Development of a Personalised 3D Mandibular Distraction Device for the Management of Craniofacial Microsomia

Submitted for the degree of MD(Res)

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London, March 2021
Hofstdaters Law

‘It always takes longer than you expect, even when you take into account Hofstadters Law’
Douglas Hofstadter

Indigo, non dimenticare mai

“I fanciulli trovano il tutto nel nulla, gli uomini il nulla nel tutto”
Giacomo Leopardi
DECLARATION OF ORIGINALITY

I, William Rodgers, confirm that the contents of this thesis are my own work. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.
Abstract

Introduction: Surgical correction of the facial skeleton in deformity has evolved significantly over the recent past as techniques and technology have improved. Where there exist significant skeletal discrepancies, large skeletal changes are required and there remains a need to further improve upon our current standard to achieve these surgical goals. Distraction osteogenesis (DO) is a technique that induces bone formation without the need for bone grafting and allows for guided shape change in addition to expanding the overlying tissue envelope. Current mandibular distractors are limited as they are bulky; there are wound problems related to the external siting of the actuator; there is a limited geometry of possible distraction; the final result is unpredictable; they function in a discontinuous rather than continuous motion and they require daily winding by the patient. There exists a clear potential benefit to patients should these drawbacks be overcome.

Aim: The aim of the project is to design a novel device to modify the shape of the deformed jaw to a prescribed, predetermined shape that is specific to the patient and that does not require external manipulation.

Methods: The mechanical properties of helical springs constructed from a nonlinear material were tested to review their suitability for use as actuators to deliver force in a fully buried continuous distractor. A finite element model was then created to generalise the concept for use where different forces may be required. Lastly a prototype was designed and empirically tested ex-vivo to assess whether the aims of the project were fulfilled.

Results: The nonlinear material was found to deliver adequate, continuous and relatively constant force over a distance in keeping with DO. The finite element model was demonstrated to accurately represent the empirical properties of the helical spring. The prototype designed was able to modify the shape of a deformed jaw to a predetermined position without requiring external manipulation in a surgical model.

Discussion: This project develops and tests a prototype that is fully buried and can achieve multiplanar continuous DO without the need for patient involvement and therefore provides novel technology as a solution to improving practice.
The body of work within this thesis offers a potential direct clinical benefit to patients. The morbidity related to the current clinical standard in distraction osteogenesis is significant and it is hoped that the novel device here presented can offer a reduced burden to those patients requiring the procedure, this is especially pertinent to the paediatric population. In addition, the patient specific nature of this project is of interest to the clinician and could deliver improved, predictable results through careful pre-surgical planning discussed herein whilst using current surgical techniques.

This thesis has the potential to stimulate further research in the area of fully buried devices for craniofacial distraction osteogenesis by offering a simple and potentially effective solution which can be readily manufactured using existing techniques and without requiring complex engineering. Presently no fully buried distraction devices are available commercially. The simplicity of this device lends itself to commercial interest which can increase the impact of this work by increasing the distribution of the device to a patients internationally.
ACKNOWLEDGEMENTS

I would like to thank the Face Value charity which has generously supported the work for this thesis.

I am extremely grateful to my supervisors, Prof. David Dunaway whose mentorship and supervision continues to inspire me in my surgical and academic career, and to Dr Silvia Schievano whose keen insight, advice and support has been key to the development of this work.

I would also like to thank Dr Alessandro Borghi for his patient and generous help, tuition, advice and input during this research without whom this work would not have been possible. I am deeply indebted to Miss Caroline Mills, Mr Peter Ayliffe and Mr Owase Jeelani for their invaluable training and clinical input, drawn from their extensive experience, which has given me a surgeons’ understanding of the challenges of craniofacial distraction. In addition, I would like to thank the other members of the research group, Naiara Rodriguez-Florez, Will Breakey, Paul Knoops and Freida Angullia for putting up with me and for their hard work, friendship and help.

Finally, my greatest love and thanks to Faye and Indigo for their love and support.
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CHAPTER 1 INTRODUCTION
1.1 INTRODUCTION

The human face has important functional roles including for feeding; breathing; the protection of ocular and cranial contents and to aid communication. Deformity and dysgenesis of facial structures can range from mild (no face is entirely symmetrical) to severe with associated airway, intracranial and visual implications. In the surgical management of deformity, the surgeons’ principal aim is therefore to restore function.

Roughly 30% of the Homo sapiens cortex is involved in visual processing, significantly more than that devoted to other senses and also significantly more than is found in lower order mammals such as the mouse. Much of this processing power serves us in the recognition and interpretation of other human faces as evidenced by advances in understanding of ‘face patches’. The importance of the face in the development of complex social interaction is widely appreciated in anthropology, primate facial muscles being unique in that they do not cross joints and can mobilise the overlying skin into intricate expressions. The evolution of our face shape is in great part governed by the positive fitness consequences it bestows both functionally and socially, this drive is evidenced in neonates who in the first days of life have been shown to imitate and discriminate between facial expressions. The significant power of the visual cortex in assessing face shape presents the surgeon with an additional challenge, beyond the restoration of function, when correcting facial deformity. A difference of a few millimetres can mean the difference between social acceptance or otherwise. To achieve a good outcome, it is necessary first to have an appreciation of the deformity to be corrected and secondly the required techniques, tools and technology to deliver it. Further, in achieving these changes a burden is placed on the patient who must undergo invasive procedures, it is therefore key that we do all we can to minimize this burden where possible.

To improve upon current outcomes, it is necessary to understand facial geometry in 3 dimensions in order to adequately describe and prescribe our surgical start and end points. The understanding of what comprises a normal human face shape has evolved over
many years. The earliest detailed representation of asymmetry in a face is found in the Venus of Dolní Věstonice XV carving dating some 26,000 years ago Figure 1-1.(7)

**Figure 1-1 The Dolní Věstonice Venus XV**
(Source: Moravian Museum, Anthropos Institute)

The analysis of facial proportion was studied in-depth by the Renaissance artists, principally Da Vinci and Dürer, who projected and used a coordinate system and showed how changes in face size and contour could be demonstrated in the transformation of this coordinate system Figure 1-2.(8,9) Camper described anthropometric methods to determine facial form and his facial line and reference plane are still used in practice today, the terms prognathic and orthognathic introduced by Retzius derive from this work.(10) Continuing this analytical approach Retzius was the first to use the cephalic index, the ratio
of the width to the length of a skull, to classify skull shape describing dolichocephalic, mesocephalic and brachycephalic head shapes.

![Image](image.png)

**Figure 1-2 Coordinate Transformation Describing Change in Face Shape**

*(Source: Durer. Vier Bücher von Menschlicher Proportion. 1528)*

With the advent of x-rays in the late nineteenth century the anthropometric methods could be applied to orthodontic diagnosis and the field of cephalometry, the study and measurement of the human head, was born which continues to be of great use today in orthognathic surgery for the correction of facial deformity. Landmarking, the process of identifying conspicuous homologous points on the radiograph Figure 1-3, could then be performed to analyse facial and skeletal proportions. Diagnosis of facial disproportion then proceeds relating to a defined normal and a plan for treatment follows usually involving movements of the upper and/or lower jaws.
Although cephalometric landmarks, placed on 2 dimensional images, are adequate to aid the surgeon in planning orthognathic surgery, much information on face shape is missed due to the limits of a 2-dimensional representation of a 3-dimensional subject.

With the development of 3-dimensional scanning techniques including computed tomography (CT) – 1970s; accurate static or handheld optical scanning devices -1980s; cone beam computed tomography (CBCT) – 1990s – and magnetic resonance imaging (MRI) – 1990s – the groundwork was laid for improvements to facial geometric analysis. Faces could now be landmarked in 3 dimensions, thus capturing far more information about face shape.

These advances in technology which allow us to more accurately assess facial deformity and which can provide patient specific prescriptions to normalize face shape thus raise the bar for the surgeon and the available surgical techniques which must match this accuracy.

Surgical techniques have improved dramatically for the management of mandibular deformity. The first mandibular osteotomy was performed in 1846 with an anterior
mandibular subapical osteotomy and setback. A variety of procedures were subsequently undertaken until the development of the most common technique used today, the bilateral sagittal split osteotomy, developed initially by Trauner and Obwegeser in 1955 and subsequently modified by Dal Pont and Hunsuck, Figure 1-4.(11)

Figure 1-4 The Origins of the Bilateral Sagittal Split Osteotomy


The orthognathic procedures for the mandible allow for correction of anterior/posterior discrepancies such as those found in Class II and Class III malocclusions and, to some extent transverse discrepancies for the correction of asymmetry. The understanding of the deformity, drawn from cephalometry, allowed for a prescription to be made for corrective bony movements. Healing is reliant on bony contact and therefore, improvements in technology for the fixation of these fragments – specifically the use of plates and screws – much improved their outcomes. The limitation of these procedures is that when more significant movements are required, where fixation with bony contact is impossible, they cannot be used. A new surgical technique was required and as will be discussed in Chapter 2, the technique of mandibular distraction osteogenesis was evolved from similar techniques performed by orthopaedic surgeons. The technique allowed for new bone growth to take place over time and therefore to correct more severe facial deformity. Craniofacial microsomia is one such deformity which can present a significant challenge for surgical correction and will be discussed in greater detail in Chapter 2. The
Deformity can include complex geometrical mandibular asymmetry in all three planes. Devices used for the correction of these deformities using the technique of mandibular distraction osteogenesis have similarly evolved over time and reflect a move toward reducing patient morbidity and improving surgical outcomes.

