zero minimum) tensile tests. The latter test is more closely applicable to an EPR application since the available telemetric data [Taylor, 1997 #56] shows that a typical EPR is subjected to stress cycles having near zero minimum values. The stress vs. cycles to failure curves given by a supplier of titanium material [Imperial Metal Industries Ltd #26] indicate that for zero minimum direct stress fatigue of a smooth
titanium 318 specimen ($k_r=1.0$) the life will exceed $2 \times 10^7$ cycles if the maximum direct stress is below 720Mpa. The corresponding value for a notched specimen ($k_r=3.0$) is 250Mpa. It is thus marginally conservative to take the permissible nominal stress to be inversely proportional to the theoretical value for stress concentration, $k_r$, and with this assumption the Von Mises failure criterion becomes:

$$\frac{1}{2} \left( (\sigma_1 - \sigma_2)^2 + (\sigma_2 - \sigma_3)^2 + (\sigma_3 - \sigma_1)^2 \right) \leq \left( \frac{\sigma_f}{k_r} \right)^2 \tag{Equation 5-2}$$

Where $\sigma_f$ is the nominal failure stress for the unidirectional tensile fatigue test for a smooth specimen and an appropriate number of cycles. For $2 \times 10^7$ cycles, $\sigma_f = 720$Mpa.

It is noted that the ratio between the fatigue limit and the yield strength for titanium is superior to that for stainless steel and cobalt chrome.

### 5.7 Bending strength of telescopic section

![Bending moment diagram for telescopic section](image)

**Figure 5-4:** Bending moment diagram for telescopic section

For a simple analysis of the bending strength of the assembly as shown in Figure 5-4 each component is considered to be a beam having cross sections which do not deform. This is approximately the case when there is a generous overlap between the telescopic parts. For a short overlap, the outer part in particular will deform to a non-circular section at the open end, causing increased local stresses and requiring a technique such as finite element analysis for detailed study.

The cross section for the inner telescopic section was taken from a standard Stanmore design of extendible EPR with ‘C’ rings as described in Section 1.10. This cross section.
which is shown in Figure 5-5, is at the small end of the range of sizes manufactured at Stanmore. It was considered that this was appropriate for the development work since it would highlight any difficulties arising from the flexibility of the inner telescopic section, for example jamming of the power screw or jamming between sections when the assembly is under bending moment.

![Cross section through inner telescopic component](image)

Figure 5-5: Cross section through inner telescopic component

This cross section shown in Figure 5-5 includes a central 8mm bore to accommodate a power screw together with flats on each side to accommodate 'C ring' spacers as shown in Figure 1-12. The bending strength of a long beam that does not buckle is proportional to the section modulus. The section modulus for the section shown in Figure 5-5 was determined by use of the 'mass properties' command included in the Autocad drawing program. Table 5-2 below compares the section modulus $Z_{xx}$ and $Z_{yy}$ for bending about the X and Y axis respectively with the value for a solid bar of the same outside diameter, both with and without the inclusion of the central hole. A similar comparison is included for the corresponding moments of inertia, $I_{xx}$ and $I_{yy}$ which are proportional to bending stiffness.
For a solid bar, 16mm diameter: \( Z_{xx} = Z_{yy} = 402 \, \text{mm}^3 \)
\( I_{xx} = I_{yy} = 3217 \, \text{mm}^4 \)

<table>
<thead>
<tr>
<th></th>
<th>( Z_{xx} )</th>
<th>( I_{xx} )</th>
<th>( Z_{yy} )</th>
<th>( I_{yy} )</th>
</tr>
</thead>
<tbody>
<tr>
<td>For section with flats as shown above, but no central hole</td>
<td>98.3</td>
<td>98.3</td>
<td>90.3</td>
<td>76.2</td>
</tr>
<tr>
<td>For section with flats and central hole, as shown above</td>
<td>92.0</td>
<td>92.0</td>
<td>82.8</td>
<td>69.9</td>
</tr>
</tbody>
</table>

**Table 5-2: Section properties for inner telescopic component**

It is seen from Table 5-2 that the inclusion of the flats and the central hole reduces the section modulus in the weakest direction to 82.8% of that for a solid bar of the same nominal diameter.

The outer diameter of the outer section of the telescopic assembly was determined with regard to the following considerations:

1. The strength must be suitable for the applied loading during all human activities, as discussed under Section 3 above.
2. The outer diameter must be sufficient to accommodate a suitable compartment for the gearing and drive components, based on the configuration shown in Figure 5-2(a).
3. For the initial design at least, the outer diameter should be compatible with existing extendible EPRs made at Stanmore. This is to simplify the customisation of the EPR to suit specific patients and to minimise variation in surgical procedure on introduction of the new system to clinical practice. Later designs may use a smaller outer diameter, subject to meeting the requirements of 1. and 2. above.

Of these three requirements it was the third requirement which in practice determined the diameter of the main batch of prototypes constructed for this project. Most of those femoral EPRs which are currently configured with prosthetic knee joints at the distal end are manufactured with a 24mm nominal outside diameter which is fitted into the femoral component of the knee joint using a heat shrink fit. For an extendible EPR, this diameter would be the outer section of the telescopic section, the inner section being proximal to the outer. For distal femoral applications there is little incentive to reduce
the diameter at the distal end of the EPR since the femoral knee components are
generally large enough to accommodate the current 24 mm diameter. Also the backup
means of extension as described in Section 5.5, requires grooves in both the inner and
outer telescopic sections. These grooves are standardised at 24mm outer and 20mm
inner diameter.

A simple analysis of the bending of a rod in tube telescopic assembly would suggest
that the bending strength of the rod should be the same as that of the tube, that is the rod
and tube should have equal section modulus.

Let

\[ D = \text{Nominal outer diameter of tube (outer telescopic component).} \]

\[ d = \text{Nominal diameter of rod (inner telescopic component).} \]

Then:

\[ \frac{\pi d^3}{32} = \frac{\pi}{32D} (D^4 - d^4) \]

\[ d^3 = \frac{(D^4 - d^4)}{D} \]

Equation 5-3

Solution of this equation by an iterative method gives \( d = 0.819D \). As noted above, the
inner telescopic section with flats and central hole has section modulus 82.8% of that of
a similar diameter rod. The appropriate modification to Equation 5-3 indicates
\( d = 0.843D \) and hence for \( d = 16\text{mm} \), \( D \) would be nominally 19mm.

An outer telescopic section having outer diameter of 24mm would thus appear to be
unnecessarily strong when used in combination with the inner telescopic section as
shown in Figure 5-5. Based on the simple theory given above, it would be feasible to
reduce the outer diameter of the outer telescopic section down to 19mm along that part
of the length between the drive compartment and the groove for the distraction tool.

Retaining a larger diameter at the open end of the outer telescopic component would
stiffen the cross section of this component against distortion when the overlap between
teleoscopic sections is small. For the smaller patients a reduction in outer diameter along
even a part of the length would make it easier for the surgeon to close the tissues after
implant of the EPR but a diameter as small as 19mm may not be feasible due to
distortion under bending moment when the overlap between telescopic sections is small.

A more detailed analysis would be required to check this. This analysis has not been
carried out at the time of writing since an FEA stress analysis program with 'gap'
elements to model contacts between mating parts has not to date been available to the
project.
The design value for the bending moment to be carried by the telescopic sections of the extendible EPR is given in section 3.4 as 100 Nm. Based on this value and using the lowest Z value from Table 5-2, the maximum direct stress in the inner telescopic section of the EPR is calculated to be 300 N/mm\(^2\) for a constant section beam without stress concentration. The sudden change in section diameter at the point marked ‘A’ in Figure 5-3 above will result in a stress concentration factor. Established data for stress concentration factor, \(k_t\), for an abrupt change in diameter of a circular section beam subject to bending indicates \(k_t\) at ‘A’ in Figure 5-3 to be 2.0, assuming a 1.0mm fillet radius as shown on current drawings [Peterson, 1953 #42]. The factor of safety for a fatigue life of \(2\times10^7\) zero minimum direct stress cycles is then estimated to be 1.2 based on the strength data for titanium alloy as given in Section 5.6.

The above discussion has considered only bending load on the telescopic assembly. The simultaneous application of axial compressive load may actually improve the fatigue life by reducing the maximum tensile stress caused by bending. The compressive stress due to the design axial load of 2.1kN is estimated to be 19N/mm\(^2\) for the section as shown in Figure 5-5. This is only 6% of the tensile stress due to bending and was ignored, as was the small adverse effect of superimposed torque loading.

The factor of safety of 1.2, as determined above, is low but is rather greater than that determined on a similar basis for a typical IM stem. As pointed out in Section 3.4, there is no advantage in making the bending strength of the telescopic section much greater than that of the stem.
5.8 Resisting rotation between the telescopic sections

For pure torque load on a circular section shaft, the principle stresses at the surface are equal in magnitude to the maximum shear stress.

Let: \( \tau_{\text{max}} = \) maximum shear stress \(-\) N/m²

\[ T_y = \text{applied torque at yield} \]

\[ I_z = \text{polar moment of inertia of circular section} \]

\[ d = \text{diameter of section} \]

\[ \sigma_y = \text{yield stress in tensile test} \]

The Von Mises failure criterion (Equation 5-1) for yield under pure torque loading then becomes:

\[ \tau_{\text{max}} = \sqrt{\frac{1}{3}} \sigma_y \]  \hspace{1cm} \text{Equation 5-4} \]

The maximum shear stress at the surface of a circular section shaft under pure torque loading is calculated as:

\[ \frac{2\tau}{d} = \frac{T_y}{I_z} = \frac{32T_y}{\pi d^4} \]  \hspace{1cm} \text{Equation 5-5} \]

If the proposed inner telescopic section of the extendible EPR, as shown in Figure 5-5 is approximated as a circular section of 16mm diameter then the torque at yield is calculated from Equation 5-5 to be = 457Nm, based on the strength data for titanium alloy as given in Section 5.6.

The design torque for the telescopic section, as detailed in Section 3.4 is 10Nm. This design torque is only 2.2% of the calculated torque at yield and so the inner telescopic section is only lightly loaded by torque.

A key and keyway, as shown in Figure 5-1(a) above, is a simple means to resist rotation between concentric cylindrical parts. Splines and other more complex arrangements are justified only when the applied torque is large in relation to the cross section or when it is particularly important to reduce sliding friction and/or wear. Since, as discussed above, the torque loading is small in comparison to the yield torque for the inner telescopic section; a relatively small keyway is sufficient to prevent relative rotation between the telescopic sections.
The most common key arrangement is where a key is fitted into a short slot in a shaft and engages a long open ended slot in the component mounted onto the shaft. For the extendible EPR application this arrangement of slots in shaft and outer component was reversed, the long slot in which the key slides being cut in the inner telescopic component. A long slot in the outer part of the telescopic body would be more difficult to produce and would unnecessarily weaken the outer part which is relatively thin walled, particularly at the point where the groove is cut for the back up extension system.

![Diagram of key and keyway](image.png)

**Figure 5-6: Detail of key and keyway for telescopic sections**

The key was fitted into a short slot cut clear through the wall of the outer telescopic component, the key being retained by electron beam welding – see Figure 5-6. The key and the slot into which it fits were both stepped so that the components are self-jigging when the assembly is set up for welding. The stepped key was made by CNC milling. The long slot in the inner telescopic component was milled using a small slot drill, although a ‘woodruff’ type cutter would be an alternative method.

If a key and keyway assembly fails under torque loading, the failure is generally due to the material of the key shearing so that the key is divided into two parts allowing relative rotation between the components into which the key is fitted. It is assumed that the key carries the entire torque loading, that is friction between the cylindrical parts is neglected. The material of the key in the region where failure occurs is assumed to be loaded in shear only so that the Von Mises criterion for failure is as for a circular shaft under torque loading, as Equation 5-4.
Let: \( w \) = width of the key measured tangentially
\[ d = \text{diameter of shaft} \]
\[ l = \text{axial length of key} \]

Then shear stress is given by:
\[ \tau = \frac{2T}{dlw} = \sqrt{3}\sigma \]

Equation 5-6

Where \( \sigma \) is the direct stress producing the same distortion strain energy as the shear stress.

The dimensions selected for the key are \( d=16\text{mm}, \ l=10\text{mm} \) (neglecting the semicircular ends) and \( w = 3\text{mm} \). For the design torque \( T = 10\text{Nm} \) these dimensions give an equivalent direct stress \( \sigma = 72\text{Mpa} \). Comparison with the direct stress limit for fatigue loading indicates a factor of safety of 10.0, assuming no stress concentration and based on a life of \( 2\times10^7 \) cycles (See Section 5.6 above) zero minimum loading.

This factor of safety is considered satisfactory to allow for possible error in stress estimation. The actual stress may be less than that estimated due to the effect of friction between the telescopic sections absorbing part of the applied torque, or it may be higher due to slight longitudinal misalignment of the key or key way causing uneven stress distribution along the length of the key.
5.9 Power screw thread form

Plain threaded power screws are designed with a variety of threads that are not necessarily similar to the threads used for static fastening applications. When a thread form is selected for a power screw application it is usually desirable to reduce friction between thread and nut whereas for a fastening application it may be advantageous to deliberately increase friction to avoid unwanted loosening.

![Diagram showing forces acting on a small region of contact between threaded surfaces](image)

**Figure 5-7: Forces acting on a small region of contact between threaded surfaces**

Friction on screw threads is discussed in textbooks on mechanics and is summarised as follows:

Figure 5-7 shows a small region of contact between threaded surfaces. The normal to this region is inclined to the axis of screw rotation according to the both the lead angle of the screw thread (angle \( \lambda \)) and the angle of the thread profile (angle \( \alpha \)), these angles being measured in orthogonal planes. For a standard metric thread \( \alpha \) is 30 degrees, for a square thread it is 0 degrees. The external loading and torque applied to the assembly result in forces \( w \) and \( q \) respectively acting on the small element of the screw component which contacts the nut in the small region of contact drawn. Summing the force \( w \) for all such regions of contact gives the total axial force \( W \) acting on the screw and summing the product of \( q \) and mean contact radius \( r \) gives the total torque applied to the screw, \( T \). In steady state motion, the forces \( w \) and \( q \) are balanced by a normal
contact force $F_n$ and a perpendicular friction force as shown. Assuming a coefficient of friction $\mu$ then the friction force is $\mu F_n$.

Machinery Handbook [Green, 1996 #22] gives static friction coefficients for various combinations of materials. Although cobalt chrome alloy and titanium, the materials for the EPR power screw and internal thread, are not included, 0.4 would be a typical dry static friction coefficient for dissimilar metal combinations, e.g. Steel on cast iron. The power screw in the EPR will be wetted by body fluids but for a conservative calculation the dry friction coefficient is used since continuous load while the parts are not in motion may squeeze out lubricating fluid.

Summing the forces acting on the element of contact surface in the direction of $q$:

$$ q = F_n(\mu \cos \lambda + \cos \alpha \sin \lambda) \quad \text{Equation 5-7} $$

Summing the forces acting on the element of contact surface in the direction of $w$:

$$ w = -F_n(\mu \sin \lambda - \cos \alpha \cos \lambda) \quad \text{Equation 5-8} $$

eliminating $F_n$:

$$ q = \frac{w(\mu \cos \lambda + \cos \alpha \sin \lambda)}{\cos \alpha \cos \lambda - \mu \sin \lambda} \quad \text{Equation 5-9} $$

summing $w$ and product of $q$ and $r$ for whole screw:

$$ Q = \frac{Wr(\mu \cos \lambda + \cos \alpha \sin \lambda)}{\cos \alpha \cos \lambda - \mu \sin \lambda} \quad \text{Equation 5-10} $$

dividing numerator and denominator by $\cos \lambda$:

$$ Q = \frac{Wr(\mu + \cos \alpha \tan \lambda)}{\cos \alpha - \mu \tan \lambda} \quad \text{Equation 5-11} $$

$\lambda$ is related to the lead of the thread $L$ by:

$$ \tan \lambda = \frac{L}{2\pi r} \quad \text{Equation 5-12} $$

$T$ is related to $Q$ by:

$$ T = Q \pi r \quad \text{Equation 5-13} $$

Hence:

$$ T = \frac{W r(2\pi \mu + L \cos \alpha)}{2\pi \cos \alpha - L \mu} \quad \text{Equation 5-14} $$
The work done by the screw in one revolution is $WL$, and the energy input to the screw per revolution is $2\pi T$, hence the mechanical efficiency of the screw, $\eta$, is given by:

$$\eta = \frac{WL}{2\pi T} = \frac{L \left( \frac{2\pi \cos \alpha - L \mu}{2\pi \mu + L \cos \alpha} \right)}{2\pi}$$

Equation 5-15

Evaluation of Equation 5-15 for various values of lead $L$ and with fixed values for other parameters shows that the optimum lead angle for an efficient power screw is much greater than that which would normally be used for a threaded fastener. For example, Figure 5-8 below shows the variation in efficiency with lead angle for 8mm nominal diameter, a thread form angle $\alpha$ of 30 degrees and assuming 0.4 for the friction coefficient, as discussed above. Both low and high values of lead angle are inefficient and the optimum value is approximately 32 degrees, which corresponds to 15mm lead for 8mm nominal diameter. This optimum pitch angle is found to be almost independent of thread form for values of $\alpha$ from 0 to 30 degrees. A value of lead angle as large as 32 degrees would in practice require a multi-start thread in order to optimise the load carrying and wear properties of the power screw.

![Figure 5-8: Effect of power screw lead angle on efficiency](image)

For the application under consideration, the power screw must develop a required output force with the minimum input torque and this requires a minimum lead angle consistent with practical considerations and certainly a lead angle less than that for maximum power efficiency. Efficiency of the screw is not of direct importance, the consequence of low efficiency being only an increase in the time taken to extend the EPR. However, for any lead $L$ and output force $W$, the input torque is inversely proportional to efficiency and so Equation 5-15 was evaluated for various values of thread profile angle $\alpha$, to assess how this angle would affect efficiency and hence the
required power screw input torque. An 8mm nominal screw diameter, 1.25mm lead and friction coefficient of friction of 0.4 were assumed, producing a curve as Figure 5-9 below.

![Figure 5-9: Effect of thread form on power screw efficiency](image)

Standard metric threads have 30 degrees thread profile angle, $\alpha$. A zero value for $\alpha$ is difficult for turning since the cutting tool tends to bind on the side of the cut. A value of 5 degrees is a practical minimum and is used for the Acme thread often found in machine tools. It is seen that efficiency does improve as $\alpha$ reduces but the effect is small. The small reduction in power screw input torque which could be achieved by use of an Acme thread profile rather than a standard ISO 60 degree included angle profile, for which $\alpha = 30$ degrees, was not considered to be worth the complication of using special taps and thread cutting tools. Hence the thread used for the power screw was a standard ISO coarse series thread, the nominal diameter of this thread being selected on strength considerations as discussed in Section 5.10 below.
5.10 Strength of power screw

The following modes of failure of the power screw are considered:

1) Column buckling.
2) Yield under direct compression loading.
3) Thread failure where the screw engages the threaded inner telescopic component.

The power screw can be considered to be a strut loaded in compression and pin jointed at the ends since neither the thrust bearing at one end nor the short female thread at the other can be assumed to support the screw rigidly against small bending deflections.

The length of this strut is equal to the maximum extension of the EPR plus an allowance for the small length under compression when the EPR is at minimum extension. The maximum extension of the EPR will vary from one patient to another since the telescopic sections will be cut to length according to the growth potential of individual patients, as discussed in Section 3.2. The maximum growth to be accommodated is determined from Table 3-1 to be 100mm. For the design as currently envisaged the unsupported length of power screw for the maximum extension of 100mm is taken to be 105 mm.

Let: $L =$ unsupported column length = 0.105m
$E =$ Youngs modulus for screw material (cobalt chrome) = 230Gpa
$I =$ Bending moment of inertia of screw

Then the Euler buckling load $W_h$, at which the compressed column becomes unstable, is given by:

$$W_h = \frac{\pi^2 EI}{L^2}$$  \hspace{1cm} \text{Equation 5-16}

For a screw threaded component it is only slightly conservative to base the bending moment of inertia on the core dimension of the thread since the material of the threads adds very little to bending stiffness. Table 5-3 below gives the buckling loads $W_h$ for several thread sizes based on Equation 5-16 with the data quoted above. Also tabulated are the direct compressive stresses corresponding to the buckling load for each of the thread sizes considered.
<table>
<thead>
<tr>
<th>Thread size</th>
<th>Core diameter (minimum of tol.) mm</th>
<th>Buckling load $\text{N}$</th>
<th>Direct stress on core diameter at buckling load $\text{N/mm}^2$</th>
</tr>
</thead>
<tbody>
<tr>
<td>M5</td>
<td>3.842</td>
<td>2.20</td>
<td>190</td>
</tr>
<tr>
<td>M6</td>
<td>4.536</td>
<td>4.28</td>
<td>265</td>
</tr>
<tr>
<td>M7</td>
<td>5.369</td>
<td>8.40</td>
<td>371</td>
</tr>
<tr>
<td>M8</td>
<td>6.230</td>
<td>15.22</td>
<td>499</td>
</tr>
<tr>
<td>M10</td>
<td>7.888</td>
<td>39.13</td>
<td>801</td>
</tr>
</tbody>
</table>

Table 5-3: Buckling loads for power screw

Since a single load application can cause failure by buckling, the value for $W_b$ should exceed the maximum instantaneous load that is anticipated rather than the maximum fatigue loading due to walking and other cyclic activities. A value of 10 bodyweights, or 7kN, is taken for this maximum load, as given in Section 3.4. As discussed in Section 5.9, a standard metric thread is used for the power screw and from Table 5-3 an M8 thread is required to give a factor of safety of 1.5, based on failure by buckling.

Inspection of the tabulated nominal compressive stresses at the buckling load indicates that for all thread sizes up to M10 inclusive, buckling will occur before the compressive stress reaches the tensile yield stress of the cobalt chrome alloy.

The length of thread engagement between the power screw and the female thread in the inner telescopic component must be sufficient to avoid thread stripping. The theoretical prediction of thread stripping forces is complex since the load distribution between multiple turns of an engaged thread is dependant on small deformations of the parts and it is found that successive turns of thread carry reducing proportion of the total load. However, a guide is that the dimensions of a standard full nut having a length of thread engagement of approximately half of the nominal screw diameter have been found to provide thread strength greater than the maximum axial load which can be carried by the screw. The length of thread engagement for the power screw in the extendible EPR was chosen to be well in excess of half the nominal screw diameter but an extreme length of thread engagement was avoided so as to allow some possibility for small angular movement as the EPR deflects under loading.
5.11 Thrust bearing for power screw and connection to gear output shaft.

The compression load carried by the power screw is transferred to the inner telescopic sections through the thread engagement and to the outer telescopic section, which contains the power screw drive, by a thrust bearing. The power screw needs to be rotated by the output from the gearing and given the limited diameter available within the body of the EPR this almost certainly requires a concentric connection from gearing to power screw through the centre of the thrust bearing. There is hardly space for alternatives such as driving the power screw through a gear attached to the screw. A further requirement is that the connection between gear output and power screw can be disengaged simply by withdrawing one telescopic section from the other. This allows a surgeon to easily assemble or disassemble the EPR in situ in the patient, as may be necessary both for initial implant and for revision operations to replace one or more components of the EPR assembly. It is also desirable that the connection between gear output and power screw allows some bending flexibility so that neither the gear output shaft or the power screw carries excessive bending moment as a result of small bending deflections of the whole EPR assembly.

The thrust bearing arrangement based on the above requirements is shown in Figure 5-10 below, this diagram also indicating the 'O' ring seals which prevent body fluids from entering the cavity containing the magnet and gearing.

With reference to Figure 5-10, the seal housing is electron beam welded into the body of the EPR and carries the output shaft from the gearing in 'O' ring seals - see Section 8. The seal housing is arranged so that when the inner telescopic section is fully retracted most of the length of the seal housing is recessed into the end of the inner telescopic section; this minimises the retracted length of the EPR. It is noted that the seal housing must be placed into the outer telescopic section prior to the key being welded into this section, otherwise it is not possible to fit the seal housing.
Figure 5-10: Arrangement of power screw thrust bearing with connection to gearing and seals for gear cavity.

The end of the gear output shaft is machined with four flats engaging a square recess cut in the end of the power screw by spark erosion. The flats are a deliberately loose fit in this square recess so as to ease assembly of the telescopic sections and to allow the connection some flexibility to accommodate small bending deflections of the whole EPR assembly. The end face of the power screw rests on a polymeric thrust washer, which is recessed into the seal housing. Prior to final assembly of the telescopic sections this thrust washer is retained by interference fit in the seal housing.

To further ease entry of the gear output shaft into the recess in the end of the power screw, the seal housing is extended to provide a guide for the end of the power screw. Also, the square end of the gear output shaft is chamfered to more easily engage the square recess in the power screw. Even with these precautions, there is a possibility that
the EPR could be inadvertently assembled with the power screw at an unsuitable angle in the inner telescopic section so that the end of the gear output shaft fails to engage with the power screw. If this happens, the axial load carried by the power screw would fall on the gearing rather than on the thrust washer and this could cause damage. Since final assembly of the telescopic sections of the EPR may need to be done by the surgeon in the operating theatre it is important to provide the surgeon with clear written instructions to ensure that the power screw is suitably positioned so that it engages with the gear output shaft on assembly. The outer telescopic section, containing the gearing, can be assembled at manufacture so that the flats on the gear output shaft are at a known position relative to the key that engages the keyway in the inner telescopic section. It is then only necessary for the surgeon to use a simple square ended tool to rotate the power screw to a suitable angular position relative to the keyway in the inner telescopic section. To simplify this procedure, it may be advantageous to engrave or machine four marks equi-spaced around the end of the power screw, these marks being visible through the slot formed by machining the key way at the inner end of the inner telescopic section. The marks would be located such that when any mark is fully visible the power screw is correctly aligned for assembly. Before making the final assembly, the surgeon may choose to adjust the axial position of the power screw in steps of one-quarter screw pitch so as to achieve the required initial tension in the tissues surrounding the EPR.

As discussed above, the end of the power screw rests on a thrust washer to provide a thrust bearing. This washer is machined from UHMWP, a polymer which is fully accepted in orthopaedic implant use and which has excellent wear and low friction properties. UHMWP is however a relatively low strength material having a yield stress in a tension test in the region of 20MPa and it subject to significant creep at room temperature. The compressive stress on this thrust washer is calculated as follows:

Let \( \sigma_c = \) nominal compressive stress on thrust washer - N/m²

\( W = \) axial load applied to thrust washer - N

\( D, d = \) outer and inner diameter of washer respectively - m

Then:

\[
\sigma_c = \frac{4W}{\pi(D^2 - d^2)}
\]

Equation 5-17

The design axial load on the thrust washer is 7kN, see Section 3.4 above, and Equation 5-17 indicates 160N/m² compressive stress for this load and with inner and outer
diameters 5mm and 9mm respectively. This compressive stress exceeds the yield stress of the polymeric material and so if the washer were unsupported at the unloaded surfaces it would be expected to distort under this load and it could undergo significant creep at lower loads. However, with the arrangement shown in Figure 5-10, all surfaces of the thrust washer are adjacent to metal surfaces. Any distortion of the thrust washer will cause compressive loads from adjacent surfaces and these loads which will act to reduce the Von Mises Stress according to Equation 5-1. Because the UHMWP material is subject to creep it may be expected that after a period of use the material of the washer will flow until eventually all surfaces are under equal compressive stress. In this case the loading becomes equivalent to hydrostatic loading, and the Von Mises stress in the material is then zero regardless of the load transferred from the power screw. In calculating the friction torque of the thrust bearing it is conservative to assume that the stress is distributed in this manner and an allowance should then be included for friction between the inner cylindrical surface of the thrust washer and the surface of the gear output shaft.

Let  
\[ T = \text{thrust bearing torque} \quad \text{Nm} \]
\[ t = \text{washer thickness} \quad \text{m} \]
\[ \mu = \text{friction coefficient for cobalt chrome on UHMWP} \]
then if \( \sigma_c \) is assumed constant over all surfaces of the washer, by integration with respect to radius:
\[ T = \pi \mu \sigma_c \left[ \frac{1}{6} (D^3 - d^3) + \frac{1}{2} t d^2 \right] \]
**Equation 5-18**

In Equation 5-18 the first term within square brackets is the friction torque integrated over the annular face of the washer and the second term is the friction torque on the inner cylindrical surface of the washer.

The dynamic coefficient of friction between flat surfaces of polished cobalt chrome alloy and UHMW polyethylene has been found to be in the region of 0.03 to 0.11 at a contact pressure of 6.9Mpa (1000psi) [McKellop et al, 1978 #37] and using calf serum to simulate the presence of body fluids. This coefficient of friction was found to decrease slightly as contact pressure increased. To start the power screw turning it is necessary to overcome static friction, which is typically in the region of twice the dynamic friction. The static coefficient of friction for the power screw bearing was taken to be 0.2. This corresponds to an ‘angle of repose’ of 11 degrees, the angle of
repose being the steepest slope on which an object will remain at rest under the braking effect of friction. A simple test was carried out in which a block of UHMW polyethylene was placed on a polished metal surface and the angle of repose was verified to be in the region of 10 degrees.

When the extendible EPR is actually extending the maximum axial load on the thrust washer is considered to be the design distraction load, which is 700N, see Section 3.1. Using Equation 5-17 to determine $\sigma_c$ for this load and using this value in Equation 5-18 with a coefficient of friction of 0.2 indicates the thrust bearing friction torque to be 1.1Nm, of which the term for friction between the thrust washer and the gear output shaft contributes 11%.

The friction torque for the thrust washer is a significant part of the total torque required to be produced by the gearing. There is only limited scope for reducing this friction torque by reducing the diameter of the thrust washer since the inner diameter of the thrust washer has to be large enough to accommodate the gear output shaft and as shown in Section 5.12, this shaft is highly stressed with the current nominal diameter of 5mm.

Consideration was given to the use of a rolling contact thrust bearing to support the end of the power screw since this might offer much reduced friction compared with a plane thrust washer. The inner diameter of such a bearing would need to be around 5mm in order to accommodate the gear output shaft. Roller or taper roller bearings are not normally made in such small size and so a bearing incorporating balls rather than rollers is the most likely possibility. RMB AG of Bienne, Switzerland is a manufacturer of miniature ball thrust bearings. The RMB technical catalogue details a miniature thrust bearing, reference B614, which has 7 balls of 2.381 mm diameter positioned between two thrust washers of 13.8mm outside diameter. The material of this bearing is AISI 440C stainless steel. This material would corrode in the in-vivo environment, especially in the presence of titanium, but it may be feasible to have such bearings made in cobalt chrome alloy, albeit at high cost. Another possibility may be to mount the thrust bearing(s) on the gear output shaft within the sealed gear cavity, but this would require the connection between output shaft and power screw to carry high axial load. The static axial load capacity of the B614 bearing is stated to be 1962N, based on a permanent deformation of the balls not exceeding 1/10,000 of ball diameter. This capacity is
insufficient for the extendible EPR application. It is unlikely that much larger bearing dimensions would be possible without increase in the overall diameter of the EPR. Stacking several thrust bearings together would be a bulky arrangement with some method such as spring washers needed to ensure that load is shared between individual bearings.

5.12 Strength of gear output shaft

The gear output shaft needs to be the minimum size consistent with carrying the output torque from the gearing. Increase in the size of this shaft leads to an increase in the size of the thrust washer, see 5.11, and hence in the torque loss at the thrust bearing.

As shown in Figure 5-10, the gear output shaft terminates with a square section spigot that is a loose fit in a square recess in the end of the power screw. To permit assembly, the dimension across the corners of this square section cannot exceed the diameter of the gear output shaft and hence the square spigot is weaker in torque loading than the cylindrical region of the shaft.

A finite element analysis (FEA) was carried out to investigate the stress in the gear output shaft. The weakest part of the shaft was expected to be the junction between the square spigot and the circular section. To reduce stress concentration in this area, the flats of the square spigot were cut using a milling cutter having a corner radius so as to produce a fillet at the inner end of the flats.

The 'Cosmos' software supplied by Structural Research and Analysis Corporation was the only FEA software available to this project and unfortunately this software does not have a fully satisfactory capability to model load carrying contacts between separate components of a mechanical assembly. Hence it was not possible to model the connection between gear output shaft and power screw as a complete assembly which would have allowed realistic modelling of the load distribution at the loaded contacts and optimisation of all dimensions of the assembly. Instead, the gear output shaft was modelled alone, the loading of the square section spigot being by applying appropriate point loads in a tangential direction to a number of nodes near the end corners of the square spigot. This approximation produces unrealistic stress and deformation in close
proximity to the loaded nodes but stresses at a distance from the loaded nodes should be more realistic.

It was found that the 3D modelling facility built into Cosmos failed to produce a model of the gear output shaft in a suitable form for automatic mesh generation. This was overcome by modelling the geometry using the Unigraphics three dimensional CAD package which provides a facility to export 3D geometry to Cosmos. After importing the geometry into Cosmos the features of Cosmos were used for automatic meshing with 10 node tetrahedral elastic elements, to apply loads constraints and material properties and then to run an elastic static analysis.

