# A WIRELESS TELEMETRY SYSTEM FOR MEASUREMENT OF FORCES IN MASSIVE ORTHOPAEDIC IMPLANTS *IN VIVO*

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## 1. ABSTRACT

A wireless telemetry system is described for measurement of forces acting upon massive orthopaedic implants, in man, to determine the load distribution in the fixation during routine activities and how this changes over long periods. The system comprises: the permanently implanted instrumented prosthesis, modified to enclose strain gauges and electronics, a single inductive link for powering the implant and telemetering the data, a microcontroller-based signal processor, a UHF radio link, and lap-top PC for real time data logging. The subject wears a small battery-powered inductive energiser, induction coil and microcontroller during the measurements. The strain gauges and implanted instrumentation are hermetically sealed inside cavities within the prosthesis, and are connected via a feedthrough to a small implanted induction coil. This coil is located outside the body of the prosthesis to maximise the power coupling efficiency, and is encapsulated using silicone rubber. Four prostheses have so far been implanted and data recorded over 1.5-3 years for each to date. This paper will focus on the electrical aspects of the telemetry system. Extracts of the axial force, bending moment and axial torque data will also be presented for the first Mk2 instrumented distal femoral replacement, during walking.

## 2. INTRODUCTION

Massive orthopaedic implants are those where a segment of the bone shaft (for example the femur or tibia) as well as the joint itself, is replaced with a metal prosthesis in cases of bone tumour. This is in contrast to a total joint implant (for example the hip or knee joint) where only the joint itself is replaced. An intramedullary (IM) stem, integral with the prosthesis shaft, is cemented into the medullary cavity of the remaining bone. This method of fixation has been used for the last 40 years at Stanmore, and has been largely successful. A serious problem remains however in the medium to long term, because of

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aseptic loosening of the prosthesis in the bone and often eventual failure of the fixation, experienced as pain and loss of support. Bone remodelling at the transection site starts to occur

after insertion of the prosthesis due to the altered loading conditions, and the accompanying bone loss and interface changes combine to weaken the fixation.

The current telemetry work was initiated to investigate the mechanism of load transfer in massive fixations, and to provide a quantifiable means of testing various methods of enhancing fixation. Direct measurement of forces acting upon and distributed throughout the prosthesis would provide reliable *in vivo* data over extended periods, enabling testing of improvements in methods and materials to prolong the life of the fixation. Two generations of instrumented prosthesis (Mk1 and Mk2) were developed for measurement of forces and moments in the prosthesis during activity. Each prosthesis has permanently implanted instrumentation for strain measurement, and power is supplied (and data telemetered) using magnetic coupling.

The Mk1 instrumented prosthesis has 2 strain channels, measuring axial force at the mid-shaft level and at the tip of the IM stem. The ratio of these forces is of particular interest in determining the loosening mechanism (Taylor et al 1997). The Mk2 instrumented prosthesis has 6 strain channels to telemeter bending moments and axial torque in the shaft as well as the forces. In addition, both devices measure temperature and humidity within the cavities occupied by the electronics. The Mk1 instrumented prosthesis has been implanted into two subjects (in July and December 1991), and the Mk2 device implanted into two further subjects (in February and November 1995).

## 3. DESIGN CONSTRAINTS AND CHOICES

The implanted portion of the instrumentation was the most critical part of the telemetry system design because of the restricted space available, and because of its inaccessibility and vulnerability. Key requirements were that it should be small, light, robust, consume low power and operate reliably over long periods of time. Key aspects of the implant instrumentation design were the method of power supply, the location of strain sensors and of the implanted electronics required for amplification, signal conditioning and telemetry. The choice of any one option for each of these aspects has a bearing upon the choice of the others. The key features of the type of implant power supply and the type and location of the strain gauges and instrumentation will first be addressed.

### 3.1 Implant power supply options

The implanted prosthesis should be able to remain functional for several years, although needing to be powered only periodically. Several options exist for its power supply:

1 A connection to an external power supply, by direct wires,
2 An implanted battery, continuously powering the implant,
3 An implanted battery, supplying power only when measurements are required,
4 An inductive power supply.