Any novel device designed should be mindful of the benefits and limitations of currently available similar devices and aim to build upon these concepts and improve upon them through the use of available technologies.

1.2 AIMS OF THE PROJECT

The purpose of the proposed project is to design a novel method of modifying the shape of the deformed jaw to a prescribed, predetermined shape that is specific to the patient and that does not require external manipulation. The mandibular distraction device should satisfy the following criteria:

small in size, fully-buried and biocompatible
programmable to distract to a patient specific shape
distract continuously without the need for patient involvement
provide sufficient force generation
robust enough to withstand the in-vivo environment

1.3 OUTLINE OF THE THESIS

Chapters 2 & 3 provide background to the thesis. Chapter 2 investigates the clinical background including our understanding of Craniofacial microsomia, the origins of distraction osteogenesis and the current state of distraction osteogenesis in the mandible today, it also reviews novel concepts that are not currently used in clinical practice and their potential benefits and reviews data on forces required for distraction. The use of springs in current clinical practice will be investigated as a potential model for a new distractor. Chapter 3 provides a technical background to the thesis beginning by reviewing the
biomechanics of springs in current clinical use and the potential drawback of their use for mandibular distraction osteogenesis. The potential of non-linear materials, specifically nitinol, are investigated and its shape memory and superelastic properties described. In Chapter 4 the potential of a nitinol helical spring is investigated, and tensile testing is used to select the most appropriate spring which corresponds to a relevant force for mandibular distraction. Chapter 5 uses the technique of finite element modelling to generate a simulation of spring kinematics. The model can then be used to help tailor springs with different properties which could be used in a potential device.

In Chapter 6 the work of Chapters 2, 3, 4 & 5 is built upon to design a prototype for potential future clinical use. An index patient with craniofacial microsomia is described and used as a surgical model. The problems of multivector distraction using the novel distractor are discussed, the shape of the distracting arm required for distraction in 3 planes is reviewed and cutting guides designed. Proof of concept is demonstrated by performing a virtual operation on a model and assessing outcome.

Chapter 7 concludes this thesis by summarising the key results and outlining remaining research issues for future work.
CHAPTER 2 CLINICAL BACKGROUND
2.1 **Introduction**

Craniofacial Microsomia (CFM) describes a spectrum of congenital abnormalities affecting the soft and hard tissues of the face, microsomia refers to an abnormal smallness of these structures which is typically asymmetric. It is also known by a variety of other names including Goldenhar syndrome; Hemifacial Microsomia; Oculoauriculovertebral syndrome. It is a rare disease affecting roughly 1 in 5,600 live births and is the second most common congenital disorder of the face after cleft lip and palate. The aetiology remains uncertain though the phenotypic appearance suggests a disruption to those structures of the 1st and 2nd branchial arch during the first 6 weeks of gestation. This is demonstrated by artificially induced CFM phenotypes produced in animal models by reducing flow in the stapedial artery,(12) other theories of genesis include an error in the migration of neural crest cells.(13) The structures affected include the orbits, ears; facial soft tissue; facial nerve and mandible and diagnosis is based on clinical findings. Extracraniofacial anomalies are well described affecting almost half of all those with CFM and include vertebral (28%), circulatory (21%) and central nervous system (11%) anomalies.(14)

Structures of the head and neck originate from six pharyngeal apparatus which are made up of a pouch, a groove, an arch and a membrane. The 1st and 2nd arches appear at the time of closure of the cranial neuropore, the anterior opening of the neural plate following neurulation, at around 4 weeks with the migration of neural crest cells. The following arches forming by the end of the 4th week – except the 5th arch which fails to form. Each arch consists of a core of somatic mesoderm and neural crest mesenchyme which form muscle, artery, nerve and cartilage specific to each arch. The 1st pharyngeal arch has two prominences, a maxillary prominence and a mandibular prominence. The 1st arch is associated with the trigeminal nerve, the maxillary artery, the maxilla and mandible and the muscles of mastication. The 2nd pharyngeal arch is associated with the facial nerve, the stapedial artery, the stapes and hyoid bone and the muscles of facial expression.
The majority of cases of CFM are simplex, occurring sporadically in a single individual, and are not inherited however, approximately 1-2% of families demonstrate an autosomal dominant inheritance pattern. Though the genetics remains uncertain, linkage studies of some cases point towards a region on chromosome 14q32, an area which includes the gene Goosecoid which is expressed in the branchial arches during embryogenesis. A multifactorial inheritance pattern is suggested by an increased recurrence risk in first-degree relatives of an affected individual of 2-3%.

From early in life patients with CFM may encounter functional and aesthetic problems. Orbital pathology includes epibulbar dermoids, eyelid colobomas, orbital dystopia and microphthalmos. Ear pathology is on a spectrum varying from microtia to anotia with meatal atresia. The function of the facial nerve can be variable from unaffected to profound weakness across all branches and soft tissues similarly may vary from unaffected to severe deficiency. Deformity of the mandible in CFM is complex and typically includes asymmetry of ramus height and length of hemimandible, often involving the temporomandibular joint (TMJ), glenoid fossa and cranial base. The severity of the deformity can be scored according to Kaban’s modification of the Pruzansky classification (Table 2-1):

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<td>I</td>
<td>Small ramus with identifiable anatomy</td>
</tr>
<tr>
<td>IIa</td>
<td>Functioning TMJ but with an abnormal shape and glenoid fossa: The glenoid fossa is in an acceptable functional position</td>
</tr>
<tr>
<td>IIb</td>
<td>Functioning TMJ but with an abnormal shape and glenoid fossa: The TMJ is abnormally placed and cannot be incorporated in the surgical construction</td>
</tr>
<tr>
<td>III</td>
<td>Absent ramus and non-existent glenoid</td>
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**Table 2-1 Modified Pruzansky Classification for Mandibular Deformity in CFM**

Of those with unilateral CFM, Pruzansky I (27%) and IIa (27%) are most common whilst Pruzansky IIb (23%) and III (16%) are less common. Functionally, mandibular deformity
can lead to malocclusion or in severe cases airway compromise. The OMENS (Orbit/Mandible/Ear/Nerve/Soft Tissue) classification system, first proposed by Vento et al. (19) and later developed by Horgan et al. and Gougoutas et al. (13,20) builds on the mandibular classification and seeks to classify the presentations of CFM and is seen in Figure 2-1.

**FIGURE 2-1 CLINICAL FEATURES AND PICTOGRAPHIC REPRESENTATIONS OF THE OMENS CLASSIFICATION SYSTEM**

(Source: Gougoutas et al 2007)

At present, there is no consensus on the treatment of the varied presentation of CFM deformity with regards to timing of intervention, type of intervention or surgical technique. In a recent study of 565 patients with CFM,(18) Pluijmers et al. report 78% of all patients received some form of operative intervention. Whilst half of patients will receive an intervention to correct ear deformity or soft tissue deformity, mandibular procedures are the third most common intervention with 43% of patients receiving a procedure at some point. Surgical options include alloplastic grafting, genioplasty, mandibular osteotomy,
costal cartilage graft and mandibular distraction osteogenesis. As may be expected, the more severe the deformity the more likely the patient is to have multiple procedures to correct the deformity. As a general rule surgical intervention for the type I mandible may wait until the permanent dentition is present, treatment for type IIA, IIB and III may be performed over several stages to include costochondral rib grafting (aged 7-11), mandibular distraction osteogenesis (aged 8-13) and orthognathic surgery (aged 18+) as appropriate.(18,21). The Pruzansky type III mandible presents the most challenging problem to the surgeon given that there are no temporomandibular joint structures at either the mandible or the skull base. These patient’s will typically have more than two procedures including costochondral grafting to reconstruct the temporomandibular joint, distraction osteogenesis and an osteotomy or genioplasty.(18) In this thesis we will be focusing on the technique of Mandibular Distraction Osteogenesis.

2.2 Distraction Osteogenesis

Healing of bone after fracture follows a well-defined path. Initially there is haematoma formation as blood fills the fracture site. With the influx of mesenchymal stem cells which differentiate to form cells including osteoclasts, fibroblasts, chondroblasts and osteoblasts, a callus forms. Of significance, callus has greater viscoelasticity than normal bone and is therefore more malleable. Over a period of months, the callus ossifies, becoming more rigid with greater mechanical stability. Distraction osteogenesis (DO) takes advantage of the viscoelastic and osteogenic properties of the callus to effect geometrical change in the healing bone by exerting a force in a desired vector.

DO was first described by Codivilla in 1905(22) and later developed and popularised by Ilizarov.(23–25) DO has several key advantages over previously available surgical techniques including the induction of new bone formation without the need for bone grafting; the concurrent expansion of the overlying soft tissue envelope and the ability for guided shape change in the affected bone. The challenge posed by the malpositioned healing of fractured bones was no small problem and is remembered in the name of the
specialty which treats this pathology today – ortho (straight) paedics (children). Codivilla demonstrated the potential for DO when treating patients who had fractures of the long bones of the limbs which had healed in a poorly functioning position. He showed that following re-fracture, and with traction in an appropriate vector, the limbs could be encouraged into a functioning position Figure 2-2.