Output from the FEA described above is shown in Figure 5-11. This contour plot shows the distribution of surface Von Mises stress for 1.0 Nm torque loading on the shaft. Since the shaft is only torque loaded during the occasional EPR lengthening operations, these stresses should be compared with the yield stress of the cobalt chrome material rather than the fatigue limit for the material. The high Von-Mises stress at the end corners of the shaft spigot may be ignored since these stresses are due to the unrealistic modelling of load transfer to the shaft. As expected, the next highest Von-Mises stresses are at the filet radius where the square section blends into the circular section, these stresses being in the region of 190N/m$^2$ for 1Nm torque loading. The design maximum torque required to turn the power screw is taken to be 3.5 Nm, as discussed in Section 6.1. Based on this torque and taking the yield stress of the wrought cobalt chrome material to be 1585N/m$^2$ (Section 3.6), this gives a factor of safety of 2.4 for the weakest part of the gear output shaft.

If the gear output shaft should fail under torque loading, as might occur if the resistance to extension of the telescopic sections is higher than predicted, then it is desirable that the failure should occur outboard of the 'O' ring seals shown in Figure 5-10. Failure of the shaft outboard of the seals would mean that further extension of the EPR would require use of the 'C' ring system but the patient would continue to be fully protected from substances within this cavity. The FEA results shown in Figure 5-11 indicate that there is a slight stress concentration at the large and abrupt change in section at the junction with the web of the final output internal gear, this web being machined integral with the shaft. The surface Von Mises stress in this region is approximately 90Mpa. Although this is higher than the stress in the gear disc or in the circular section region of
the shaft, it is clearly not a weak point when compared with the change in section at the root of the square spigot. The shaft can thus be expected to fail at the root of the square spigot, which is well outboard of the seals.

### 5.13 Strength of seal housing

An FEA analysis was applied to the welded assembly of the seal housing and the outer telescopic component, these being as shown in Figure 5-10. The purpose of this analysis was to check that stress due to cyclic loading for walking is within the fatigue limit and that the maximum occasional stress anticipated is within the yield strength of the material. It was also required to determine whether deformation of the seal housing could cause the bore of the seal housing to pinch radially inward against the gear output shaft.

The assembly was assumed to be rigidly fixed at the closed end of the outer telescopic component, i.e. the nodes at this end were fixed in all degrees of freedom to simulate the closed end of the telescopic assembly being an interference fit in a relatively rigid femoral knee joint component as would be used for a distal femoral tumour site. The loading was modelled as a uniform pressure applied over the surface of the seal housing which contacts the thrust washer. This pressure was calculated to correspond to a nominal axial load on the thrust washer of 1.0 kN and the results of the elastic analysis were then scaled for the full design axial load. An axi-symmetric model of the outer telescopic assembly and the seal housing was generated using the geometric modeller within the Cosmos package. The material was treated as continuous across the regions of electron beam welding, which is realistic for full penetration defect free welds. The model included the whole of the outer telescopic section although much of this structure had negligible effect on the results in the area of interest. Since both the geometry and the loading were axi-symmetric a two dimensional axi-symmetric elements could have been used, but it was found to be more straightforward to use the automatic mesh generator within the Cosmos package to produce a three dimensional mesh of ten node tetrahedral elements.

The results showed that both the maximum Von Mises stress and the maximum resultant deformation occurred at the inner rim of the annular face of the seal housing
which is in contact with the thrust washer. The Von Mises stress at this point was 27.2 kN/m² per kN of axial loading. The design maximum occasional axial load was taken to be 7kN and this gives a factor of safety of 5.1 based on the yield strength of the titanium alloy.

For cyclic loading, as discussed in Section 5.6, the maximum permissible Von Mises stress for the titanium alloy is 250 N/m², based on 2x10⁷ zero minimum fatigue cycles and with stress concentration factor $k_t$ of up to 3.0. The design cyclic axial load range in the femur for walking is considered to be 2.1 kN, as discussed in Section 3.4. Using the FEA results this gives a range of Von Mises stress of zero to 57N/m² which is well within the maximum for the material even allowing 3.0 for the stress concentration factor. This allowance for stress concentration is conservative since the FEA prediction of Von Mises stress takes account of stress concentration due to the details of the geometry, although the element size used may not have been small enough to accurately model the peak stress concentrations.

During the extension procedure the patient is relaxed and the axial load is not expected to exceed 700N, as discussed in 3.1. For this axial load the FEA predicted the inward deformation of the seal housing at the point of greatest deformation to be 3 microns. This is less than the radial clearance at maximum metal condition as indicated on the working drawings used for prototype manufacture and so the seal housing should not pinch the shaft during extension procedures. At the maximum design axial load of 7kN the radial deformation of the seal housing is 28 microns inwards and the housing will then grip the shaft, but this loading is only expected to occur briefly and occasionally and so contact with the shaft is considered to be acceptable. At an axial load of 2.1kN, which is typical of walking and the other activities of daily living, the seal housing should be just clear of the shaft for the maximum metal condition.
Deformation plots for the region of the seal housing were derived from the FEA and are shown in Figure 5-12. These views are half sections through the assembly with the components represented as hollow shells rather than solid bodies.
Section 6: Method of Torque Amplification

GEAR OUTPUT SHAFT - TORQUE = 1.0 NM

Figure 5-11: Gear output stubshaft - Contour plot of Von Mises surface stress.

Figure 5-12: Deformation plots of seal housing assembly

Unloaded assembly

Loaded assembly
Section 6  METHOD OF TORQUE AMPLIFICATION

The conclusion from Section 4 is that an externally generated magnetic field that rotates a small magnet within the extendible EPR is an appropriate method of transferring mechanical power to extend the EPR. A conclusion from Section 5 is that a power screw is an appropriate method of transforming rotary motion into the slow linear motion required for extension of the EPR. However, the spinning magnet within the extendible EPR is not expected to provide sufficient torque to turn the power screw directly. Some form of gearing or other torque amplification mechanism is required between the magnet and the power screw. Section 6.1 outlines the design requirements for this torque amplification system. Section 6.2 considers a range of possible mechanisms for torque amplification, both with and without the use of gears. Section 6.3 compares the advantages of the various alternatives considered in Section 6.2 and concludes with a choice of system for further development.

6.1 Requirements

The design distraction force to be provided by the power screw is 700N (see Section 3.1 above). The power efficiency of a power screw having ISO metric coarse M8 thread is calculated in Section 5.9 above to be 11%, taking the static coefficient of friction to be 0.4. The input torque to the power screw can then be determined by rearrangement of Equation 5-14 to be 1.27Nm. In addition to overcoming the screw thread friction, the gearing has to overcome the friction torque of the power screw thrust bearing which is calculated to be 1.12Nm (see Section 5.11 above), giving a total torque requirement of 2.39Nm.

Static coefficients of friction are used in determining the power screw torque requirement since the gearing has to start the power screw turning from rest. There is uncertainty in selecting values for static friction coefficient, this coefficient being dependent on the state of lubrication, the effect of fretting between mating parts during the period that the mechanism is inactive, the effect of any deposits of biological material etc. To take account of such uncertainties, the nominal output torque
requirement for the gearing was taken to be 3.5Nm, allowing approximately a 50% margin above the value predicted previously.

The diameter of the cylindrical space envelope available for the magnet and gearing was taken to be 18mm. This is to suit the proposed 24mm outer diameter of the shaft of the EPR and allows 3mm wall thickness for bending strength and for resistance to the compressive hoop stress which would result from a heat shrink fit into the femoral component of an artificial knee joint.

The input torque available to drive the mechanism is directly proportional to the magnet volume for a given magnet material and magnetic flux density. An important design aim is to minimise the space requirement for the complete drive mechanism including both the magnet and the gearing. Having accepted an overall diameter for the assembly, this leads to a trade-off between the axial length of the magnet and the length allocated to the gearing. A reasonable axial length was initially assumed for the magnet and a check was later made to determine whether a change in the length of the magnet with consequent change in magnet torque could give an overall reduction in axial length of the drive assembly. The length initially assumed for the magnet was 6.0mm and the magnet volume was determined assuming that the magnetic material would be encapsulated in a titanium can of 0.5mm wall thickness having a central 2.5mm hole for a spindle. Taking the diameter of the can to be 17.7mm to give a running clearance with the casing, this gives approximately 1000m³ of magnetic material which can produce a torque of approximately 20mNm with a magnetic flux density of 0.2 Tesla (see Section 4.3 above). The torque amplification factor required of the gearing is then 185:1. This may be a conservative assumption since it is feasible to initially reverse the mechanism then use the backlash of a gear system to allow the inertia of rotating parts to provide impact to overcome starting friction.
Based on the above, the design requirements for the gearing or other torque amplification mechanism are summarised as follows:

- Output torque 3.5Nm.
- Outer diameter 18mm, preferably with scope for future reduction in this dimension to widen application of the system.
- Torque amplification in the region of 200:1
- Minimum overall axial length.

It is noted that efficiency is not an important design requirement for this gearing. A poor efficiency simply means that the gearing will require greater velocity ratio to achieve the necessary torque amplification. A greater velocity ratio will increase the time required to complete a given extension increment but this is not a great disadvantage provided the extension rate is not extremely slow. The patient should be able to sit comfortably during the extension process and possibly read or watch television.

A long operating life is also not an important requirement. The longest total extension capability envisaged is 100mm and the proposed power screw pitch is 1.25mm so if the gearbox velocity ratio were, say, 1,000 to one, the maximum number of gearbox input revolutions during the life of the device is in the region of 80,000. This is a much shorter life than is typically required for small gearboxes. For example, the gearing in a motor car windscreen wiper mechanism would accumulate a similar number of revolutions within a few minutes of use.
6.2 Alternative mechanisms for torque amplification

Section 6.1 above outlines a requirement for a torque amplifying mechanism offering large torque gain and output torque capability within a restricted space envelope. A number of possible mechanisms are described under subheadings 6.2.1 to 6.2.8. Some less appropriate torque amplification mechanisms are excluded from this comparison, for example, worm gear mechanisms are one of the most frequently used methods to increase torque in machinery but their angled and offset input and output shaft orientation clearly does not suit the application under consideration.

6.2.1 Torque amplification by impact between rotating parts.

A force of approximately 3000N is required to drive a 3mm diameter round nail into a block of softwood, as was verified using the universal testing machine in our laboratory. The force applied manually to a carpenter's hammer is likely to be around 10N and so an impact can provide useful force amplification provided that it is acceptable for the output force to be only momentarily available.

Some consideration was given to the use of an impact device comparable to an impact screwdriver to amplify the small torque available from a spinning magnet. A rotating magnetic field external to the limb would apply angular acceleration to a permanent magnet mounted on bearings within the extendible EPR. When a certain angular velocity is reached, a centrifugal clutch engages, connecting the magnet to the power screw. As the magnet rapidly decelerates a relatively large torque is briefly transferred through the clutch to the power screw and the clutch then disengages. By repeating this cycle the power screw could be made to rotate in small increments. This type of mechanism may offer a reduced number of parts by comparison with an equivalent gearing system. A significant further advantage is that the magnet, bearings, clutch etc. can all be within a sealed metallic housing which is integral with the power screw – see Figure 6-1. This avoids the need for the shaft seal that is a necessary component of the alternative systems using gearing for torque amplification.

The centrifugal clutch is a critical part of this system and a trial and error development may be necessary to produce a reliable mechanism. A magnetically retained pawl or clutch plate is a likely approach, since a permanent magnet is in any case an inherent
part of the mechanism. The magnetic attraction between a steel part and a magnet falls rapidly as the steel part separates from the magnet introducing an air gap into the magnetic circuit. Centrifugal force could be used to separate a steel part from a magnet to trigger the sudden engagement of a clutch.

A centrifugal friction clutch would require a rather large contact force to provide sufficient torque transfer in the small space available. For example, suppose that the centre of area of the friction surfaces are at a radius of 8mm from the centre of rotation and the coefficient of friction is 0.4 then a contact force of 440N is required to transmit the design torque of 3.5Nm. Considering a mass rotating at, say, 8mm from the central axis then this mass would need to be 35 grams for a rotation speed of 12,000 rpm, this being a typical maximum speed achievable using a commercially available three phase inverter to energise the field windings. However, this mass is impractically large, the space available within the EPR would not allow such a mass even with a high-density material such as tungsten. A more likely mass would be around 5 grams, requiring a rotation speed of some tens of thousands of rpm. A lever mechanism might amplify the centrifugal force but not without additional complexity.

A ‘dog’ clutch transmitting torque by positive engagement avoids the large contact force required for a friction clutch. A dog clutch is normally used where engagement and disengagement can be made when the parts are not rotating but for a mechanism which is not required to have a long operating life it may be feasible to engage a dog clutch at a high rotation speed. Figure 6-1 shows a preliminary design based on this concept.

With reference to Figure 6-1, the power screw that extends the telescopic sections is integral with a hermetically sealed housing which contains the magnet mounted on a spindle. This housing has to be of relatively thick walled construction since it carries the full axial loading on the EPR. The back end of the housing rests on a polymeric pad acting as a thrust bearing to carry the reaction load from the power screw. All parts other than the magnet and ball are of non-magnetic metals, e.g. titanium or cobalt chrome alloy. When the magnet is not turning, the ball is in contact with the magnet and is located in a hole in a metal ring bonded to the periphery of the magnet with adhesive.
When the magnet spins, the ball breaks away under centrifugal force and travels in a slightly spiral trajectory under the effect of the magnetic field then impacts the end of a slot which is cut in the housing around the magnet as shown. The impact transfers angular momentum and kinetic energy to the housing. Some of this kinetic energy will be lost by conversion to strain energy as the power screw twists and other parts distort and/or impact against each other, but if sufficient energy is available from the clutch engagement there will be a small rotation of the power screw. Once the system has come to rest, the attractive force between magnet and ball must be sufficient to ensure that the ball retracts back to the magnet regardless of the alignment relative to the gravitational field.
Section 6: Method of Torque Amplification

Figure 6-1: Impact mechanism for extending EPR
The attractive force between the magnet and ball is difficult to determine analytically and so a simple test was set up as shown in Figure 6-2. A 16.5mm diameter by 5mm axial length neodymium iron boron permanent magnet having a diametrical direction of magnetisation was mounted on an aluminium block placed on the pan of a precision electronic balance which was positioned under the cross head of a universal testing machine. The aluminium block acted as a spacer and was found to be necessary to avoid interaction between the magnet and metal parts within the balance. A 2mm steel ball was attached to a light thread using epoxy adhesive and was suspended from the crosshead of a universal testing machine. The ball was lowered to bring the ball into contact with the magnet and the balance was zeroed with the thread slack. The crosshead was then raised slowly while data logging the force readings using a PC and the RS232 interface provided with the balance. A computer program was written to record the minimum reading occurring as the ball separated from the magnet. The light spring shown in the diagram reduced the rate of change of the readings so that the maximum reading could be more accurately detected. This procedure was repeated with non magnetic spacers of various thickness placed between magnet and ball to produce the plot shown in Figure 6-3.

Let \( r \) = radius of ball - m  
\( \rho \) = density of ball - kg/m\(^3\)  
\( R \) = radius of magnet - m  
\( F_m \) = attractive force between ball and magnet - N  
\( \omega \) = rotation speed - radians/s

Then if the magnet rotates at speed just sufficient to separate ball from magnet:

\[
F_m = \frac{4}{3} \pi r^3 (R + r) \omega^2
\]

Equation 6-1

Taking values \( r = 1\)mm and \( R = 5.5\)mm, based on the preliminary drawing, Figure 6-1, and taking \( \rho = 7800 \) kg/m\(^3\) (steel) and \( F_m = 0.46\)N from Figure 6-3, the angular speed at the moment of separation is calculated by rearrangement of Equation 6-1 to be 1230 radians/s which is 11,700 rpm.
Section 6: Method of Torque Amplification

Crosshead of universal testing machine
Light spring assists in obtaining steady readings
Thread glued to ball
Steel ball
Plastic spacer
Cylindrical magnet fixed with blue tack

Electronic balance

Figure 6-2: Measurement of force between a ball and magnet

Figure 6-3 – Results of measurement of attractive force between ball and magnet
A commercially available three-phase variable frequency inverter could be used to energise field windings to rotate the magnet. Such units are typically capable of maximum motor speeds of 12,000 rpm and this is just sufficient to separate the ball from the magnet. After the dog clutch has engaged the ball will be spaced approximately 2mm from the surface of the magnet and Figure 6-3 then indicates that the magnetic force on the ball is reduced to $7.5\times10^{-2}$N. This force is satisfactorily since the weight of the 2mm diameter ball is calculated to be $3.2\times10^{-4}$N and so the magnetic force is still more than an order of magnitude greater than the weight of the ball, hence the ball should reliably return to the magnet once rotation has stopped.

The above suggests that the simple design of centrifugally actuated dog clutch shown in Figure 6-1 should be feasible for engagement speeds in the region of 12000 rpm. Higher engagement speeds could be possible if a suitable inverter is available and if the ball were to be retained in a hemispherical shaped recess in the magnet so as to increase the magnetic ball retaining force. Engagement speeds below about 3000 rpm may not be feasible since the magnetic force would need to be reduced to a level comparable to the weight of the ball and in any case the kinetic energy transferred at impact would probably be insufficient.

The principle of conservation of momentum can be applied to the engagement of the clutch between the magnet and the power screw/magnet housing assembly.

Let:

- $J_m =$ Moment of inertia of magnet prior to clutch engagement
- $J_i =$ moment of inertia of magnet, magnet housing assembly and power screw
- $\omega_m =$ angular velocity of magnet prior to clutch engagement
- $\omega_i =$ angular velocity of magnet, magnet housing assembly and power screw immediately after clutch engagement.

Then:

$$J_m\omega_m = J_i\omega_i \quad \text{Equation 6-2}$$

Approximate values of $J_m$ and $J_i$ are calculated to be $2.43\times10^{-7}$kgm$^2$ and $14.46\times10^{-7}$kgm$^2$ respectively, based on dimensions from the preliminary design shown in Figure 6-1.
For a clutch engagement speed of 12,000 rpm, Equation 6-2 indicates the angular velocity after engagement, $\omega_t$, to be 210 radian/s. Equating the kinetic energy of the assembly of magnet, magnet housing and power screw with the energy dissipated in rotating the power screw by an angular increment $\Delta \theta$ against a torque $T$:

$$\frac{1}{2} J \omega_t^2 = T \Delta \theta$$  \hspace{1cm} \text{Equation 6-3}

Assuming that the full design torque of 3.5 Nm is required to rotate the power screw and using the above estimated value for $\omega_t$, it is calculated that the power screw would rotate by 0.84 degrees for each clutch engagement. Hence, with 1.25 mm screw pitch it would require approximately 340 clutch engagements to extend the EPR by one millimetre, each clutch engagement cycle taking perhaps a few seconds. This is a rather slow rate of lengthening but would be acceptable. The particular frequency inverter finally selected for use with the magnet drive system has a maximum speed of 30,000 rpm and so a higher clutch engagement speed may be feasible provided that the higher stresses at impact are not destructive.

The simple method described above for estimating the rotation increment for clutch engagement may be optimistic since energy transferred at impact will be dissipated in other ways than by useful rotation of the power screw. For example, energy will be transferred to torsion strain energy in the power screw and this will then oscillate in torsion until this energy is dissipated thermally by friction. Also, the magnet is likely to engage with the housing with multiple small impacts between parts. Although conservation of angular momentum still applies in this situation, the transfer of momentum will result from a lower mean torque level applied for a longer time period than for the idealised single impact.
6.2.2 Torque amplification by crank and ratchet mechanism.

Figure 6-4: Simple crank and ratchet mechanism for torque amplification

Figure 6-4 shows a simple ratchet mechanism for producing a high torque intermittent rotary output from a lower torque continuous rotary motion. A disadvantage of this mechanism for the extendible EPR application is that the output motion is not reversible by reversal of the input motion. Another disadvantage is that the likely arrangement of magnet and power screw within the body of the EPR requires the output rotation from the torque amplification mechanism to be concentric with the input. Although a ratchet torque amplifier could be so configured, this would require a rather awkward arrangement of the parts.

The torque amplification of a ratchet mechanism such as that shown in Figure 6-4 varies over each rotation cycle of the input shaft, the maximum useful torque amplification being the minimum instantaneous value taken over a full rotation of the input shaft. Assuming that the crank or cam connected to the input shaft gives a simple harmonic motion, the minimum torque amplification occurs at mid throw. In the absence of friction this torque amplification would be \( tD \) where \( t \) is the peak to peak amplitude of the crank or cam motion and \( D \) is the diameter of the ratchet wheel. The ratchet wheel diameter will be limited by the limit on overall diameter of the mechanism so increasing
the torque amplification requires reducing the crank throw and hence the dimensions of the ratchet teeth. As the ratchet teeth are made smaller the strength of the teeth will limit the output torque which the mechanism can develop. A similar limitation on output torque applies to a gear system. Achieving high torque amplification with a set of gears requires small teeth and the strength of the teeth then limits the maximum output torque. Increasing the face width of the teeth increases their strength but this also increases overall bulk. A large face width may also lead to difficulty in distributing loads evenly across the width. The strength of ratchet teeth may be greater than that of gear teeth of similar angular pitch and face width since the tooth loads can be applied near the tooth root, reducing bending moment. Against this, epicyclical gearing arrangements can share the total output torque over several tooth engagements.

Another approach might be to replace the ratchet and pawl with a sprag clutch. This is a device transmitting rotary motion in one direction only by friction acting on a number of rollers that wedge between driven and driving parts. The catalogue of W.M. Berg Inc. lists a sprag clutch having overall dimensions 14mm diameter, 12mm axial length with quoted maximum torque 5.3Nm. These dimensions might just be acceptable for the EPR application, but smaller dimensions would be preferred.

6.2.3 Cyclo speed reducer

The principle of the ‘Cyclo’ speed reducer is shown in Figure 6-5. Another mechanism based on a generally similar principle is known as the ‘Twinspin’ speed reducer. A disc with a cycloidal profile around its periphery fits into a circular array of rollers mounted from the fixed frame. There are one fewer lobes on the cycloidal profile than there are rollers on the frame so that when the cycloidal profile is ‘wobbled’ by the eccentric attached to the input shaft a relative rotation occurs between the cycloidal profile and the fixed frame. This relative rotation is transferred to the output shaft by a second set of rollers mounted on a flange on the output shaft and engaging holes in the profiled disc as shown.

An advantage of this mechanism is that there is no sliding at point or line contacts as occurs between the gear teeth of conventional gearing. In the Cyclo speed reducer all sliding takes place at rotary bearings, e.g. between the rollers and their spindles, so avoiding wear and friction associated with sliding at highly loaded point or line
contacts. The Cyclo speed reducer also offers a relatively large velocity ratio in a single reduction stage and can be manufactured with low backlash. The Cyclo speed reducer is well suited to heavy-duty long life and low backlash applications but may not be well suited to manufacture in the miniature sizes required for this project. The numerous small pins and rollers in particular could be complex to manufacture in small sizes.

![Figure 6-5: Cyclo speed reducer](image)

### 6.2.4 'Q-Ten' ball speed reducer

This unusual mechanism transmits torque through balls rolling in grooves cut in the opposing faces of two discs. The mechanism has some similarity with the Cyclo speed reducer in that the input is used to drive an eccentric to induce a lower speed output rotation. The principle of operation is described in the manufacturer’s literature and is summarised as follows:

Suppose a single ball is compressed between two discs A and B as shown in Figure 6-6. An eccentric driven by the input shaft imparts a wobbling motion to disc B, but this disc is prevented from rotating relative to the machine frame by a separate mechanism that is not shown in the diagram. Suppose that disc B wobbles whilst disc A remains fixed. The ball centre will then trace a circular path relative to both discs A and B. Suppose now that a slow rotary motion is applied to disc A. The path of the ball relative to both discs A and B becomes a ‘wavy’ path around the centre of these discs. If grooves are cut in the discs following these ‘wavy’ paths, the ball will be forced to roll along these
grooves when an input motion is applied to the eccentric in disc B. This will impart a reduced speed circular motion to disc A from which the output is taken. In a practicable version of the mechanism a number of balls are located between the two discs to share the torque transfer and an ‘Oldham’ coupling comprising two slides at right angles is used to prevent rotation of disc B relative to the machine frame whilst allowing the wobbling motion of disc B. The slides in the Oldham coupling are ball slides and the shaft bearings are ball races and so this mechanism completely eliminates sliding contacts.

Figure 6-6: Principle of Qten speed reducer

The advantages claimed for the Qten speed reducer are similar to those claimed for the Cyclo speed reducer, i.e., high efficiency and long life due to the elimination of sliding contacts, high torque amplification in compact dimensions and low backlash. The Qten speed reducer may be rather more suitable than the Cyclo speed reducer for manufacture in miniature sizes. The smallest commercially available size of Qten speed reducer measures 50mm diameter over the outer casing. Although this is too large for the EPR application, it is smaller than the smallest Cyclo speed reducer.
6.2.5 Harmonic Drive

The principle of the ‘Harmonic’ drive is detailed in the manufacturer’s literature and is summarised with reference to Figure 6-7 as follows:

A thin flexible externally toothed annulus ‘A’, referred to as a flexispline, fits within an internal gear ‘B’. The flexispline has a slightly shorter periphery than the internal gear and it also has two fewer teeth than the internal gear. The teeth of the flexispline are brought into engagement with those of the internal gear by elastic distortion produced by the elliptical rotating cam ‘C’, which is referred to as the wave generator. Balls rolling between the wave generator and the flexispline reduce frictional losses. The wave generator is driven by the input and for each rotation of the wave generator; the flexispline rotates by two teeth relative to the internal gear that is attached to the frame of the machine. Thus, if the output drive can be taken from the rotation of the flexispline, the angular velocity ratio is half the number of teeth on the internal gear. There are two alternative arrangements used to connect the flexispline to the output shaft. One arrangement is for the flexispline to be the distorted open end of a thin walled cylinder, the closed end of which is attached to the output shaft. Alternatively the flexispline can engage not one but two internal gears, there being a tooth number discrepancy between these gears so that one connected to the output rotates relative to one fixed to the frame.

Figure 6-7: Principle of ‘Harmonic’ drive
The harmonic drive offers high torque amplification and high output torque in a single stage of gearing and is used in the motorised joints of robotic machines. The high output torque capability is due to load sharing between multiple teeth.

At the time that the author was comparing alternative gear configurations for this project, the smallest available size of Harmonic gearing had a nominal casing diameter of 35 mm. This was considered too large for the application. More recently, a smaller size of Harmonic gearing has become available this having a casing diameter of 20 mm. This diameter would be suitable for some of those cases having tumour sites in the leg but would not be applicable to the younger patients or to those with humeral tumour sites. The applicability would be widened if the internal gear components of the drive could be made integral with the telescopic body of the EPR. The manufacturer rates the maximum output torque for the 20 mm diameter Harmonic drive at 3.0 Nm which is slightly less than the design torque stated in Section 6.1 but is likely to be satisfactory, given that this application requires only a short rotating life. The manufacturers of the Harmonic drive have indicated that these drives are not expected to become available in sizes smaller than 20 mm casing diameter within the foreseeable future, this being on account of the difficulties in manufacturing the flexispline in small sizes.

6.2.6 Spur gear train

Compound spur gear trains achieve higher torque amplification in given casing dimensions than is feasible with a single spur reduction stage. A possible arrangement is to have multiple stages mounted on two parallel spindles as shown in Figure 6-8. Each pinion gear, apart from the input pinion, is attached to a larger spur gear to form an assembly known as a cluster gear. For mass-produced light duty speed reducers these cluster gears are often of plastic such as ‘Delrin’ and are injection moulded in one piece. For high torque applications, such as that under consideration, metal gears are required and can be machined by shaping but not by hobbing. Alternatively, the pinion can be pressed, glued, splined or welded into the attached spur gear. The face width of the gear teeth may be increased towards the output end of the gear train to match the increasing torque; alternatively it may be preferred to use identical parts for each stage in order to save cost. Sometimes plastic gears are used at the low torque end of the gear train and metal gears at the high torque end.
The tooth size for the gearing will be determined by the torque requirement and having fixed the tooth size there is a minimum tooth number to avoid excessive tooth undercutting and hence a minimum pitch circle diameter for the pinion gears. This makes the torque amplification possible per stage of gearing with a given tooth face width proportional to the diameter of the spur gears. The maximum output torque for the final reduction stage may also be proportional to spur gear diameter since it is likely to be limited either by side load on the output shaft bearings or by the strength of the gear teeth. Hence, to minimise the number of reduction stages and to achieve high output torque, the spur gears would normally be as large as the casing dimensions allow. It is an advantage for many applications, including the current application, to have a cylindrical casing with concentric input and output shafts. This requires a layout such as that shown in Figure 6-8, in which the spur gears are rather less than half the internal casing diameter, hence the requirement for concentric input and output shafts does significantly increase the overall dimensions for a given torque amplification and output torque. Frictional losses are also increased since more stages are needed to achieve the required output torque. Despite these limitations, a number of commercially available speed reducers are internally arranged as shown in Figure 6-8 and are sometimes described as ‘epicyclic’ which is a misnomer.

Figure 6-8: Compound spur gear train on parallel spindles
6.2.7 Multistage epicyclical gear train

An epicyclical gear train is a gear train in which the centre of rotation of one or more of the gears revolves in addition to the gears themselves revolving. The most commonly used arrangement is shown diagrammatically in Figure 6-9.

Rotation of the sun pinion ‘A’ causes the planet gear ‘B’ to roll around the inside of the internal gear ‘C’. The planet gears are mounted on the planet gear carrier ‘D’, this being a frame which can itself rotate about the central axis. Figure 6-9 shows two planet gears although three is the most usual number and four or five are occasionally used. Multiple planet gears avoid heavy side load on the output shaft bearings and allow the output torque to be shared between the planet gears although this torque sharing may be unequal due to manufacturing tolerances. Of the three components, the sun pinion, the planet gear carrier and the internal gear, any two can be used as input and output whilst the third is held fixed relative to the frame of the machine. This results in three possible input and output arrangements but the most usual arrangement for speed reduction is to have the internal gear fixed, the input taken to the sun gear and the output taken from the planet gear carrier. With this arrangement the internal gear can conveniently become the housing for the gearbox and in a multistage arrangement the sun gear for each stage except the first can be directly linked to, or can be integral with, the planet carrier of the preceding stage. The alternative speed reducing arrangement in which the planet carrier is fixed and the input and output are from the sun and internal gears respectively is less suited to a multistage arrangement.

Figure 6-9: Simple epicyclical gear stage, diagrammatic
The velocity ratio of a simple epicyclic train having the internal gear fixed and the input and output connected to the sun and planet carrier respectively can be determined by considering the tangential component of velocity of the gears as measured at the pitch circle diameters.

Let:  
\[ \omega = \text{angular velocity of gear or planet carrier} \]  
\[ r = \text{pitch circle radius of gear, or radius of planet carrier to planet axis} \]  
\[ N = \text{number of teeth on a gear} \]  
\[ V = \text{tangential velocity of gears at specified tooth engagement (on pitch circle) or of planet carrier at planet gear axis.} \]  
\[ VR = \text{Velocity ratio of gearing, expressed as } \frac{\omega_{\text{input}}}{\omega_{\text{output}}} \text{ for reduction gearing.} \]

Subscripts p, pc, ig, s denote planet gear, planet carrier, internal gear and sun pinion respectively.

For contact of the gear pitch circles it is necessary that:
\[ r_i = r_s + 2r_p \] \hspace{1cm} \text{Equation 6-4}

Considering the planet gear as a body having an instantaneous centre of rotation at the common tangent point of the internal gear and planet gear pitch circles it follows that:
\[ V_{pc} = \frac{1}{2} \omega_p r_s \] \hspace{1cm} \text{Equation 6-5}
\[ \omega_{pc} = \frac{V_{pc}}{(r_s + r_p)} \] \hspace{1cm} \text{Equation 6-6}

The velocity ratio (input/output) for the simple speed reducer having the internal gear fixed is given by combination of Equation 6-4 to Equation 6-6:
\[ VR = \frac{\omega_s}{\omega_{pc}} = \frac{r_s + r_{ig}}{r_s} \] \hspace{1cm} \text{Equation 6-7}

The number of teeth on each gear is proportional to the gear radius, hence:
\[ VR = \frac{\omega_s}{\omega_{pc}} = \frac{N_s + N_{ig}}{N_s} \] \hspace{1cm} \text{Equation 6-8}
By contrast, a simple epicyclical speed reducer having the planet carrier fixed has the velocity ratio of a simple gear train since the axis of all gears are fixed relative to the frame of the gearbox. This velocity ratio is:

\[ VR = \frac{\omega_s}{\omega_g} = \frac{N_s}{N_g} \]

The velocity ratio for practical small sized single stage epicyclical gears is usually in the region 3:1 to 5:1. Large epicyclic gears as used in marine applications may have larger velocity ratios.

Figure 6-10 shows a two-stage epicyclical speed reducer in practical form, this diagram being produced by dismantling a gearbox from a scrapped item of equipment and measuring the parts. This particular gearbox has an overall diameter of 27 mm, which is too large for the extendible EPR application but similar gearboxes are available in smaller sizes and also in larger number of stages for higher velocity ratios.
The maximum output torque that can be achieved with an epicyclical stage is limited by the strength of the planet gear bearings and shafts as well as the strength of the gear teeth. Multiple planet gears increase the maximum torque although the benefit may not be proportional to the number of planets since manufacturing tolerances may cause unequal load sharing between the planets. Planet gear mountings are sometimes designed to be intentionally flexible so as to improve load sharing but this is difficult to incorporate in miniature sizes.