The first option requires a transcutaneous connection. For long term measurements to be possible, the subcutaneous part would need to be exposed during measurements and remain implanted at all other times without risk of repeated infection. Furthermore, the leads to the strain gauges would require excellent long term protection against mechanical damage and moisture ingress if the very small leakage currents (which would cause large and unpredictable measurement inaccuracies) were to be prevented. This method has only been used over short

periods (Rydell 1966), and longer term measurements could not be carried out with confidence about maintained accuracy.

The second option is non-invasive but offers only a finite useful lifetime for the implanted instrumentation. Even if the implant current were as low as 100 microamps, a 300mAh 9V battery would only provide an implant life of 125 days. There is also the possibility of excess current being drawn due to leakage paths. A further disadvantage is that batteries contain highly toxic substances with the possibility of evolution of gas.

The third alternative is to connect the battery to the implant circuit via a magnetic device such as a reed switch, figure 1 (top). This method has been used by others, but problems have been experienced with failure of the reed switch in the 'on' state, causing the battery to be exhausted rapidly (Davy et al 1990). Possible solutions to this problem might include a timer to limit the maximum ‘on’ time or the use of two switches in series. However, this all adds additional hardware.

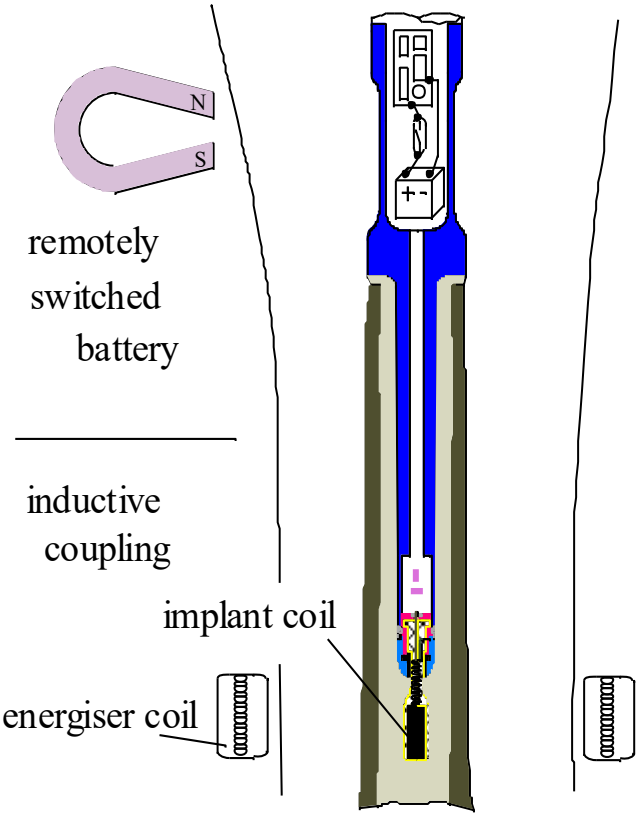


Figure 1: Two alternative methods of powering the implanted prosthesis: a (remotely switched) implanted battery (top), and inductive coupling (bottom).

The fourth alternative, inductive coupling, is the most attractive option in terms of reliability, safety and required space (for a small implant coil). Furthermore, if operated at radiofrequency, sufficient bandwidth is available for implant data to be telemetered over the same link in the opposite direction. Inductive powering requires two coils, one connected to the implant and the other externally applied, to be sufficiently coupled electromagnetically so as to enable enough power to be induced for the implant to operate, figure 1 (bottom). This method was chosen for powering the implant. The inductive link used here consists of one implanted and one external tuned circuit having the same resonant frequency, 1.4MHz. The external circuit is tuned to the implant circuit to operate the link. Figure 1 also shows the location and size of the implant coil used in the Mk1 proximal femoral replacement.