![Figure 2-2 Limb Lengthening and Correction of Deformity](image)

**Figure 2-2 Limb Lengthening and Correction of Deformity**

(Source: Codivilla A. The classic: On the means of lengthening, in the lower limbs, the muscles and tissues which are shortened through deformity. 1905. Clin Orthop Relat Res. 2008;466(12):2903–9.)

Gavril Ilizarov founded the basic science of DO in limbs through a series of experiments spanning several decades from the middle of the last century. His principles remain the standard of surgical technique and are as follows: maximum preservation of extraosseous and medullary blood supply; stable fixation; a latent period prior to distraction of 5-7 days; distraction at a rate of 1mm/day in small steps; a period of consolidation.
following distraction to allow for ossification of the callus; and finally, physiologic use of the limb. It was not until the work of Joseph McCarthy and others towards the end of the last century when the technique for DO in the mandible was developed, of note Ilizarov’s original paper does describe DO in the cranium.

Technically many of the same concepts are carried over from the work of Ilizarov when carrying out distraction in the craniofacial skeleton. There are several key anatomical and physiological differences between distraction in long bones and distraction in the mandible that would suggest that a different approach may be possible. In particular, there is a comparatively good blood supply which favours more rapid healing, and in addition the stresses experienced by the craniofacial skeleton differ significantly from those in the limbs. It has therefore been suggested that the latency period and rate of distraction in mandibular DO can be modified from that used in long bones.

McCarthy’s initial experimental studies describe well the histological appearances and changes at the distraction site in the mandible. During the latent phase, typical fracture healing is seen with the formation of haematoma, migration of inflammatory cells, synthesis of the collagen matrix and angiogenesis. In the initial phase of distraction, a fibrovascular matrix is seen at the bony gap aligned along the vector of distraction with osteoid appearing from 14 days following commencement of distraction. Calcification of the collagen bundles is seen at 3 weeks and McCarthy describes four zones in the distraction gap. A fibrous central zone, an osteoid transition zone, a remodelling zone and a mature bony zone. The zones describe how mineralisation spreads from the edges of the bony gap toward the centre with subsequent union of the immature bone which remodels to form mature bone. Of key importance, the tension at the distraction site effects not only bone but also the soft tissue envelope, delivering an increase in the amount of soft tissue and muscle in the region.

There are a large range of potential applications for distraction osteogenesis in the craniofacial skeleton. It can be used to increase cranial vault volume with posterior vault distraction or transverse width for example in sagittal craniosynostosis. In the maxilla,
distraction osteogenesis is typically used in transverse discrepancies for example in Transpalatal Distraction Osteogenesis. It may be used to reconstruct a variety of pathology including congenital, oncologic or post-traumatic related deformities. In this thesis, we will be concentrating on mandibular distraction osteogenesis.

Today a typical protocol for DO in the mandible includes a latent period of 5 days; distraction at 1mm/day – with 0.5mm in the morning and 0.5mm in the evening – typically performed by the patient or parent; a 3-month period of consolidation followed by removal of the distraction device. The distractor device consists of proximal and distal attachments with a variable length span connected to an actuator which protrudes through the tissue to allow for daily winding. Current concepts in mandibular DO leave scope for considerable further improvement and will now be discussed.

2.3 THE CURRENT STANDARD OF TREATMENT

There are several available devices on the market today specifically for use in distraction osteogenesis of the mandible. The three principle companies that provide devices are Synthes, KLS Martin and Stryker. Stryker manufactures an external distractor, the Multi-Guide II, which they advertise as being easier to apply surgically with good control of the mandibular segments in all planes and allowing for independent linear distraction of the ramus and body Figure 2-3.(33)
Synthes manufactures both a linear and curvilinear distraction device for use in the mandible. These are both semiburied devices and are offered in 1.3mm or 2mm thick plates. The curvilinear device shown in Figure 2-4 is marketed to advance and rotate the mandible along a curve, increase posterior facial height and to lengthen bone in two planes simultaneously, it can be used to close an anterior open bite. As a semiburied device there is an extension arm that projects through the tissue, once fixed to the mandible, and is manipulated with a screw driver to achieve distraction. (34)
KLS Martin manufacture semiburied linear distractors which are featured as low-profile with an anti-relapse ratchet. They are able to distract along a single plane and require activation via a protruding arm Figure 2-5.

**Figure 2-5 KLS Martin Linear Distactor**
(Source: KLSMartin.com)

2.4 **Limitations with Devices for Mandibular Distraction**

As previously discussed, there are significant drawbacks with currently available distractors, in particular the need for protruding metalwork required to activate the device causing problems with infection. Table 2-2 is taken from Joseph McCarthy’s review on the evolution of and their experience with mandibular distractors and provides a representative impression of the problems surgeons and patients face with current devices.(35)
A recent literature review has demonstrated the wide variety of complications from mandibular DO. Complications following this procedure are seen in 20-35% of cases, the majority of which relate to relapse (65%), though infection (9.5%), pain on activation (9%) and inappropriate vector distraction (8.8%) are also common.\(^{(36)}\)

Problems with devices used for DO in the mandible include:

- Bulky design: Although there has been incremental improvement to device design since conception with an evolution from external devices, as used in limb DO, to internal semi-buried devices\(^{(39)}\) they remain bulky. This is due to the need for multiple moving parts and an actuator which must penetrate the skin to be externally manipulated. There is therefore a significant risk of infection, which

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**TABLE 2-2 INCIDENTS IN MANDIBULAR DISTRACTION OSTEOREGENESIS**

(Source: Davidson et al. 2010)

<table>
<thead>
<tr>
<th>Minor incident</th>
<th>External Devices in Native Bone ((n = 120) procedures)</th>
<th>External Devices in Grafted Bone ((n = 37) procedures)</th>
<th>Semibuired Devices in Native Bone ((n = 45) procedures)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difficulty in device activation</td>
<td>4</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Device backup</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Improper vector</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Inadequate device length</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Pain on activation</td>
<td>8</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Hypertrophic scar</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Cyst caused by pins</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Psychological problem</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Neuropathia (inferior alveolar nerve)</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Infection (oral antibiotics sufficient)</td>
<td>13</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Trismus during treatment or device removal</td>
<td>2</td>
<td>2</td>
<td>7</td>
</tr>
<tr>
<td>Parotid gland injury</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Subtotal (incident rate)</td>
<td>33 (26%)</td>
<td>14 (38%)</td>
<td>28 (62%)</td>
</tr>
<tr>
<td>Moderate incident</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Improper vector</td>
<td>6</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Device backup</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Loose device</td>
<td>16</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>Device deformation breakage</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Premature ossification</td>
<td>2</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Scar requiring revision</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Infection (requiring intravenous antibiotics)</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Additional incision to remove device</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Subtotal (incident rate)</td>
<td>28 (22%)</td>
<td>11 (30%)</td>
<td>8 (18%)</td>
</tr>
<tr>
<td>Major incident</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unstable device</td>
<td>0</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Tooth follicle or damaged teeth</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Premature consolidation</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>TMJ ankylosis and degenerative changes</td>
<td>1</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Fracture</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Hypertrophic scar</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Subtotal (incident rate)</td>
<td>5 (4%)</td>
<td>5 (14%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Total (incident rate)</td>
<td>66 (51%)</td>
<td>30 (81%)</td>
<td>36 (80%)</td>
</tr>
</tbody>
</table>

TMJ, temporomandibular joint.
may jeopardise the outcome of distraction and negatively affect the patients’ experience of the procedure.

Limited geometry: Current devices are restricted by a limited geometry of possible distraction, those devices most commonly used distract only in a single plane and cannot accommodate rotational deformity or complex multiplanar 3-dimensional distraction. Although work on 3 dimensional distractors is in development, devices which permit movement in multiple planes remain in the prototype stage.(41–43)

Variability of distraction: In spite of pre-surgical planning the outcome of the distraction is heavily reliant on the surgeon’s eye as to deciding when distraction is complete, a judgement which is frequently hampered by soft tissue swelling and in addition which is susceptible to cognitive bias.

Discontinuous distraction: Currently used devices distract the callus discontinuously, usually twice per day. This is in spite of the fact that the advantages of continuous distraction are well described including: lower distraction forces; potential for faster rates of distraction; and improved quality of bone regeneration.(4, 9, 10, 11,16)

Patient compliance: Devices used today require the patient or parent to actuate the distractor by means of daily winding. This can be distressing and painful for both and introduces the possibility of erroneous distraction. If we are to advocate for these procedures it is key that we improve upon the patients experience of them alongside other objective outcomes.
There is therefore scope for novel development to improve upon current concepts, techniques and designs used for mandibular DO. To reemphasise the aims of the project, the mandibular distraction device should satisfy the following criteria:

- **small in size, fully-buried and biocompatible**
- **programmable to distract to a patient specific shape**
- **distract continuously without the need for patient involvement**
- **provide sufficient force generation**
- **robust enough to withstand the in-vivo environment**

It is now necessary to review the literature to understand what concepts are currently under investigation to improve upon our standard.

### 2.5 Novel Concepts in Continuous Distraction Osteogenesis

A PubMed search was performed in September 2015 using the keywords (automat* or continuous or spring or motor or hydraulic) and (mandib* and distract* or distraction osteogenesis). Those studies describing distractors that did not distract continuously or automatically were excluded.

An additional PubMed search was carried out in September 2015 using the keywords (force or newton or torque) and (mandib* and distract*). Those studies not describing the measurement of forces in DO of the mandible were excluded.