Comparing an epicyclical speed reducer such as that shown in Figure 6-10 with the non-epicyclical multistage arrangement shown in Figure 6-8, the following points are apparent:

- For a given tooth strength, i.e. tooth module, face width and material and given diameter of cylindrical casing, the maximum output torque of the epicyclical arrangement is significantly greater than that of the non-epicyclical arrangement shown in Figure 6-8. This is partly due to load sharing between multiple planet gears and partly because the tangential component of the tooth forces for the final stage act on a larger moment arm about the output shaft axis. If the moment arm for the tooth forces is approximately doubled by use of epicyclical gearing and if loads can be uniformly shared between three planet gears then the output torque capability is increased six times, subject to other components such as planet gear shafts having adequate strength. The epicyclical arrangement is also more efficient since friction losses at both gear bearings and tooth engagements are related to tooth force and the epicyclical arrangement has lower tooth forces for a given output torque.

- The velocity ratio for each stage of the epicyclical arrangement is greater than for the non-epicyclical arrangement, assuming a similar tooth module and casing diameter. This is mainly because the requirement for the output shaft to be concentric with the cylindrical casing limits the diameter of the spur gears for the non-epicyclical arrangement. However, for a given gear face width, each stage of epicyclical gearing occupies approximately twice the axial length than does each stage of the non-epicyclical arrangement due to space taken up by the planet carrier. This offsets the greater velocity ratio per stage available with the epicyclical
arrangement and for a given overall velocity ratio both types of speed reducer may have fairly similar axial length.

- The bearings which support the output shaft of the epicyclical arrangement are not loaded as a result of tooth contact forces whereas they are so loaded for the non epicyclical arrangement. Thus, although the strength of these bearings may limit the maximum output torque of the non-epicyclical arrangement this will not be a limiting factor with the epicyclical arrangement.
Figure 6-11 shows how the output torques of epicyclical speed reducers increases with increasing overall casing diameter. This data is from a range of standard speed reducers from a single manufacturer (Minimotor SA, Switzerland) and so the basis on which output torque ratings are quoted can be expected to be comparable for all sizes. These speed reducers are all high quality units with steel gears and ball race output shaft bearings and are intended for OEM supply to manufacturers of scientific instruments, medical equipment etc.

Of the two data sets plotted in Figure 6-11, that for intermittent operation is appropriate for the EPR application since the required running life is short. As the casing diameter increases the output torque increases at an increasing rate since the larger casing diameter allows both a larger tooth module and a larger radius for tooth tangential force to act about the output shaft. The larger units are also likely to have gear teeth with greater face width and space for stronger planet gear mountings etc.

By interpolation between the plotted data points, the casing diameter for the required design torque of 3.5Nm would be 26mm and the nearest size available from this...
manufacturer is 30mm. Another manufacturer, Interelectric AG, Switzerland, offers a unit having 26 mm casing diameter with 3.0Nm intermittent torque rating, 199.3:1 reduction ratio and 61% power efficiency. This torque output rating is likely to be adequate for the short running life required. The quoted reduction ratio and efficiency correspond to a torque gain from input to output of approximately 121:1. This is less than the preliminary design value of 200:1 given in Section 6.1 so either a larger magnet is required to drive the input or an additional stage of gearing is required. A larger magnet is likely to be the preferred option, involving no extra parts and only a few millimeters increase in axial length.

A casing size of 26mm, as determined above, would be too large for many patients requiring an extendible EPR. If this casing were to be inserted as a complete unit within the outer telescopic section of the EPR, the diameter of the EPR would be in the region of 32mm. It is understood that the non-invasively extendible EPR prototypes constructed at the University of Twente, [Verkerke et al, 1991 #68] contained an ‘off the shelf’ epicyclical speed reducer and had an outside diameter of 35mm which surgeons considered to be too large.

Some saving in overall diameter of the EPR could be achieved if the body of the EPR could be used as the casing of the gear system, internal gear teeth being cut directly in the outer telescopic section. However, this would require gear shaping down a relatively deep bore and would also require the gears to be cut in a bio-compatible material, probably titanium, which is not a good material for gearing.

It may be that for the very short running life required for this application the gear manufacturer’s maximum intermittent torque rating could be exceeded. This could best be determined by testing sample gear systems to destruction.
6.2.8 Some high ratio epicyclical gear configurations

Figure 6-12, Figure 6-13 and Figure 6-14 show epicyclical gear stages which offer higher velocity ratio per stage of gearing than is practical for the simple epicyclical stage discussed in Section 6.2.7 above. Figure 6-12 and Figure 6-13 show arrangements which have been used commercially and Figure 6-14 shows a novel arrangement which has not been commercially available, as far as the author is aware.

Figure 6-12: High ratio gear stage using only external gears

With reference to Figure 6-12, a pair of planet gears are connected together on each planet carrier stub shaft and engage two sun gears. Because the two planet gears on each stub shaft are of slightly different sizes they rotate with slightly different tangential velocities at the pitch circle radius and hence there is a slight difference in the angular velocities of the two sun gears. If one sun gear is anchored to the frame of the machine, as shown, the other will revolve at slow speed relative to the frame of the machine.

The velocity ratio for this arrangement is determined as follows, using the nomenclature given in Section 6.2.7 and with additional subscripts 1 and 2 for the left and right hand planet sun gears respectively, as shown in Figure 6-12:

\[ V_{pc} = \omega_{pc} \left( r_{p1} + r_{p1} \right) = \omega_{pc} \left( r_{p2} + r_{p2} \right) \]

Equation 6-10
The instantaneous centre of rotation of the planet gear pair is at the engagement of the right hand planet (planet 2) with the fixed sun gear (sun gear 2). Hence considering tangential velocities measured at the pitch circle for the engaged teeth:

\[ V_{pi} = \frac{V_{p2}(r_{p2} - r_{p1})}{r_{p2}} \]  
\[ \omega_{sl} = \frac{V_{pi}}{r_{sl}} = \frac{V_{p1}}{r_{sl}} \]

Equation 6-11
Equation 6-12

Combining equations Equation 6-10, Equation 6-11 and Equation 6-12:

\[ \frac{\omega_{pc}}{\omega_{sl}} = \frac{r_{si}r_{p2}}{(r_{s2} + r_{p2})(r_{p2} - r_{p1})} \]

Equation 6-13

For maximum reduction ratio the difference in the number of teeth between the planet gears is one tooth. If all gears have, say, approximately 25 teeth then the reduction ratio is approximately 13:1. Larger numbers of teeth give greater reduction ratio but for given casing dimensions this requires smaller tooth size reducing the maximum torque output.

Figure 6-13: High ratio gear stage using two internal gears and six planets
The arrangement shown in Figure 6-13 has some similarity to that shown in Figure 6-12 but the pairs of linked planet gears engage two internal gears rather than two sun gears. This gives a higher torque capability for a given tooth strength since the tangential forces on the output gear teeth act on a greater radius about the output shaft axis, and the velocity ratio is potentially much greater as shown by the analysis below. On the other hand, cost may be increased by including the internal gears since these require to be manufactured by a shaping or broaching operation rather than by hobbing. Hobbing is the most widely used and readily available gear cutting method but is not suited to internal gears.

Using the nomenclature given in Section 6.2.7 and with additional subscripts 1 and 2 for the left and right hand planet/internal gears respectively, as shown in Figure 6-13 the gear system is analysed as follows:

The instantaneous centre of rotation of the planet gear pair is at the engagement of the fixed internal gear with the left-hand planet gear, hence:

\[ V_{pc} = \frac{1}{2} \omega_s r_s \]  

Equation 6-14

Considering the tangential velocity of the right hand planet gear at the engagement with the right hand internal gear to be \( V_{p2} \):

\[ V_{p2} = \frac{V_{pc} \left( r_{p1} - r_{p2} \right)}{r_{p1}} \]  

Equation 6-15

\[ \omega_{ig2} = \frac{V_{p2}}{r_{ig2}} \]  

Equation 6-16

\[ r_{ig2} = r_s + r_{p1} + r_{p2} \]

Combining Equation 6-14, Equation 6-15 and Equation 6-16:

\[ VR = \frac{\omega_s}{\omega_{ig2}} = \frac{2r_{p1} \left( r_s + r_{p1} + r_{p2} \right)}{r_s \left( r_{p1} - r_{p2} \right)} \]  

Equation 6-17

For maximum velocity ratio tooth number difference between the planet gears in each pair can be one tooth and the sun pinion can have the smallest practical number of teeth to avoid excessive tooth undercutting, say 18 teeth. To maintain approximately the same casing diameter with the same tooth module as the above example based on Figure 6-12, the number of teeth on each pair of planet gears could be, say, 25 and 24. The gear radii
being proportional to the numbers of teeth on the gears, Equation 6-17 indicates the velocity ratio to be 178:1.

As far as the author is aware, the arrangements shown in Figure 6-12 and Figure 6-13 are no longer commercially available as “off the shelf” units. This may be because they have been superseded by the Harmonic drive and the Cyclo drive; these possibly giving higher efficiency and torque output for a given size and reduction ratio. For small batch production the arrangements shown in Figure 6-12 and Figure 6-13 retain an advantage in that they can be assembled from relatively easily made parts such as gears, bearings etc. The Cyclo and Harmonic drives both require components that are specific to these particular mechanisms.

![Diagram](image)

**Figure 6-14: High ration gear stage using two internal gears and three planets**

The arrangement shown in Figure 6-14 has similarity to that shown in Figure 6-13. The input is to a sun gear driving two or more planet gears, the face width of these planet gears being such as to engage two internal gears which have differing number of teeth. The difference in tooth number between the internal gears causes a relative rotation between these internal gears so that if one is fixed to the casing a low speed output can be taken from the other. This arrangement requires the two internal gears to have the same pitch circle diameter but to have differing numbers of teeth. This implies that the angular spacing of the teeth on at least one of three meshing gears differs from that which would normally be used for the chosen pitch circle diameter and shaping cutter.
tooth module. It has been found to be practical to produce such gearing by appropriate setting up of the gear shaping machine that generates the internal gears. The planet carrier for this arrangement is in the form of a 'cage' having radial slots to accommodate the planet gears. This planet carrier 'floats' within the mechanism, being radially located by the tooth contacts. The tooth number difference between the two internal gears must be a multiple of the number of planet gears; otherwise the gears do not fit together. In practice this tooth number difference needs to be equal to the number of planet gears so as to maximise velocity ratio and to avoid excessively distorted tooth form. The number of planet gears needs to be at least two to balance forces about the central axis of the mechanism.

Assuming the tooth difference between the internal gears is \( n \), that is \( n \) planet gears are used, each rotation of the planet gear carrier rotates the output shaft by the angle subtended by \( n \) teeth on the output internal gear. Because of the adjustment made to angular tooth spacing this is the same angle as is subtended by \( n \) teeth on the fixed internal gear.

The velocity ratio between the planet carrier and the output gear is:

\[
\frac{\omega_{pc}}{\omega_{g2}} = \frac{N_{g2}}{n}
\]

Equation 6-18

Equation 6-17 applies to the arrangement shown in Figure 6-14 as for that shown in Figure 6-13, hence:

\[
\omega_{pc} = \frac{V_{pc}}{r_s + r_p} = \frac{\omega_s r_s}{2(r_s + r_p)}
\]

Equation 6-19

The overall velocity ratio of the mechanism is given by:

\[
VR = \frac{\omega_s}{\omega_{g2}} = \frac{\omega_s}{\omega_{pc}} \frac{\omega_{pc}}{\omega_{g2}} = \frac{2N_{g2}(r_s + r_p)}{nr_s}
\]

Equation 6-20

To maintain similarity in casing diameter with the examples given for the arrangements shown in Figure 6-12 and Figure 6-13, the sun gear could have, say, 18 teeth, the planet gears say 24 teeth and the internal gears 66 and 64 teeth with two planet gears in the planet carrier. The velocity ratio is then 149.3:1. For comparison, the velocity ratio for a simple epicyclical stage having 18 tooth sun gear and 24 tooth planets would be 4.66:1 (Equation 6-8).
The use of three rather than two planet gears with the arrangement shown in Figure 6-14 reduces the velocity ratio by two thirds but potentially increases the output torque capability by the inverse ratio, provided that loading can be effectively shared between the planet gears.

The advantages of the arrangement shown in Figure 6-14 include:

- **High maximum torque for given overall dimensions.** The tangential components of tooth force which generate the output torque are transferred from the teeth of the fixed internal gear to the planet gear teeth and then directly back to the teeth of the output internal gear without applying torque loading or large bending moment to any shaft or applying large radial loading to any bearings. The teeth of the planet gears carry the tooth load as shear stress acting on a plane perpendicular to the gear axis as well as by direct stresses due to bending of the teeth about the tooth root. This is expected to allow higher tooth forces and hence greater output torque for a given casing diameter than conventional epicyclical gearing. The bearings supporting the input sun gear and the output internal gear are lightly loaded since the tooth forces acting on these gears are balanced. The tooth forces acting on the planet gears are also balanced in a plane transverse to the axis of rotation since no torque is taken from the planet carrier. The tooth forces acting on the planet gears do apply a couple about a direction radial to the axis of the sun gear and this causes equal and opposite radial forces on the two bearings supporting each planet gear. However, these bearing forces are reduced by the axial spacing of the planet gear bearings being greater than the axial spacing of the contact points between a planet gear and the two internal gears.

- **High velocity ratio with relatively simple construction.** For a given casing diameter and tooth size this arrangement offers a single stage velocity ratio which is approximately 32 times greater than for a simple epicyclical stage as shown in Figure 6-9 and this improvement is achieved with only one additional part, this being a second internal gear. The axial length of the assembly is approximately doubled by comparison with the simple single epicyclical stage.
6.3 Selection of mechanism for torque amplification

Section 6.2 included diagrams and descriptions of 10 different torque amplification mechanisms. These are listed in the table below, with a rating for the suitability of each mechanism. Each mechanism was rated against the design requirements listed in Section 6.1 and was subjectively scored A, B or C, A being the closest fit with the requirements.

<table>
<thead>
<tr>
<th>Fig. No. And description</th>
<th>Comments</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Figure 6-1: Impact torque amplifier</td>
<td>Unique advantage that no output shaft seals are required. Uncertainty as to torque capability. This would require detailed analysis or testing to verify.</td>
<td>C</td>
</tr>
<tr>
<td>Figure 6-4: Ratchet torque amplifier</td>
<td>Not well suited to concentric input and output in cylindrical casing.</td>
<td>C</td>
</tr>
<tr>
<td>Figure 6-5: ‘Cyclo’ speed reducer</td>
<td>Expected to be difficult to manufacture in small sizes.</td>
<td>C</td>
</tr>
<tr>
<td>Figure 6-6: Q-ten speed reducer</td>
<td>Expected to be difficult to manufacture in small sizes.</td>
<td>C</td>
</tr>
<tr>
<td>Figure 6-7: Harmonic speed reducer</td>
<td>Not available in size required for smaller patients. ‘Off the shelf’ unit feasible for larger patients.</td>
<td>B</td>
</tr>
<tr>
<td>Figure 6-8: Multistage non-epicyclical gearing</td>
<td>Simple to manufacture but may not be feasible to achieve required output torque with suitable casing diameter.</td>
<td>C</td>
</tr>
<tr>
<td>Figure 6-10: Multistage simple epicyclical gearing</td>
<td>High torque output for given casing diameter. Multistage arrangement can have many identical parts. Good power efficiency. Available as off the shelf units although these may be too bulky for use with most patients. Low ‘technical risk’ since this is a widely used type of mechanism.</td>
<td>B</td>
</tr>
<tr>
<td>Figure 6-12</td>
<td>Avoids need to cut internal gears. Maximum torque is lower than for alternatives using internal gears.</td>
<td>C</td>
</tr>
<tr>
<td>Figure 6-13</td>
<td>High torque output for given casing diameter. Very high velocity ratio per stage.</td>
<td>B</td>
</tr>
<tr>
<td>Figure 6-14</td>
<td>Highest torque output for given casing diameter of all options considered, with possible exception of Harmonic gearing. High velocity ratio per stage.</td>
<td>A</td>
</tr>
</tbody>
</table>

Table 6-1

In the early stages of this project, the author gave detailed consideration to the impact torque amplifier since there had been concern regarding the use of elastomeric shaft seals in-vivo. The impact torque amplifier avoids the need for any such seals. Following the manufacture and satisfactory testing of prototype seals this advantage was
considered to be of lesser significance and the impact torque amplifier was abandoned due to uncertainties regarding reliability and output torque capability.

The non-gear based mechanisms such as the Cyclo drive, the Q-ten drive and the ratchet systems were regarded as being less well suited to miniaturisation than the gear systems. The example of the watch making industry demonstrates that gears can be produced in sizes even smaller than are required for this project, although this expertise may no longer be readily available in the UK.

The Harmonic drive is a gear mechanism in the sense that it includes meshing gear teeth. Had this mechanism been available at the start of the project in the size in which it is now available, it is likely that it would have been adopted and alternative mechanisms would not have been given further consideration. The Harmonic drive is now available with a casing diameter of 20mm and with adequate output torque. This casing diameter could just fit within a telescopic section having the standard 24mm outer diameter currently used with the largest patient group, those patients having a distal femoral tumour site. However, it is clear that there is a need for extendible EPRs for bone tumour patients in sizes below 24mm overall diameter and there are also further orthopaedic applications for devices in the region of 10mm overall diameter. Since the manufacturers of the Harmonic drive have indicated that they do not envisage sizes below 20mm overall diameter, the development of alternative small torque amplifiers is considered to be justified.

A multistage epicyclical arrangement, such as that shown in Figure 6-10, is a widely used mechanism for large torque amplification. Off the shelf units are available, avoiding the need for development work and the cost of custom parts. However, the available torque for a given casing diameter is rather lower than for the Harmonic drive. Based on manufacturer's torque ratings, the design torque requirement given in Section 6.1 would require an overall diameter of EPR in the region of 32 mm and this would be too large for many patients. It should be noted that for both the Harmonic drive and for the epicyclical speed reducers the manufacturers torque ratings may be conservative for an application which is only required to operate for approximately 100 rotations of the output shaft during the life of the device. If such devices were to be given further consideration for this application then it would be worthwhile carrying out tests to destruction to establish a safe torque limit for the short operating life.
Of the arrangements shown in Figure 6-12, Figure 6-13 and Figure 6-14, that shown in Figure 6-14 is the most attractive. As discussed in Section 6.2.8, this mechanism offers a combination of high torque output for a given casing diameter, concentric input and output shafts and small axial length for a given overall torque gain. These advantages were considered to justify the construction and testing of prototypes, given that if this development work was not successful it would be possible to revert to the use of a proven mechanism such as a Harmonic drive.

In a gear system comprising multiple reduction stages all fitting within a uniform casing diameter, the best configuration for the output stage may not be the best configuration for the input and intermediate stages. Torque capacity is likely to be a critical requirement only for the output stage. Hence, whilst the output stage may need to be designed for maximum torque capacity, the input stages may be of a design which has lower torque capacity but offers some other advantage such as better power efficiency or easier manufacture.

For the prototype extendible EPR the final reduction stage was as shown in Figure 6-14. Allowing for friction losses, this gear stage produced a torque gain less than the design requirement. A simple epicyclical stage could have been used as an input stage and this would have achieved the design torque gain with minimum axial length. However, it was preferred to make the input stage also as shown in Figure 6-14 and to use identical gears for both stages. This gives a greater velocity ratio and torque gain considerably greater than is actually necessary but reduces the number of different types of parts require.
Section 7  DESIGN OF GEAR MECHANISM

Section 6 discusses a number of alternative mechanisms for torque amplification between the magnet and power screw of the extendible EPR. Of these alternatives, the gear system shown diagrammatically in Figure 6-14 was selected for further development. This section discusses detail design aspects of this mechanism.

7.1 General arrangement

Figure 7-1 is a general arrangement of a two stage reduction gear mechanism based on the outline configuration shown in Figure 6-14. This general arrangement is typical of the prototype gear mechanisms made for this project. Figure 7-1 shows the moving parts axially 'exploded' and omits the body of the EPR which acts as a casing to enclose all the parts shown. The parts shown in this figure are all stainless steel 316, with the exception of part 2 which is titanium 318 and part 16 which is cobalt/chrome alloy.

Prototype gear mechanisms as shown in Figure 7-1 have to date been constructed in two slightly different versions to suit EPR body diameters of 21mm and 24 mm, the gear details for these two sizes being tabulated as follows:

<table>
<thead>
<tr>
<th>OD of EPR body mm</th>
<th>OD of fixed internal gears mm</th>
<th>Nom. PCD of internal gears mm</th>
<th>Number of teeth on gears</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>16.8</td>
<td>14.4</td>
<td>18 27 69 72</td>
</tr>
<tr>
<td>24</td>
<td>18.0</td>
<td>15</td>
<td>21 27 72 75</td>
</tr>
</tbody>
</table>

Table 7-1: Gear dimensions for prototype construction

With reference to the part numbers circled in Figure 7-1, the parts are described follows:

**Part 1:** This is an axial spindle on which the driving magnet rotates. The upper end (as oriented in Figure 7-1) of the spindle fits into a recess in part 16 and the lower end locates in a recess in the end cap which seals the body of the EPR. The lower end of this spindle is pointed with a 60 degree included angle so that the spindle is guided into the recess in the end cap. The end cap is then joined to the body of the EPR by an electron beam weld.
Figure 7-1: General arrangement of two stage gear mechanism
The presence of the magnet within the assembly causes a deflection of the welding beam during the final operation of electron beam welding this end cap into the body. However, provided that the magnet remains stationary as the assembly is rotated in the welding chuck, the deflection of the beam is constant and can be offset by the beam deflection coils in the welding equipment. To ensure that the magnet does not rotate when the assembly rotates in the chuck, a second magnet is mounted alongside the assembly and supported on a stand placed in the welding chamber.

**Part 2:** This is a titanium capsule enclosing the permanent magnet to provide a second layer of sealing between body tissues and the potentially toxic material of the magnet. The first layer of sealing is provided by the body of the EPR and the shaft seal that runs on the output shaft, part 16. The magnet capsule provides a secure backup in the event of leakage past the shaft seal or structural failure of the body of the EPR. It may be that clinical experience will suggest that the magnet capsule is an unnecessary precaution in which case it could be omitted at a later stage in the development.

The permanent magnet is manufactured by a sintering process and is supplied in final form so that no further machining of the magnet is required. The magnet is supplied without magnetisation and with a nickel coating which protects against corrosion in transit and storage. The magnet fits inside the annular capsule and a little epoxy adhesive is used to ensure that the magnet will not rotate within this capsule. The capsule is machined as two parts with a nominal wall thickness of 0.5mm and after inserting the magnet these two parts are joined by two rotary electron beam welds. It is important to note that this welding cannot be carried out if the magnet is magnetised since the magnetic field would deflect the electron beam used for welding. For this reason the magnet is supplied without magnetisation then after welding the capsule the assembly is returned to the supplier of the magnet to be magnetised with a field direction parallel to a diameter of the capsule. The magnet capsule is titanium since this material is well suited to electron beam welding and it provides a higher level of corrosion resistance than would stainless steel in the event of ingress of body fluids into the cavity containing the magnet and gearing.

**Part 3:** This is the input pinion to the first stage of gearing. The pinion is bored to be a free running fit on the spindle, part 1 and has a plane boss that is fitted into part 2 using an anaerobic curing adhesive.
Isometric views on two halves of planet carrier

Figure 7-2: Assembly of planet carrier

Parts 4 and 7: These two parts fit together as a spigot and socket to form the planet carrier assembly as shown in Figure 7-2. The planet carrier parts shown in this figure are machined with three slots at 120 degrees to each other so as to accommodate three planet gears. A prototype gear mechanism was also made with a single diametrical slot to accommodate two planet gears spaced at 180 degrees and with the internal gear teeth adjusted accordingly.

Central tapped hole to secure planet carrier assembly with single screw

Figure 7-3: Jig for electron beam welding planet carrier assembly.

After the planet gears, part 6, have been inserted into the assembly of parts 4 and 7 this assembly is held in the jig shown in Figure 7-3 by means of a single screw through the centre holes of parts 4 and 7. This jig together with the planet carrier assembly is then placed in the rotary chuck of an electron beam welding machine and a light weld is
made around the whole periphery of the assembly to permanently join the two halves of the planet carrier. The welding jig is made from copper and has castleations which shield the planet gears as they pass the welding beam, copper being a material which absorbs the energy of the welding beam with little effect.

**Part 6:** Planet gears. Each gear stage has two or three identical planet gears that are fitted into the planet carrier assembly prior to this assembly being completed by electron beam welding. Each planet gear is machined with a small integral stub shaft at each end, these stub shafts locating in holes in each half of the planet carrier assembly. The planet gears for both stages of the mechanism are made identical.

**Parts 5 & 12:** These are the fixed internal gears for the first and second reduction stages respectively. These gears each mesh with approximately half of the face width of a set of planet gears and are fixed into the body of the EPR by use of an anaerobic curing adhesive, as discussed in Section 7.3. One external corner of these components has a small chamfer to retain the adhesive as the component is slid into the bore of the EPR body. A sharp corner at this point might tend to scrape off the adhesive. When the two fixed internal gears are bonded into the body of the EPR, a small axial clearance is required between these fixed gears and the adjacent rotating internal gears. These clearances were set by inserting a disc of 'cling film' between the fixed and rotating gears as they were inserted into the body of the EPR. Once the adhesive securing the fixed gears had cured, the cling film disc was removed with forceps leaving a suitable clearance. The thickness of cling film is approximately 0.008 mm.

**Parts 8, 9 & 10:** This assembly transfers the output from the first stage of gearing to the input of the second. The assembly consists of a gear web, part 9 which is bonded with anaerobic curing adhesive to both the rotating internal gear of the first stage of gearing and the input pinion of the second stage of gearing. The equivalent joint at the output of the second stage of gearing is made by electron beam welding but this is not necessary for the relatively low torque at the output of the first stage of gearing. The internal gear and the gear web were made as separate parts for ease of cutting the internal gear by a shaping process. It is possible that the gear and web could be integrated into a single part if an undercut were formed at the inner end of the internal gear teeth, the shaping cutter cutting through into this undercut. However, unless the axial length of the
assembly is increased, this would allow little space for the shaping cutter and so the machining subcontractor preferred the two part assembly.

**Parts 11, 12, 13 & 14:** These parts are the fixed internal gear and the planet gear and planet carrier assembly for the second stage of gearing. For simplicity these parts are made identical to the corresponding parts 4, 5, 6 & 7 of the first stage of gearing.

**Parts 15 and 16:** Part 15 is the rotating internal gear for the second stage of gearing and this is electron beam welded to part 16 which is the output shaft which passes through ‘O’ ring seals to drive the power screw as shown in Figure 5-10. Part 16 is of cobalt chrome alloy since the outer end of the output shaft is in contact with body fluids and so cannot be stainless steel 316 since this material would corrode in the presence of the body fluids and the titanium body of the EPR.

Part 16 is a spigot fit into a socket machined in part 15 so that this assembly is self jigging when set up for welding. Although electron beam welding produces minimal thermal distortion it was found that the heating effect of the welding could cause parts 15 and 16 to separate during the welding process. To avoid this it is essential to start the weld with three small ‘tack’ welds equi-spaced around the joint.

Part 16 is shown with a short spigot that locates in a bore in one side of the planet carrier, part 14. The purpose of this spigot was to ensure that the planet carrier is accurately centred in the mechanism and a similar spigot was provided on part 9 to centre the first stage planet carrier. It has been found in testing that the planet carriers are adequately centred by gear tooth contact alone and so the spigot on part 16 could be omitted. It may be desirable to retain the spigot on part 9 since this slightly increases the length of bore for locating part 10 in part 9.
7.2 Computer program for analysis of gear meshing.

As discussed in Section 6.2.8, the gear mechanism used for this project requires gears cut with non-standard settings of the gear cutting machinery. A computer program was written to simulate the gear cutting process so as to predict the tooth form and contact geometry in order to check that the gear teeth will engage satisfactorily and to provide a basis for any subsequent analysis of strength, wear and power loss due to friction.

Gear teeth are generally of involute form since this form can give constant angular velocity ratio as teeth move into and out of engagement. A constant angular velocity ratio is an important requirement, particularly for high speed gearing where variation in velocity ratio would produce large inertial forces. The principles behind the design of involute tooth gears are given in many textbooks [Dudley, 1984 #8] and are briefly outlined as follows.

![Diagram of involute gear teeth generation](image)

Figure 7-4: The generation of involute gear teeth.
An involute curve is the locus of the end of a taught string unwound from a cylinder. If driving and driven cylinders are mounted on shafts and connected by a string as shown in Figure 7-4 this is effectively a belt drive and provides a constant angular velocity ratio between the cylinders. If the cylinders are now extended with flanges and a point on the connecting string is projected onto these flanges, this point will trace involute curves on both flanges as the cylinders rotate and the string winds off one cylinder and onto the other. Cutting the flanges along these curves thus produces gear teeth that mesh to give the same constant velocity ratio as would apply for the belt drive. The diameter of the cylinder from which a gear tooth profile is generated is termed the base circle diameter (BCD) of the gear. If one gear of a pair has a very large base circle diameter, the involute tooth form for this gear approaches a trapezoidal form since the string shown in Figure 7-4 would be wound or unwound from a point which is remote from the tooth engagement zone. In the extreme, the large gear becomes a straight rack having infinite radius of curvature and with truly trapezoidal tooth form. Involute gear teeth can thus be generated by traversing a shaping cutter having a rack tooth profile tangentially to a rotating gear blank and one type of gear cutting machine does function in this manner.

The pitch circle diameter (PCD) of each gear in a meshing pair is the diameter of the plain cylinder which would be substituted for the gear in a friction drive having the same velocity ratio and centre distance as does the pair of gears. [Dudley, 1984 #8]. In Figure 7-4, the two pitch circles are indicated chain dotted. The pressure angle, \( \phi \), for a gear pair is the angle which the contact force on the gear teeth makes with the common tangent to the two pitch circles, neglecting friction at the contact. This is also the angle between the line joining the gear centres and the radius drawn from the centre of either gear to the point on the base circle from which the string wraps/unwraps in Figure 7-4. From the geometry shown in Figure 7-4:

\[
\frac{BCD}{PCD} = \cos \phi
\]  

Equation 7-1

The most widely used pressure angle is 20 degrees. The pressure angle of gear teeth is a compromise between strength and wear characteristics. A larger angle, typically 25 degrees, may be specified to give approximately 12% greater tooth bending strength than the standard 20 degree angle, or a smaller pressure angle, typically 14.5 degrees, may be specified for reduced wear. For this project a large pressure angle would be
suitable since wear is not particularly important but a 20 degree pressure angle was used due to the limited availability of suitably small cutters for alternative pressure angles.

The size of gear teeth on a gear having $N$ teeth is specified by the tooth module, $m$, where:

$$m = \frac{PCD}{N}$$  \hspace{1cm} \text{Equation 7-2}

The gears for the prototype mechanisms made for this project were all cut using cutters for a tooth module of 0.2mm. This was the smallest tooth module for which the company that machined the gears had tooling available. It is possible that in future a still smaller tooth module might be adopted if further miniaturisation were required.

Some of the gears made for this project were cut with a centre distance between cutter and blank which did not correspond to the number of teeth being cut and the tooth module of the cutter. In such cases the gear tooth module is considered to be a nominal figure only and all gears used in this project are considered to be nominally 0.2mm module, despite the small variations made to the ratio $PCD/N$.

Shaping cutter oscillates and rotates

Gear blank rotates

Ratio between angular velocities of shaper and blank determines number of teeth cut on blank

Figure 7-5: Principle of gear shaping machine

The computer program simulates the process of using a straight rack to generate an externally toothed gear wheel from a blank. This gear wheel is then considered to be a ‘cutter’ and is used to generate further gear profiles that may have varying number of either external or internal teeth. This computer simulation models the operation of a gear shaper this is a machine tool that cuts both external and internal gears as shown in Figure 7-5.
The generation of an involute profile gear tooth flank, as illustrated in Figure 7-4, can extend radially inwards only as far as the base circle of the gear, the involute curve not being defined inside the base circle. In practice, it is necessary for the gear teeth to be cut deeper than the base circle diameter in order to allow clearance for the teeth of the mating gear to pass, to allow for a tooth root fillet radius to reduce stress concentration and to allow for lubricant to be expelled as the teeth engage. The radial depth to which the teeth are cut inside the PCD is known as the dedendum and the radial height to which teeth extend outside the PCD is known as the addendum. Normally the addendum is made equal to the tooth module, \( m \), and the dedendum is made \( 1.25 \times m \). These values of addendum and dedendum were used in the computer program for simulating the cutting of externally toothed gears and the computer program extended/trimmed the generated tooth profiles as required to achieve these dedendum/addendum dimensions based on the nominal tooth module. For simulating the cutting of internally toothed gears, the cutter addendum was increased by 15\% of the module so as to provide the internal gear with a tooth tip clearance with a mating externally toothed gear.