3.2 Options for location of strain gauges and implant electronics

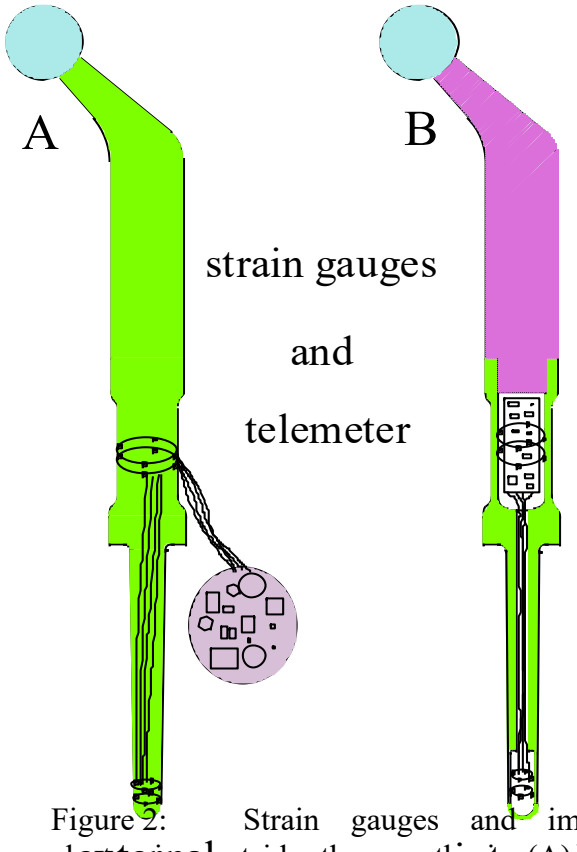


Figure 2: Strain gauges and implant electronics outside the prosthesis (A), and hermetically sealed inside the prosthesis (B). The latter option was chosen for the instrumented prostheses.

An obvious and easy method of instrumenting the prosthesis is to attach the strain gauges to the external surface, figure 2(A). The instrumentation and telemeter could then be sited in soft tissue, separated from the prosthesis, and connected to the strain gauges with an umbilical cable. The advantages of such a method are that:

a) no structural modifications to the implant are required;

2) strain gauges could easily be bonded and inspected;

c) the telemeter could be subcutaneous, and therefore close to the external coil, giving better coupling.

However, if the gauges were protected only by soft adhesive encapsulant several likely problems remain:

a) The gauges and their connecting wires are exposed to forces applied by muscles;

b) The umbilical cable is vulnerable to shearing movements of muscles over the surface of the prosthesis causing fatigue fracture;

c) The gauges are at risk of corrosion, or shunting by ionic leakage currents, due to the possibility of liquid condensation at the encapsulant-gauge interface resulting from poor bonding to either the gauge alloy or its connecting wires. This would be observed as strain gauge drift, before eventual failure.

These disadvantages are made more severe because of the need to make long-term measurements, over several years. It would be impossible to distinguish between a gradual change in strain due to bone remodelling and a real or apparent change in electrical resistance of the gauge due to corrosion or leakage currents developing over a period of time.

These constraints on the accuracy of the measurements and the integrity of the implant were considered unacceptable, and an alternative scheme was adopted: the strain gauges and electronics would be housed in welded cavities within the body of the prosthesis, figure 2(B). This would greatly alleviate doubt about the integrity of the strain gauges, particularly if they could have a dry environment, and if the humidity was monitored to confirm this. The main penalty for this method is that the gauges must be bonded to the internal cavity walls, unless an insert is used. However, such 'down-hole' gauging techniques are well established. Creating a large cavity inside the prosthesis reduces the bending stiffness and strength, but the design can still be kept within the safe limits for the maximum anticipated loads. Both the gauges and electronics would thus be housed in a mechanically secure, low humidity environment. Wire

connections between the gauges and electronics would be short and secure mechanically and electrically, and the implanted electronics kept dry and at constant temperature.

### 3.3 Options for the location of the implanted coil

If the implant coil was placed within a cavity inside the prosthesis (in order to hermetically seal it) the shielding effect of the titanium would result in very poor coil coupling, even if a high permeability material was used to concentrate the magnetic flux. This would preclude the use of a portable battery-powered energiser even if the implant current were as low as 1 mA. Furthermore, such high permeability materials are usually most efficient at audio frequencies, which severely restricts the signal bandwidth if the same link is used to telemeter the data. The data must in that case be telemetered from the implant by a separate radiofrequency channel, which requires an electromagnetic 'window' through which to pass. This type of design is used in one implanted telemetric hip which has a ceramic head, allowing radio propagation (Bergmann et al 1990). Since massive prostheses are usually made at Stanmore with a cobalt-chrome femoral head, a feedthrough would be required for the aerial in this case.