225 matches were returned by the initial search of which 15 described relevant devices which met the criteria for automated continuous DO in the mandible. The papers were further subdivided according to the method of distraction either mechanical or spring driven.

87 matches were returned in the second search of which 5 met the criteria for the measurement of force in DO of the mandible. Relevant papers were subdivided into animal and human models.
2.5.1 MECHANICAL DEVICES

In 2001 Wiltfang et al. (37) used a microhydraulic cylinder to perform continuous distraction in 6 minipigs following mandibular osteotomy Figure 2-6. There was a 7-day latency period prior to distraction. One group was distracted discontinuously, and a second group was continuously distracted at 1.5mm/day for 10 days. Continuous distraction produced improved bone healing as demonstrated by electron microscopy and ultrasonography.

![Microhydraulic Distractor in situ on a Pig’s Mandible](image)

FIGURE 2-6 MICROHYDRAULIC DISTRACTOR IN SITU ON A PIG’S MANDIBLE


Ayoub et al. in 2001(38) published a novel design for a hydraulic distractor Figure 2-7. The device consisted of two parts, an internal implantable distractor attached to bone and an external, identical part connected via tubing which is activated by a battery powered driver system. Each unit is made of two telescoping tubes enclosing nickel bellows and the incompressible fluid ensures expansion of the distraction component. The device was later tested in 11 sheep, (39) there were 3 controls and 8 distracted sheep. A 25mm mandibular
defect and a 20mm tooth bearing transport disc was created. There was a 1-day latency period prior to continuous distraction at 1mm/day for 25 days followed by an 8-week consolidation period. In 2005 the group published a case report of the use of the device to improve mandibular symmetry in a 65 year old man which successfully distracted the mandible by 20mm.(40)

![Figure 2-7 Hydraulic Distraction Device](image)

**Figure 2-7 Hydraulic Distraction Device**


In 2009 Magill et al. designed a novel device using a spring driven hydraulic pump connected to an implanted actuator composed of a piston, slider rail and footplate, which is attached to the mandible.(41) The device can produce up to 40N of distraction force and can be used in curved paths Figure 2-8. The device was tested in 2013 by Peacock et al. in a minipig model.(42) A mandibular osteotomy was created in 10 minipigs and a curvilinear distractor placed. There was no latency period. The minipigs were divided into a discontinuous distraction and continuous distraction group. The continuous distraction group was further subdivided into two groups according to distraction rates of 1.5mm/day or 3mm/day. The discontinuous group was further subdivided according to distraction rates of 1, 2 and 4 mm/day. Similar bone formation was found in the discontinuous 1mm/day group and the continuous 1.5mm/day and 3mm/day groups, which were found to be
superior to the other discontinuous groups according to clinical appearance, stability and radiographic appearance.

**Figure 2-8 Curvilinear Hydraulic Distraction Device**


In 2013 Goldwaser et al. developed and tested a distraction device capable of distraction in 3 dimensions in minipigs. (43) There were 3 components to the device, an implanted distractor, a power source and a handheld user interface. A mandibular osteotomy was performed initially in 2 cadaveric animals to demonstrate proper functioning of the device and then in 5 live animals. There was no latency period and distraction was a 1mm/day with 24 days consolidation. Distraction distance was assessed by radiographs and by eye at sacrifice. In 1 animal there was device failure. In the 4 remaining animals, the distraction gap was found to be 7mm, and good bony infill was found in 3 of the 5 animals.

A motor-driven continuous distractor was developed by Schmelzeisen et al. in 1996. (44) The device consisted of 2 sliding plates attached to either side of an osteotomy. A motor was fixed to the posterior part and distraction occurred along a thread. Power was supplied by lithium batteries which were implanted subcutaneously and connected to the
motor. The device was implanted in 3 minipigs and distraction proceeded for 14 to 21 days. Callus formation was observed in one animal with 11mm of lengthening, there was premature sacrifice of one minipig due to fracture of the mandible and there was infection in the one animal following reoperation to correct device failure with an ultimate distraction of 13mm.

Ploder et al. developed and tested a novel motor-driven device in 1999 consisting of a driver-module with built-in micromotor and gearing allowing distraction steps of 0.04 mm/hr Figure 2-9.(45) The device and battery were fully implantable and tested in 3 sheep. There was a latency of 5 days prior to a 14-day period of distraction, histological and radiological examination demonstrated good cartilaginous bone formation to a maximum lengthening of 13.6mm.

**Figure 2-9 Motor Driven Continuous Distraction Device**

In 2008 Zheng et al. (46) tested a motor driven distraction device in 5 rabbits. Their device consisted of an automatic driver attached to a commercially available distractor via a flexible shaft Figure 2-10. The automatic driver is comprised of a driving unit (A), flexible shaft (B) and mounting mechanism (C). The torque generated by the driving unit is transmitted to the activation rod of a distractor (D) through the flexible shaft and mounting mechanism. Following placement of the distractor there was a 3-day latency period after which the distractor arm was attached to the automatic driver. There was an 11-day period of continuous distraction at 0.9mm/day followed by 4 weeks of consolidation. Following sacrifice the distraction gap was found to be successfully filled with bone both histologically and radiographically.

**Figure 2-10 Automated Distraction Device**


Park et al. (47) designed a piezoelectric motorised distractor in 2011. The device included a driving unit, a microcontroller and a communicating unit. This allows for a variety of distraction protocols controlled by a computer-based program. Figure 2-11 shows the actual size of the manufactured device. The fixed and moving plates were 0.5 mm thick, and they had a 7-mm stroke distance and a total size of 35 mm. Laboratory testing showed a
maximum force of distraction of 3N. This device has not yet been tested in an animal or human model.

![Image](image)

**FIGURE 2-11 PIEZOELECTRIC DISTRACTOR**


2.5.2 SPRING DRIVEN DEVICES

There were 5 relevant papers on spring mediated DO. In 2003 Mofid et al.(48) report results from unilateral mandibular DO using a nitinol spring in rabbits in 20 rabbits. The spring was u-shaped and fixed to the mandible with stainless steel wire. Figure 2-12 shows a Nitinol spring secured at either end with a pinball which has been bent into an inferiorly based arc and secured to the hemimandible with stainless steel wire. To allow for a latency phase a securing wire was placed that was later cut to allow distraction to begin. 5 of the rabbits were excluded due to device failure/infection/non-union. Radiographic data was used to assess length of distraction at 6 weeks with a mean distraction of 1.2mm (maximum 3.7mm). Histologic examination demonstrated complete bone bridging in all mandibles except one. In addition, biomechanical testing was carried out in a temperature-controlled environment showing linear increase in force generation between 23-37°C from 4.24 N to 4.96 N with a reduction in force from 4.96 N to 4.76 N at 37°C with increased displacement.
In 2004 Idelsohn et al. report results from DO with a novel use of commercially available orthodontic nitinol springs in 6 rabbits. Figure 2-13 shows the shape memory alloy springs (S), bone plates to fix the mandible and reduce unwanted movements (P), the segment that is going to be displaced forward (B), and newly formed bone (C). The spring was placed 5 days after a segmental mandibulectomy of 8mm and corticotomy and left for 2 months. Results showed 2-5mm of lengthening after 1 week and 7-13mm after 3 weeks. Histology confirmed intramembranous ossification in the distracted segment.
In 2004 Zhou et al. tested a sinusoidal nitinol spring mandibular distractor in rabbits after removing a 15mm segment. (50) Figure 2-14 shows the sites of the osteotomies (upper), the removed segment (middle) and the fixation of the Nitinol spring and other devices (lower). Distraction was found to be 9mm in 5 days and histology at 8 weeks showed new bone formation. In a follow-up study in 2006 Zhou et al. report DO in a canine model using similar nitinol springs. (51) A unilateral mandibular osteotomy was performed to create a defect and a tooth bearing bony transport disc, a sinusoidal 1.3mm nitinol spring was placed and distraction began immediately. A control group underwent the same procedure without spring placement. Biomechanical testing of the unloading spring demonstrated a plateau phase with a force of 8-10 N, measurement of distraction showed an initial rate of 3mm/day slowing to 1mm/day. Histology showed new bone in all those animals that were distracted and none in the control group.
In 2010 Wang et al. carried out a feasibility study into the use of infrared light controlled nitinol spring mandibular DO using a rabbit model Figure 2-15. (52) A 15mm segmental mandibular osteotomy was performed to create a defect and a free bony transport disc was made with a further osteotomy. A sinusoidal nitinol spring was inserted and activated on the second post-operative day and continued for 9 days. Bony regrowth was observed in all experimental subjects and the defect repaired.
2.5.3 **Distraction Forces – Animal Model**

Kessler et al. assessed the effect of the magnitude and frequency of distraction forces on tissue regeneration in mandibular DO in 2002.\(^{(53)}\) Trials were carried out using 12 pigs, two groups were assigned, one to a continuous microhydraulic distractor and one to a discontinuous protocol at a rate of 1.5 mm/day. Distraction proceeded after a 5-day latency period for 10 days. Figure 2-16 shows distraction pressure curves in continuous distraction (top) and noncontinuous (bottom) distraction. The dotted line shows mean value. Distraction pressures were found to be 3 times greater in the discontinuous group compared to the continuous distraction. The discontinuous group demonstrated a sudden sharp pressure increase which decreased rapidly. The average distraction distance was similar in both groups 13.3 mm with continuous distraction compared to 13.7 mm in discontinuous distraction. Importantly bone regeneration was assessed, demonstrating intramembranous bone formation in continuous distraction compared to chondroid bone formation in discontinuous distraction. Bone regeneration was found to proceed at a faster
rate in continuous distraction compared to discontinuous distraction with a mature lamellar structure found at 12 weeks post-distraction.