The computer program was written by the author of this thesis in 1993 and is for use with the MSDOS operating system that is now superseded by various versions of Windows operating system. The program will run in a Windows MSDOS window. The program is written using Borland Pascal version 6.0 and utilises the low-level graphics routines provided with this language (Borland Graphics Interface). The program considers individual gears to be objects of a class called gear, objects being software entities that conveniently group together inter-relating data and procedures. The data included in each gear object includes basic parameters such as number of teeth, tooth module etc. together with two-dimensional co-ordinate data detailing the tooth profile as a series of points. All the teeth on a gear are assumed to be identical and so data only needs to be stored for a typical tooth. Most gear teeth are nominally symmetrical about an axis which is a radius of the gear wheel but the gear class was written to store the profiles for each side of a typical tooth separately so as to allow for the possibility of extending the program to model asymmetric tooth wear effects. The procedures included in the gear class allow operations such as displaying the gear graphically on screen, rotating the gear by a specified angle, saving the gear data to a disc file, loading the gear data from a disc file and cutting a ‘blank gear’ by considering the existing gear data to represent a shaping cutter as would be used in the machine shown in Figure 7-5. A ‘blank gear’ is an object of the gear class for which design data such as number of
teeth and tooth module have been defined but for which the co-ordinate tooth profile data has not yet been determined. Software classes include a 'constructor(s)', this being a procedure(s) used to 'instance', i.e. set up, objects of the class when they are first used in the program. The first stage of running this program is to instance a gear object of infinite diameter, i.e. a rack. The constructor for a rack calculates the tooth profile co-ordinates whereas the constructor for other gears only sets up the gear as a blank gear with specified design parameters but with tooth form as yet undetermined. The tooth profile co-ordinates for a rack are straight forward to calculate since the teeth are trapezoidal hence points on the tooth profile can be determined by linear interpolation. The rack gear instanced at the start of the program can then cut a gear with external teeth and this can be considered to be a shaping cutter and can be used to cut either another externally toothed gear or an internally toothed gear. This process models real gear manufacturing operations. The software procedure used for gear 'cutting' takes a series of steps as follows:

A single point on the known tooth profile of the cutter is selected and the cutter and blank are then rotated together in a number of small angular increments at the correct velocity ratio for the tooth numbers of the two gears. To save computing, only those angular positions for which the selected point on the cutter overlaps the blank are considered. For each cutter position the selected point on the cutter is used to generate a point in a co-ordinate system that rotates with the blank. This gives a series of points on the blank all of which are within that region of the blank that would be removed by the cutter in a real machining operation.

This process is repeated for a second point on the cutter tooth profile. One approach would be to continue this repetition for all the points on the cutter tooth profile to build up a large array of points all of which lie in the region of blank which will be cut away. The blank tooth profile could then be determined by finding an enveloping boundary around all these points. However, this would require co-ordinate data for a large number of points to be generated and stored prior to determining the boundary. This storage requirement was found to be excessive and would have caused programming complications due to the normal 64 kilobyte data segment size for DOS based programs. To avoid this large storage requirement, the program was written to eliminate the points that do not lie on the boundary as the cutting operation proceeds. Suppose that two points on the cutter profile have been traced across the blank to produce points in the
blank gear co-ordinate system. The next step is to reorder these points in memory so that they are in order of increasing angle subtended from the centre of the blank. Next, each successive triple of points is considered and two gradients determined, one for the line joining the first point of the triple to the second point and one for the line joining the second point of the triple to the third. If the second of these gradients is greater than, or equal to, the first, all the points in memory are compacted to overwrite the second point of the triple. Effectively this removes all re-entrant corners from the path linking all the points and this produces a 'convex hull' enveloping all the points. This method is described in textbooks on graphical applications of computers [Hill, 1990 #9]. This procedure is repeated as each point on the cutter tooth profile is selected and used to generate further points on the blank gear. On completion of this procedure the blank gear data contains points lying on the outline of a typical tooth profile. These points will be irregularly spaced along the whole tooth profile for both sides of the tooth. The next stage is to divide these points to create separate curves for the two sides of the tooth. The final stage is to use an interpolation method to re-space the points so that they are at uniform intervals of distance from the blank centre. The interpolation method used fits a parametric spline through the irregularly spaced points initially available, then finds the intersections of this spline with a series of circles centred on the blank centre.

The computer program includes procedures to export tooth profiles as drawing exchange format (DXF) files which can be imported into a CAD program for further editing or into a finite element analysis program for stress analysis. Figure 7-6 is based on such a DXF file and shows three teeth from a 27 tooth gear wheel generated from a 0.2mm module rack using the process described above. This is the gear wheel used as a planet gear in the prototype gear mechanisms. Practical gear tooth profiles normally include fillet radii at the tooth roots but these are omitted from Figure 7-6 since they are not generated by the computer program and are not required for the initial investigation of tooth engagement geometry.
The shaping cutter used to cut all the internal gears for this project had 40 teeth with 0.2mm module. This cutter was required to generate two internal gears which would engage with the same set of planet gears despite there being a difference in tooth number between these two internal gears, this difference being equal to the number of planet gears used. These internal gears were cut on a gear shaping machine using similar cutter to blank centre distance for both gears but varying the angular velocity ratio between cutter and blank so as to produce the difference in tooth number.

To use the computer programme to simulate the process of cutting these internal gears, the profile of the 40 tooth 0.2mm module shaping cutter was first generated from a rack and this shaping cutter was then used to generate the internal gear tooth profiles. The addendum of the cutter tooth profile was extended by 15% of the module in order to cut the internal gears with clearance for the planet gear teeth.

Figure 7-6: Part of gear with 27 off 0.2mm module teeth on 5.4mm PCD.
Thin line: 27 tooth gear, 0.2mm tooth module
Thick line: Internal gears with varying tooth number
Note: All internal gears cut with 40 tooth cutter at 3.5mm cutter to blank centre distance

Figure 7-7: Range of internal gears shown superimposed on 27 tooth planet gear
Typical results of this simulated gear cutting process are shown in Figure 7-7. This figure shows part profiles of five internal gears (the heavy outlines) having tooth numbers varying from 69 to 81 teeth, these internal gears all being cut with the same distance between the centre of the 40 tooth 0.2 module cutter and the centre of the blank. This centre to centre distance was 3.5mm which gives the normal cutter position for cutting a 75 tooth internal gear, hence the 69 tooth and 72 tooth gears have wider than normal tooth spacing and the 78 and 81 tooth gears have closer than normal tooth spacing. In practice, the cutter would be ground to provide a fillet radius at the root of both the internal and external gears but these fillet radii are not included in this simulation.

The profile of the 27 tooth 0.2 module planet gear is superimposed on each internal gear profile shown in Figure 7-7 (the light outlines). In each case shown, the planet gear centre is placed at a distance of 4.8mm from the internal gear centre. This is the normal centre to centre distance for a 27 tooth 0.2 module planet gear engaging a 75 tooth internal gear. As would be expected, the planet gear is a close fit with the 75 tooth internal gear but it is a clearance fit with the other internal gears.

It is seen from Figure 7-7 that the internal gears with 69 and 81 teeth have excessive material removed by the cutter. In the case of the 81 tooth gear this significantly reduces the internal gear tooth height by cutting away the tip of the teeth. It is clear from these figures that it is not practical to use a tooth number departing too widely from the standard tooth number for the cutter to blank centre distance used.
The computer program described above was extended to find the contact points between the teeth of internal and planet gears meshing with a specified angular position for the planet gear.

The method used was to intersect the tooth profiles of all the meshing teeth of both gears under consideration with a circle, radius $R$, centred on the planet gear axis as shown in Figure 7-8. To save computing time, the program ignored those tooth pairs that cannot be in mesh since the profile of one tooth in the pair is completely outside the tip circle of the other tooth in the pair.

The angle $a$, as shown in this figure, was calculated for various values of $R$ to find the value of $R$ giving a minimum value of $a$, using a process of successive approximation. This was repeated for every pair of meshing teeth to find the minimum of $a$ for all the tooth pairs so as to locate the contact point between the gears when the planet gear is driven anti-clockwise. This procedure was repeated for angle $b$ to find the contact point between the gears when the planet gear is driven clockwise. The backlash angle as measured at the planet gear centre is then the sum of the minimum value of $a$ with the minimum value of $b$. A check was made for negative backlash since this indicates that the gears jam together.

Figure 7-8: Tooth clearances
It is noted that the method for finding tooth contact points as described above does not take account of the effect of distortions of the gears under load.

![Graph showing Backlash vs. Internal Gear Tooth Number for Constant Cutter to Blank Centre Distance](image)

Notes: This plot is based on a 27 tooth planet gear meshing with internal gears cut with a 40 tooth 0.2 module cutter using a 3.5mm cutter to blank centre distance. Normal internal gear tooth number for this cutter centre to blank centre distance is 75 teeth. The distance from the planet gear centre to the internal gear centre is 4.8mm. Backlash angle is measured at centre of internal gear.

Figure 7-9: Backlash vs. internal gear tooth number for constant cutter to blank centre distance

The backlash was calculated at each of a number of angular increments over a tooth engagement cycle to find a mean backlash value for the gear pair. The range of variation in the minimum of \( a \) for all teeth and all \( R \) values and the minimum of \( b \) for all teeth and all \( R \) values was also determined at increments over a tooth engagement cycle. This variation indicates the transmitted angle error, that is the difference between the actual output angle of the gear pair and that which would be predicted from the mean velocity ratio as given by the ratio of tooth numbers for the gear pair.

Cutting an internal gear with either more or less than the normal number of teeth for the cutter to blank centre distance increases the backlash when the internal gear is meshed with a planet gear having fewer teeth than the cutter. This is apparent from inspection of Figure 7-7 and is quantified in the graph shown in Figure 7-9. In addition to an increase in backlash, a transmitted angle error is introduced. The computer program calculates this effect as the peak to peak range of the deviation of the internal gear angle from that which would be predicted from the mean velocity ratio of the gear pair. For an internal
gear having the normal number of teeth for the cutter to blank centre distance the
backlash and the transmitted angle error are virtually zero, as would be expected. The
computer programme actually predicts a small negative backlash due to errors
introduced by approximate numerical procedures. Reducing the internal tooth number to
72, as would be used in combination with a 75 tooth internal gear for a 3 planet gear
configuration, increases the backlash to 0.11 degrees and also introduces a transmitted
angle error range of 0.00058 degrees, both these angles being measured at the internal
gear centre. This range of error in transmitted angle, being approximately 2 arc seconds,
is negligible for most practical purposes. The backlash angle is also of no importance
for the application under consideration since precise control of output angle is not
required. The backlash could be significant if this type of mechanism were to be used as
a positioning drive, although the calculated backlash is less than backlash angles
specified for many commercial gear systems.

For satisfactory meshing of loaded gears the curved flanks of adjacent teeth should
come into contact rather than the tip corner of one tooth contacting the curved flank of
another. If contact does occur at the tip corners of the teeth this will increase contact
pressure and wear rate. This effect may possibly be alleviated, at the expense of
increasing transmitted angle error, by introducing a fillet radius at the tip corners. Wear
at the tip corners will in any case produce such a radius in time. Tooth tip corner
contact may be acceptable for the application under consideration since the design
running life is short, but it is preferable to design the gear system to avoid such contact
and the computer programme for tooth mesh geometry was used for this purpose.

The procedure to find the contact point between two meshing gears, as described above,
was repeated for small increments of gear rotation in order to examine the way in which
the contact point moves along the tooth flanks and jumps from tooth to tooth as the
gears rotate. For this study it was assumed that the gear mechanism would include
internal gears having 75 and 72 teeth.

Initial inspection of Figure 7-7 suggests that of the five internal gears shown in this
diagram, only those with 75 and 72 teeth offer a possibility of avoiding tip corner
contact with the 27 tooth planet gear which is also shown in this diagram. Hence the
computer program was used to find the contact points between the 27 tooth planet gear
and the 75 and 72 tooth internal gears, the results being shown in Figure 7-10 and Figure 7-11 respectively.

Figure 7-10 and Figure 7-11 both show the outline of the teeth in the region of mesh for 10 positions equally distributed over one cycle of tooth engagement. The planet gear is assumed to be under anticlockwise torque and so contact occurs between the left hand side of a planet gear tooth and the right hand side of an internal gear tooth, the contact points being indicated by the solid filled circles in the diagrams.

With reference to Figure 7-10, the gears shown were cut with normal cutter to blank centre distance and are meshed at normal centre distance so contact occurs on a line tangential to the planet gear base circle and angled at the pressure angle to the common tangent of the pitch circles. The gear diameters are large enough that this line intersects two loaded tooth flank pairs giving two contact points between the gears throughout the tooth engagement cycle. It is possible that manufacturing tolerances will cause contact to only occur at one of these contact points and it is conservative practice to base gear strength calculations on this assumption.

With reference to Figure 7-11, the internal gear shown was not cut with normal cutter to blank centre distance and one effect of this is that the computer program indicates only a single contact point between the gears throughout the tooth engagement cycle. However, although only one contact point between the gears is predicted, there is also a point at which contact almost occurs, this point being indicated for each gear position by the open circles in Figure 7-11. The clearance at these points of near contact is predicted to be very small, varying between approximately 0.01 micron and 1.0 micron as the gears rotate. Because of possible manufacturing tolerances there is uncertainty as to whether contact will actually occur at the predicted contact points shown by the filled circles or at the points of near contact shown by the hollow circles, or whether there will be load sharing between these points. As the teeth move anticlockwise through the engagement cycle the predicted contact point moves radially outward and momentarily reaches a point very close to the planet gear tooth tip, this occurring at the position 10 shown in the diagram. Since the contact point does not quite reach the tooth tip and is well clear of the tooth tip throughout most of the engagement cycle it is not expected that this tooth engagement geometry will result in significantly greater wear or friction than that shown in Figure 7-10.
Figure 7-10: Meshing of 27 tooth planet gear with 75 tooth internal gear
Section 7: Design of Gear Mechanism

Figure 7-11: Meshing of 27 tooth planet gear with 72 tooth internal gear

- **POSITION 0**
  Pinion angle = 0

- **POSITION 1**
  Pinion angle = 1.33

- **POSITION 2**
  Pinion angle = 2.66

- **POSITION 3**
  Pinion angle = 4.00

- **POSITION 4**
  Pinion angle = 5.33

- **POSITION 5**
  Pinion angle = 6.66

- **POSITION 6**
  Pinion angle = 8.00

- **POSITION 7**
  Pinion angle = 9.33

- **POSITION 8**
  Pinion angle = 10.66

- **POSITION 9**
  Pinion angle = 12.00

**Pinion gear**
27 teeth 0.2 module 5.4 PCD

**Internal gear**
72 teeth 0.2 module cut with 40 tooth 0.2 module cutter with 3.5mm centre of cutter to centre of blank

**Key**
Filled circles show predicted contacts for anti-clock. torque on pinion. Open circles are points of second closest contact.
A single tooth is marked X for each position.
7.3 Securing the gearing to the body of the EPR

An attempt was made to test the prototype gear system to destruction by driving the input with a small motor while increasing the output torque loading to the point of failure. The test rig is shown in Figure 2-3. The test showed that although the design torque output was exceeded, the entire gear mechanism started to rotate within the body of the EPR before any gear parts failed. This suggests that the attachment of the gearing to the body of the EPR is a critical area of the design.

One of the internal gears for each stage of the gearing has to be fixed to the body of the EPR in order to transfer a reaction torque which is equal to the output torque less the input torque for that stage of gearing. The body and the internal gears are close fitting cylindrical components and so the methods that could be considered to fix them together include shrink fit, welding, adhesives and mechanical locking methods such as keys, splines or cross pins.

The mechanical locking methods are generally unattractive since they require some feature, e.g. a hole or key way cut into or attached to both the EPR body and the internal gears. If excessive stress concentration is to be avoided this will increase the minimum radial thickness of these parts and hence increase the overall diameter of the EPR.

If the body were machined with a small internal step at the position of the internal gears then these gears could be welded to the body using electron beam welding with the beam entering the open end of the body parallel to the longitudinal axis. Even using the beam deflection facility of the electron beam welding machine to deflect the beam away from the axis of rotation of the welding chuck, the step in the inner wall of the body would need to be a minimum of approximately 0.5mm deep to ensure that the beam does not impinge on the body wall. The cost of machining the body is increased and the overall diameter of the EPR has to be increased by at least 1mm for each stage of gearing. This is considered to be an unacceptable increase in overall diameter.

A thermal shrink fit of the internal gears to the body would carry limited torque due to the thin section of the internal gears. Also heating the body to insert the second internal gear would loosen the first gear to be inserted.
An adhesive bond between the internal gears and the body of the EPR avoids the disadvantages of the methods discussed above but the strength of the adhesive bond becomes critical.

High strength adhesives used for metal to metal joints in engineering include 2 part epoxy adhesives and anaerobic curing cyanoacrylate adhesives. The shear strength available with the strongest of both these types of adhesive is fairly similar at around 20 to 30 N/mm². An anaerobic curing adhesive was preferred since it is available in lower viscosity than epoxy adhesive and so although it does not have gap filling capability it is probably better suited to a close fitting joint.

Loctite 620™ was selected as an appropriate adhesive although a comparable product from another manufacturer was also used in some tests. The Loctite design handbook [Reis (ed.), 1998 #43] indicates that for Loctite 620™ the optimum diametrical clearance between parts for slip fit assembly is 0.02 to 0.07mm and the nominal shear strength of the bond by test to ISO10123 is 27N/mm².

The Loctite design handbook describes a method for the estimation of the torque capacity of a bonded cylindrical joint as follows:

Let \( T_B \) = Shear strength of bond by test to ISO10123 – N/mm²
\( T \) = Torque capacity of joint - Nm
\( d \) = Diameter of joint - mm
\( l \) = bond length - mm
\( P \) = pressure between bonded parts N/mm²
\( \mu \) = effective coefficient of friction
\( f_c \) = a factor dependant on materials and various other bonding conditions, as detailed in the Loctite literature.

Then:
\[
T = \frac{\pi d^2 l}{2000} \left[ (T_B f_c) + (P \mu) \right] 
\]

Equation 7-3

For convenience of assembly and to avoid distortion of the internal gears it is preferred to avoid interference fit and so \( P \) in Equation 7-3 is zero. The Locktite handbook does not include data to determine \( f_c \) for a bond between titanium and stainless steel. The company acknowledges that titanium, like stainless steel, may give poor bonding due to
the presence of an oxide layer. Also, $f_c$ is stated to be a function of the ratio $l/d$ for the joint surface and data is only provided covering the range of $l/d$ from 0.5 to 2 whereas for the current application $l/d = 2.5/18 = 0.139$. An extrapolation of the available data with the assumption that a bond between stainless steel and titanium is similar to that between stainless steel and stainless steel would indicate $f_c$ to be approximately 0.5, although the validity of such an extrapolation is questionable. Based on this value of $f_c$, the torque capacity indicated by Equation 7-3 for the current application is approximately 17Nm which gives an acceptable 'factor of safety' of 4.8 based on 3.5Nm design torque output for the second stage of gearing.

To measure the torque that could be transferred through the bonded joint between an internal gear and the body of the EPR a test rig was set up as shown in Figure 7-12. A thick walled tubular component turned from titanium 318 represented the body of the EPR and a disc turned from stainless steel was bonded into the bore of this component to represent the internal gear. Torque was applied to the disc through a cardan shaft connected to a drum carrying a low stretch cord attached to the cross head of a universal testing machine. The crosshead was raised at a slow steady speed while data logging the applied tension using a load cell.

The bonding procedure was:
- Parts were cleaned and degreased in an ultrasonic cleaner.
- Approximately 3 drops of anaerobic curing adhesive were placed around the bore at an axial location approximately 2mm from the final position of the centre thickness of the disc.
- The disc was inserted with a rotary motion to spread the adhesive circumferentially. A small chamfer turned on the edge of the disc was intended to retain adhesive and avoid it being entirely scrapped off the surface as could possibly occur with a sharp cornered disc.

Early results using the apparatus shown in Figure 7-12 suggested that re-making a failed bond on the same surfaces may produce poor bond strength. In order to eliminate any such effect a new disc component was then used for each test and approximately 1.5 times the disc thickness was faced from the outer component before bonding so that the bond was on a new region of the surface.
Figure 7-12 Measuring the strength of adhesive bond as used to secure internal gears

The results of the tests using the apparatus shown in Figure 7-12 were displayed as a plot of nominal shear stress on the adhesive against time. The nominal shear stress was determined from the load cell readings and the nominal dimensions of the bonded parts. A typical plot is shown in Figure 7-13 below. Since the crosshead was moving at constant velocity, the ‘X’ axis for this plot represents the crosshead position, but because of the elastic distortion of the cord and other components of the test rig this crosshead position does not indicate the shear strain applied to the glue layer.

With reference to Figure 7-13, the movement of the cross head initially caused elastic deformation so that the shear stress applied to the glued joint increased at an approximately constant rate. When the torque had increased to the point at which the glued joint failed, a movement between the glued parts caused a sudden fall in the
applied torque. After this initial movement, the torque built up again and sliding occurred at the glued joint. It is noted that as this sliding continued the torque carried by the failed joint continued to increase for some time, possibly because particles from the broken adhesive layer became jammed between the metal parts. For some of the specimens tested, the maximum torque as the glued parts were sliding subsequent to failure actually exceeded the torque at failure. The test was repeated a number of times to see whether bond strength was consistent over a number of assemblies.

![Plot of torque vs. time for test on glued joint.](image)

**Figure 7-13: Plot of torque vs. time for test on glued joint.**

Comparing the results for 10 assemblies which were all bonded following the procedure detailed above and which all had finish turned surfaces with tolerances within the recommendations of the adhesive manufacturer, it was found that the bond shear strength varied in the range 5N/mm² to just over 10N/mm². The particular bond represented in Figure 7-13 was the strongest achieved.

Some other tests were carried out with variations to the bonding procedure as follows:

1. An activator was applied to the surfaces before bonding with adhesive. This activator is supplied by the adhesive manufacturer and is intended to increase the rate of cure of the adhesive but the manufacturer does not expect that this will increase the bond strength.

2. The bond was cured for one hour at 100 degrees C rather than at room temperature. The adhesive manufacturer expected this to increase the rate of cure achieved but not the bond strength.
3. The disc surface was roughened by scribing typically 72 grooves across the bonded surface and parallel to the disc axis. This was done by mounting the disc in a dividing head and passing it under a point mounted from the spindle of a milling machine. The effect was similar to a fine knurling.

4. A comparable adhesive from an alternative manufacturer was used in place of Loctite 620™.

It was found that none of the alternatives listed 1 to 4 above had an obvious positive or negative effect on bond strength. The number of tests carried out to date is not sufficient to justify further statistical analysis.

From the results discussed above it is concluded that the use of Loctite 620™ in accordance with the manufacturer's recommendations will normally achieve bond strength in excess of 5N/mm² when bonding titanium and stainless steel parts as described. This bond strength is considerably lower than would be expected when bonding carbon steel components. A bond strength of 5N/mm² corresponds to a torque of 6.4 Nm on the internal gear bonded into the body of the EPR. This gives a factor of safety of 1.8 based on the design torque output of the gearing. It is noted that when an attempt was made to test the gearing to destruction the bond between the internal gear and the casing failed at approximately 6.5Nm output torque without any apparent damage being sustained by the gears.

The factor of safety calculated above is considered to be marginally adequate but it is planned to continue testing with the aim of improving the consistency of the bond strengths achieved. Consideration might also be given to alternative surface treatments of the bonded parts, for example grit blasting or emery paper.

It is noted that if the EPR design were to be further miniaturised then the bond between the gears and the casing will become critical before the strength of the gearing. In order to utilise the full torque available from the gearing it may be necessary to increase the axial length of the final stage internal gear in order to increase bonded area or consider alternative means to fix this gear to the casing.
7.4 Lubrication of the gearing.

The compartment containing the gearing within the extendible EPR should be fully sealed from body fluids but it is still preferred to avoid the use of a conventional machine lubricant which would be harmful in contact with body fluids.

For the short running life required of the gearing in the EPR it may be possible for the gears to be run without any lubrication but some lubrication is considered preferable since stainless steel gears are known to be prone to surface galling.

A high purity medicinal paraffin is not harmful in the body in small quantities and is used for the lubrication of surgical instruments and it is proposed that this lubricant will be placed on the gears of the extendible EPR at final assembly. Only a small quantity of lubricant should be used. If more liquid is present than can be retained on the gears by surface tension there is a possibility of excess liquid contaminating the electron beam weld which seals the end cap onto the body of the EPR following final assembly of the internal mechanism.

The Locktite 620™ adhesive currently used in the assembly of the gear mechanism in the extendible EPR is not significantly affected by the presence of hydrocarbon liquids. For example, a joint bonded using this adhesive showed no measureable loss of strength after exposure to motor oil at 125 degrees C. for a period of 1000 hours [Reis, 1998 #43].

The gears of the first prototype extendible EPR were lubricated with a small quantity (one drop) of a non-medicinal grade of paraffin and, as discussed in 0, this prototype has now achieved a total extension distance under load which is well in excess of that required in clinical servic
Section 8  SHAFT SEALING

As discussed in Section 5, the proposed configuration of the extendible EPR allows the compartment containing the magnet and the gearing to be sealed by a single rotary shaft seal fitted around the output shaft from the final stage of gearing. The purpose of this seal is:

1) To prevent ingress of body fluids which could cause corrosion within the sealed cavity and which could impede the free rotation of the magnet.
2) To prevent egress of toxic substances from the sealed cavity into the surrounding tissues.

The sealed cavity contains a permanent magnet composed of material that is potentially toxic if it were to come into contact with body fluids for a period of time. For the prototype EPRs constructed under this project the permanent magnet is sealed within a welded titanium capsule to provide a second barrier between the magnet and the body fluids, in addition to that provided by the shaft seal. This arrangement is described in Section 7.1.

8.1 Selection of seal type

Various types of rotary shaft seals are available to cater for conditions of high pressure differential, high rotation speed, corrosive or abrasive fluids or high ambient temperature. For the EPR application a sophisticated seal design is unlikely to be required since pressure differential is low, rotation speed is very low and intermittent and the ambient temperature is body temperature (37 degrees C). There are however limitations on the materials which can be used, as discussed in Section 3.6, and this requires seals custom manufactured in specialised material.

A simple and compact seal arrangement is a torroidal elastomeric plug fitted between shaft and housing. This type of seal is available with various cross sections for the torroidal element, these often being designed to provide a line contact against the shaft
so as to achieve adequate local contact pressure for sealing whilst minimising friction and hence heat generation at high speed. For the EPR application, where shaft speed is very low, a line contact on the shaft is not necessary and an 'O' ring seal having a circular cross section is simpler to manufacture and has a greater resistance to vapour diffusion through the elastomeric material as is discussed in Section 0.

Silicon rubber is an appropriate elastomer for the 'O' ring seal, being available in grades which are approved by the Food and Drugs Administration of the USA (FDA) for in-vivo application. Silicon rubbers are available in a wide range of shore hardness and the tensile strength of silicon rubber for a given hardness is at least comparable to other elastomers used for sealing applications, for example nitrile rubbers. Silicon rubber is also frequently selected for high temperature tolerance, but this property is not required for the current application.

The seal configuration selected is a pair of silicon rubber 'O' rings mounted as shown in Figure 5-10. The use of a two 'O' rings in series was prompted by the inconsistent quality of the second batch of prototype 'O' rings produced for this project as discussed in Section 8.3. A much better quality of moulding was subsequently achieved, but the use of two seals was retained since the extra cost is negligible and two seals give additional security and increased resistance to vapour transfer. Such a double seal configuration is to be avoided for high pressure applications since air trapped between the two seals at the time of assembly will compress under pressure causing distortion of the seals. This is not a difficulty with the current low pressure application. The extra length of the housing required for the two seals has no effect on the overall length of the EPR or the extension possible since this housing is recessed into the inner telescopic component when the telescopic assembly is retracted.

8.2 Dimensions of 'O' ring seal, shaft and housing.

The inside diameter of the 'O' ring was selected to suit the 5mm nominal diameter of the gear output shaft. The outside diameter of the 'O' ring was made as large as practical since an 'O' ring having a larger cross sectional diameter is better able to accommodate small misalignments of the shaft and small movements of the shaft as the assembly bends slightly under load. It was also considered desirable to use 'O' ring dimensions
complying with an accepted standard. The British Standard BS4518 [British Standards Institution, 1982 #3] gives recommended 'O' ring, shaft and housing dimensions for both static and dynamic (sliding) sealing and for various configurations of 'O' ring retaining grooves. The size selected from this standard was 'O' ring reference number 0046-24 the dimensions being as tabulated overleaf:

<table>
<thead>
<tr>
<th>Dimensions for ‘O’ ring Size Reference 0046-24 – mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nominal shaft diameter</td>
</tr>
<tr>
<td>Nominal housing diameter</td>
</tr>
<tr>
<td>Internal diameter of ‘O’ ring</td>
</tr>
<tr>
<td>Section diameter of ‘O’ ring</td>
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<tr>
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<td></td>
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<tr>
<td>Groove radial depth, maximum limit - $F_{max}$</td>
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<tr>
<td></td>
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<tr>
<td>Groove radial depth, minimum limit - $F_{min}$</td>
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<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Max. limit of groove (housing) diameter</td>
</tr>
<tr>
<td>Min. limit of groove (housing) diameter</td>
</tr>
</tbody>
</table>

Table 8-1: ‘O’ Ring dimensions.

The groove radial depth is the compressed radial dimension of the 'O' ring section. Groove radial depth is specified for static, dynamic hydraulic and dynamic pneumatic applications. The EPR application was considered to be effectively a static sealing application since the shaft turns not more than 80 revolutions during the life of the EPR. The dimensional specification tabulated above is constructed such that tighter shaft tolerances allow correspondingly wider housing tolerances. The chosen shaft diameter limits were 4.990 to 4.970 mm and based on the above table for static sealing this gives housing diameter limits 8.910 to 8.670. The shaft was manufactured by grinding to achieve a fine surface finish and with this method it is rather easily possible to meet these tolerances and hence the actual dimensions indicated on the drawings were placed near the centre of this tolerance band.
8.3 Manufacture of prototype 'O' ring seals

To date, three batches of 'O' rings have been moulded for this project by specialist moulding subcontractors. The first batch of ten samples was moulded from a medical grade silicon rubber supplied by Dow Corning and six of these samples were satisfactorily tested using the apparatus shown in Figure 8-1, the test procedure being as discussed in 8.4. On completion of this test, a second larger batch of 'O' rings was produced from the original tooling, the intention being to use these for prototype EPRs and possibly for implanted EPRs. Unfortunately it was found that this second batch of 'O' rings had surface roughness and traces of flashing in the region where the two halves of the mould mate. This was presumably due to some deterioration of the tooling or inconsistency in the process. When these 'O' rings were tested, again using the apparatus shown in Figure 8-1, visible leakage of dye occurred almost immediately.

In view of the inconsistent quality of the 'O' rings supplied to that point, a change was made to an alternative moulding subcontractor and new mould tooling was constructed under the supervision of this subcontractor. It was also found necessary to change to a new supplier of silicon rubber compound since the principle manufacturers of silicon rubber had by that time chosen to withdraw completely from medical markets following costly litigation resulting from the use of silicon rubber in medical applications not related to orthopaedics. The new supplier, Nusil Inc., California, USA, specialises in medical applications and can supply a range of materials with an FDA certificate of approval, although this certification significantly increases the cost above that of nominally identical material supplied without such certification.

The silicon rubber used for the third batch of 'O' rings made for this project was selected according to the recommendations of the suppliers as follows:

Catalogue reference: Nusil MED4050
Shore A hardness: 45-55
Tensile strength: 8.3N/mm² (minimum)
Elongation %: 750 (minimum)
This material can be supplied with FDA certification and in this case it is referred to as catalogue reference MED4750. Since the project was at prototype stage the extra cost of certification (in excess of £600-00 for a minimum order) was not considered justifiable.

The MED4050 material is supplied to the moulding subcontractor as two solid components that are blended together by mechanical milling before moulding. The blended components are moulded at high pressure and the temperature in the mould is maintained for 10 minutes at 116 degrees C to complete curing.

The quality of surface finish of the third batch of 'O' rings was visibly better than the first and second batches and this third batch of 'O' rings has proved satisfactory in the leakage tests carried out to date.

8.4 Testing the 'O' ring seals

The first apparatus constructed to test 'O' ring seals is shown diagrammatically in Figure 8-1. With reference to Figure 8-1, the 'O' rings each seal between a cavity containing intensely dyed water and a cavity containing clear water. Any transfer of dye across the seal will be visible and could be quantified by use of an optical densitometer to compare the contaminated water with samples of water containing known concentrations of dye. For detecting the occurrence of leakage, as opposed to quantifying leakage, the human eye is likely to be more sensitive than the available optical densitometer.