Despite the clear advantage of having the implant coil integral with the electronics inside an hermetic cavity, it was considered most desirable for the patient to be unencumbered by a heavy trailing power lead. If the coil could be encapsulated outside the titanium body, a vast improvement in coupling could be achieved, allowing battery powering, and a radio frequency passive telemetry system (Donaldson 1986) to be used for data transmission. The telemetered data could then be retransmitted by UHF radio to a nearby receiver. A biocompatible coil, wound on a ferrite former, was encapsulated in void-free silicone rubber, the arrangement designed to resist breakdown by moisture over extended periods. An hermetic feedthrough was used to connect the coil to the implanted electronics, and an adhesive rubber was used to encapsulate the feedthrough insulator between the pin (connected to one end of the coil) and the prosthesis body (connected to the other end of the coil).

The location of the implant coil on the Mk1 prosthesis was different to that of the Mk2. In the case of the Mk1, the coil was positioned 5mm from the stem tip, cast in silicone rubber and PMMA bone cement, figure 1. This enabled the coil to be located away from the metal prosthesis, and also enabled a smaller diameter external coil since the thigh girth reduces towards the knee. Both of these features maximised the magnetic power efficiency. In the case of the Mk2, the use of thin film strain gauges necessitated a different mechanical arrangement at the stem tip, and the more severe bending moment acting on the distal femoral stem tip required the tip cavity to be shorter than the Mk1. Both of these considerations meant that less space was available at the tip both for electronics and for the mechanical arrangement required for the interface to the coil. The coil was therefore resited in the main shaft region, closer to the main electronics cavity, figure 3. This had the additional advantage that the external coil was then closer to the knee, maximising the coil coupling. The implant and external coils were aligned to be coplanar, and despite the large disparity in areas a useful power transfer efficiency (power into the load divided by power input to the energiser) of 10% was obtained.

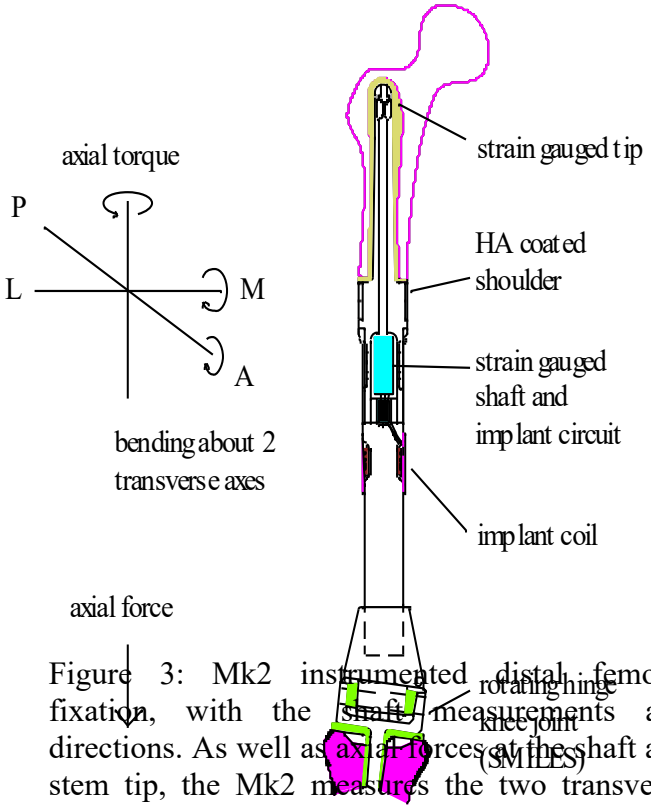


Figure 3: Mk2 instrumented distal femoral fixation, with the shaft measurements and directions. As well as axial forces at the shaft and stem tip, the Mk2 measures the two transverse bending moments and axial torque.