This work was followed up by Kessler et al. with further testing in 12 pigs. The pigs were divided into two equal groups of continuous and discontinuous distraction. There was a 5-day latency period prior to distraction at 1.5 mm/day. Chondroid ossification was seen with intermittent distraction and intramembranous ossification in continuous distraction. Results confirmed the earlier findings with identical distraction distances. Distraction forces were measured and were found to increase linearly over the period of distraction to a maximum of 76 N for intermittent distraction and 28 N for continuous distraction at 10 days Figure 2-17.

**Figure 2-16 Distraction Pressure vs Time**

Singare et al. assessed distraction forces according to varying latency periods in 36 rabbits. The rabbits were divided into equal groups of 12. All rabbits had an osteotomy with placement of a unilateral internal distractor with attached strain gauge. Discontinuous distraction at a rate of 1 mm/day proceeded for 8 days following a latency period of 0, 4 and 7 days. Initial distraction forces were found to be 3 N in rabbits with no latency period rising to 6 N in rabbits with a 7-day latency period. At day 8 of distraction forces were 28 N in rabbits without a latency period rising to 39 N in rabbits with a 7-day latency period Figure 2-18. Bone mineralization was measured and found to be reduced in rabbits with no latency compared to those with 4 or 7 days latency.
2.5.4 DISTRACTION FORCES – HUMAN MODEL

Robinson et al. collected data for torque-force values of an internal distraction device and correlated these values to in-vivo torque readings made during mandibular DO in 8 patients aged 6 to 20 years. (56) In vitro torque-force values were measured by adding 5 lb weights increments and activating the device using a calibrated torque wrench. In vivo distraction was carried out for mandibular hypoplasia, there was a 6-day latency period followed by distraction at a rate of 0.5mm twice a day also using a calibrated torque wrench. Mean distraction distance was 11.2mm (range 4-17mm). They found that the average torque for distracting 0.5 mm twice a day to be 4.2 N-cm which correlated to a force of 35.6 N.

Burstein et al. measured torque during mandibular distraction in 26 patients ranging from 9 days to 12 years old. (57) Patients underwent discontinuous distraction at a rate of 2 mm/day following a 48-hour latency period. Resorbable devices were used and a mean
distraction distance of 25 mm was achieved. Distraction forces were inferred from in-vitro laboratory testing correlating torque to force. After conversion, distraction forces with a range of 4 N (1 lbf) to 60 N (13.6 lbf) were found with a mean of 22 N (5 lbf). Greater force was required in older patients and there was a modest increase in force required with increasing time Figure 2-19.

![Boxplot of Distraction Force vs Distraction Length](image)

**Figure 2-19 Distraction Force vs Distraction Length**


In 2005 Ayoub et. al., as previously described, performed continuous DO in a human subject using a microhydraulic distraction device.(40) Figure 2-20 shows the distractor connected by a flexible drive cable, which was passed through a skin incision at the angle of the mandible, to an external plunger mounted in an ambulatory infusion pump. The team were able to measure force directly from the device as the hydraulic activator was a syringe pump with known pressure. The device was able to successfully distract the mandible using a force of 20N to drive 1mm/day distraction to a distance of 16mm.
2.6 CONTEMPORARY CLINICAL USE OF SPRINGS

The use of springs for distraction osteogenesis in the mandible has several desirable characteristics including that they can be fully buried and require no intervention from the patient. Whilst the use of springs to effect change in the mandible remains experimental, springs are well established in clinical use for cranioplasty. Craniosynostosis is a condition in which there is premature fusion of one or more of the cranial sutures which leads to an abnormal growth of the skull. Craniosynostosis is frequently seen in patients without any
underlying condition though may also be seen as part of a syndrome for example in Apert or Crouzon syndrome. Traditional surgical treatment for the management of nonsyndromic sagittal craniosynostosis is a total calvarial vault remodelling, a significant operation in which a large part of the calvarium is osteotomised, re-configured into a more normal shape and then fixed into place. Since the 1990s a different procedure with a shorter operation time and fewer osteotomies has gained popularity involving springs to modify head shape. Spring-assisted cranioplasty (SAC) is one proposed treatment for the management of non-syndromic sagittal craniosynostosis. Sagittal craniosynostosis is the premature fusion of the sagittal suture and is the commonest form of craniosynostosis. As the cranium grows perpendicularly from the sutures, according to Vichow’s law, the premature fusion leads to an abnormal scaphocephalic calvarial geometry with frontal bossing, protruding occiput and a reduced biparietal distance. SAC represents a more minimally invasive procedure for the management of this condition when compared to total calvarial remodelling (TCR) with reduced scar length, reduced hospital stay and reduced blood loss. SAC was first reported in 1998 by Lauritzen et al.,(58) by using the viscoelastic properties of the infant skull the cranial vault may be widened in a process synonymous with DO.(59) Criticism of the technique observes the need for a second procedure to remove the springs; incomplete correction of cranial deformity; and lack of long-term follow up. The operative technique continues to be improved upon and there remains neither a standard technique nor spring design. To review the technique and clinical outcomes of this procedure a quantitative analysis of 100 cases undergoing cranioplasty for non-syndromic sagittal synostosis from a single institution was undertaken, those with multisutural or syndromic synostosis were excluded.(60)

2.6.1 Operative Technique

The patient is placed in the sphinx position (A) and an 8cm scalp incision is made midway between the anterior and posterior fontanelles, perpendicular to the sagittal suture (B), see Figure 2-21. The subgaleal plane is dissected to the fontanelles anteriorly and posteriorly. Avoiding the sagittal sinus, a square craniectomy is performed roughly
halfway along the fused suture and the dura is dissected from the inner table (C). Parasagittal osteotomies are then made from the craniectomy anteriorly to the coronal sutures and posteriorly to the lambdoid sutures (D). Two springs are then placed into prepared grooves to ensure the springs are firmly sited to allow distraction (E) in a vector perpendicular to the suture line.

**Figure 2-21 Operative Technique**

(Source: Rodgers et al. PRS 2017)

2.6.2 Spring Design

Stainless steel wire-form spring distractors are used which have a central loop and hooks at each leg to fit into the prepared groove. Unloaded opening is 6cm and three
models of spring bearing the same geometry but different wire thicknesses of 1.0, 1.2 and 1.4mm are used.

2.6.3 CEPHALIC INDEX

Cephalic index, the ratio of the biparietal diameter to the occipito-frontal diameter, was 67.7 ± 3.6 preoperatively, 71.0 ± 4.5 at day 1, 72.2 ± 4.8 at 3 weeks and 72.1 ± 3.5 at 6 months. Figure 2-22, interrater agreement using a Bland-Altman plot confirmed an acceptable bias of 0.3 ± 0.9. The alternative hypothesis that cephalic index had increased at different time points was confirmed by analysis of variance. Dunnett post-test confirmed statistical significance (p < 0.0001).

![Figure 2-22 Change in Cephalic Index with Time](Source: Rodgers et al., PRS 2017)

2.6.4 DISCUSSION

This is the largest series of SAC for non-syndromic sagittal craniosynostosis reviewed to date. This study adds to the body of literature published that shows that the technique
is safe, well tolerated and effective at modifying head shape. SAC gives a significant and sustained improvement in cephalic index which is comparable to the SAC literature(61–65) and also to total calvarial vault remodelling techniques.(66–69) The study confirms that distraction osteogenesis techniques using springs to effect change are currently a clinical reality, which lays the foundation for this project as a means of improving upon currently available devices. There is now a body of literature that has demonstrated that the use of springs for distraction osteogenesis is physiologically acceptable in-vivo and gives rise to acceptable outcomes. Springs therefore offer a potential avenue for research in the improvement of mandibular DO. It is understood that osteogenesis in the calvarium has several key differences compared to that in the mandible. Specifically, ossification in the calvarium is reliant upon the pericranium and the dura which represents a relative advantage. Further, in comparison to the mandible, the calvarium has relatively little musculature that could affect the distraction stability and any new device must consider these differences.

2.7 REQUIREMENTS FOR A NOVEL DISTRACtor DESIGN

Thus far we have seen the current standard in clinical and experimental use for distraction osteogenesis in the craniofacial skeleton. The principles of the ideal distractor were discussed in the aims of the project Chapter 1.2 and are the foundation to the requirements for a novel design. The distractor must be small in size to facilitate placement and to minimise tissue disruption. The device must be fully buried and biocompatible to avoid the significant morbidity associated with an externally sited actuator and also to remove the need for patient involvement to turn the actuator. A novel device must reflect the trend towards a patient specific approach and therefore must have the ability to distract in multiple planes to produce a predictable and patient specific distraction. The device should harness the benefits of continuous distraction. In addition, the device should be of simple design with easy activation, deliver sufficient force and be robust enough to withstand the in-vivo environment.
The use of springs as a distractor has shown promise experimentally in the mandible and also in current clinical practice in the calvarium. It is noted however, that the calvarium faces a different set of challenges in distraction as discussed above. The use of nitinol as a material for springs experimentally has shown several advantages as outlined above and could be used in any novel device. Further work is required to understand the technical aspects of potential materials prior to the design of a novel device.