The shafts for all the 'O' rings under test are geared together and can be occasionally rotated by hand to simulate rotation of the gear output shaft when the EPR is extended. The apparatus can also apply a continuous small oscillatory or wobbling motion to the shafts which pass through the 'O' rings so as to simulate the effect of the EPR bending slightly under cyclic loading. The wobbling motion is generated by weighting the ends of the shafts which pass through the 'O' rings and rotating the whole assembly about a horizontal axis by means of a motor drive. Adjustable screw stops limit the amplitude of the wobbling motion and these were set to give an angular amplitude 1 degree each side of longitudinal alignment.
The entire assembly is mounted in bearings and rotated about a horizontal axis at approximately 50rpm by a motor and belt drive. (Bearings, support frame, motor etc. not shown in this diagram)

This assembly repeated six times (three only shown in this diagram)

Figure 8-1: Arrangement for long term test of 'O' ring seals with 'wobbling' motion
The apparatus shown in Figure 8-1 was used to test five samples taken from the first batch of 'O' rings produced for a period of 60 days during which 3 million cycles of wobbling motion were applied and the shafts were rotated by 100 revolutions. There was no visible contamination of the clear water for any of the seals.

As discussed in Section 8.3 the second batch of 'O' rings manufactured were also tested with the apparatus shown in Figure 8-1, but significant leakage occurred almost immediately and was clearly attributable to poor moulding quality of the 'O' rings.

Figure 8-2: Simple arrangement for long term test of 'O' ring seals

Five samples from the third batch of 'O' rings manufactured were tested using the arrangement shown in Figure 8-2, this being a model of the proposed EPR sealing arrangement. Each seal was tested by being used to seal a cobalt chrome part, representing the gear output shaft, into the opening of an initially dry cavity machined in a titanium bar, this representing the sealed cavity in the body of the EPR. The five assemblies were immersed in a salt water solution (Ringer's solution) to simulate the corrosive effect of body fluids. A small tube of stainless steel, type 303, was placed inside the sealed cavities to determine whether leakage or vapour diffusion across the seals would lead to any corrosion. The dimensions for the shaft and housing diameter were deliberately varied over the range of machining tolerance specified in British Standard BS4518 [British Standards Institution, 1982 #3]. The five assemblies were placed in an oven to maintain temperature at nominally 37 degrees C. and were inspected at approximately two monthly intervals to check for any liquid or sign of
corrosion in the sealed cavity. This test continued for 9 months without visible liquid leakage or corrosion in any of the five sealed cavities. A sixth cavity that was not sealed did show corrosion of the stainless steel part. To check for any possible effect of temperature cycling the test was then continued for a further four months (to date of writing) with the parts being moved in and out of the oven several times each week so that they are subject to temperature changes greater than occur in-vivo. To date of writing there has been on visible liquid transfer or corrosion of the test pieces within the sealed cavities, either with or without temperature cycling.

8.5 The possibility of vapour diffusion through elastomer

If an elastomeric sealing element is compressed against smooth metal surfaces then liquid passage across the seal will be negligible at moderate pressure differential. It is only when the pressure differential is such as to distort or extrude the elastomer, or when wear has roughened the mating surfaces, that significant liquid leakage may occur. However, if there is a vapour pressure difference across the seal there remains a possibility of mass transfer by vapour diffusion through the elastomer.

Vapour diffusion rate is proportional to vapour pressure gradient though the elastomeric material and no steady state vapour diffusion will occur when the vapour pressure is equalised across the seal. The EPR seal has liquid water on one side and so after initial implant in the body vapour diffusion would be expected to continue until the water vapour pressure within the sealed cavity of the EPR is at the saturation point (dew point) for the in-vivo temperature. Any small fall in temperature of the cavity would then cause some condensation to liquid water to occur in the cavity. A subsequent rise in temperature would re-evaporate at least some of this condensed water. However, during the period of this evaporation some additional water may enter the cavity by diffusion through the elastomeric material since while evaporation is occurring in the cavity the vapour pressure in the cavity must be below saturation level. It would thus seem possible that continued temperature cycling of the EPR, as might be caused by any small irregularities in body temperature, could eventually cause the cavity in the EPR to fill with liquid water, but this is expected to be a very slow process. The metals present in the cavity include stainless steel and titanium and these could be subject to corrosion...
should the cavity fill with water and should there also be traces of soluble substances present which could form an electrolyte.

As discussed in Section 8.4 the long term tests carried out to date using the most recently manufactured batch of prototype 'O' rings have shown no visible passage of liquid water across the seals over a period exceeding 12 months. On the basis of this test vapour diffusion across the seals is not considered to be a significant difficulty.
The field windings are an annular assembly of current carrying coils into which the limb containing the extendible EPR is to be inserted when extension of the EPR is required. The field windings are required to generate a magnetic field to act on the permanent magnet within the EPR in order to produce the mechanical power required to extend the EPR. This section discusses the design of the field windings assembly including an outline of relevant electromagnetic principles, the selection of the basic configuration and the detailed design and construction procedure. Section 1 considers the power supply, control and cooling systems that are associated with the field windings.

9.1 Electromagnetic principles

This subsection briefly outlines those electromagnetic principles that are relevant to the design of the magnetic drive system for the extendible EPR. A fuller explanation of these principles is given in textbooks on electromagnetic principles. [Duffin, 1990 #11], [Hughes, 1960 #24]

9.1.1 The magnetic effect of an electric current

The flow of electric current produces a magnetic field, this being defined as a region where magnetic flux can be detected. Magnetic lines of force are used to represent the direction of the magnetic flux vector throughout a magnetic field. Figure 9-1 shows two long conductors aligned perpendicular to the paper and located in ‘free space’, that is not in proximity to any magnetic material such as iron. If a current flows only in the left-hand conductor this produces a circular pattern of lines of force as shown.

Figure 9-1: Two long parallel conductors.
A current carrying conductor aligned perpendicular to a magnetic field experiences a mechanical force in a direction with is orthogonal to both the current flow and the magnetic field. Thus, if the right hand conductor in Figure 9-1 also carries current there is a force acting between the two conductors.

Let: \( I_1, I_2 \) = the currents in two long parallel conductors - A
\( r \) = separation of the conductors - m
\( l \) = length of the conductors - m
\( F \) = Force acting on the conductors - N

Then:

\[
F = \frac{\mu_0 I_1 I_2}{2\pi r}
\]

Equation 9-1

where \( \mu_0 \) is a natural constant, the permeability of free space. Equation 9-1 is a fundamental relationship which is used to define the unit of electric current in terms of units of length and force, that is in terms of the fundamental measured quantities mass, length and time. The value of the constant \( \mu_0 \) depends on the magnitude of the chosen unit for current. The SI unit of current, the ampere, is chosen for historical reasons such that \( \mu_0 = 4\pi \times 10^{-7} \).

The strength of a magnetic field at any point is represented by the magnetic flux density, \( B \). Magnetic flux density is defined in terms of the force produced on a current carrying conductor placed in a magnetic field. Using the nomenclature previously defined, where \( l \) is perpendicular to the field direction:

\[
F = BIl
\]

Equation 9-2

The SI unit of magnetic flux density is the Tesla (T).

Integrating the flux density with respect to area measured perpendicular to the lines of force gives the total magnetic flux \( \Phi \). The SI unit of magnetic flux is the Weber, this being the flux passing through an area of 1m\(^2\) measured in a plane perpendicular to a magnetic flux density of 1 Tesla.

The only known source of magnetic flux is an electric current. This statement includes magnetic flux produced by a permanent magnet since it is believed that such flux is due to the circulation of electrons in the magnetic material, this circulation constituting an
electric current. Magnetic force, $H$ is considered to be that effect of an electric current that is responsible for the production of magnetic flux. In free space, i.e. not in the presence of a magnetic material, magnetic force $H$ and the resulting flux density $B$ are related by:

$$B = \mu_0 H$$  \hspace{1cm} \text{Equation 9-3}

In the presence of magnetic material, Equation 9-3 is modified to become:

$$B = \mu_0 \mu_r H$$  \hspace{1cm} \text{Equation 9-4}

where $\mu_r$ is the relative permeability of the magnetic material. The magnetic materials relevant to this project are ferromagnetic materials for which $\mu_r$ is not a constant but is a non-linear function of $B$.

The increment of magnetic force $dH$ which is due to current $I$ flowing in a short increment of conductor length $dl$ located at distance $x$ from the point at which $H$ is determined is given by the Biot-Savart Law:

$$dH = \frac{I \sin \alpha}{4\pi x^2} \, dl$$  \hspace{1cm} \text{Equation 9-5}

where $\alpha$ is the angle between the direction of current flow and the direction from the point at which $H$ is measured, see Figure 9-2.

\begin{figure}[h]
\centering
\includegraphics[width=0.5\textwidth]{figure92.png}
\caption{Field strength due to current in a short length of conductor}
\end{figure}
The value of $H$ at any point in proximity to a finite length of conductor can be obtained by integration of Equation 9-5 over the whole length of the conductor. For the case of an infinitely long straight conductor this integration gives $H$ at a distance $r$ from the conductor as:

$$H = \frac{I}{2\pi r} \quad \text{Equation 9-6}$$

$$B = \mu_0 H = \frac{\mu_0 I}{2\pi r} \quad \text{Equation 9-7}$$

Combining Equation 9-1 and Equation 9-2 also produces Equation 9-7, hence it can be seen that the Biot-Savert law is consistent with the fundamental definitions of current and magnetic flux density.

For the case of a helical coil of current carrying wire, termed a solenoid, where the length, $L$ of the solenoid is much longer than the diameter and there are $N$ turns of wire in the solenoid, integration of Equation 9-5 over the whole length of conductor gives $H$ at any point on the solenoid axis which is clear of the ends as:

$$H = \frac{NI}{L} \quad \text{Equation 9-8}$$

Thus the units for $H$ are quoted as Ampere-turns per metre or sometimes as Amperes per meter.

### 9.1.2 Permanent magnetic materials

The spin of an electron around a nucleus can be considered to be an electric current generating a magnetic force perpendicular to the plane in which the electron spins. For non-magnetic materials, the directions of magnetic force produced by electron spins are randomised such that there is no net field. Ferro-magnetic materials contain domains, typically 0.1mm across, over which there is a general alignment of electron spins. With the material in a demagnetised state the alignment of the directions of magnetisation of these domains is randomised. When a magnetic force is applied to the material, the directions of magnetisation of domains changes such that the overall flux density produced is greater than the flux density which the magnetic force due to the solenoid would produce in free space. This accounts for the relative permeability $\mu_r$ for ferromagnetic materials reaching values much greater than unity. In the case of permanent magnetic materials, a part of the additional flux due to the alignment of the electron...
spins within the material is retained when the externally applied magnetic force is removed and so these materials can act as a permanent source of magnetic flux.

**Figure 9-3: A current loop**

A tiny part of a permanent magnet can be considered to contain a current loop represented by Figure 9-3. If the loop is rectangular having dimensions $a$ and $b$ and is aligned relative to an externally generated magnetic field of strength $B$ such that the $b$ dimension is parallel to the field and the $a$ dimension is perpendicular, then for current $I$ flowing around the loop the sides of the loop of length $b$ are subject to equal and opposite forces of magnitude $Bla$ according to Equation 9-2. The torque on the loop is then $Blab$ or $HIA\mu_0\mu_i$, where $A$ is the area of the loop and $H$ is the applied field strength. The quantity $\mu_0\mu_iA$ for a small region of the material is termed the magnetic moment for that small region. The magnetic moment per unit volume of material is termed the magnetisation of the material, $M$. Thus if the magnetisation $M$ of a permanent magnet is perpendicular to a magnetic field strength $H$, the torque $T$ per unit volume of the magnet is given by $MH$. In vector terms:

$$T = M A H$$

The dimensions of magnetisation $M$ are those of magnetic flux density $B$. If a piece of magnetic material is placed in a solenoid which provides field strength $H$ then the magnetic flux density within the material is given by:

$$B = \mu_0 H + M$$
In this equation the term \( \mu_0 H \) is the field strength produced by the solenoid alone, which would be present without the magnetic material, and \( M \) is the extra field strength which results from the alignment of the magnetic axis of the domains of the magnetic material.

**Figure 9-4: Hysteresis loop for permanent magnetic material**

The characteristics of permanent magnet materials can be illustrated by a hysteresis loop as Figure 9-4 which is plotted for the case of a torroidal sample of the material with a solenoid wound around this torroid as shown to the lower right of the diagram. As the field strength of the solenoid is increased from zero the magnetic flux density in the material increases, the initial gradient of the curve being \( \mu_0 \) since \( M \) is negligible at small field strength (see Equation 9-10). As \( H \) increases, the \( B-H \) curve steepens along the path ‘O’ to ‘A’. At ‘A’ the material becomes saturated and no further increase in \( M \) is possible hence the gradient of the \( B-H \) plot is again equal to \( \mu_0 \). If \( H \) is then reduced to zero the field strength falls not to zero but to a value \( B_r \), this value being known as the remanence for the material. As \( H \) is then made increasingly negative, \( B \) continues to fall along a curve as shown in the upper left quadrant of the hysteresis plot, this being known as the demagnetisation curve which is shown as a heavy line above. In most practical applications a magnet is operating in this upper left quadrant of the hysteresis
loop and so suppliers of magnetic materials normally provide the demagnetisation curve but not the rest of the hysteresis loop in technical literature. The amplitude of the negative magnetising force which is required to reduce $B$ to zero is $H_{cb}$ this being known as the Coercivity, or coercive force of the material. A parameter that can be derived from the demagnetising curve is the $(BH)_{\text{max}}$ value, or maximum energy product for the magnetic material. This is the maximum, for any point along the demagnetisation curve, of the product of the magnitudes of the $B$ and $H$ vectors, these vectors being directly opposed in direction. $(BH)_{\text{max}}$ is a figure or merit for practical magnet applications. For example, if a section is cut away from a torroidal sample of magnetic material to produce an air gap this reduces the magnetic flux density around the torroid and so has a similar effect to a negative value of $H$ in Figure 9-4. The $(BH)_{\text{max}}$ value is indicative of the ability of the magnet material to maintain a high flux density against adverse magnetising force or across a large air gap.

9.1.3 Inductance of a coil

The magnetic flux 'linking' with a coil of wire is considered to be the number of turns in the coil, $N$, multiplied by the total magnetic flux passing through the coil, $\Phi$. According to Lenses Law, a change in the flux linking a coil induces a voltage, $E$, in the coil, the direction of the voltage being such as would produce current to resist the change in magnetic flux. The change in flux linkage may be due to a change in the current applied to the coil in which case the induced voltage is given by:

$$E = -N \frac{d\Phi}{dt}$$

Equation 9-11

The quantity $N.\Phi \, dl$ is the inductance of the coil $L$. The units of $L$ are flux linkage/ampere, named the Henry in the SI system.

$$E = -L \frac{dl}{dt}$$

Equation 9-12

The voltage required to produce an alternating current in an inductive coil of wire can be considered to consist of two components 90 degrees out of phase with each other. A voltage in phase with the current is required to overcome the resistance of the coil. A second voltage component which is 90 degrees behind the current phase is required to overcome the inductance of the coil, the magnitude of this voltage being given by Equation 9-11. These two voltage components can be represented using complex numbers and can be combined by vector addition.
9.2 Configuration of the magnetic drive

A magnetic field generated externally to the limb is required to act on a permanent magnet within the EPR so as to produce mechanical power in a form that can be conveniently coupled to the gear system within the EPR. Alternative configurations for such a system are shown in Figure 9-5, Figure 9-6, Figure 9-7 and Figure 9-8.

Figure 9-5: Two orthogonal coils with two phase energisation

Figure 9-5 shows two coils energised with sinusoidal alternating current to produce magnetic fields having a sinusoidal variation in field strength. The coils are positioned close to the limb so that in the region where the permanent magnet is located the magnetic force fields are orthogonal both to each other and to the long axis of the limb. If the currents in the two coils are 90 degrees out of phase with each other the resulting fields combine to produce a total field which rotates about the long axis of the limb. A magnet freely mounted on bearings on this axis will rotate with this field. This is effectively a two-phase synchronous motor. The system is described as synchronous since the magnet must turn at the same angular velocity as the rotating field in order to produce a torque output. If the magnet rotates at any other velocity it will be subject to a sinusoidal torque and the mean torque output will then be zero.
Using complex numbers to represent the components of the rotating magnetic force, as detected in a plane perpendicular to the limb:

Let $H_{\text{max}} = \text{peak field strength for each phase (vector)}$

$H_r = \text{combined magnetic field strength for both phases (vector)}$

$f = \text{frequency for each phase - Hz}$

$t = \text{time - s}$

Then:

$$|H_r| = \left| H_{\text{max}} \left( \cos(2\pi ft) + i \cos(2\pi ft + \pi / 2) \right) \right|$$

Equation 9-13

Hence for a two phase system, as shown in Figure 9-5, the magnitude of the rotating field is equal to the peak magnitude of the fields generated by each phase individually.

An alternative three-phase system can be constructed having three coils spaced 120 degrees to each other around the axis of the limb and energised with a phase difference of 120 degrees between the coils. In this case:

$$|H_r| = \frac{3}{2} H_{\text{max}}$$

Equation 9-14

The magnitude of the rotating field is equal to the peak magnitude of the fields generated by each coil individually multiplied by a factor of 1.5. If it is assumed, perhaps simplistically, that the field strength which can be generated by a coil is proportional to the mass of conducting material in the windings of the coil, then both the two and three phase systems give the same strength of rotating field for a given total mass of conducting material. Systems with more than three phases are also possible but again there is no advantage in terms of field strength produced for a given mass of conducting material.

For both the two phase and three phase alternatives, the coils shown in Figure 9-5 may each be replaced by pairs of coils, the coils in each pair being mounted on a diameter through the centre of the limb. For a two phase system this gives the arrangement shown in Figure 9-6, having four coils spaced 90 degrees apart around the limb. The advantage of replacing single coils with pairs of coils is that the field strength becomes more
uniform over the central region of the limb, as is discussed in more detail under Section 9.3.5. For the current application it is feasible to have an annular assembly of coils completely surrounding the limb, as Figure 9-6, the limb being inserted foot or hand first into the central space between the coils. For possible future applications where the magnet may be in an area of the body such as the hip, an arrangement with single coils for each phase, as Figure 9-5, might be re-considered since an annular array of coils large enough to enclose the trunk of the body may be cumbersome and have an excessive power requirement.

An alternative to the use of current carrying coils arranged around the limb, as Figure 9-7 or Figure 9-6, is to have a magnet with poles each side of the limb, this magnet being bodily rotated about the limb axis by a mechanical system. This external rotating magnet could be either a permanent magnet or an electro-magnet energised with direct current. This approach has been previously used [Verkerke, 1991 #68]. The design adopted comprised an electro-magnet mounted with ball slides on a circular track. The electro-magnet was energised through slip rings from a 24V DC supply and was rotated about the limb at up to 340 rpm by means of an electric motor and belt drive. A field of up to approximately 40mT was produced in the middle of the limb and the power consumed by resistive losses in energising the electro-magnet windings was in the region of 600W. This type of system requires bulky components mounted around the limb and this may restrict access for the patient’s limb, particularly for patients having limited mobility. Such a system also requires large moving parts and is likely to be heavy and noisy. Because of these disadvantages it was preferred to adopt an electro-magnetic system having no moving parts external to the limb.

Figure 9-6: Two orthogonal pairs of coils with two-phase energisation

An alternative to the use of current carrying coils arranged around the limb, as Figure 9-7 or Figure 9-6, is to have a magnet with poles each side of the limb, this magnet being bodily rotated about the limb axis by a mechanical system. This external rotating magnet could be either a permanent magnet or an electro-magnet energised with direct current. This approach has been previously used [Verkerke, 1991 #68]. The design adopted comprised an electro-magnet mounted with ball slides on a circular track. The electro-magnet was energised through slip rings from a 24V DC supply and was rotated about the limb at up to 340 rpm by means of an electric motor and belt drive. A field of up to approximately 40mT was produced in the middle of the limb and the power consumed by resistive losses in energising the electro-magnet windings was in the region of 600W. This type of system requires bulky components mounted around the limb and this may restrict access for the patient’s limb, particularly for patients having limited mobility. Such a system also requires large moving parts and is likely to be heavy and noisy. Because of these disadvantages it was preferred to adopt an electro-magnetic system having no moving parts external to the limb.
For completeness, Figure 9-7 and Figure 9-8, show two further configurations for coils external to the limb driving a magnet within the EPR.

Figure 9-7: Two coils at 45 degrees slant to the limb axis

Figure 9-7 shows the limb inserted into two current carrying coils large enough to be slanted to approximately 45 degrees from the transverse plane across the limb so that there is approximately 90 degrees between the axis of the two coils. The coils are energised with alternating current and a 90-degree phase difference between the coils produces a magnetic field rotating about an axis transverse to the longitudinal limb axis. A permanent magnet is mounted on bearings within the EPR, these bearings also being transverse to the limb axis so that the magnet rotates with the field. To keep the current carrying conductors as close as possible to the magnet it is desirable for the coils to be wound on elliptical rather than circular formers.
Figure 9-8: Coil perpendicular to limb and driving oscillating magnet

Arrangement Figure 9-8 shows a single coil wound around the limb and energised with alternating current to produce a magnetic field which is aligned with the limb axis and which cyclically reverses direction. A permanent magnet is magnetised in a direction parallel to the limb axis and is mounted so that it can oscillate in this direction with a mean position that is asymmetrical relative to the plane of the coil. It is noted that this asymmetry is necessary to produce force on the magnet, if the magnet is symmetrical with respect to the coil, the forces on the two magnet poles cancel for both field directions.

For the present application, the configurations shown in Figure 9-5 and Figure 9-6 have a significant advantage over those shown in Figure 9-7 and Figure 9-8 in that the mechanical power is produced as a rotation about the limb axis, this allowing straightforward coupling to the intended gear system.

The configuration shown in Figure 9-8 would be difficult to couple to a gear system. A further disadvantage is that the force on the magnet is cyclically varying so that some form of energy storage system, for example a flywheel, would be required within the EPR if continuous power output is required. Also the power output is relatively small for a given field strength since opposing forces are generated on the two poles of the magnet and it is only the asymmetry of the position of the magnet relative to the coil which produces a net force output.
The configuration shown in Figure 9-7 is also not well suited to the present application but could be worthy of further consideration for any future application for which it is an advantage to have the axis of rotation of the magnet transverse to the limb axis.
9.3 **Design of the field windings**

Section 9.2 concludes that the most suitable configuration for the field generator is an arrangement of current carrying coils, or windings, placed around the limb with multi-phase energisation producing a magnetic field which rotates about the long axis of the limb. It is now required to design the assembly of windings so as to obtain a suitably high magnetic field strength without incurring excessive resistive heating losses that would cause overheating of the windings.

The torque generated on the permanent magnet within the EPR initially increases linearly with magnetic field strength. There is a limit to the field strength that can be usefully employed since increasing field strength will eventually re-magnetise the permanent magnet and the torque will then reach a ceiling. In effect the magnetic poles will then rotate within the magnet rather than the magnet itself rotating. The field strength at which re-magnetisation occurs is higher than can easily be obtained using the methods considered for this project and so the prime aim in designing the windings is to maximise field strength in order to minimise the necessary size of the magnet. The practical limit on the field strength which can be obtained is likely to be set by the temperature rise of the windings caused by resistive heating effect rather than by the output of the electrical power supply equipment. A final check and/or practical measurement can determine whether the field strength generated will re-magnetise the magnet and if necessary the current can be limited accordingly.

It was envisaged at the outset that the windings would consist of bundles of turns of enamel insulated copper wire, these bundles being mounted within a liquid tight annular housing which fits around the limb. The heat generated by resistive heating can then be removed by a pumped circulation of liquid coolant through the housing, this coolant coming directly into contact with the windings. Given this basic style of construction, it is now required to optimise the layout of these bundles of windings within the annular housing.

It was initially assumed that the bundles of windings would be circular in cross section, this being the cross section which naturally results when a number of wires are bound together using electrician’s lacing cord. It was later chosen to split each large bundle into four smaller bundles spaced slightly apart in order to improve cooling, but this
refinement does not affect the optimisation of the overall geometry of the windings bundles.

The magnetic force generated at any point by a bundle of windings is proportional to the total of the currents flowing in all the wires of the bundle. Subdividing this total current among a number of separate turns of wire has no effect on the magnetic force generated but does alter the electrical impedance resulting when each turn is connected in series. The magnetic field can thus be optimised assuming a total current flow in each bundle and then the number of turns and the diameter of wire to make up these bundles can later be selected so as to match the impedance to the available power supply.

The diameter of the windings bundles is determined mainly with regard to the resistive heating effect together with consideration of the limited space around the limb. For a very simplified thermal analysis it could be assumed that the entire temperature difference between the copper windings and the bulk of the liquid coolant occurs across a thermal boundary layer which surrounds the bundles of windings. This implies that the thermal conductivity of the copper is such that the temperature can be considered to be uniform within the copper and the turbulence of the forced flow of liquid coolant is such that uniform temperature can also be assumed within the bulk of the coolant. The upper limit on the temperature of the copper is in practice set by the type of electrical insulating material used. The bulk temperature of the coolant can be kept close to ambient air temperature if the coolant is circulated through a liquid to air heat exchanger of generous capacity. With these simple assumptions, the permissible heat generation per unit length of a windings bundle is directly proportional to the surface area per unit length of the windings bundle.

Let \( Q = \) heating power of electric current per unit length of a bundle of windings - W/m  
\( D = \) diameter of a bundle of windings - m  
\( \rho = \) resistivity of windings conductor material – ohm m.  
\( I = \) total current flowing in all conductors of windings bundle - amperes  
\( h = \) surface thermal resistance coefficient W/(m² °C)  
\( \Delta t = \) temperature difference between copper and main coolant flow – °C
Then:

\[ Q = \pi D \cdot h \cdot A \]

Also:

\[ Q = \frac{4 I^2 \rho}{\pi D^2} \]

\[ I = \frac{\pi D^2}{2} \sqrt{hA} \]  

Equation 9-15

The permissible current and hence the magnetic force, is proportional to the diameter of the wire bundles raised to a power of 1.5. If provision of an adequate electrical power supply is not a limitation, Equation 9-15 suggests that the bundles of windings should be as large in diameter as space permits. However, increasing the diameter of the bundles increases the mean distance between the individual wires and central region of the windings where the magnet within the EPR is situated and this does reduce the benefit of larger diameter bundles of windings.

For design purposes, the bundles of windings were initially considered to be 20mm diameter. For the prototype construction the quantity of copper in the windings was approximately equivalent to tightly packed 20mm bundles although the actual cross section was larger due to subdivision of the bundles and imperfect packing of the wires. For a future construction some further increase in copper content may be possible but not without some difficulty in forming the windings and fitting them into the space available. The prototype windings have been found to be capable of providing adequate field strength when energised with a current which was found experimentally, as discussed in Section 9.3.7, to be within that which could be sustained without overheating the electrical insulation of the windings.

A computer program was written to predict the magnetic field strength and hence flux density produced by various windings configurations. The bundles of windings were each represented by a single turn of wire following the centreline of the whole bundle. For an approximate estimate of flux density, the total flux due to the whole bundle can be calculated assuming that a single central wire carries the total current.

The computer program considers the centre wire of any of the bundles of windings to take a typical form as shown by the heavy line in Figure 9-9. This is a rectangle with radius corners, this rectangle being ‘wrapped’ around a cylinder through which the limb...
This single winding turn can be considered to consist of four identical quadrants, each of these quadrants consisting of three sections as marked I, II and III in Figure 9-9. Section I is an arc about the axis of the cylinder. Section III is a straight line parallel to the axis of the cylinder. Section II is a fillet radius blending between the sections I and III.

See Figure 9-10 for position of coordinate system.

Figure 9-9: A single turn of the windings.
The software includes a subroutine which calculates the magnetic flux produced at any specified point by a current flowing in a single turn of the windings, the geometrical form of this single turn being as shown in Figure 9-9. The input for this subroutine includes four parameters specifying dimensions as shown in Figure 9-9 and listed as follows:

- $R$ – The radius of the cylinder around which the turn of winding is wrapped.
- $L$ – The length of the turn of winding measured along the axis of the cylinder about which the turn is wrapped.
- $A$ – The angle subtended by the turn of windings from the centre of the cylinder about which the turn of winding is wrapped.
- $R_f$ – The fillet radius at the corner of the rectangular turn of the windings prior to this being wrapped around a cylinder. An equal fillet radius is assumed for each of the four corners.

The remote point at which the magnetic flux density is to be determined is specified in a Cartesian co-ordinate system. The X and Y-axis for this co-ordinate system are diameters of the cylinder shown in Figure 9-9, the X-axis passing centrally through the turn of the winding. The Z-axis for the co-ordinate system is the axis of the cylinder.

The calculation of field strength and hence flux density at any required point in the region of the windings was made by a numerical integration of Equation 9-5 over the whole length of the windings turn shown in Figure 9-9. For the purpose of numerical integration the computer program considers a series of short sections of conductor and a vector sum is made of the flux due to each of these short sections.

For convenience of programming Equation 9-5 can be rewritten using a vector notation:

Let $\vec{\Delta H}$ = vector increment of field strength – ampere-turns/m
$\vec{l}$ = vector increment of conductor length - m
$\vec{p}$ = position vector indicating position of conductor length increment relative to position at which field strength is to be calculated - m

Then:

$$d\vec{H} = \frac{l \Delta l \wedge \vec{p}}{4\pi|\vec{p}|^3}$$

Equation 9-16

The vector increments of field strength for each short element of the turn of the windings are summed to give the total field strength vector at the point of interest. By
repeating this process, the field can be mapped over a three dimensional grid of points. The results were presented in terms of the resulting free space flux density by scaling the field strength vector by $\mu_0$, the permeability of free space.

Considering the typical windings turn shown in Figure 9-9, the output of the computer program described above shows that the effectiveness of a unit length of conductor in generating field strength and hence torque on the magnet varies along the length of the conductor. All sections of the conductor carry the same current and so contribute equally to the power supply requirement and the heating effect, but the useful magnetic effect per unit length of conductor varies according to the orientation of the conductor and the distance from the magnet within the EPR. This variation is shown in the graph, Figure 9-10 and pictorially in the isometric view, Figure 9-11. Both these figures are based on the following geometric parameters, these being similar to those used in the construction of the field windings for the prototype system:

- $R=95\text{mm}$
- $R_f=20\text{mm}$
- $L=180\text{mm}$
- $\alpha=108$ degrees (see above for definition of parameters)

![Graph](image)

**Figure 9-10: Variation in flux generated along length of winding turn.**

The magnetic flux density plotted is the magnitude of the diametrical component calculated for a point at the centre of the array of windings. This is the magnetic flux
which is effective in generating torque on the EPR magnet when the magnet is centrally located in the windings assembly and the axis of rotation of the magnet is aligned with the axis of the windings assembly.

Figure 9-11 is an isometric view showing one quarter of the windings turn as a heavy line wrapped around the base cylinder. The cross hatched area around this heavy line is drawn with a width, as measured perpendicular to the line, directly proportional to the diametrical component of flux density produced per unit length of conductor at the central point in the windings array. It is clear from this diagram that the most effective part of the windings is section III, the straight length which runs parallel to the long axis of the limb. The least effective part of the windings is the transition between Section I and Section II.

Conductor shown as heavy line is one quarter of a turn of windings.

Width of cross hatch is proportional to X component of magnetic flux at centre point ‘O’, per unit length of conductor

Figure 9-11: Quarter of typical windings turn showing variation in effectiveness in generation of useful flux density
9.3.1 The diameter of the cylinder on which windings are mounted.

It is clearly desirable to minimise the diameter of the cylinder on which the windings are mounted since, as shown by Equation 9-5, the field strength produced at the centre of the array of windings by any short section of conductor within the windings is inversely proportional to the square of the radius from the centre to the conductor. The minimum feasible inner diameter for the windings housing is principally determined by the diameter assumed for the patient’s limb. After discussion with medical staff, the maximum limb diameter was taken to be 160mm. A mock up of the windings assembly was carved from expanded polystyrene with a central bore of this diameter and this was fitted to several typical patients without undue difficulty. The inner radius of the annular housing which contains the windings was thus taken to be nominally 80mm. To this inner radius was added a 3mm allowance for the thickness of the inner wall of the housing plus a 2mm clearance between the wall and the copper. An additional 10mm was added, assuming for an initial calculation that the windings are in bundles 20mm diameter and that a central wire in the bundle is to be considered as typical for the purpose of flux calculation. Hence the value of \( R \), as shown in Figure 9-9, was taken to be 95mm and the prototype windings housing was made with a nominal inner diameter of 80mm.

More recent discussions with medical staff have suggested that the prototype windings housing may be a rather tight fit on a minority of patients and so the diameter would be slightly increased if a second unit were to be constructed. If the same magnetic flux is to be maintained, this increase in diameter would require an increase in the output of the power supply. The power supply currently in use does have some spare capacity to support a modest increase in diameter of the windings housing, as is discussed in Section 10.2.
9.3.2 The axial length of the windings.

The axial length for the windings, as measured in the direction of the limb axis, is a compromise between achieving a high magnetic flux density and minimising the overall length of the windings housing. If the windings housing is excessively long then access for the patient's limb would become difficult, particularly for those patients for which the magnet in the EPR has to be proximally located in the femur.