### 3.4 Possible strain gauges types

For the Mk1 device, it was thought desirable to have the simplest combination of mechanical geometry and strain gauges, to avoid complicating the transducer. This was achieved with a single solid tubular shaft and foil gauges mounted on the inside walls, figure 2(B). Thin film strain gauges were used in the Mk2 design instead of foil gauges. This was for two main reasons: possible drift of foil gauges, and reduced implant power consumption. Foil gauges are bonded to the implant surface using a thin adhesive layer. Under certain environmental conditions laboratory tests have shown that gauge drift can occur over time (Taylor & Donaldson, 1992). Thin film gauges have no adhesive layer, both the insulator and conductor layers being formed on the substrate by sputtering. They are therefore believed to be more stable than foil gauges at high strain and/or high humidity. (However, the low strain, low humidity environment of the Mk1 gauges ensured that there was only a small likelihood of drift having occurred in the Mk1 devices.) No measurable drift was found after fatigue testing the Mk2 design (2.3kN peak load for 15M cycles), which gave confidence about the stability of the gauges over multiple load cycles at physiological strain levels. A further reason for choosing thin film gauges was the high values of resistance achievable due to the combined effects of the high resistivity alloy, the thin conductor film and the long and narrow conductor pattern produced by laser etching. In order to maximise the sensitivity to each stress type it was desirable to retain the existing basic Mk1 circuit topography, in which each strain channel had its own fully contributive bridge of 4 strain gauges. The use of thin film gauges allowed 20kΩ gauges to be used for all 5 strain channels, thereby almost halving the total bridge current of the two 5kΩ Mk1 channels. Since thin film gauges must be deposited onto an external surface, the Mk2 shaft was constructed as two overlapping cylinders, figure 3, and the gauges deposited onto flats on the outer surface of the inner part. These were then welded together after wiring the gauges to the electronics.

## 4. SYSTEM OPERATION AND SIGNAL PROCESSING

Figure 4 shows the electrical system schematic. The system is in three physically separate parts: the implant, a portable patient box and external coil, and a remote receiver / data logger. When the energiser is active, the voltage induced across the implant tuned circuit is rectified, smoothed and applied to a precision voltage reference, whose output supplies the strain gauge bridges and implant electronics. Measured strains, together with temperature and humidity

signals, are amplified and converted to a serial pulse-position modulated signal and telemetered via impedance modulation of the same inductive link. This method of 'passive signalling' is possible because, even when the two tuned circuits are loosely coupled, the impedance of the implant circuit is reflected in the energiser circuit and forms a significant part of the total energiser impedance. Abruptly modulating the implant circuit impedance with the serial data causes a corresponding reflected impedance change in the external coil. This signal is detected and amplified, and periods of the signal corresponding to data are then digitised using a fast counter controlled by a microcontroller. The encoded data stream is serially transmitted as RS-232 at 9600 Baud from the subject over a 418 MHz UHF radio link to a receiver linked to a 486/100MHz PC. The data capture software, written in C++, decodes the serial data stream and displays the forces and moments dynamically in real time according to algorithms derived during calibration. In the Mk2 version of the system, an inverted calibration matrix is used to correct for small cross-sensitivities in the shaft channels found during calibration.