2.8 Discussion

CFM is a complex disease with variable pathology affecting structures of the 1st and 2nd branchial arches which produces anatomical and geometrical challenges for the surgeon in the correction of the mandibular deformity. Though there remains debate on the timing and format of surgical intervention, mandibular distraction osteogenesis is a well-recognised treatment in the more severe forms of the disease and is typically performed between the ages of 8 and 13. Current concepts in mandibular DO are hampered by difficulties with infection due to protruding device parts, bulky design, inappropriate and limited distraction vectors and patient compliance – especially in the paediatric population. There is evidence that the craniofacial skeleton has advantages in comparison to the long bones such that increased rates of distraction and reduced latency periods are possible. The benefits of continuous distraction over discontinuous distraction have been demonstrated. Non-standard rates of distraction are possible. In particular, faster rates of distraction can be achieved continuously which histologically compare favourably to discontinuous distraction.

There are currently no available continuously distracting devices that fulfil the criteria of being small in size; fully buried and biocompatible; able to distract in multiple planes simultaneously; have a predictable distraction endpoint and do not require patient involvement.
There is limited data on the forces required to adequately distract the mandibular callus. A reduced force of distraction is possible if achieved continuously, in humans the force required varies according to the age of the patient, a reflection of the variability of the viscoelasticity of bone and the soft tissue envelope with age.

Spring devices, whilst currently not in use for mandibular distraction, have been used for several decades in the calvarium successfully, though there are anatomical and physiological differences between the two such that a spring device for the calvarium may not be suitable for the mandible.

Nitinol spring distractors demonstrate several key advantages over motor or hydraulic actuators given the shape memory and superelastic properties. A discussion of the technical potential for a spring driven device now follows in Chapter 3.
CHAPTER 3 TECHNICAL BACKGROUND
3.1 **INTRODUCTION**

There has been significant progress in the surgical technique and technology for addressing the deformed mandible. As discussed in Chapter 2 however, currently there is no available distractor that fulfils the desired criteria of being:

- *small in size, fully-buried and biocompatible*
- *programmable to distract to a patient specific shape*
- *distract continuously without the need for patient involvement*
- *provide sufficient force generation*
- *robust enough to withstand the in-vivo environment*

Novel concepts in mandibular distraction include hydraulic devices, motor driven devices and spring devices. The advantages of a spring-based device include its simplicity, with a reduced number of working parts, the potential for a completely buried device and the for continuous distraction. As discussed in Chapter 2, spring devices for use in the mandible are in experimental stages only however, they are in regular clinical use in the calvarium and thus the biomechanics of such a device is of interest to this discussion. The question of whether materials and technology in current clinical use would be suitable for use in mandibular distraction must be answered initially as this will guide in large part the direction of the thesis. In order to understand the biomechanics of the material in current clinical use a study of their biomechanics was undertaken.

3.2 **ASSESSMENT OF CRANIOFACIAL SPRINGS BIOMECHANICS**

As discussed above, spring assisted cranioplasty is a surgical technique to effect change in cranial geometry with strategically placed springs. The technique is becoming increasingly popular internationally and has benefits in terms of reduced morbidity, hospital stay and transfusion requirements. It is of importance that the forces delivered by the springs in-vitro are fully characterised in order to understand the biomechanics in-vivo therefore the relevant literature was reviewed. (70)
In practice, three springs with similar geometry but differing in wire thickness (S10 – 1.0mm; S12 – 1.2mm; S14 – 1.4mm) are used. The GOSH springs are made of stainless steel and follow Hookean behaviour such that when they are compressed, they generate a force which is proportional to their displacement. At rest the springs have an opening of 60mm and upon insertion they are crimped to approximately 20mm.

Testing demonstrated peak spring forces of roughly 25N, 15N and 7N for springs S14, S12 and S10 respectively, see Figure 3-1. Of note the tests show non-recoverable deformation due to the yielding of stainless steel upon crimping.

Nonlinear behaviour was noted on both loading and unloading stiffness and final opening following crimping are shown in Figure 3-2.
**Figure 3-1 Unloading Force / Opening Curve for the Three Spring Models (S10, S12 and S14)**


<table>
<thead>
<tr>
<th>Spring Model</th>
<th>Unloading Stiffness, K (N/mm)</th>
<th>Final Opening, OP_∞ (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S10</td>
<td>0.17</td>
<td>60.7</td>
</tr>
<tr>
<td>S12</td>
<td>0.39</td>
<td>57.3</td>
</tr>
<tr>
<td>S14</td>
<td>0.68</td>
<td>55.6</td>
</tr>
</tbody>
</table>

**Figure 3-2 Stiffness and Final Opening for the 3 GOSH Spring Models**

The evaluation of spring mechanics in the lab is key to understanding their biomechanics in-vivo. The GOSH springs clearly follow Hookean behaviour such that the greatest force is generated at maximal crimping and declines roughly linearly with opening. The results found here tie in well with what is seen in practice as described above.

The use of springs to effect change in the craniofacial skeleton is well established and the action of the spring appears to be well tolerated. Spring biomechanics taken in conjunction with clinical outcomes show that the majority of distraction appears to happen in the first 24 hours following spring placement. Whilst this behaviour has been demonstrated to be successful in practice for cranioplasty, taking advantage of its favourable physiology, it is likely that such a rapid expansion would not be ideal in the mandible. The use of currently available spring material is therefore not appropriate for this thesis.

Nitinol springs have previously been used experimentally for mandibular distraction as described in Chapter 2. In addition, they have a long history of clinical use in medicine and dentistry being used in cardiac stents, catheter tubes, guidewires, stone retrieval baskets, dental files and archwires. Nitinol is popular due to its biocompatibility, fatigue and kink resistance and superelastic properties which give considerable advantage over other materials such as stainless steel. An introduction to Nitinol now follows.

3.3 AN INTRODUCTION TO NITINOL

Nitinol was first developed at the space programme of the Naval Ordnance Laboratory in the USA in the 1960s. It was discovered by a metallurgist, W. Buehler, investigating nonmagnetic, salt resisting alloys and its name is an acronym for the elements from which it is composed; ni for nickel, ti for titanium, and nol in reference to the Naval Ordnance Laboratory. Nitinol covers the family of intermetallic alloys of nickel and titanium which demonstrate the properties of shape memory and superelasticity. Shape memory refers to that ability of the material to return to its original shape following deformation and
superelasticity refers to the property of the material such that upon unloading, the material returns to its original shape without permanent deformation over a large range. These properties derive from its temperature and stress dependent crystalline structures – Austenite and Martensite – which have very different properties. Of note, many other metals have austenitic and martensitic phases however, their properties are less different. Crystallographically, the cubic structure of the austenite phase undergoes a spontaneous transformation at a lower temperature through an orthorhomboid structure to a monoclinic structure, martensite Figure 3-3. In this structure, the bonds are free to move, though they are not broken, allowing the material to non-permanently deform. However, when heat is applied the cubic structure returns and with it the original shape, giving the material its shape memory property.(72) Practically, this means that in the martensitic phase the material is malleable and readily deformable whilst in the austenitic phase the material is rigid.

Although the transformation from martensite to austenite and vice versa is temperature dependent, there is a range over which the complete transformation takes
place. Hysteresis is the difference between the temperatures at which the material is in the martensitic or austenitic phase, Figure 3-4. A material with a low hysteresis will therefore undergo its transformation within a narrow temperature range and would thus be suitable for use in the human body.

![Diagram of hysteresis and martensitic transformation](image)

**Figure 3-4 Hysteresis of Martensitic Transformation**

(Source: Thompson et al.)

Fortunately, the properties of nitinol can readily be adjusted according to the Nickel/Titanium ratio Figure 3-5 to ensure the mechanical properties of the material are appropriate for use at body temperature.
Stress is the force per unit area \( [\sigma = \text{force} / \text{area}] \) and strain is defined as the deformation due to stress \( [\text{strain} = \text{change in length} / \text{initial length}] \). The stress-strain curve for Nitinol differs from standard metals and varies both with temperature and when in tension or compression. Typical curves for Nitinol are shown in Figure 3-6 and Figure 3-7.
FIGURE 3-6 STRESS-STRAIN CURVES FOR NITINOL VS TEMPERATURE

Note the material demonstrates an austenitic phase with increasing temperature (Source: Shape Memory Materials; K. Otsuka; C.M. Wayman)

FIGURE 3-7 A TYPICAL STRESS-STRAIN GRAPH FOR NITINOL

Note the different properties of the material in tension and compression (Source: http://help.solidworks.com/)
For the purposes of this work it is key that the nitinol used in this project be applicable for use in humans at body temperature such that it is austenitic, with superelastic properties, at body temperature and preferably with a low hysteresis. It is also desirable that it demonstrates a stress-strain curve that fulfils the force requirements as described in Chapter 2. A remarkable property of the material is that there exists a plateau over which a relatively constant force is delivered in either tension or compression.

3.4 Nitinol Helical Spring

In variation to a typical U-spring design as used in spring assisted cranioplasty, a helical spring may also be used and offer similar properties. A helical spring offers the advantage of being more compact in size and amenable for use in the above described prototype.