![Graph](image)

**Figure 9-12: Effect of varying axial length of field windings on diametrical flux generated at centre of field windings**

To examine the effect of varying $L$, the axial length of the single windings turn forming the central wire of a bundle as shown in Figure 9-9, the computer program described above was run using a range of values for $L$ whilst keeping the other parameters constant as follows:

- $R = 95$ mm
- $R_f = 20$ mm
- $\gamma = 108$ degrees
- $I = 1.0$ ampere

For each value of $L$, the diametrical component of flux density was determined at the centre point of the windings assembly and the magnitude of this component is plotted against $L$ in Figure 9-12. It is seen that increasing $L$ increases the flux density but the rate of increase falls with $L$. For large values of $L$, the flux at the centre of the windings assembly is almost entirely due to section III of the typical windings turn shown in Figure 9-9, sections I and II at the ends of the windings having little effect.
Figure 9-13: Effect of varying axial length of field windings on useful flux
generated at centre of field windings per unit length of conductor

The plot shown in Figure 9-13 is similar to that shown in Figure 9-12 except that the
flux density values are divided by the length of conductor in the winding turn. For a
given current and conductor section, the power required to overcome electrical
resistance is proportional to the length of conductor. Hence this plot indicates how
effective the windings are in producing useful magnetic flux density for a given
resistive power loss. Judged on this basis, the most efficient length to diameter ratio for
a single windings turn is found to be 0.63, corresponding to \( L = 120 \) for \( R = 95 \text{mm} \).

The choice of \( L \) for the prototype windings assembly was 180mm, which is greater than
that which gives maximum flux for a given length of conductor, maximising the flux
density being considered more important than the power requirement. For \( L = 180 \) the
useful flux at the centre of the windings is 78\% of that which would be obtained with an
infinitely large \( L \) value. A further advantage of using a relatively large value for \( L \) is that
this reduces the sensitivity of the diametrical flux component to the axial position of
magnet relative to the windings housing. Hence the torque available to drive the
magnet is less affected by any small movement of the patient's limb within the field
windings.

The overall length of the windings housing for prototype construction was 210mm.
With \( L = 180 \text{mm} \) for a central wire in a 20mm diameter bundle of windings this allows
for the wall thickness at each end of the housing and a small gap between the housing
wall and the copper.
9.3.3 Selection of angle subtended by each winding from centre of cylinder on which windings are mounted.

The value selected for $\alpha$, the angle subtended from the axis of the windings by a turn of winding, as shown in Figure 9-9, depends on whether two or three phase energisation is to be used. The number of phases determines the number of bundles of windings which require to be fitted around the periphery of the windings assembly, as discussed in Section 9.3.5 below.

To examine the effect of varying the parameter $\alpha$, the computer program was run using a range of values for $\alpha$ whilst keeping the other parameters constant as follows:

- $R=95\text{mm}$
- $R_f=20\text{mm}$
- $L=180\text{mm}$
- $I=1.0\text{ ampere}$

For each value of $\alpha$, the diametrical component of flux density was determined at the centre point of the windings assembly this being the flux density component which generates useful torque on the magnet. The magnitude of this component is plotted against $\alpha$ in Figure 9-14.

![Graph](image)

**Figure 9-14:** Effect of varying the angle subtended by windings on flux density.
Figure 9-14 shows that the maximum useful flux is generated when $\alpha=180$ degrees, giving a windings bundle which wraps halfway around the limb. With two-phase energisation using two windings bundles placed around the limb it is possible for $\alpha$ to be close to 180 degrees without overlapping the bundles. With three phase energisation having three or six bundles this value for $\alpha$ would give an awkward arrangement with many overlaps between the bundles. This is further discussed in Section 9.3.5 below.

Figure 9-15: Effect of varying the angle subtended by windings on flux density per unit length of conductor

Figure 9-15 is similar to Figure 9-14 except that the flux density is divided by the length of conductor in the windings turn to indicate the effectiveness of the windings turn in generating useful flux for a given heating effect. Judged on this basis, the optimum value of $\alpha$ is 122 degrees which is approximately the value for three bundles of windings equi-spaced around the windings housing.

9.3.4 Selection of the fillet radius at the corners of the windings.

As discussed above, the geometry of a single turn of the windings is considered to be a rectangle with radius corners, this being wrapped around a cylinder – see Figure 9-9. By selecting a suitably large fillet radius, together with suitable dimensions for the length and angle subtended by the base rectangle, this model can represent a circular coil wrapped around a cylinder. At the other extreme the fillet radius can be reduced to zero to model a square winding wrapped around a cylinder. To compare these two extremes, the computer program described above was run to give the output summarised in Table 9-1.
<table>
<thead>
<tr>
<th>Geometrical parameters (see figure Figure 9-9)</th>
<th>Length of conductor in single turn. Mm</th>
<th>Diametrical flux at centre of windings μT/amp.</th>
<th>Diametrical flux at centre of windings per length of conductor μT/(amp.m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fillet radius R_f - mm</td>
<td>R mm</td>
<td>L mm</td>
<td>A Deg.</td>
</tr>
<tr>
<td>0 (square winding turn)</td>
<td>95</td>
<td>180</td>
<td>108</td>
</tr>
<tr>
<td>89 (circular winding turn)</td>
<td>95</td>
<td>180</td>
<td>108</td>
</tr>
<tr>
<td></td>
<td>720</td>
<td>3.58</td>
<td>4.97</td>
</tr>
<tr>
<td></td>
<td>565</td>
<td>3.28</td>
<td>5.81</td>
</tr>
</tbody>
</table>

Table 9-1: Comparison of square and circular single winding turns.

The fillet radius of 89 mm, as included in the lower line of Table 9-1, gives a circular winding turn, that is with the selected values of A and L, the length of sections I and III in Figure 9-9 become negligible. The fillet radius of zero indicates a square windings turn.

Table 9-1 shows that a square windings turn produces about 9% greater useful flux at the centre of the windings assembly than does a circular turn but at the expense of increasing the length of conductor by a factor which is equal to $\frac{4}{\pi}$.

For a more detailed comparison between the circular and square windings turns, the computer program was used to map the diametrical component of field strength across the plane $y=0$, using the co-ordinate system described above and indicated in Figure 9-11. This produced the contour plots shown in Figure 9-16 and Figure 9-17. For both these plots the line $x=0$ is the longitudinal axis of the windings assembly and the windings turn for which the flux is calculated is on the right hand side of the plot.
Note: Flux is calculated in micro-Tesla for one ampere and single windings turn with:
$R=95\text{mm}$, $R_f=89\text{mm}$, $L=180\text{mm}$, $A=108\text{degs}$.

**Figure 9-16: Variation in diametrical component of flux over plane $y=0$ for circular winding**

Note: Flux is calculated in micro-Tesla for one ampere and single windings turn with:
$R=95\text{mm}$, $R_f=0\text{mm}$, $L=180\text{mm}$, $A=108\text{degs}$.

**Figure 9-17: Variation in diametrical component of flux over plane $y=0$ for square winding**
The contour plots, Figure 9-16 and Figure 9-17, show that not only does the square windings turn produce slightly more useful flux at the centre of the windings assembly (point x=0 and z=0 in these plots) but there is also a smaller variation in this useful flux strength with displacement parallel to the z axis. For example, considering flux measured along the longitudinal axis for which y=0 and x=0, with the square windings turn an x direction component of flux exceeding 3 μT is maintained over a range of z from -53 to +53 mm. With the circular windings turn this range is reduced to -31 to +31 mm. Hence the square windings turn is slightly more tolerant to axial error in location of the EPR magnet within the annular windings assembly as could be due to patient movement during the extension procedure.

For the prototype field generator it was intended that both the electrical power supply and the liquid cooling system would be of generous capacity. The advantage of the square winding turn in providing slightly higher flux more evenly distributed along the limb axis was considered more important than a slightly greater peak flux for a given power requirement available with the circular winding turn. Hence the windings were made rectangular with the corners as sharp as possible. In practice there is a minimum value for $R_f$, the fillet radius at the corners of the bundles of windings, since it is not feasible to form a thick bundle of wires around a sharp corner. This minimum radius was taken to be 20 mm.
Figure 9.18: Variation in X component of flux along diameter Z=0, Y=0 for square

X component of magnetic flux density plotted along X-axis for 1 ampere current in
single turn of winding as shown by
dot/dashed line. Dimensional parameters for
winding turns:
- R - 95mm
- Rf - 0mm
- Thickness of bundle = 20mm
- L - 180 mm
- A = 108 degrees
(see text for nomenclature)
9.3.5 Alternative arrangements of windings with 2 and 3-phase energisation

Sections 9.3.1 to 9.3.4 have discussed the flux density distribution produced by a single bundle of windings wrapped around a cylindrical housing into which the limb is placed. It is now required to consider how best to configure a number of such bundles with multiphase energisation so as to produce a rotating magnetic field to drive the magnet within the EPR. The aim is not only to maximise the torque which can be applied to the magnet when this is centrally located within the windings housing but also to design the system to be tolerant to the magnet being radially and/or longitudinally displaced from the ideal central position. It is found that displacement of the magnet from the central position generally reduces the flux density and hence torque which can be applied to the magnet and also introduces a flux density 'ripple' as the field rotates. If the kinetic energy of rotation of the magnet is small, then the drive torque which can be taken from the magnet is the torque which can be produced by the minimum flux density taken over a cycle of rotation. This is the situation when the rotation speed of the magnet is low, for example at starting from rest. At higher speeds the kinetic energy of the magnet will tend to keep the magnet rotating and so the flux density ripple will have less effect on the useful driving torque.

For design purposes the maximum radial eccentricity of the magnet within the windings housing was taken to be 50mm and the maximum axial positioning error was taken to be +/-50mm. These errors are expected to be partly due to movement of the patient's limb during the extension procedure and partly due to the difficulty the operator of the equipment may have in estimating the exact position of the magnet in the limb. It is noted that unless the limb is of such diameter that it is a close fit in the windings housing it will be desirable to use small cushions to support and centralise the limb.

The following analysis considers both 2 phase and 3 phase energisation. The use of a larger number of phases is not considered since appropriate power supply equipment would not be readily available.

Both Figure 9-16 and Figure 9-17 show that the diametrical component of flux density produced by a single windings turn decays along the diameter through the centre of the windings turn as the point at which the flux is calculated becomes more distant from the current carrying conductor. This is also shown by Figure 9-18 which is a plot of flux density superimposed on a cross sectional view through the mid axial length of two
coils, A and A' which are diametrically opposed to each other. The windings in this pair
of coils are connected so that their magnetic fields add rather than cancel. The plotted
flux density is the component in the direction of the x-axis, using the co-ordinate system
shown on the drawing. If it were simply required to maximise the flux density per
ampere turn, as measured at the centre of the windings assembly, i.e. at x=0, there
would be no advantage in dividing the windings into two diametrically opposed coils
since a single coil would provide the same central flux density as would two
diametrically opposed coils each having half the number of turns. The advantage of two
diametrically opposed coils is that the total flux density becomes much more uniform
across the region between the two coils. The thin plotted lines in Figure 9-18 show the
symmetrical flux density distributions produced by coil A and coil A' individually and
the thick line shows the combination of these flux density distributions.

Figure 9-19 shows six alternative windings configurations, identified by the circled
reference numbers in the centre of each diagram. A seventh configuration, which was
that finally selected for the prototype construction is shown in Figure 9-20.
Configurations numbered 1, 2 & 3 are suitable for 2-phase energisation, having a relative
angular displacement of 90 degrees between the coils connected to each phase.
Configurations numbered 4, 5, 6 & 7 are suitable for 3-phase energisation, having a
relative angular displacement of 120 degrees between the coils connected to each phase.
Configurations numbered 2, 3, 5, 6 & 7 have diametrically opposed pairs of coils for each
phase whereas 1 & 4 have single coils for each phase.

Table 9-2 shows the assumed geometry and energisation for the configurations 1 to 7
and Table 9-3 shows the flux density produced by each configuration. The flux density
values in this table were calculated using an extended version of the computer program
discussed above in this section.

For the purpose of comparison between these seven configurations, the conductor
group geometry and current for each configuration was adjusted so that all the configurations
have the same electrical power requirement and the same current density flowing in the
bundles of windings. To determine the geometry for each configuration, the computer
program used an iterative procedure as follows:
1. The total length of conductor, $L_{\text{total}}$, for the central turns of each coil of the windings is calculated based on initial approximate values assumed for the variables $R, R_f, L$ and $A$ (see Figure 9-9 for definition of these variables).

2. The current flowing in each bundle of windings was determined as $I_b = C_1 L_{\text{total}}$ where $C_1$ is a constant. The bundles of windings are considered to be made up from a number of turns, $I_b$ being the total of the currents for all turns. The current $I_b$ is a nominal value and is used only for comparison between the alternative configurations, it is not the actual current used in the final design.

3. The cross sectional area of the bundles, $a_b$, was determined as $I_b C_2$ where $C_2$ is a constant. $C_2$ was chosen to be $\pi \times 10^{-4}$ amps per m$^2$, this value giving a current of 1 ampere for a 20mm diameter bundle of windings. The value of the constant $C_1$ was chosen to be 4000. These values of $C_1$ and $C_2$ produced bundle diameters in the range approximately 20 to 30mm diameter. The bundle diameter, $D_b$ was determined from $a_b$, assuming that the bundles were of circular cross section.

4. The values of $R, L$ and $A$ were recalculated to take account of the new estimate of bundle diameter. For example, if the bundle diameter had increased then half the increase was added to $R$ so as to maintain the same internal diameter for the windings housing. Similarly $L$ was reduced by the increase in bundle diameter and $A$ was adjusted so that the bundles of adjacent coils were separated by a constant gap taken to be 1mm. The exception was for configuration 1 for which $A$ is not restricted by the need to pack several coils around the circumference. For configuration 1, $A$ was fixed at 125 degrees, which Figure 9-15 shows to be the optimum value for maximum flux for a given current density and resistive heating effect.

5. The new values of $R, L$ and $A$ were compared with the previous values and if the difference was considered to be negligible the process was ended, if not the programme returned to step 1 above for a further iteration.
The purpose of the iterative procedure described 1 to 5 above is to ensure that comparison between the alternative windings configurations is made on the basis of similar resistive heating power. If both the current density, $j_a/a_b$ and the product $I_b \times I_{total}$ are the same for all the configurations then the resistive heating power will also be the same. There may be a difference in the heat dissipation characteristics since those configurations having larger diameter bundles will have a smaller surface area between copper and coolant. In a practical design the heat dissipation characteristics may be improved for any of the configurations by subdividing the bundles of windings into several smaller bundles spaced slightly apart to increase surface for heat transfer.

Figure 9-19: Alternative 2 phase and 3 phase windings configurations.

(For configuration 7, see Figure 9-20)
### Table 9-2: Geometrical parameters and current for alternative windings configurations.

<table>
<thead>
<tr>
<th>Configuration – Refer to circled ref. Nos. in Figure 9-19</th>
<th>Geometry of centre turn of coils</th>
<th>Coil current Assumed for flux calculation Amperes</th>
<th>Total length of conductor in central turn of all coils mm</th>
<th>Bundle diameter mm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$R$ mm</td>
<td>$R_T$ mm</td>
<td>$L$ mm</td>
<td>$A$ Deg.</td>
</tr>
<tr>
<td>1</td>
<td>100.7/132.1</td>
<td>20</td>
<td>168.6</td>
<td>125.0</td>
</tr>
<tr>
<td>2</td>
<td>95.3/115.9</td>
<td>20</td>
<td>179.4</td>
<td>166.4/168.8</td>
</tr>
<tr>
<td>3</td>
<td>98.3</td>
<td>20</td>
<td>173.4</td>
<td>73.3</td>
</tr>
<tr>
<td>4</td>
<td>99.2</td>
<td>20</td>
<td>171.7</td>
<td>102.5</td>
</tr>
<tr>
<td>5</td>
<td>94.6/113.8</td>
<td>20</td>
<td>180.8</td>
<td>107.1/109.3</td>
</tr>
<tr>
<td>6</td>
<td>96.9</td>
<td>20</td>
<td>176.2</td>
<td>47.7</td>
</tr>
<tr>
<td>7*</td>
<td>95.0/79.0</td>
<td>20</td>
<td>180/</td>
<td>108/150</td>
</tr>
</tbody>
</table>

* This configuration differs from 1-6 in that three coils are radially displaced by 36mm as shown in Figure 9-20.

### Table 9-3: Flux density generated by alternative windings configurations.

<table>
<thead>
<tr>
<th>Configuration – Refer to circled ref. Nos. in Figure 9-19</th>
<th>Flux density component in plane perpendicular to z axis - $\mu$T – for current as Table 9-2 above.</th>
<th>Eccentricity (e – mm) at which flux is calculated</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>$e = 0$</td>
</tr>
<tr>
<td></td>
<td>Mean</td>
<td>Range</td>
</tr>
<tr>
<td>1</td>
<td>7.53</td>
<td>2.76</td>
</tr>
<tr>
<td>2</td>
<td>8.31</td>
<td>2.04</td>
</tr>
<tr>
<td>3</td>
<td>8.87</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>9.73</td>
<td>0</td>
</tr>
<tr>
<td>5</td>
<td>8.93</td>
<td>0</td>
</tr>
<tr>
<td>6</td>
<td>6.92</td>
<td>0</td>
</tr>
<tr>
<td>7</td>
<td>9.72</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 9-3: Flux density generated by alternative windings configurations.
As for previous calculations, the flux density calculations summarised in Table 9-3 are based on a single central winding turn located at the centre of each bundle of windings. The flux densities tabulated are the components in a plane at mid-length of the annular windings assembly and perpendicular to the long axis of the assembly. This is the flux density component that generates torque on the EPR magnet when this is mounted with the axis of rotation parallel to the axis of the windings assembly. The flux densities tabulated in Table 9-3 are determined for the corresponding geometries and current values tabulated in Table 9-2 and are the vector sum of the flux densities produced by all the electrical phases. For each configuration, these flux densities are determined for three values of the eccentricity, \( e \), this being the displacement of the rotation axis of the magnet from the axis of the windings assembly. The values for \( e \) quoted below are all in mm units. For non-zero values of \( e \) the flux density is found to vary over the cycle of the alternating current supply and also to vary according to the angular position of the magnet relative to the centre of the windings assembly. The figures quoted in Table 9-3 are mean, range and minimum values taken over a full cycle of the AC supply and over a 360 degree range of angles for the magnet position.

With reference to Table 9-3, it is seen that when the magnet in the EPR is ideally located in the windings (\( e=0 \)) then configurations 3,4,5,6 and 7 all produce a steady flux density magnitude but when the magnet is offset from the centre (\( e=25 \) & \( e=50 \)) the flux density magnitude becomes variable.

Considering initially the configurations 1-6, if the selection of the best configuration is based on the highest minimum flux, that is the highest continuously available torque at low speed when the effect of magnet inertia is small, then configuration 4 is best with \( e = 0 \), but configuration 5 is best with \( e = 25 \). At \( e = 50 \), the superiority of configuration 5 is increased. The advantage of configuration 4 over configuration 5 at \( e=0 \) is due to the windings being in fewer but larger bundles which makes a slightly smaller overall diameter.

Taking the above into account, configuration 5 was considered to be the best of the alternatives 1 to 6. The prototype construction was based on a modified version of this configuration that is numbered configuration 7 and is as shown in Figure 9-20.
With reference to Figure 9-20, the left-hand view (a) shows the two diametrically opposed windings bundles for one of the three phases. The right hand of these two bundles is a shorter axial length (perpendicular to the paper) than the left hands, is a smaller radius and is displaced radially as shown. This allows three pairs of bundles, one pair for each phase, to be positioned around the windings housing as shown in the right hand view (b).

Figure 9-20: Coil arrangement as used for prototype construction

Table 9-3 shows that with the magnet centrally located, configurations 5 and 7 produce almost the same flux density and hence magnet torque but when the magnet is offset from the central position configuration 7 will have a smaller torque ripple effect. A further advantage of configuration 7 over configuration 5 is that there is less concentration of copper at the ends of the windings housing since the coils are wound with differing axial length. This should improve cooling of the copper by the liquid coolant.

Based on the above analysis, the design of the prototype windings was based on configuration 7. The distribution of flux density for this configuration was calculated for a grid of points across a diametrical plane as shown in the plots of Figure 9-21. Slightly different plots are obtained with different diametrical planes but for brevity plots for a single plane are presented, this being the plane containing the X and Z-axis as shown in Figure 9-20. These plots provide an indication of the sensitivity of magnet torque to
error in axial positioning of the limb in the windings. With the EPR magnet concentric with the windings, but displaced +/-50mm axially from the mid position, the flux density is reduced to 83.6% of that for an axially central position. It is noted that all the plots shown in Figure 9-21 are asymmetric about the axis X = 0. This is because a diametrical section through the z axis of the windings geometry shown in Figure 9-20 is asymmetrical.
Figure 9-21: Magnetic flux density for configuration 7 (Figure 9-20 above) plotted over plane y=0.
9.3.6 Possible use of high permeability material

Magnetic lines of flux run in closed loops and this gives rise to the concept of a magnetic circuit. An example of a magnetic circuit is a torroidal 'core' of ferromagnetic material on which is wound a current carrying coil, as in a torroidal transformer. The coil provides the magnetic force that produces magnetic flux in the core.

Let:

\[ L = \text{length of core in direction of flux} \quad \text{m} \]

\[ a = \text{cross sectional area of core perpendicular to flux} \quad \text{m}^2 \]

\[ \mu_0 = \text{permeability of free space} \]

\[ \mu_r = \text{relative permeability of core material} \]

The total magnetic flux produced in the core by a given coil is inversely proportional to the reluctance of the core, \( S \), where:

\[ S = \frac{L}{\mu_0 \mu_r a} \]

Equation 9-17

If a magnetic circuit consists of sections linked together in series, each section having a different reluctance, the total reluctance of the circuit is the sum of the reluctances of the individual sections.

As previously stated, the drive system for the extendible EPR is a form of electric motor. The magnetic circuit for an electric motor normally consists of a high permeability ferro-magnetic material in series with the minimal air gaps that are necessary to separate the armature and stator. The total magnetic circuit reluctance is the sum of the reluctance for the ferrous magnetic material and for the air gaps. It is desirable to minimise this total reluctance so as to achieve the highest magnetic flux for a given ampere turns in the windings and so the length of the air gaps, as measured in the direction of the flux, are kept to a minimum. Eliminating the ferrous magnetic material from such a motor would enormously increase the reluctance since the core material carries the flux over almost the whole length of the magnetic circuit and has a magnetic permeability which is typically three or four orders of magnitude greater than that of an air gap.

If ferrous magnetic material were to be included in the magnetic circuit of the EPR drive system then this material could only comprise a relatively small part of the total magnetic circuit length since the air gap must remain large enough to comfortably accommodate a patient's limb. Hence the use of ferrous magnetic material in the field
windings assembly for the EPR has much less effect in reducing total magnetic circuit reluctance than it does for a conventional motor with small air gaps.

A ferrous magnetic core could be added to the field windings by placing an annulus of iron, say 25mm thickness, around the periphery of the windings assembly. To reduce eddy current losses this core could be laminated from stampings of silicon iron sheet. If the nominal diameter of the iron annulus is taken to be $D$, then the length of the air gap part of the magnetic circuit for any one phase could be considered to be approximately $D$ and the length of the iron part to be $\pi D/2$. If the iron has negligible reluctance compared to the air gap then the inclusion of the iron as opposed to adding the length of the iron to the air gap would reduce the circuit reluctance by a factor of $\pi/(2+\pi)$ i.e. approximately 60%. In practice the iron will fail to capture all the magnetic flux, particularly at the ends of the assembly and so a reduction in reluctance of around 50% or less could be expected. This implies that the magnetic flux could at best be doubled for a given ampere-turns in the windings. However, the weight of the required iron would more than double the total weight of the windings assembly, cost and complexity of construction would be increased and the iron would interfere with the free flow of liquid coolant. Basically, the limited space available in the windings assembly is to be filled with copper, coolant and optionally iron. All these materials need to be positioned as close as possible to the inner diameter of the annulus for best effect. If iron is to be included, the benefit must be weighed against the alternative benefit of more copper and/or a better flow of coolant. An optimisation based on a detailed analysis would be complex and has not been attempted at this stage. Iron was omitted from the prototype assembly and this gives a simple and relatively low cost construction that has been shown to produce satisfactory field strength.

The above has considered the possible advantage of an iron core in improving the magnetic flux produced by a given ampere-turns in the windings. A second advantage of having an annular iron core surrounding the field windings would be a reduction in the 'stray' magnetic flux generated externally to the windings assembly. It has been noted that the cathode ray tube displays of computers located within approximately two to three meters of the prototype field coil assembly are subject to flicker when the field coils are operating. To date this has caused no damage to computers or other electronic equipment and there has been no loss of data stored on magnetic discs. As a precaution, it is proposed to restrict access to the area of the field generator equipment in a manner
similar to that by which access is restricted to areas containing magnetic resonance scanning equipment. This implies that notices will be placed to warn against bringing other electronic equipment or magnetic data storage media into the area where the field generator is used. Staff responsible for operation of the field generator will be instructed to question persons entering this area to ensure that they are not carrying credit cards or other items which might be affected by magnetic field and that they do not have implanted electronics such as heart pace makers.

9.3.7 Resistive heating

Having determined an appropriate geometry for the windings, as discussed in Section 9.3, the current density and hence the magnetic flux density that can be produced is determined mainly by thermal considerations.

The limit on the temperature at which the copper windings can operate is likely to be set by the properties of the electrical insulation on the windings. Field windings are normally insulated with a thin layer of enamel insulation. The use of a thicker insulation layer, such as an elastomeric sleeve or coating, would reduce the cross section of the conductor possible within given overall dimensions and this would increase the resistive heating effect for a given current. A typical maximum continuous operating temperature within the windings of an electric motor is 80 degrees C and this temperature was adopted as the upper limit for the operation of the prototype field windings. This temperature limit may be conservative since the windings were constructed from a wire having a high temperature enamel insulation rated at 200 degrees C.

Thermistors were placed in the prototype field windings and were used to monitor the temperature as discussed in Section 10.4. The windings for the prototype system have not to date been operated with these thermistors reading in excess of 80 degrees centigrade and a temperature limiting circuit has been constructed which automatically cuts the power supply if this temperature is exceeded.

Section 9.3.6 has considered the windings to be circular bundles of tightly packed wires with typically 20 mm bundle diameter. For the prototype construction these bundles were each subdivided into a square array of four bundles with a minimum separation of
approximately one millimetre, this subdivision being intended to improve heat transfer. The cross sectional area of this group of bundles was found to be at least twice that for an equivalent tightly packed circular bundle. This increase in cross sectional area was partly due to the spaces provided between the four sub-bundles and partly due to the practical difficulties of manually forming the windings into compact bundles of the required geometry.

Given the overall dimensions of the windings assembly, the quantity of copper incorporated in the prototype construction is thought to be approaching the maximum which is feasible. More copper would improve the field strength but the improvement would be relatively small since the additional copper would need to be less favourably located than the existing copper. More copper would also further restrict the free flow of coolant.

**Figure 9-22: Testing heat dissipation of windings**

Prior to finalising the design of the windings, measurements were made to determine the resistive heating power that could be dissipated from the windings. Three coils of roughly similar geometry to that proposed for the prototype construction were connected in delta connection to the output of a three phase frequency inverter which was equipped with an adjustable current control – see Figure 9-22. The three coils were immersed in a bath of oil coolant that was pumped through a liquid to air heat exchanger. The flow from the inlet pipe to the coolant bath was directed onto the coils so as to approximate the cooling conditions expected for the prototype field windings.
The currents and voltages in a three-phase system can be represented as vectors. For the delta connection, as shown on the left of Figure 9-22, the line current $I_{line}$ is the vector sum of $I_{phase_1}$ and $-I_{phase_2}$, the opposite signs of these current variables indicating that one current is entering the line connection and the other is leaving it. With a 120 degree angle between these phase current vectors and assuming a balanced system in which all phase current magnitudes are equal and all line current magnitudes are equal, the magnitude of line current is then given by:

$$|I_{line}| = \sqrt{3} |I_{phase}|$$  \hspace{1cm} \text{Equation 9-18}

Using the apparatus shown in Figure 9-22, a steady current was applied until the thermistor readings stabilised. This was repeated with progressively higher currents until the proposed thermal limit of 80 degrees C was reached, this occurring with a continuous phase current of approximately 5 amps RMS which corresponds to a line current of 8.7amps according to Equation 9-18. The coils used for this test were wound from 0.8mm nominal diameter wire and for which this phase current gives 9.95A/m² current density in the copper. This current density was used in selecting an appropriate wire diameter and number of turns per phase so as to match the resistive and inductive impedance of the prototype field windings to the selected power supply unit, as discussed in Section 10.1.

The flux density calculations detailed in Section 9.3.5 were based on 20 mm diameter bundles of tight packed circular wires which is a total copper cross section for the whole bundle of approximately 250mm². Based on a maximum flux density of 8 amps per mm² this gives 2000 ampere turns in each bundle. In Section 9.3.5 it was calculated that for the windings configuration 7, as shown in Figure 9-20, the magnetic flux density at the centre of the windings would be 10.03 mT for 1.0 ampere turns in each windings bundle. Scaling this for 2000 ampere turns gives a flux density of approximately 20 mT (200 gauze). This figure was used in predicting the continuously available magnet torque available from the magnetic drive system – see Section 4.3. If necessary, a higher field strength and hence torque can be produced intermittently, allowing the windings to cool between periods of energisation.
9.3.8 Possible use of superconductors

Brief consideration was given to the possible use of super-conducting windings since this would eliminate the resistive heating effect.

Traditional metal alloy superconductors become super-conducting when cooled to a few degrees Kelvin and can then carry very large currents in high magnetic fields. This principle is used to make powerful electro-magnets for applications such as the separation of magnetic materials from domestic and industrial waste. Cooling is by liquid helium and the cost and bulk of such a cooling system probably makes the use of this type of super-conducting material impractical for the present application. However, materials that become super-conducting at the temperature of liquid nitrogen are now beginning to find some commercial applications.

These materials, known as high temperature superconductors, are ceramic materials and become super-conducting when cooled to around 100 degrees Kelvin. High temperature superconductors progressively lose their superconductivity when subjected to increasing magnetic field strength but this would not be a limitation at up to around 0.2T (2000 gauss) flux density which is more than would be required for the present application. High temperature super-conducting materials are too brittle to be formed into wires and coils and so they are usually used as a powder encapsulated in a small bore tube of a malleable metal such as silver. BICC at Hepburn on Tyneside have a pilot plant producing such conductors in 100m lengths. Cooling can be by liquid nitrogen which can be kept at below boiling temperature by a Stirling cycle refrigeration unit. The casing for the coil windings would need to be suitable to enclose liquid nitrogen and would need to be thermally insulated. The thickness of insulation required between the coolant and the limb would increase the distance between the EPR magnet and the coils, partially offsetting the advantage of greater current carrying capability and making the whole assembly more bulky and more difficult to fit around the limb.

It was decided that super-conducting materials would not benefit the project at the present stage of development. The use of super-conducting materials might be reconsidered if it were required to develop the system for applications where the magnetic field has to be maintained over a larger air gap, as for an endo-prosthetic device in the trunk of the body rather than in a limb.
9.4 Constructional details of the field windings

This section describes the method of construction of the field windings assembly; the configuration and design of which are covered in Sections 9.2 and 9.3 above.

9.4.1 Winding the coils

The windings were made up from coils of enamel insulated copper wire, each coil being a rectangle curved to fit around the annular field windings housing. Two methods for winding the coils were tried:

1. The rectangular bundles were wound using a former mounted in the chuck of a centre lathe. The former consisted of a rectangular plywood board with four posts fixed in a rectangular pattern to suit the size of each of the required coils. The lathe was run at about 100 rpm and the 0.8mm diameter enamelled wire was tensioned by gripping it in a cloth as it was wound onto the former.

2. A part cylindrical wooden former was used. Four posts were fixed to the curved surface of this former in positions to suit the size of each of the required coils and the wire was wound round these posts turn by turn.

The second winding method was slower than the first but was the preferred method since it produced neater coils. With the first method the coils were initially flat and then needed to be bent to fit the housing and this bending tended to disorder the windings.

The length of wire in the coils was checked by weighing the coils at intervals during the winding process. After winding each coil the windings were bound together using electricians lacing cord tied at approximately 20mm intervals.
9.4.2 The housing for the windings

The annular housing for the windings was constructed from glass reinforced plastic (GRP). GRP is an electrical insulator and this provides safety for the patient in the event of breakdown of the insulation of the windings or the leads to the windings. The design was arranged so that there are no external metallic parts which might come into contact with the both the windings and the patient or the operator. The housing was laminated using an epoxy laminating resin and glass cloth reinforcement. Epoxy resin is more expensive than the more widely used polyester resin but is stronger and has better long term solvent resistance. The nominal wall thickness of the housing was 2.5mm.

Simple mould tooling for one off GRP construction can be made from wood, medium density fibreboard etc. Before laminating onto such moulds the surface is coated with filler, sanded and a release agent is applied. For very small volume production it is less important to obtain a high finish on the moulds than for volume production since small defects may well be easier to correct on the moulding than on the mould.

Figure 9-23: Construction of windings housing
The sequence of construction of the windings housing is described with reference to Figure 9-23 and Figure 9-24 as follows:

1. Male tooling for the inside surfaces of the annular housing was turned from a block of hardwood as shown at the upper left-hand side of Figure 9-23.

2. This tooling was used to laminate two cylindrical components with integral flanges. These components were then trimmed to size and joined end to end with the flanges outermost, the join being made by tapering down the wall thickness at the ends using an angle grinder before applying several layers of fibreglass tape and epoxy resin.