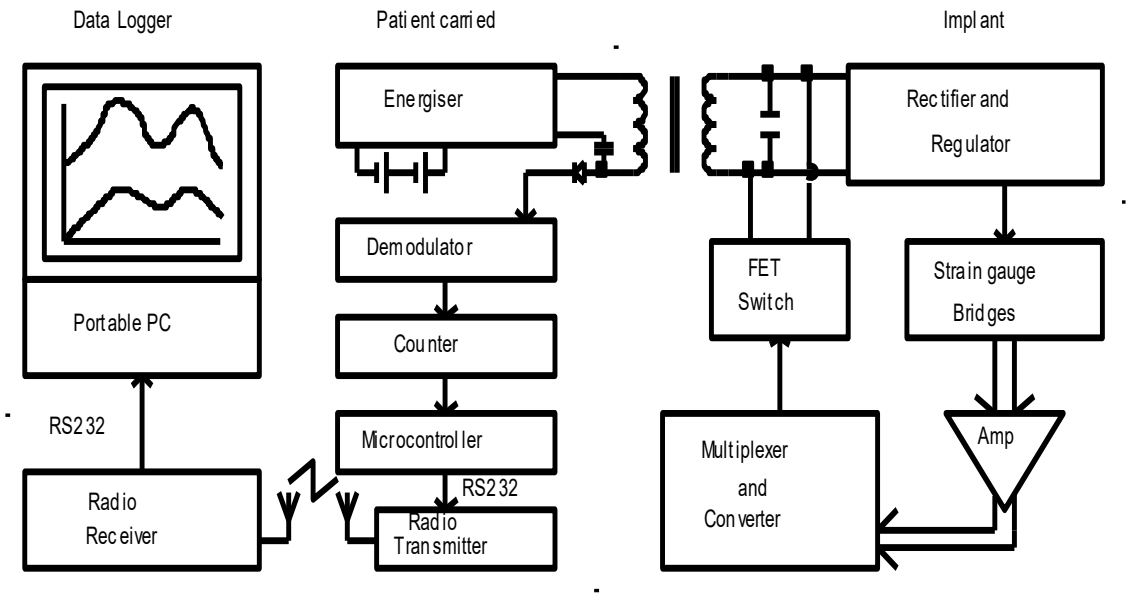


Figure 4: The telemetry system electrical system schematic. The inductive link operates both as a power source for the implant and as the transcutaneous telemeter. Strain gauge bridge outputs are amplified and converted to a serial pulse stream, which modulates the impedance of the implant circuit. This signal is detected in the energiser circuit, the data encoded using RS-232 protocol, and radiotransmitted to a remote PC.

Each strain channel is sampled at 200Hz (Mk1) or 100Hz (Mk2), the timing controlled by a crystal in the implant. In the event of failure of any channel, clamp circuitry ensures that all other channels are unaffected. The implant voltage is telemetered to ensure that the induced voltage is sufficient to operate the voltage reference, and a warning is flagged if this voltage falls below a threshold at any time during a capture.

## 5. DATA FOR WALKING FROM MK2 SUBJECT

Forces and moments are captured over periods of 5 to 15 seconds during controlled activities. A typical data sample is shown in figure 5. This single gait cycle was captured during a 15

second walk at 1.2m/s, at 2 years post-op. The subject walked unaided with no obvious gait abnormality. The shaft force peaked 3 times during stance: at heelstrike (1050N), mid-stance (1500N) and late stance (2050N). The tip force showed 3 corresponding peaks (900N in late stance). The bodyweight was 67kg. The bending moment about the A-P axis peaked at 45Nm (varus) in late stance, the bending moment about the M-L axis peaked at 33Nm (hip flexion) in mid-stance, and the axial torque peaked at 10Nm (internal rotation) in late stance.

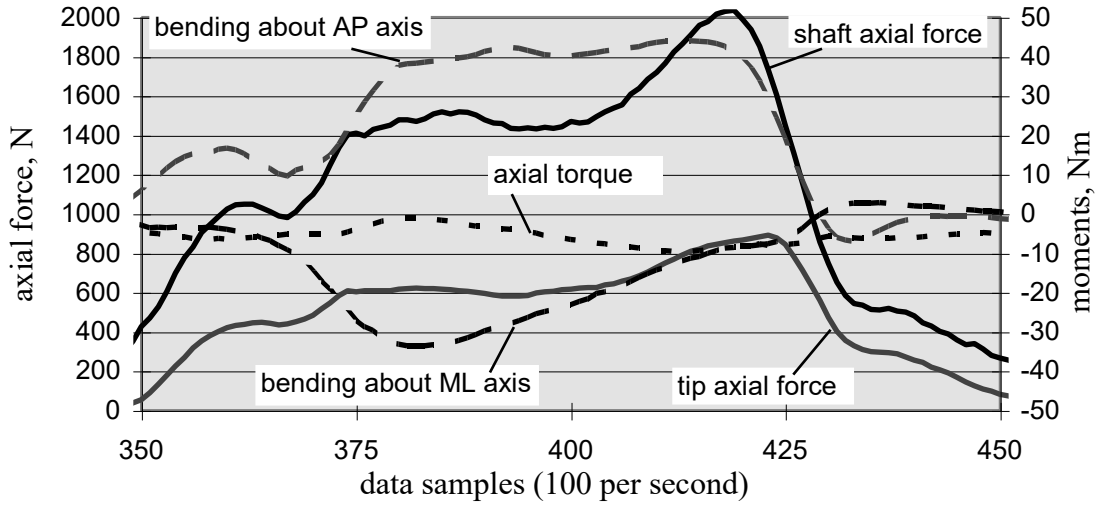


Figure 5: Forces and moments recorded during walking at 1.2m/s

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