Springs which demonstrate approximately constant force are routinely used in day to day life and include the watch spring and gas spring. The watch spring is not appropriate for use in this device due to the low force generated relative to the size of the spring. Whilst the gas spring provides sufficient force over an appropriate displacement, the spring functions due to the properties of highly pressurised gas and requires oil lubrication which make it unsuitable for use in the human model. Use of a nonlinear material such as nitinol to provide a constant force is therefore preferential.

The ideal nitinol spring must deliver sufficient force which is relatively constant over a displacement that is compatible with mandibular DO. The spring should be in a martensitic phase below body temperature to allow for easy manipulation and application during the surgical procedure but then become austenitic when warmed to body temperature. Ideally therefore, the hysteresis of the nitinol should be low – of the order of 10-15ºC – for ease of use. The force of the nitinol helical spring is proportional to the wire diameter, spring diameter, pitch, transition temperature and number of active turns. (73)
Describing empirically the behaviour of a spring is of great value to this thesis in order to demonstrate its potential for use in a novel device, this will therefore be discussed in greater detail later in Chapter 4.

As the device is intended to be patient specific, different magnitudes of forces may be required according to the patient. In order to easily design a spring which will deliver an appropriate force and reduce the need for multiple empirical tests it will also be necessary to build a simulated model of the spring. This can be achieved through a process known as Finite Element Modelling, which will be discussed briefly here by way of introduction but will be discussed in detail in Chapter 5.

3.5 **Finite Element Modelling**

In order to predict the performance of a given nitinol helical spring prior to implantation in the body it is of use to construct a simulated model which predicts the expected behaviour. A model can be designed based on the principal variables that will affect this behaviour. The finite element method simplifies a model into discrete parts called elements which are organized into a mesh, the model can thereby be solved by assessing the behaviour of each element and using this to understand the behaviour of the whole. Using empirical data, this model of helical spring behaviour can be adjusted to fit reality and the resultant model can act as a proxy to test the device. This process can then be used to optimise the design and reduce the need for lengthy and costly testing of multiple spring types.

3.6 **Discussion**

The biomechanics of springs in current clinical use highlights the limitations of this spring design for use in mandibular distraction. The Hookean behaviour is able to deliver clinical results in calvarial distraction however, as the force diminishes rapidly with spring opening it is unsuitable for the challenges faced in the mandible.
Nitinol is a material with nonlinear properties, in particular it has superelastic properties which make it potentially suitable for use in this project. The ideal nitinol spring for use in mandibular distraction osteogenesis is difficult to define due to a lack of basic research in distraction forces. The forces required for distraction were discussed in Chapter 2 and vary principally with age though are also affected by underlying condition, distance of desired distraction, the maturity of callus and the effect of soft tissues. Further work into understanding the biomechanics of a nitinol helical spring is required to review its potential for use in mandibular distraction and will be investigated in the following Chapter.
CHAPTER 4 Testing the Nitinol Spring
4.1 INTRODUCTION

Understanding the behaviour of any spring to be used in a novel device is key to predicting surgical outcomes. In the craniofacial springs discussed above, rapid initial expansion was found, reflective of the Hookean nature of Stainless Steel. This would not be ideal in the mandible due to physiological differences discussed above. For this reason, the focus has turned towards Nitinol and its nonlinear, superelastic properties. The potential biomechanical interactions between the device and the mandible will affect the predictability of results and a comprehensive understanding of the behaviour of a potential spring for use in the distractor. Any spring will also need to fulfil the desired criteria of being small in size, biocompatible, provide sufficient force for distraction and to be robust enough to withstand the in-vivo environment. Nitinol is certainly a robust material, such that it is considered by aerospace engineers in various modalities including spaceflight,(74) it also has multiple current uses in medicine and therefore has demonstrated its biocompatibility.

In a classical spring, Hooke’s law applies such that:

\[ F = -kx \]

\( k = \text{spring constant}; \ F = \text{force}; \ x = \text{displacement} \)

and in a helical spring, the spring constant can be found according to the following equation:
This linear relationship would not be ideal for DO in the mandible as the force required to distract remains constant or even increases as the displacement increases, as discussed in Chapter 2. Nonlinear materials such as nitinol will not demonstrate this linear relationship and with their superelastic properties have potential as actuators for a novel device.

Helical springs offer the advantage of a relatively small profile compared to other spring types. Their properties can be modified according to their wire thickness, the diameter of the spring and the number of turns of coils. In addition, the spring behaviour will be modified by the pitch, the difference in height between one coil and the next, and the length of the spring Figure 4-1 – a function also of the number of coils of the spring, given there is no dynamic change in pitch or spring diameter.
To demonstrate that a helical spring can be constructed which is small in size and able to deliver sufficient force for distraction a study of the behaviour of nitinol springs was thus undertaken to review their suitability for use in distraction osteogenesis.

4.2 METHODS

Testing in tension and compression was performed using a Zwick uniaxial tensile test machine with a 5kN load cell. A novel jig was made to allow for compression testing, Figure 4-2, using a 2mm thick central rod.
The jig allowed for passive movement of the rod whilst restricting the spring and allowing testing in compression and preventing buckling of the spring. Four springs were tested in compression with variation in wire diameter, pitch, length of spring and number of active turns. Spring characteristics were measured with digital callipers (RS Pro 150mm Digital Calliper, RS Components Ltd, UK). All springs had a mandrill – or central barrel - size of 2.4mm to allow room for the central testing rod. Springs were constructed from NiTi and were manufactured (Kellogg’s Research Labs, Hudson, NH, USA) to be austenitic at body
temperature - 37°C. Testing was temperature controlled at 37°C through the use of a thermostatically controlled water bath and was repeated on 3 occasions to demonstrate repeatability, the mean value of the 3 data sets recorded was used for the results. Data were collected on Zwick TestXpert II and analysed using Excel. Force/opening curves were plotted during both the loading and unloading phases. Springs were loaded until compressed completely before unloading began.

4.3 RESULTS

The 4 springs tested in compression demonstrate a variety of force-displacement curves, all displaying nonlinear behaviour. The first spring tested had a mandrel size of 2.4mm, wire width of 1.25mm, a pitch of 5mm, total length of 51mm. Results are shown in Figure 4-3 and show the expected plateau phase between 10mm and 25mm with mean force of 33.1N and standard deviation of 1.8N.

The second spring tested had a mandrel size of 2.4mm, wire width of 1.25mm, a pitch of 3.75mm and total length of 55mm. Results are shown in Figure 4-4 and demonstrate the expected plateau phase between 12mm and 25mm with a mean force of 39.4N and standard deviation of 2.7N.
The third spring tested had a mandrel size of 2.4mm, wire width of 1mm, a pitch of 3mm and total length of 52mm. Results are shown in Figure 4-5 and demonstrate the expected plateau phase between 15mm and 30mm with a mean force of 24.4N and standard deviation of 2.7N.

The fourth spring tested had a mandrel size of 2.4mm, wire width of 1mm, a pitch of 4mm and total length of 50mm. Results are shown in Figure 4-6 and demonstrate the
expected plateau phase between 15mm and 30mm with a mean force of 32.2N and standard deviation of 2.8N.

![Figure 4-6 Force Opening Graph for Nitinol Spring of Wire Width 1mm, a Pitch of 4mm and Total Length of 50mm](image)

4.4 DISCUSSION

Using Nitinol helical springs to generate the force for distraction has several potential advantages including their relatively low profile, their nonlinear mechanical properties, their biocompatibility and the robustness of the material to withstand the in-vivo environment.

The performance of the helical springs is key to the progression of this thesis and the results are encouraging. All springs tested demonstrate a plateau effect though varied in the length of this period and in how constant this force was found to be, reflected in the standard deviation across the plateau.

The most appropriate spring for potential use in mandibular distraction osteogenesis from testing is that which demonstrates a plateau force in keeping with our understanding of required distraction forces. The most appropriate spring will also demonstrate a plateau over a distance in keeping with mandibular distraction and will show relatively small variation in the force provided over this plateau. Accordingly, the most appropriate spring
is that highlighted in Figure 4-3. It has a wire diameter of 1.25mm, pitch of 5mm and total length of 51mm. It has a quasi-constant force between 10mm and 25mm with mean force of 33.1N and standard deviation of 1.8N.

Potential limitations of the spring test include the need for a jig with which to test the spring in compression. The jig was necessary to maintain the stability of the spring without buckling whilst in compression. Whilst the jig was designed to be as friction free as possible, it is not possible to remove all interference which will affect results. Further, as the test is ex-vivo the potential interaction of soft tissues on any spring driven device remain unknown.

These preliminary results are encouraging for the success of a spring driven prototype using a nitinol helical spring. For the purposes of this project it would be of use to have an accurate description of which spring would be appropriate for a variety of forces and distraction distances such that it could be designed for use in paediatric or adult cases and designed for patient specific distraction distances. This can be achieved with the use of a finite element (FE) model which will now be discussed.
CHAPTER 5  **FINITE ELEMENT MODELLING**
5.1 INTRODUCTION

Finite element modelling (FEM) is a computer-based analysis tool which acts to simulate the behaviour of engineering products under expected physical conditions. Whereas previously, new products have been developed through a process of prototyping and evaluation, FEM allows products to be tested and optimised virtually thus reducing the amount of time needed for testing physical prototypes. The simulation can also indicate how a product will behave mechanically during use, in a way which may not be obvious through standard testing and experimentation. The process relies on simplifying the complex ‘real’ problem into a numerical model that describes the real-life behaviour. In order to achieve this, assumptions must be made about the physical properties and characteristics of the product and therefore the model will always remain incomplete. Any simulations should therefore be used to aid, rather than replace, physical testing.