3. The bundles of windings, which had previously been produced as described in 9.4.1, were placed around the inner part of the GRP annulus and were fixed in position by binding the coils together with polyester cord. The individual bundles of conductors forming the coils were separated by at least 1mm from each other and from the GRP structure. This was achieved by fitting spacers made from small pieces of nitrile rubber between adjacent bundles and binding these spacers into position. The aim was to allow circulation of coolant around all the bundles of conductors.

Figure 9-24: Mould for outer surface of the windings housing
4. A male mould, as shown in Figure 9-24, was made by rolling 20 gauge mild steel sheet into a tubular form and inserting removable wooden formers at the ends, as shown. A sheet of polyester (‘Mylor’) film was wrapped around this mould before laminating with GRP. After the lamination was completed, the wooden formers at the ends of the mould were removed and the steel sheet sprung to a smaller diameter to release the moulding. This method avoided the need for a mould with a draught angle.

![Diagram showing electrical and coolant connection to windings housing]

**Figure 9-25: Electrical and coolant connection to windings housing**

5. A welded mild steel fabrication was constructed as shown in Figure 9-25 to support the coolant and electrical connections to the coil housing. This box shaped fabrication was then mounted over a square hole cut into the tubular GRP component described in 4 above and was fixed in position by moulding additional GRP over the metalwork. The metalwork included a weld-stud used to bond to the earth of the incoming power cable. Holes punched in the sheet metal achieve a strong joint with the GRP.

The fabrication shown in Figure 9-25 includes welded in 20mm outside diameter spigots for connection of the coolant piping and two sealed glands for electrical cables. A deflector plate was welded at an angle across the inlet pipe stub so as to deflect the incoming coolant in a tangential direction away from the outlet.
connection. This promotes a swirling motion around the annular coil housing to improve heat transfer.

6. The internal GRP component described in 1 above, together with the fully assembled windings, was fitted into the external tubular component described in 5 above and the joints were sealed using several layers of glass tape and epoxy resin. Before applying this tape, the adjoining surfaces were tapered in thickness by grinding so as to achieve a smooth joint externally.

7. The assembly was filled and faired externally and painted with two-pack epoxy paint.

It is noted that although the glands which seal the electrical cable connections through the wall of the windings housing are manufactured to a fully watertight specification (IP68) there has been a trace of leakage of transformer oil. Transformer oil has a low viscosity and appears to penetrate joints and spread across surfaces. It evaporates more slowly than water and so any slight leakage remains on the surface and is much more noticeable than water leakage would be. An attempt will be made to apply a sealant externally to the cable glands of the prototype field windings housing. For future construction alternative types of liquid tight cable gland or feed-through could be considered.

A difficulty was also encountered with leakage of oil coolant along the inside of the electrical cables connecting into the field windings. This leakage occurred between the copper strands of the multi-core cables and/or between the outer cable sheath and the insulation on the cores. It was found that a significant quantity of oil was leaking along the whole length of the cable and exiting within the casing of the frequency inverter. The sealing device shown in Figure 9-26 was fitted into the cable and was effective in preventing this leakage.
Figure 9-26: Oil sealing arrangement for cable to field windings
9.5 *Possibility of adverse health effects due to magnetic field*

The National Radiation Protection Board (NRPB) is the UK body responsible for providing advice on protection against ionising and non-ionising radiation, including exposure of the body to magnetic fields. The NRPB publish a booklet [NRPB, 1993 #40] which sets out guidelines on exposure of the body to static and time varying electromagnetic fields.

Exposure of the body to a time varying magnetic field causes electric current to circulate through the tissues of the body. It has been suggested that such circulating currents may have subtle effects on the central nervous system and to avoid this possibility an advisory maximum limit is set for the induced current density in the head, neck and trunk of the body. This limit is 100 milli amps (rms) per m$^2$. There is no limit set for induced current density in the limbs.

The NRPB guidelines do set a maximum limit of 5 Tesla for exposure of any part of the body, including the limbs, to static magnetic fields and time-varying magnetic fields having frequencies below 1Hz. This limit is two orders of magnitude higher than the maximum magnetic flux density that can be produced by the equipment constructed for use with the extendible EPR.

The NRPB guidelines are in any case specifically not intended to apply to people who are exposed to magnetic fields for medical therapeutic or diagnostic reasons. Hence the equipment developed under this project does not contravene these guidelines, firstly because the region of exposure is a limb rather than the head, neck or trunk of the body and secondly because the exposure is for medical therapeutic reasons.

The NRPB set out criteria for determining whether there is a possibility that magnetic field exposure may cause current density exceeding the advisory limit for head, neck and trunk exposure. These criteria are termed investigation levels. If such an investigation level is exceeded this does not necessarily mean that the maximum current density will be exceeded but it does mean that the exposure situation should be further investigated.
For magnetic fields of frequency range 0.4Hz to 1kHz, the investigation level for flux density is set at 80mT (RMS) for a frequency of one Hz and is inversely proportional to frequency. For the EPR field windings, the maximum frequency envisaged is 50Hz, but lower frequencies could be used if a longer extension period is acceptable. For 50Hz frequency the investigation level for flux density is $80/50 = 1.6$ mT (RMS). The flux density produced at the centre of the EPR field windings during the successful functional test described in 0 was approximately 10 mT (RMS). When operating on an intermittent basis using the maximum amps output of the currently available power supply, the equipment is expected to be capable of generating approximately 30 mT (RMS), but it should only be necessary to use this flux density in the case of exceptional tissue stiffness.

These flux density levels do exceed the advisory investigation levels set by the NRPB, hence further investigation would be appropriate if this were a non medical application where the head, neck or trunk are exposed. There may be possible future orthopaedic applications for the magnetic drive system within the trunk of the body. In this case a clinical judgement might be required to determine whether the clinical benefits outweigh possible health hazards, although at the present time such health hazards appear to be minimal and are difficult to precisely identify or to quantify. Assuming that the purpose of such an application of the magnetic drive would be to avoid surgery and consequent risk of infection, it is the opinion of surgeons involved with this project that such a judgement would favour use of the magnetic drive system.
9.6 *Possible accidental exposure to fields that could drive the extendible EPR*

It is highly unlikely that patients could be inadvertently exposed to a magnetic field that could drive the extension mechanism so as to cause a significant unwanted change in length of the extendible EPR. The friction at the magnet spindle and first stage of gearing in the EPR is such that the magnet does not rotate relative to the body of the EPR as a result of the earth's magnetic field. A child patient playing with a large permanent magnet could rotate the magnet within the EPR but the gear ratio is such that it would take at least hundreds of revolutions in a consistent direction to cause a significant extension and this is hardly likely to occur accidentally. In any case, the resulting discomfort would be expected to discourage such activity before any irreversible harm was caused. Rotating magnetic fields are generated within electric motors but these are generally well contained within the motor since a compact magnetic circuit is desirable for motor performance and efficiency. As a check, the first prototype of the extendible EPR was placed in various positions adjacent to a running 30 horse power induction motor and no rotation of the magnet occurred.
10.1 The need for frequency control

The field windings for the extendible EPR produce a rotating magnetic field using a three-phase power supply and this is also true of the windings for a three-phase induction motor. A significant difference between these two applications is that an induction motor requires the angular velocity of the field to be greater than that of the armature, this difference in angular velocities being known as slip. For the extendible EPR system, no slip can be tolerated since any lasting discrepancy between the rotation speed of the field and that of the magnet results in a sinusoidal torque being applied to the magnet and the net torque is then zero. The result is that the magnet oscillates back and forth rather than rotating.

When an industrial induction motor is operating at normal running speed the slip is typically 5% of the motor speed, this small slip being necessary to energise the armature with induced current. When an induction motor is started directly from a mains supply the slip is initially 100% of the field rotation speed. This causes high currents to flow in the armature but this situation can be tolerated momentarily. If the extendible EPR drive system is started in this way the field rotation may overtake that of the magnet and the magnet will then fail to start turning.

Let:

\[ T_m = \text{torque applied to magnet by field} \quad \text{Nm} \]
\[ T_g = \text{torque applied by magnet to gear system and bearings} \quad \text{Nm} \]
\[ H = \text{magnitude of rotating field strength vector} \quad \text{ampere-turns/m} \]
\[ M = \text{magnetisation of magnet} \quad \text{Tesla} \]
\[ V = \text{volume of magnet} \quad \text{m}^3 \]
\[ J = \text{Polar moment of inertia of magnet and attached parts} \quad \text{kgm}^2 \]
\[ \theta = \text{angle of rotation of magnet} \quad \text{radians} \]
\[ \omega = \text{speed of rotation of field} \quad \text{radians/s} \]
\[ t = \text{time} \quad \text{s} \]

Then from Equation 9.9:

\[ T_m = MHV \sin(\omega t - \theta) = J \frac{d^2 \theta}{dt^2} + T_g \quad \text{Equation 10-1} \]
Clearly the electrical system could be simplified if it were possible to start the magnet rotating by simply applying a 50Hz three-phase supply to the field windings. The supply could then be a direct connection to three phase mains or to a three-phase mains transformer.

To determine whether this is feasible, a computer program was written for the numerical solution of the differential Equation 10-1 by considering successive small time intervals. The program included a loop that reduced the time step until the effect on the results was negligible. The product $MH$ was initially taken to be $2 \times 10^4 \text{Nm}$, as for the preliminary torque calculation given in Section 4.3. The dimensions and mass of the magnet were initially considered to be as for the prototype construction. $H$ in Equation 10-1 was assumed to be a constant although immediately after start up $H$ will be reduced by transient effects due to the inductance of the windings and possibly also the characteristics of the supply system. The driving torque taken from the magnet $T_g$ was assumed to be zero or alternatively a small viscous damping term was included in order to ensure that the output of the program eventually stabilised. The assumption that $T_g$ is small or zero is optimistic, although it should be feasible to minimise $T_g$ at start up by initially reversing the field then driving through the backlash of the gear box. The behaviour of the magnet, as predicted by the program, was found to depend on the angular position of the magnet relative to the field direction at the instant of start up. The program predicted that for field starting angles within approximately 90 degrees of the magnetisation of the magnet, the magnet would rotate continuously in the direction of the field but for other starting positions the magnet would fail to rotate continuously in the field direction.

It was later found by practical test with the field windings energised by a frequency inverter that, regardless of the initial magnet position, the magnet would not start to rotate in the correct direction with field rotation at 50Hz. The magnet could be started by spinning it manually but if the magnet were then stalled it would not restart. This departure from the computer simulation may be due to frictional torque or to an underestimation of the inertia or to the starting characteristics of the power supply. It was found that when the magnet was manually assisted to start then sometimes the magnet would rotate in the reverse direction to the field and at a lower speed than the field rotation. Similar behaviour was predicted by the computer simulation for some starting conditions.
The computer simulation was run with various length to diameter ratios for the magnet whilst keeping the magnet volume constant. It was found that reliable starting was predicted with the diameter reduced from 16mm to 8mm and length increased four times. It has not been determined whether this would give reliable starting in practice since a magnet of this form is not available. The increase in length would in any case be an unacceptable increase in the length of the EPR assembly.

The use of a variable frequency power supply with a ramped frequency at start up overcomes the difficulties discussed above. If the acceleration of frequency is suitably low, the maximum driving torque of the magnet can be available to turn the gear system almost immediately after initial start up. Variable frequency three phase power supplies are now mass produced for use as speed controllers for induction motors and are known as frequency inverters. The cost of a frequency inverter is relatively low in comparison to the total cost of the prototype field generator system so it was clearly advantageous to include such a unit. An alternative, which was briefly considered, was the use a three-phase transformer with alternative tapings selected by a heavy duty relay. A high voltage could then be applied briefly to the field windings to assist starting, this voltage then being reduced to give a current that could be sustained without overheating. However, the cost of such a system would not be significantly less than that of a frequency inverter.

Modern frequency inverters generally have a sophisticated control system offering further benefits, apart from ensuring reliable starting of the magnet. These benefits include:

- Running speed can be adjusted according to required limb lengthening rate.
- Current control and limiting is normally included.
- Many parameters such as direction of field rotation, current, frequency ramps etc. can be conveniently selected by a built in keypad or by digital inputs.
- A display of output frequency, current, voltage, power, running time etc. is normally provided by a LCD panel.
- In smaller sizes, a frequency inverter having single-phase input can provide a three-phase output, avoiding the need for a three-phase mains supply.
10.2 The frequency inverter

A commercially manufactured frequency inverter, as used to drive a standard induction motor, is normally programmed to provide an output voltage which is approximately proportional to the output frequency and is zero or near zero at start up. This is because most of the voltage applied to an induction motor is required to overcome the back electromotive force (back EMF) of the motor, only a small voltage being required to overcome the impedance of the motor windings. The back EMF of a motor increases from zero at start up and so the frequency inverter ramps up both the output frequency and the output voltage to accelerate the motor from rest.

Unlike an industrial induction motor, the voltage applied to the field windings for the extendible EPR is required mainly to overcome the impedance to the windings themselves since the rotation of the small magnet surrounded by a large air gap produces negligible back EMF. The impedance of the windings has resistive and inductive components. If the design operating speed is taken to be 3000 rpm then the impedance at start-up, which is entirely resistive, is found to be around one third of the impedance at the operating speed. To maintain constant current and hence magnet torque across the speed range, the starting voltage must thus be in the region of one third that at the design operating speed. The torque required to turn the magnet at start up may well be higher than that needed to keep the magnet turning at higher speed and so it may be desirable to increase this starting voltage, or possibly to make the applied voltage constant across the speed range.

Industrial frequency inverters usually include a facility to modify the frequency vs. voltage characteristic so that the output voltage can be boosted to above zero at start, this boost falling off as frequency increases. This facility can be used to provide extra starting torque with an induction motor. However, most frequency inverters do not allow the voltage boost at start to be set to more than 15% of the full speed voltage. This is the maximum starting voltage that can usually be applied to a standard type of induction motor without risk of thermal damage and/or excessive current draw from the supply. For the field windings of the EPR a higher starting voltage would be preferred and ideally voltage control should be independent of frequency so that the torque vs. frequency characteristic can be freely programmed.
Generally, modern frequency inverters include a micro-controller based control system with inbuilt software and so the manufacturer is unlikely to be willing to provide modified control functions on a one off or small volume basis. The specifications for commercially available frequency inverters were studied during 1994 and it was found that at that time there were just two manufacturers of frequency inverters that offered control of output voltage independently of output frequency. This allows maximum torque to be applied to the magnet at start up and as speed increases this torque can either be maintained or can be reduced to reduce thermal heating, the maximum torque not being required once the magnet is turning at speed. The simpler and cheaper of these two frequency inverter units was controlled by two independently adjustable 0-10v analogue inputs used to set output frequency and output voltage. The alternative unit, as manufactured by Danfoss, had a micro-controller based system with a keypad and display which could be used to initially programme alternative frequency vs. voltage relationships which could then be selected using digital inputs to the unit. The analogue control system was considered to be simpler to use, particularly for the initial experimental testing. Unfortunately, as discussed in Section 2, the frequency inverter with this analogue control system proved to be unreliable and could not be repaired by the manufacturer. The more expensive micro-controller controlled unit was later purchased and this has now proved to be fully satisfactory.

Section 9.3.7 described a test which showed that the maximum continuous current density to keep the windings temperature below 80 degrees C is in the region of 10 amps per mm$^2$ of copper conductor. The diameter of the bundle of conductors and the cooling conditions used in this test approximated those for construction of the prototype field windings. This data was used as the basis for matching the windings to the frequency inverter.

The arrangement of windings used for prototype construction is shown in Figure 9-20. With this arrangement, each phase is connected to a pair of coils in series and the combined length of a central turn for both coils in a pair is calculated to be 1379mm. The cross sectional area of copper for all turns of each coil is approximately 250 mm$^2$, this being as for the test described in Section 9.3.7.
It is now required to select an appropriate wire diameter to match the impedance of the windings to the voltage and current output of a frequency inverter. The resistive impedance of the windings was considered as follows:

Let:

\[ I_{\text{phase}} = \text{phase current (RMS)} - \text{A} \]
\[ d = \text{wire diameter} - \text{m} \]
\[ N_{\text{phase}} = \text{Number of turns of wire for a single phase (total for pair of coils)} \]
\[ R_{\text{phase}} = \text{electrical resistance for a single phase - ohms} \]
\[ L_{\text{coil}} = \text{Length of coil centre wires for single phase (total for pair) - m} \]
\[ L_{\text{wire}} = \text{Length of wire connected to a single phase - m} \]
\[ \rho = \text{resistivity of material of wire - ohm \text{ m}} \]
\[ V_r = \text{resistive voltage drop through windings - V} \]

The maximum current density in the copper is considered to be \(10^7\) amps/m\(^2\) - see Section 9.3.7. Hence:

\[ I_{\text{phase}} = 10^7 \times \frac{\pi d^2}{4} = 7.85 \times 10^6 d^2 \]

Equation 10-2

Also the two coils for a phase are intended to each have 250mm\(^2\) cross section area of copper so:

\[ N_{\text{phase}} = 2 \times 250 \times 10^{-6} \times \frac{4}{\pi d^2} = \frac{6.37 \times 10^{-4}}{d^2} \]

Equation 10-3

If the two coils for each phase are in series the resistance per phase is given by:

\[ R_{\text{phase}} = \frac{4 L_{\text{wire}} \rho}{\pi d^2} = \frac{4 L_{\text{coil}} N_{\text{phase}} \rho}{2 \pi d^2} \]

Equation 10-4

At the maximum working temperature, 80 degrees C, \(\rho = 0.0195\ \mu\text{ohm-m}\) Also \(L_{\text{coil}} = 1.38\) m, hence:

\[ V_r = R_{\text{phase}} I_{\text{phase}} = \frac{4 \times 1.38 \times 0.0195 \times 10^{-6}}{2 \pi d^2} \times \frac{6.37 \times 10^{-4}}{d^2} \times 7.85 \times 10^6 \times d^2 \]

\[ V_r = \frac{8.56 \times 10^{-5}}{d^2} \]
Figure 10-1: Resistive voltage drop vs. wire diameter for maximum continuous current density and chosen coil dimensions.

The plot shown in Figure 10-1 is based on Equation 10-5. The selection of wire diameter is based on this plot together with Equation 10-2. An excessively large wire diameter will draw a large current at a low voltage, thus implying an unnecessarily expensive frequency inverter that will never operate close to its maximum voltage output. Too small a wire diameter will not allow sufficient current to energise the windings to the chosen current density at the maximum output voltage. It is noted that only a part of the available output voltage can be used in overcoming the resistive voltage drop of the windings since as frequency increases there will also be an inductive voltage drop, this being in the region of twice the resistive impedance at a frequency of 50Hz.

The maximum output voltage of a frequency inverter is normally close to that of the mains supply voltage. For some inverters the maximum output voltage is slightly higher than the mains supply voltage since the rectification of the mains supply within the frequency inverter produces an intermediate DC voltage which is higher than the RMS mains voltage.

A delta connection was used for the prototype construction so that the available voltage across phases is nominally 415V. The selected wire diameter was 0.8 mm. From Figure 10-1 this gives 134V resistive volt drop at the maximum continuous current, the remainder of the voltage across the phases being available to overcome the inductive
impedance of the windings at higher frequency and/or to provide a higher current intermittently, allowing the windings to cool at intervals.

Had the windings been connected with a star rather than delta configuration the voltage across phases would be the line voltage multiplied by a factor of $(1/3)^{0.5}$ and the phase current would be increased by the reciprocal factor, that is the phase current would become the line current. To maintain the same ratio of resistive volt drop to total volt drop it is then necessary to increase the wire diameter by a factor of $3^{0.25}$, that is 1.316. The nearest standard wire size would then be 1.0mm rather than 0.8mm.

For future construction, a star rather than delta connection might be used, together with an increase in wire diameter to 1.0mm. The advantages are marginal but fewer turns of thicker wire would be slightly quicker to wind manually and heat conduction from the centre to the periphery of the coil bundles might be slightly improved since the number of interfaces between wires would be reduced.

For 0.8 mm wire diameter, the resistance $R_{\text{phase}}$ as determined from Equation 10-4 is 26.6 ohms at 80 degrees C, equivalent to 23.5 ohms at 20 degrees C. After winding the prototype field windings the actual value of $R_{\text{phase}}$ was measured at 20 degrees and was found to be 22 ohms. This small departure from the design value is readily attributable to the practical difficulties in maintaining the design dimensions of the coils and possibly also to tolerance on the wire diameter. Further calculations are based on the measured windings resistance of 22 ohms at 20 degrees C.

The type of frequency inverter used for this project is available in a wide range of sizes giving output power from 1.9 to 313kVA, these units being suitable to drive induction motors from approximately 1.1 to 250kW shaft output. The size of unit selected for the EPR drive application was rated as follows:

<table>
<thead>
<tr>
<th>Manuf./ type:</th>
<th>Danfoss VLT3008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Input:</td>
<td>3-phase 415V at 50 or 60 Hz. Max. 17A.</td>
</tr>
<tr>
<td>Output:</td>
<td>3-phase 0-415V at 0-500 Hz. Max. 16A. (efficiency 96%)</td>
</tr>
</tbody>
</table>

Table 10-1: Frequency inverter rating.
Figure 10-2 shows a simplified block diagram for the frequency inverter unit. The incoming 3-phase supply is rectified then smoothed to produce a DC voltage (known as the link voltage) which is approximately 520V, for a 415V AC supply. This DC voltage is switched at a frequency which is much higher than the smoothed output frequency, the pulse width of the switched output being varied such that the effective output voltage is approximately sinusoidal on 3 phases. Output filters reduce the effect of pulse width modulation. The switching method used by this particular manufacturer varies both the pulse width and the switching frequency over the output voltage cycle. This is claimed to give smoother output so that a connected motor does not require to be derated when run from the frequency inverter rather than directly from mains supply. A micro controller based control system with user keypad and LCD display controls the switching of the DC link voltage and allows a large number of parameters to be programmed by the user.

At low speed, when inductance is negligible, 203V out of the nominal maximum voltage of 415V is required to supply the maximum current output of the frequency inverter with the measured 22ohm phase resistance, $R_{\text{phase}}$, and 110 volts is required to supply the design maximum continuous running current. Under these conditions the control system in the inverter will operate to regulate the voltage to avoid over current. For higher speeds the inductance of the windings must be taken into account as follows:

Let:

- $V$ = Line voltage (also phase voltage for delta connection) - V
- $Z_{\text{phase}}$ = Impedance of windings for one phase – ohm
- $X_{\text{phase}}$ = Reactance of windings for one phase – ohm
- $L_{\text{phase}}$ = Inductance of windings for one phase – Henry
- $f$ = frequency – Hz
Then:
\[ |Z_{\text{phase}}| = \sqrt{R_{\text{phase}}^2 + X_{\text{phase}}^2} = \frac{V}{I_{\text{phase}}} = \frac{\sqrt{3}V}{I_{\text{line}}} \]

**Equation 10-6**

Where:
\[ X_{\text{phase}} = 2\pi f L_{\text{phase}} \]

**Equation 10-7**

Measurements of voltage, \( V \), and line current \( I_{\text{line}} \) were taken from the frequency inverter front panel display with the output frequency, \( f \), set to 50Hz. The magnitude of \( Z_{\text{phase}} \) for the prototype field windings was calculated from these measurements and was 62.9 ohms. Based on the measured value of \( R_{\text{phase}} \) (22 ohms), Equation 10-6 then gives \( X_{\text{phase}} = 58.93 \) ohms and \( L_{\text{phase}} = 0.188 \) Henry.

Having measured the resistance and inductance of the windings, as above, the impedance, \( Z_{\text{phase}} \), can be calculated for a range of frequencies. The operating limits for the combination of frequency inverter and field windings can then be plotted as shown in Figure 10-3.

![Figure 10-3: Operating limits for prototype field windings and frequency inverter](image-url)

Note: plot assumes delta connection to windings.
With reference to Figure 10-3, the dotted line is a constant current line corresponding to $I_{\text{phase}} = 5.0\,\text{A}$ ($I_{\text{line}} = 8.66\,\text{A}$ for delta connection), this being the current which is expected to heat the windings to 80 degrees C which is the design maximum temperature. The heavy line is a constant current line for speeds less than about 2000 rpm. Up to this speed the current is the maximum current output of the frequency inverter, that is $I_{\text{line}} = 16\,\text{A}$ ($I_{\text{phase}} = 9.23\,\text{A}$ for delta connection). Above this speed the current is limited by the maximum voltage output of the inverter.

The combination of frequency inverter and field windings is expected to be capable of operating continuously at operating points below the dotted line, and intermittently at points between the dotted and solid lines. For speeds up to 2000 rpm, intermittent operation can potentially achieve 83 % greater voltage, and hence current and magnet torque, than can continuous operation. This can be used to provide a torque 'boost' for use in the event of exceptional resistance to extension.

The functioning of the frequency inverter is dependent on the values of over a hundred adjustable parameters. These parameters define, for example, current limits, acceleration and deceleration rates, the assignment of various screw terminal connections and even the language in which the menus are presented. The unit can be programmed with up to four modes of operation each of these modes potentially having a completely different set of operating parameter values. However, all parameters have factory set default values for all modes and so it is normally only necessary to change a few values to suit a particular application. After the unit has been programmed by setting parameter values for the required operating modes, it is then possible to switch between modes either from the front panel or by two digital input lines. Such mode switching is possible while the unit is running.

Two of the maximum of four modes have been used to date. The parameter values associated with these modes have been programmed to give a normal running mode and a boost mode. The operator may select the boost mode in the event that the normal mode does not provide sufficient magnet torque. When the boost mode is selected the unit is operating above the dotted line in Figure 10-3 and so this mode can only be used briefly or on an intermittent basis.
For both normal and boost modes non-default parameter values are set to specify voltage vs. frequency relationships. These voltage vs. frequency relationships are defined as straight lines characterised by a starting voltage and a full speed voltage. A more recently available version of the frequency inverter permits voltage vs. frequency relationships to be set as a series of points but this refinement is not essential for the EPR application. It is noted that however the voltage vs. frequency characteristic is programmed, the current limit control will override this characteristic as necessary. The voltage at 50Hz for the normal mode should not be set to more than 300V to allow continuous operation – see Figure 10-3. For either normal or boost mode the voltage at 0 Hz may be set above that for continuous operation since the unit only operates briefly at low speed, that is when starting or stopping.

Some preliminary parameter values for the normal and boost modes are given in Table 10-2. These values may be adjusted in the light of clinical experience.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Normal running mode</th>
<th>Boost mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full speed frequency - Hz</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>Voltage at zero Hz - V</td>
<td>100</td>
<td>150</td>
</tr>
<tr>
<td>Voltage at 50 Hz - V</td>
<td>200</td>
<td>400</td>
</tr>
<tr>
<td>Ramp speed up duration - s</td>
<td>5.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Ramp speed down duration - s</td>
<td>5.0</td>
<td>1.0</td>
</tr>
</tbody>
</table>

Table 10-2: Preliminary parameter values for normal and boost modes.

The full speed frequency of 50Hz gives a magnet speed of 3000 rpm, which extends the prototype EPRs by one millimetre in about five minutes. This speed could readily be adjusted after experience in clinical service.

It has been found that the EPR is capable of extending against the design loads without operating above the dotted line shown in Figure 10-3. If experience in clinical use shows that it is never necessary to exceed this limit then, for future construction, it would be possible to use a frequency inverter of smaller current output or alternatively to energise larger size field coils with the existing frequency inverter. To change to a smaller output frequency inverter it would be necessary to have more turns of a smaller diameter wire in the field windings such that the full output voltage of the frequency
inverter does not exceed the thermal limit at the normal operating speed. A reduction in the operating speed would also reduce the size of frequency inverter required.

Medical staff have recently suggested that an increase in the bore diameter of the field windings would make limb access easier. It is desirable that this increase in diameter should not be accompanied by a proportionate increase in the axial length of the field windings assembly since this might make limb access more difficult for some tumour sites.

The computer program for calculating magnetic flux density, as described in Section 9, was run for a series of field windings dimensions to suit increasing bore of the field windings assembly whilst retaining the current axial length for the field windings assembly. The graph shown in Figure 10-4 shows how the number of turns in the windings would need to be increased to maintain a constant flux density as measured at the centre of the windings housing. The increase in resistance of the windings is plotted in Figure 10-5, this increase being due to both the increase in the number of turns required and the greater length of conductor in a turn.

![Graph showing effect of bore of windings housing on number of turns required to maintain flux density.](image)

Note:
Axial length of windings housing remains constant
Flux density/amp as measured at centre of windings housing remains constant

**Figure 10-4:** Effect of bore of windings housing on number of turns required to maintain flux density.
Figure 10-5: Effect of bore of windings housing on resistance of windings

Equation 9-11 indicates that for a constant flux density per ampere, the inductance of the windings will increase in proportion to the product of the number of turns and the area of the coils as measured perpendicular to the lines of force. For a constant axial length, this area is approximately proportional to the length of conductor per turn of the windings and hence the percentage increase in the inductance of the windings is expected to be similar to the percentage increase in the resistance of the windings.

Based on the above, it is estimated that an increase in bore diameter from 160 mm to say 180 mm, without change in axial length, would increase the total impedance by 27% for all frequencies. The existing frequency inverter would be capable of meeting this increased impedance whilst maintaining the design maximum current for continuous operation. The reserve available for a boost mode setting would be reduced.
10.3 Cooling System

As discussed in Section 9.3.7, the use of a liquid cooling system for the field windings significantly increases the current which can be applied to the windings and hence the magnetic flux density which can be achieved. The chosen coolant was Dialla oil, as supplied by Shell. This is very low viscosity oil that is used as a coolant for the windings of large power transformers. The oil is an electrical insulator and can be circulated in contact with the windings. Occasional minor scratches on the enamel insulation on the windings are almost inevitable in the course of construction and the oil will maintain insulation at these points provided that actual contact does not occur between bare copper surfaces.

The liquid cooling system includes a centrifugal pump and oil to air heat exchanger with finned tubes and an integral electric fan. These components were generously sized. The higher is the capacity of the cooling system the closer will the coolant temperature approach the ambient air temperature and the greater is the current which can be passed through the windings for a given maximum copper temperature. Also, as discussed in Section 10.5, a fairly large and heavy cabinet is required to balance the weight of the field windings assembly on a cantilevered support arm and the heat exchanger provides part of the weight needed in this cabinet.

The selected oil to air heat exchanger has a specified nominal capacity of 20kW at 100 degrees C temperature differential between the oil inlet and the ambient air, this being based on an oil flow rate of 1.8 litres per second and an air flow rate of 470 litres per second. For the extendible EPR application a much smaller oil to air temperature differential must be used, both for the comfort of the patient whose limb may be in contact with the windings housing and to also to maximise the current which can be passed through the windings. For a parallel flow or counter flow heat exchanger the heat transfer capacity can be predicted on the basis of the logarithmic mean temperature (LMTD) between the two streams of fluid passing through the heat exchanger. The heat exchanger used for this application resembles a large car radiator and is a cross flow heat exchanger. Charts are available for determining a corrected LMTD for a cross flow heat exchanger [Simonson, 1967 #52] but since the characteristics of a cross flow heat exchanger depend on the cross mixing which is allowed for the two fluid streams it was
preferred to write a simple computer program to model the actual configuration of the heat exchanger. This program models four banks of finned tubes arranged perpendicular to the air flow. It is assumed that there is a constant of proportionality relating the heat transfer rate per unit length of tube to the local temperature differential between oil and air. The first stage of the computer program determines this constant of proportionality by an iterative process that matches the nominal capacity of the heat exchanger to the conditions for which this capacity is specified. The program then uses this constant to determine the oil temperatures for any required capacity, oil flow rate and ambient air temperature.

The calculation of heat transfer starts by considering the first bank of tubes. The temperature of the approaching air is ambient temperature along the whole length of the tubes in this first bank. Heat transfer rates are determined for small increments of length along the tubes in the first bank and this gives the oil temperature at outlet from the first bank of tubes together with the air temperature distribution applied to the second bank of tubes. This process is repeated for all tube banks to determine total heat transfer and by an iterative process the fluid temperatures for any required total heat transfer rate.

The computer program described above was used to produce the results plotted in Figure 10-6.

![Figure 10-6: Oil temperatures vs. heat transfer rate for forced air oil cooler](image)

Note: Based on: 20 deg. C ambient air temperature
0.3 l/s oil flow rate.

Figure 10-6: Oil temperatures vs. heat transfer rate for forced air oil cooler
The phase current which produces design maximum copper temperature of 80 degrees C is approximately 5.0 amps RMS, as discussed in Section 9.3.7 and the measured phase resistance of the windings is 22 ohms.

Let \( Q = \) heating power for three phases combined \( \text{W} \)
Then:

\[
Q = 3 \times I_{\text{phase}}^2 \times R_{\text{phase}}
\]  \hspace{1cm} \text{Equation 10-8}

For the measured values as above the heating power, \( Q \) is 1650 W and Figure 10-6 then indicates the inlet oil temperature, which is the bulk oil temperature in the windings housing, to be about 26 degrees. This is considered acceptable. The actual temperature may be slightly lower due to heat loss from the windings housing and pipe work.

The coolant circulating pump is a centrifugal type having a bronze body and impeller and a spring loaded ceramic seal unit. A flow meter is fitted in the pipe work to measure oil flow rate and this measured flow rate was used for the prediction of coolant temperatures as above. The flow meter is a paddle wheel type having an infra red LED and phototransistor to detect rotation of the paddle wheel. It was originally intended to use the flow meter to stop the frequency inverter in the event of a low flow rate but this has not been implemented since the cut out based on windings temperatures will also operate reliably in this fault condition.

A small expansion vessel of 1 litre nominal capacity is connected to the cooling circuit to provide for thermal expansion of the coolant relative to that of the containing system. This expansion vessel contains an elastomeric membrane separating the coolant from nitrogen pressurised at approximately \( 3 \times 10^4 \text{N/m}^2 \) (5psi). This expansion vessel is of a type used in hydraulic oil circuits. The cheaper type used in some domestic central heating systems was found to be unsatisfactory, the membrane being soluble in the oil used as coolant.
10.4 Electrical system for field generator unit

The complete electrical system for the field generator comprises the frequency inverter discussed in Section 10.1 together with switch gear for the incoming supply, a user control panel and a system to monitor the temperature of the windings and shut down the frequency inverter in the event of this temperature exceeding a limit.

The complete electrical system as currently constructed is shown in Figure 10-7. The control panel layout is considered in Section 10.5, other details of the system are described as follows:

The 3-phase supply is connected to the equipment via a flexible 5-core cable (3 phases, neutral and earth). This supply is switched by a 4 pole (3 phases and neutral) contactor controlled by an on/off switch mounted externally on the main cabinet as shown in Figure 10-11. The supply from the contactor is connected to the input of the frequency inverter and also to the pump and fan for the oil cooling circuit and a small 24vDC switched mode power supply, which is used to energise ancillary control circuits. The pump, fan and DC power supply run whenever the contactor is on, regardless of whether there is power supplied to the field windings. The contactor and associated screw terminal connectors are DIN rail mounted within an enclosure within the main cabinet and a switch is arranged to break the current to the contactor coil if the cover of this enclosure is removed. A second DIN rail mounting is provided for low voltage control circuits. Such circuits were built using strip board and housed in DIN rail mountable boxes that have screw terminals for all external wiring connections.
Control systems for the field windings

Section 10: Power Supply, Cooling and
The temperature of the field windings is measured by a number of thermistors that are buried within the turns of the windings. These are small epoxy bead thermistors, these being selected for small size, low cost and high sensitivity to temperature change in the range of interest. Thermocouples might have been a similarly compact sensor type but they would have required more complex signal conditioning. The thermistors used have a negative temperature coefficient, that is the resistance of the device falls as temperature increases. The relationship between thermistor resistance and measured temperature is non-linear.

Let:

- \( R_t \) = measured thermistor resistance at unknown temperature \( T \) (Kelvin scale)
- \( R_0 \) = thermistor resistance measured at a reference temperature \( T_0 \) (Kelvin scale)
- \( \beta \) = coefficient characteristic of a particular thermistor and specific to reference temperature used. 298K is the reference temperature normally used by thermistor suppliers.

Then:

\[
R_t = R_0 e^{\beta \left( \frac{1}{T} - \frac{1}{T_0} \right)}
\]

Equation 10-9

Figure 10-8: Single temperature measurement channel

The thermistors are energised from a stabilised 5V supply in series with a fixed resistance as shown in Figure 10-8 to provide a DC output which rises with temperature. The thermistor leads are inevitably routed in close proximity to the field windings and are subject to electromagnetic pick-up that is smoothed by the capacitor in parallel with the thermistor. For data logging temperatures using a computer based data acquisition system, both the thermistor outputs and the thermistor supply voltage were sampled so that the effect of supply voltage variation could be eliminated.
A temperature vs. output voltage plot for the circuit shown in Figure 10-8 and based on Equation 10-9 is shown in Figure 10-9 below. The value of the fixed resistor in Figure 10-8 was selected so as to make this plot approximately linear in the temperature range 40 to 100 degrees C, this being the intended working temperature range for the field windings. When the windings temperatures were recorded using a computer data acquisition system the outputs from the thermistors were linearised on the basis of Equation 10-9.

![Figure 10-9: Output voltage vs. temperature for thermistor measuring circuit.](image)

Two of the thermistors in the field windings are used to provide high temperature warning and cut out signals. The remaining thermistors were used only for development work to explore the temperature distribution through the windings.

With the current control panel arrangement, as shown in Figure 10-10, the operator both starts the frequency inverter and selects the direction of rotation using a three position rotary switch, this being connected directly to the start and direction control terminals of the frequency inverter. A prominent front panel light indicates when the field windings are energised, this light being connected through a programmable status indication relay provided in the frequency inverter.

With reference to Figure 10-7, thermistors S1 and S2 produce analogue temperature signals which are taken to the non-inverting inputs of a dual op-amp. This op-amp acts as a comparator to compare the temperature signals with threshold voltages which can be set individually for each thermistor using potentiometers which are accessible only from within the main cabinet of the field generator. The op-amp outputs switch
transistors to produce 24V digital signals that are low for a high temperature condition. One of these signals is used as a warning signal to illuminate an amber warning light on the front panel. The second temperature signal, which is set higher than the warning signal, is taken to a terminal on the frequency inverter that disables the output of the frequency inverter when the signal is low. A latching circuit, based on the op-amp OP77 shown in Figure 10-7, holds this signal low until the front panel reset button is pressed to cancel the fault condition, allowing the unit to re-start.

For development work, a PC based data acquisition system was used to monitor the temperature from all thermistors distributed in the windings in addition to a thermistor sensing coolant return temperature, a flow meter sensing coolant flow rate and a Hall effect sensor measuring current to the windings independently of the current measurement built into the frequency inverter. The software was written using the Pascal high level language, this software displaying the logged parameters as a moving scroll chart. A further program was produced to read back from the output disc files to produce charts as postscript files for hardcopy output.
10.5 Industrial design and ergonomics of the field generator unit

The field generator unit comprising the field windings assembly and a cabinet containing the power electronics and liquid cooling system is the visible part of the extendible EPR system. As such, this equipment was the subject of an industrial design study aimed at achieving the following:

- Comfort for patients during the extension procedure. A typical extension procedure is expected to take ten minutes for a two millimetre extension.
- Portability such that the equipment can be moved around a hospital building.
- Non-intimidating appearance to minimise anxiety for patients. Working parts to be concealed behind housings.
- Controls which are convenient to use and no more complicated than is necessary.
- Easy to clean.

The field generator unit is shown in Figure 10-11, Figure 10-12, Figure 10-13, Figure 10-14 and Figure 10-15. The unit includes a wheeled cabinet from which the field windings assembly is mounted on a swinging counterbalanced arm to allow height adjustment.

The field windings assembly weighs about 25 kilograms and having this assembly permanently mounted on a counterbalanced support makes it easier for hospital staff to position the assembly over the leg or arm of a patient. It also avoids the risk of the field windings being dropped and damaged or slipping while on the limb. A gas strut housed within the cabinet provides the counterbalance force. This gas strut acts on a lever attached to the axle on which the support arm for the coil housing is mounted. The geometry of this lever mechanism is such that the lifting force due to the gas strut is approximately uniform over the range of height adjustment of the field windings. The gas pressure in the gas strut is adjustable downwards from the factory set pressure by use of a small release vent. The gas pressure was adjusted so that the lifting force is slightly less than the weight supported. To adjust the height of the field windings assembly, the operator presses one of two buttons mounted each side of the field windings support arm – see Figure 10-11 - and this releases a locking mechanism.
allowing the support arm to be raised or lowered then locked in a new position by release of the button. A Bowden cable, which is actually a pedal cycle brake cable, connects the pushbuttons to the support arm locking mechanism. The working height range for the field windings, as measured from the floor to the central axis of the annular housing, is 400 to 960 mm. With the patient seated, this height range should be suitable for EPRs sited in the leg or in the arm. When the system is not in use, the field windings assembly can be folded down into a recess in the cabinet to minimise floor space occupied.

The field generator unit is assembled on a frame that is a welded fabrication of 25x50mm and 25x25mm rectangular hollow steel sections. This frame is mounted on four large diameter castor wheels, two of which can be locked to prevent unwanted movement. A large push/pull handle is fitted to the back of the cabinet for moving the unit.

The cabinet has two large removable GRP casings, one on each side. The casings were laminated using moulds made from medium density fibreboard and painted with a release agent. Removal of one of these casings provides access to the electrical system. Removal of the opposite side casing provides access to the liquid cooling system. Although these casings are approximately rectilinear in form, most of the surfaces are actually slightly curved which improves the stiffness of the panels and is considered to improve appearance. Two concealed screws located at the bottom of the unit secure each of the two casings.

The oil to air heat exchanger with integral fan is mounted at a slant angle within the cabinet and draws air through a grill at the front of the cabinet and expels air through an opening under the cabinet towards the rear. Sheet metal parts act as ducting for the airflow and as the mounting structure for the heat exchanger.

The oil circulating pump is mounted low down in the cabinet with a drip tray beneath. The piping for the oil cooling circuit has a nominal diameter of 20mm throughout. The piping includes sections of flexible reinforced hose to accommodate angular movement as the field windings are raised and lowered on the supporting arm.
The control panel is mounted at the top rear of the cabinet and is slanted to face the operator. The control panel layout currently in use has a minimum of controls and indicators and is as shown in Figure 10-10. Various medical staff may require to use the system and some of these may use it only occasionally and so it is considered important to have the simplest possible controls requiring a minimum of operating instructions. A rotary switch starts and stops the field rotation and also selects the direction of rotation. The frequency inverter runs in the normal mode, see Section 10.2, by default but holding down a push button switches the frequency inverter to run in the boost mode which provides a higher maximum magnet torque. The frequency inverter remains in the boost mode only while this push button is held down. Temperature warning indicators and high temperature cut out with latched reset function are as described in Section 10.4.

**Extendible Prosthesis Drive**

1. Switch on (switch on back of unit)
2. Select EXTEND to lengthen or RETRACT to shorten
3. Select STOP to stop extension or retraction

Prosthesis may be rotation 'A' or rotation 'B' - consult patient records. EXTEND and RETRACT controls assume patient positioned according to type of prosthesis as drawn below. If patient orientation is reversed then these controls are reversed.

Hold down BOOST button for extra force only if necessary

Prosthesis may not extend if coils are not correctly positioned over magnet

If temperature warning light comes on then drive may soon stop due to high internal temperature
If drive stops due to temperature wait for warning light to go off then press RESET button to continue

**Figure 10-10: Control panel layout**
An alternative second control panel was constructed but the electrical circuit for this panel is not fully functional at the time of writing and it now unlikely that this panel will be used, the reasons for this being discussed below. This second control panel together with the associated control circuits was constructed as a teaching project by an undergraduate electronics student supervised by the author of this thesis. The panel itself is a membrane keypad made by silk screening an image of buttons and text onto flexible clear plastic film. Pressing the buttons marked on the keypad depresses small switches mounted beneath. Warning indicators are multiple LEDs mounted below clear areas of the film. The main additional feature on this control panel is an indication of EPR extension in millimetre units. This extension display is driven by a programmable logic controller (PLC) programmed to count the rotations of the field and to divide this count by the gear ratio of the EPR to determine the extension in millimetres. The PLC outputs signals to progressively illuminate a ‘bar-graph’ display consisting of a row of ten lights each representing 0.2mm extension. If the operator has not stopped the extension at 2 millimetres then the PLC stops the extension at this point to avoid the possibility of over extension due to operator failing to supervise the procedure. The operator can then restart the extension if necessary and this resets the bar graph to zero. A complication with this system is that it is unlikely that all the extendible EPRs manufactured will have the same gear ratio. The mechanical design of the EPR may be further developed, particularly to reduce the dimensions and this will almost certainly change the gear ratio. The prototype control panel with extension display has a 4 decade BCD thumb-wheel switch which the operator can use to dial in a patient specific code before starting each extension operation. This BCD switch is connected to 16 binary inputs on the PLC, these inputs indicating the approximate gear ratio of the EPR together with the direction of field rotation required for EPR extension.

The disadvantage of this system is that the indicated extension distance may be in error and an erroneous indication of extension is potentially more serious than not having an indication of extension. The indicated extension would be based only on the number of field rotations, not on a direct measurement of EPR length. Hence the extension reading could be in error should be limb be incorrectly positioned in the field windings assembly or should there be malfunction of the mechanism within the EPR. Requiring the operator to input a patient specific code also introduces a possibility of error.
In view of the above it was considered preferable to return to the simple control panel which does not include any indication of extension. The overall function of the system is simply to achieve approximate limb length symmetry. When a difference in limb length is too small to be noticeable to either the patient or the operator then it can be considered to be of no consequence. The prototype system has been set up to achieve a one millimetre extension in five minutes, based on the current design of EPR, and this allows the operator to judge approximately how long to run the system.

If there were concern that failure of the operator to supervise the procedure adequately might allow injury to the patient then it would be possible to provide the patient with a stop switch on a flexible lead and this could be used if excessive pain occurs. If this were required then it would be straightforward to implement since the frequency inverter control system provides an ‘emergency stop’ function that operates when contact is broken between two terminals on the unit.
Figure 10-11: External features of field generator unit and overall dimensions in mm

- Control Panel
- Mains power switch
- Push button to release pivot lock (one each side)
- Windings at max. height
- Handle
- Windings retracted
- Horns for cable stowage

Side view

Rear view

Dimensions:
- Side view: 553 mm x 792 mm
- Rear view: 996 mm x 996 mm
Figure 10-12: Side view on field generator unit showing liquid cooling system
Figure 10-13: Side view on field generator unit showing electrical system
Section 10: Power Supply, Cooling and Control Systems for the Field Windings

Figure 10-14: Field generator – Rear view

Figure 10-15: Field generator – Front view.
Section 11  THE PERMANENT MAGNET

11.1 Selection of material

The first permanent magnet materials used in industry were hardened high carbon steels. The magnetic properties of steel magnets were improved by the addition of cobalt and then during the 1930’s by the addition of aluminium and nickel in the alnico range of materials. Alnico magnets have typically five times the remanence of the earlier steel magnets and unlike steel magnets it is almost impossible to demagnetise an alnico magnet by mechanical shock. It was found that by heating alnico magnets and then cooling them in the presence of a magnetising field they could be made anisotropic with a higher magnetisation in one particular direction than could be achieved with isotropic materials.

Alnico magnets are expensive to manufacture and this lead to the development of ceramic ferrite magnets. Ferrite magnets are made by sintering metallic oxide powders under high temperature and pressure in a mould. Ferrite magnets have now largely superseded Alnico for applications such as loudspeakers and mass produced motors.

Rare earth magnets sintered from a samarium cobalt (SmCo) inter-metallic compound were introduced during the 1960s and offer superior magnetic properties to ceramic ferrites but at higher cost and with greater brittleness. Rare earth magnets sintered from neodymium iron and boron (NeFeB) were introduced in the mid 1980s and offer higher coercivity and energy product than SmCo but not necessarily a higher remanence. SmCo can tolerate a higher working temperature than NdFeB.

Ferrite, SaCo and NeFeB magnets are available as bonded materials as well as in a sintered form. These bonded materials consist of magnetic powder dispersed in an injection mouldable plastic. They offer lower cost of manufacture than the corresponding sintered materials, particularly for high volume applications, but have generally poorer magnetic properties. The working temperature for the bonded materials is low due to the limitation of the polymer used to bond the magnetic powder.
Within each broad group of permanent magnet materials there are numerous grades from various suppliers, these grades often having markedly differing properties. Table 11-1 is an attempt to make a broad comparison based on typical properties selected from the technical literature provided by several suppliers, but there may be some individual grades available which have properties outside the numerical ranges quoted.

<table>
<thead>
<tr>
<th>Material</th>
<th>Remanence (mT)</th>
<th>Coercivity (kA/m)</th>
<th>Maximum Energy Product (kJ/m³)</th>
<th>Maximum working temperature (°C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alnico</td>
<td>980 to 1200</td>
<td>50 to 60</td>
<td>30 to 40</td>
<td>500</td>
</tr>
<tr>
<td>Bonded Ferrite</td>
<td>120 to 160</td>
<td>80 to 180</td>
<td>4 to 16</td>
<td>150</td>
</tr>
<tr>
<td>Sintered Ferrite</td>
<td>200 to 400</td>
<td>140 to 270</td>
<td>10 to 30</td>
<td>250</td>
</tr>
<tr>
<td>Bonded SmCo</td>
<td>300 to 600</td>
<td>200 to 300</td>
<td>50 to 60</td>
<td>150</td>
</tr>
<tr>
<td>Sintered SmCo</td>
<td>800 to 1500</td>
<td>500 to 600</td>
<td>140 to 190</td>
<td>300</td>
</tr>
<tr>
<td>Bonded NdFeB</td>
<td>300 to 660</td>
<td>200 to 400</td>
<td>30 to 70</td>
<td>150</td>
</tr>
<tr>
<td>Sintered NdFeB</td>
<td>1050 to 1300</td>
<td>760 to 1000</td>
<td>215 to 290</td>
<td>80 to 150</td>
</tr>
</tbody>
</table>

Table 11-1: Typical properties of magnetic materials.

The first prototype non-invasively extendible EPR made for this project in 1994 incorporated a NdFeB magnet with unspecified properties. The magnets subsequently used for the prototype extendible EPRs are of NdFeB and have specified properties as follows:

- Remanence \( (B_r) \): 1060 mT
- Coercivity \( (H_c) \): 804 kA/m
- Maximum energy product \( (B_h)_{\text{max}} \): 215 kJ/m³
- Maximum working temperature: 150 °C

This particular material combines good magnetic properties with a relatively low cost for small batch quantities of a finished part manufactured to customer’s drawings. These magnets are supplied with a nickel plating for protection against corrosion. For the EPR application, the magnets are hermetically sealed into a titanium capsule as discussed in section 7.1. Although this titanium capsule is expected to provide a high level of protection against corrosion, the nickel coating is advantageous in that it protects the magnetic material against corrosion in transit and storage prior to encapsulation.
11.2 **Effect of temperature on magnetisation**

Although the working temperature of the selected grade of NdFeB is higher than for most alternative grades of NdFeB it was considered necessary to examine situations in which the EPR could be exposed to elevated temperatures during the period between magnetisation of the magnet and implant by surgery. Three such situations are:

1. Sterilisation – Sterilisation temperatures are summarised in Section 3.5.
2. Hydroxyapatite (HA) coating – This coating is applied by a hot plasma spray process.
3. Shrink fit – A heat shrink fit is the clinically proven method of attaching an extendible module to the femoral component a SMILES knee joint – see Figure 1-2.

The use of a SmCo magnet would have offered a working temperature well above the temperatures expected for the three situations listed above but, based on quotations received, the cost for a finished part would have been considerably higher than for the selected NdFeB material.

To check the effect of temperature on the magnetisation of the NdFeB material, one of the magnets supplied for the project was tested after being placed in an oven at a range of increasing temperatures. A simple method of testing for magnetisation was used, this being to use an electronic balance to measure the force required to pull the magnet off a block of iron. Before each pull off measurement the magnet was placed in a preheated thermostatically controlled oven for thirty minutes and then allowed to cool to room temperature. The oven temperature was increased by approximately 5 degrees C for each measurement, starting at 100 degrees. The oven temperature was measured using a PT100 platinum resistance thermometer and the temperatures recorded were the peak temperatures during the heating period. Because of the thermostat switching differential the mean oven temperature was approximately 1 degree below the peak temperature. There is no simple way to convert the measurements of pull off force to magnetisation in Tesla units since the pull off force is dependant on the contact geometry between the magnet and the iron block as well as on the magnetisation.
The plot, Figure 11-1 shows the result of this test. Although the force readings are subject to scatter, it is clear from this plot that the magnetisation appears to be little changed up to a temperature of approximately 180 degrees C. The manufacturer’s specified working temperature of 150 degrees C appears to be slightly conservative.

The three situations in which the EPR may be subjected to elevated temperature, as listed 1 to 3 above, are further considered as follows:

**Sterilisation.** The temperatures normally used for sterilisation are below 180 C. Modern sterilisation equipment generally offers a choice of programs, with longer time periods for lower peak temperatures. It is proposed that the non-invasively extendible EPRs should be supplied with clear instructions not to use sterilisation temperatures above 140 degrees, this being 10 degrees below the manufacturer’s specified maximum working temperature.

**HA Coating.** It is anticipated that for the majority of cases where HA coating is applied to an extendible module of an EPR this coating would only be required at the opposite end of the assembly to that which contains the magnet and drive system. However, there may be applications, particularly with proximal femoral tumour sites, for which the region containing the magnet may require coating.
Figure 11-2: Mock up for testing the thermal effect of HA coating.

To check the thermal effect of HA coating a simplified mock up of the outer telescopic section of the proposed extendible section was fitted with a magnet and was HA coated using the normal coating procedure as applied by a specialist subcontractor experienced in this work. The mock up is shown in Figure 11-2. The magnet inside the mock up was within a thin walled titanium capsule as proposed for the extendible EPR. Temperature sensitive labels were applied externally to this capsule and these indicated that the peak temperature reached at the outer surface of the capsule was approximately 150 degrees C. This coincides with the manufacturer's specified maximum working temperature for the magnet but the curve shown in Figure 11-1 indicates that this temperature is below that which will cause a serious loss of magnetisation. The HA coating subcontractor has suggested that a further precaution against overheating the magnet would be to apply the coating in two layers rather than a single layer as is normal.

Heat shrink fit A mock up of the extendible section was constructed, this being similar to that used for the test with HA coating as Figure 11-2. This mock up was fitted with thermocouples mounted on self-adhesive backing tabs. The temperatures sensed by these thermocouples were recorded while the mock up was being fitted into the bore of an actual SMILES femoral component using a heat shrink fit and following the normal procedure used at Stanmore. The temperature recording was by use of a stand-alone
electronic temperature recorder that provided a facility to download the readings to a PC. The results are shown in Figure 11-3.

Figure 11-3: Test on heat shrink fit with air cooling.

The most significant thermocouple site is that on the magnet capsule and this reached 180 degrees. A pull off test confirmed that the magnetisation of the magnet was reduced.

The magnet thermocouple site was closer to the bulk of the metal in the femoral component than was the site on the interior surface of the wall of the EPR section and this accounts for a higher temperature being recorded at the magnet than on the wall.

For this test the cooling of the components after fitting together was in still air at room temperature. Accelerated cooling using a liquid coolant, either oil or water, would be expected to reduce the temperature of the femoral component much more rapidly so reducing heat transfer to the magnet. It is expected that this would significantly reduce the peak temperature reached by the magnet and a further test is planned to confirm this.
Section 12  FUNCTIONAL TESTING OF SYSTEM

An overall functional test of the complete system was made by fitting a completed prototype extendible EPR section into a frame containing a steel coil spring to restrain the extension of the telescopic section. This arrangement is shown in . The spring rate was 71N/mm; this being measured separately using a universal testing machine. With this spring rate, a 10mm compression of the spring from the relaxed state exceeds the design distraction force as detailed in Section 3.1. A 10mm extension against this spring thus represents an extreme case of an exceptionally large extension with a patient having very stiff tissues as may result from extensive and repeated surgery. To prove the reliability of the complete system of field generator and extendible EPR, a 10mm extension against the 71N/mm spring was carried out ten times in succession. At the end of each extension, the field was stopped and restarted then stopped and reversed to check that the system was capable of restarting and reversing with the EPR under full compression load. The system performed satisfactorily throughout these ten extensions and it was not necessary to use the boost setting of the field generator at any time.

A further four prototype extendible EPR sections are currently being assembled and it is proposed to repeat the above test with each of these so as to demonstrate consistent reliability over all five units.
Section 13  FURTHER WORK

The various tests carried out on the prototype system, as described in previous sections of this thesis, have demonstrated that the non-invasively extendible EPR system developed under this project is capable of meeting the design requirements listed in Section 3 with the exception of two points noted below. These two points are not tested at the time of writing but are expected to be tested in the near future.

These two points are:
1. To demonstrate adequate mechanical strength of the implantable components, particularly with regard to cyclic loading which may cause failure by fatigue mechanism.
2. To demonstrate heat shrink fit of the extendible module into the SMILES femoral component without damaging the magnet.

Point 1 above is considered in section 13.1 which follows.

Point 2 above was considered in section 11.2. An appropriate modification to the shrink fit procedure is expected to be straightforward.

13.1 Cyclic Load Testing

Before the system can be used clinically the medical ethics committee may require testing to demonstrate mechanical strength under cyclic loading conditions representing the activities of daily living, particularly walking.

Strength testing of the extendible telescopic section may be considered to be specific to various tumour sites. As discussed in Section 1, a complete non-invasively extendible EPR will be made up from an extendible module together with artificial joints and other components selected to suit particular patients.

Four prototype extendible EPR modules will be completed in the near future. It is suggested that two of these prototypes could be used for a cyclic load test with the drive
end of the extendible module fitted into a representation of the femoral component of a SMILES and the other end attached to a representation of an IM stem. The other two prototypes could be used for a fatigue test in which the drive end of the extendible module is extended with a socket and a representation of an IM stem and the other end is extended with a solid shaft. This is typical of proximal femoral applications. These two arrangements are shown in Figure 13-2. Alternative end fittings may be required to test further applications of the extendible module, including use with extra-cortical fixation as is now under development at Stanmore.

The six station hydraulic cyclic loading machines currently installed at Stanmore would be suitable for a cyclic load test on the assemblies shown in Figure 13-2. The loading apparatus shown in Figure 13-1 is proposed as a low cost alternative which could be used if these hydraulic machines are fully committed for work on other projects, as is likely to be the case. The author designed a prototype of this apparatus for use in a student project and the apparatus proved to be satisfactory over 10 million cycles of loading.

The apparatus shown in Figure 13-1 is based on a standard pneumatic cylinder having a square section extruded aluminium alloy body. A simple frame is formed by connecting four lengths of studding between the tappings provided in the cylinder body and a square plate at the top of the apparatus. A fast acting control valve controls the air pressure in the cylinder and one valve can serve several cylinders if a test with multiple specimens is required. A ‘Joucomatic Sentronic’ valve is suggested, as was used in the prototype apparatus. A load cell can be fitted between the plate at the top of the apparatus and the upper mounting for the specimen. This load cell can be used to set up the control system and to check the load range at intervals during an extended test. The load cell need not be permanently incorporated in the apparatus and a single load cell and signal conditioning can serve a number of stations. With 80mm cylinder bore, an axial load range of up to 3kN can be applied using a control valve having a 0 to 6bar output. The analogue control signals for the control valves can be generated using a signal generator or a PC card with DAC and analogue output. It has been found that the type of control valve mentioned above can adequately control the maximum load with a sinusoidal control signal at a frequency of at least 5Hz. To optimise frequency response
it is advantageous to adjust the length of the studding frame so that the dead volume above the piston is small.

There is an adjustable offset between the axial load line and the centre line of the specimen so as to apply an adjustable bending moment to the specimen in phase with the axial load. The offset of the axial load can be adjusted at each end of the specimen if it is required to vary bending moment along the length. To simulate the expected walking loads on a femoral EPR, the axial load range could be set to 2.5kN and the moment range to 100N\text{m}. The small increase in bending moment due to deflection of the specimen would be neglected.

The apparatus does not apply torque about the longitudinal axis of the specimen. If it is required to test the extendible module under torque loading then a separate test could be set up for this purpose. This would effectively be a test of the key and key way arrangement used in the telescopic sections of the extendible module.

The cost per loading station for the apparatus shown in Figure 13-1 is a small fraction of that for a typical hydraulic cyclic load testing machine.
Figure 13-1: Cyclic loading apparatus

- Slot for adjustment of moment arm
- Oilite bushes at pivot
- View on A - A (similar arrangement above and below specimen)
- Specimen
- Standard pneumatic cylinder, 80 bore extruded aluminium construction
- 10mm tube connection to fast acting proportional control valve, e.g. Joucomatic Sentronic valve. Pressure range 0-60
Figure 13-2: Proposed end fittings for cyclic load testing
Section 14 CONCLUSIONS

The aim of the project described in this thesis was to demonstrate the feasibility of using a non-invasively extendible EPR in the treatment of bone tumours in growing children. The project has now achieved this objective, as far as is possible prior to clinical application. The minor items of work still to be completed, as noted in the previous section, are not critical to the feasibility of the proposed scheme.

A number of approaches to the project were initially considered. In selecting a single approach for development to prototype stage, the important selection criteria were considered to be minimum dimensions of implanted components and adaptability to suit the largest possible section of the patient population. A lower importance was given to minimising the bulk of the equipment external to the limb, it being assumed that such equipment is not required to be portable. Had other selection criteria been used it is possible that one of the other approaches initially considered would have been selected and would also have lead to a practical solution. For example, an extension mechanism actuated by the movement of an artificial joint is attractive, particularly for distal femoral tumour sites, but would not be so easily adapted to suit proximal femoral and humeral tumour sites.

All elements of the proposed system have now been constructed in prototype form and satisfactory operation of the system has been demonstrated under simulated in-vivo loading and over an extension distance which is greater than would be required in clinical use.

The main conclusion is that a non-invasively extendible EPR is feasible as a method for limb salvage following surgical resection of a bone tumour. This main conclusion is supported by subsidiary conclusions as follows:

- The magnetic drive system used in the prototype system is a practical means to transfer mechanical power to an implanted device. This system was compared with an alternative consisting of an implanted electric motor energised by an inductive power transfer system from a coil external to the limb to a coil within the limb. It was shown that an implanted motor would be bulkier than an implanted
permanent magnet developing similar mechanical power and torque output. A magnet can also be more easily adapted to fit the form of the available space envelope within the implanted device and requires fewer separate parts.

- An arrangement of field coils arranged around the limb and energised from a three-phase supply is a practical means to generate the magnetic field required to act on the implanted permanent magnet. Such a system can be expected to be more compact, quieter and more reliable than a previously used alternative which requires a permanent or electro-magnet to be bodily rotated around the limb by a mechanical drive. It was found that a commercially available frequency inverter was a satisfactory means to control the frequency and current applied to the field windings. The frequency inverter used in the prototype system requires connection to a three phase mains supply but it is possible that such a system could also be constructed for a single phase mains supply.

- The novel gear mechanism which was devised as a means to amplify the relatively small torque available from the implanted permanent magnet has been shown to be a suitable mechanism for this application. The mechanism achieves high torque amplification with minimum diametrical and axial dimensions. By comparison with conventional epicyclical gearing of comparable dimensions, a higher torque output is possible since the planet gear teeth carry load in shear across the tooth profile as well as by cantilever bending of the teeth. In addition, the loading of the shaft and bearings which carry the planet gears is much reduced, avoiding a possible weak point in the design of conventional epicyclical gearing. Although the mechanism appears to be well suited to use with the extendible EPR a wider application may be limited by a relatively low power efficiency. Power efficiency is of lesser importance for the intended application and has not been studied in detail. In general, those gearing mechanisms which achieve a high velocity reduction with a single stage of gearing tend to have poor power efficiency since the tooth engagements carrying the load associated with the output torque run at a speed associated with the input. The ‘Harmonic drive’ is another torque amplifying mechanism which was considered but was found to be available only in sizes too large to suit some of the patient population. The construction of a ‘Harmonic drive’ in smaller size than is commercially available and in small batch quantities was not considered feasible.
• The general arrangement of the telescopic sections and power screw as used for the current design of 'minimally invasive' extendible EPR manufactured at Stanmore was found to be suitable as a basis for the non-invasively extendible design. Alternative telescopic arrangements were considered, including one having the driving mechanism inside the inner telescopic section, but these were found to be less suitable from the point of view of minimising the closed length for a given maximum extended length.

• Comparing the current design of 'minimally invasive' extendible EPR, as manufactured at Stanmore, with the prototype constructed for this project, the increase in dimensions required for non-invasive operation are minimal. The maximum diameter at the section containing the magnetic drive mechanism is similar to the maximum diameter of the 'minimally invasive' design. Further development of the non-invasive design could possibly achieve still smaller overall diameter which would be particularly advantageous for use with humeral tumour sites. The use of the non-invasive extension mechanism rather than the current 'minimally invasive' mechanism does incur approximately 12mm additional axial length for the fully closed telescopic assembly. For most patients this additional axial length is of no consequence. For a small section of the patient population the additional length will incur the removal of slightly more healthy bone stock than would be required for the 'minimally invasive' system. For such patients it may possibly be preferred to retain the minimally invasive system.

A reliable non-invasively extendible EPR offers clear advantages over a system requiring surgery for access to the EPR. The trauma and cost of surgery for extension is eliminated and it becomes feasible to extend with a larger number of smaller increments which is expected to reduce pain and limb stiffness.

The prototype extendible EPR has been constructed with a back up system to facilitate extension by surgery as an alternative to non-invasive extension using the magnetic drive system. The provision of this back up system should allow this project to continue into clinical application without further pre-clinical trials and with minimal risk to patients. Hence, on satisfactory completion of strength testing, the next stage is envisaged to be human implant.
REFERENCES

Note: References to this list from the text each include the # character followed by a number referring to an item listed below. For example, [Bramwell et al, 1992 #2] refers to reference 2 in the list below. In the electronically stored version of this document the numbers following the # are hyperlinks to the list of references.


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42. Peterson RE. Stress concentration design factors. Wiley, 1953.