The first step in the process is to create a virtual model. In this case the model will be the most ideal spring highlighted in the previous Chapter. It is possible to use the various measurements made of the spring: the height, thickness, number of turns, pitch, mandrill size, to represent accurately the spring shape. The next step involves a process called meshing. Meshing the virtual spring allows the spring to be represented as a number of individual elements. The mesh function reduces the complexity of the structure of the spring by converting it into multiple tetrahedra made up of 4 elements. The model can be made more complex by having a very large number of these tetrahedra, or less complex by having fewer. A very large number of tetrahedra will give a finer mesh and a more accurate model of real-world function however, this is at the expense of computational calculations which increase with increasing complexity. A small number of tetrahedra will mean the model behaviour can be more readily calculated though at the expense of accuracy. It is therefore necessary to find a trade-off between accuracy and computational time. A grid independence test is a procedure to allow the model to be tested at varying levels of complexity to demonstrate the limit at which further increasing the number of tetrahedra
does not significantly improve accuracy of the model. Following meshing, the virtual model must be constrained using boundary conditions. These act to fix one end of the spring and allow virtual forces to be applied. The boundary conditions replicate the loads and displacements acting on the nitinol helical spring during the mechanical test and also constrain one end of the spring while the other end was displaced, simulating tension or compression (Figure 5-1). The behaviour of the material can then be input into the model using known values and the model can then be assessed. For the purposes of this model, the empirical data from spring testing can then be used to fine-tune the model in order to ensure it corresponds to expected values.

5.2 METHODS

A geometric model of a nitinol spring was re-created using Rhinoceros® CAD software (Rhino 3D, McNeel, Seattle, USA). The spring model was imported into ANSYS workbench (ANSYS Inc., Canonburg, PA) and a mesh function applied using the in-built meshing tool to mesh into tetrahedra. A grid independence test was undertaken using node spacing of 0.25mm, 0.5mm and 1mm.

To simulate the action of the spring in its proposed use, boundary conditions were applied.
To simulate the nonlinear behaviour of nitinol a constitutive model was used based on the nonlinear material formulation listed in ANSYS Workbench. The material parameters (ANSYS 4.14 - Shape memory alloy) are shown in Figure 5-2.
Starting stress value for the forward phase transformation

Final stress value for the forward phase transformation

Starting stress value for the reverse phase transformation

Final stress value for the reverse phase transformation

**FIGURE 5-2 NITINOL MATERIAL PROPERTIES REQUIRED FOR FEM**

Top: Graphic representation of the relative positions of the phase transformations on the Stress-Strain curve of Nitinol outlined in the Table

A trial and error optimization process was used in order to find the optimal parameters which allowed the numerical model to respond like that of the spring tested empirically at 25mm displacement.

5.3 RESULTS

Grid independence testing demonstrated that distance between nodes of 1mm, 0.5mm and 0.25mm did not significantly affect the outcome of the force model. The 0.25mm node spacing had twelve times the number of nodes compared to the 1mm node spacing model and therefore required significantly more processing. Results of the grid independence test are shown in Table 5-1.
<table>
<thead>
<tr>
<th>Number of Nodes</th>
<th>Distance Between Nodes (mm)</th>
<th>Force model at 1mm Displacement (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6000</td>
<td>1</td>
<td>-10.213</td>
</tr>
<tr>
<td>20827</td>
<td>0.5</td>
<td>-9.892</td>
</tr>
<tr>
<td>72293</td>
<td>0.25</td>
<td>-9.8611</td>
</tr>
</tbody>
</table>

**Table 5-1 Grid Independence Test**

Demonstrating that 1mm node distance produces an accurate model as shown by the similar results found in 0.5mm and 0.25mm node spacing.

The optimisation process was performed using a trial and error process and fitting the results to the empirical results found in Chapter 4. Results of the optimisation process are reported in Table 5-2.

\[
\begin{align*}
E & = 52000 \text{ MPa} \\
\sigma_s^{AS} & = 500 \text{ MPa} \\
\sigma_f^{AS} & = 1100 \text{ MPa} \\
\sigma_s^{SA} & = 232 \text{ MPa} \\
\sigma_f^{SA} & = 175 \text{ MPa}
\end{align*}
\]

**Table 5-2 Results of the Optimisation Process**

\[E = \text{Young’s Modulus}, \sigma = \text{stress}\]

Figure 5-3 shows a comparison between the finite element model designed and the measurements gathered empirically which demonstrates that good matching was achieved and thus indicating the model to be representative.
FIGURE 5-3 COMPARISON BETWEEN EXPERIMENTAL DATA AND OPTIMISED MODELLING

Orange: Experimental data. Blue: Numerical simulations performed using the material parameters in Table 3.2

5.4 DISCUSSION

Finite element modelling is a powerful tool which can model the behaviour of a product. It allows for improvements in efficiency by removing the need for testing of multiple iterations of a product and focussing on just those which demonstrate promise within the model. For the purposes of this thesis, a patient specific device will likely require a patient specific force to be generated. The force required for mandibular distraction remains unclear as discussed in Chapter 2 however, it will presumably vary according to age, local soft-tissue effects and the distance to be distracted. In the craniofacial skeleton one approach has been to have a range of springs available such that the clinician can judge on-table which spring is to be used. The demonstration of the principle of using a finite element model is therefore of importance to this work as it allows for initial simulated
testing of a spring for potential use prior to empirical confirmatory testing and therefore reducing overall requirement for empirical testing.

Grid independence analysis of the model was shown to be accurate with tetrahedral elements spaced at 1mm. Reducing the spacing showed increasing demand for processing without a significant increase in model accuracy.

The finite element model constructed here shows good correlation with empirical measurement. A limitation of this model includes the inability of the model to converge for displacement over 25mm, which restricted the possibility of replicating experimental results. However, the plateau was well depicted by the model hence it is reasonable to conclude that the model describes correctly the spring mechanics over this portion. The model is further limited as it does not account for spring behaviour in-vivo and the potential interactions of soft tissues, this would require empirical in-vivo studies which are without the remit of this work.
CHAPTER 6 DEVICE OPTIMISATION
6.1 **INTRODUCTION**

The aim of this project is to modify the shape of a deformed jaw to a prescribed shape through the use of mandibular distraction osteogenesis. There are a number of conditions that cause deformity of the jaw and for which mandibular distraction osteogenesis may be required. As discussed in Chapter 2, Craniofacial microsomia is known to cause a complex geometrical deformity of the mandible and thus represents a challenge to currently used devices, it is thus a good model for this thesis.

In order to demonstrate the potential of a device it is important to have an index case which provides a challenge for any potential distraction device to correct. Craniofacial microsomia provides a geometrical challenge to good surgical correction as the deformity provides a significant anatomical, architectural and geometrical challenge to the surgeon, outcomes can be variable and unpredictable as discussed in Chapter 2 and it is thus an excellent model for the purpose of this thesis. Each patient with this condition presents a unique deformity and unique surgical need. Pre-surgical planning is vital to successful and predictable operative outcomes. Surgical planning has benefitted greatly from advances in technology over the past decades as discussed in Chapter 1. In particular, the rapid progress in computer-aided design (CAD) has been of great help to the surgical team and the patient to understand complex bony and soft tissue movements before the patient enters the operating theatre, as demonstrated by the variety of software on the market. A patient specific approach is thus key and a process for a virtual surgical procedure will be discussed in detail to maximise surgical outcome. Surgical accuracy is key to the success of this procedure. The position and angle of the osteotomies and the placement of the device must be precise in order for the prescribed change to be affected. As the change in shape of the mandible following placement of the device is a function of the shape of the distractor arm it is crucial that the shape of the distractor arm is correct and that the distractor is accurately located in the patient. The process of prescribing the distractor arm shape and the design and manufacture of cutting guides will be described.
The technological background to a potential device was discussed in Chapter 3 which highlighted the advantages of the use of a nonlinear material, nitinol, to fulfil the desired criteria of a fully buried distractor. The decision for the use of a relatively constant force spring for this device rests on the hypothesis that a constant force is physiologically acceptable to the distraction of a callus and as covered in the basic science of Chapter 2 there is good reason to believe this to be true. Although the scope of this thesis does not include in-vivo experimentation, a suitable model will be produced and tested as proof of concept in this Chapter and success will be judged on the ability of the device to re-create the prescription of the virtual surgical procedure.

We have seen in Chapter 2 the evolution of devices for mandibular distraction moving from the earlier externally sited device to the now more commonly used semi-buried device. As technology improves our understanding of the geometry of the face so does our potential to prescribe bony movements to best correct deformity. So too must we also improve upon the currently available devices to reduce the burden and morbidity to our patients. Chapters 4 & 5 reviewed the potential for a nitinol helical spring and a spring for use in the device was identified and used to create a finite element model.

Building on the ideas found in Chapter 2, 3, 4 & 5, a prototype was envisioned which has the potential to make a step change in mandibular distraction osteogenesis by delivering a simple, fully buried, small, biocompatible, multivector, continuous distractor that requires no patient input and is robust enough to withstand the in-vivo environment.

By separating the actuator and shape giving parts of the device, a rod and spring design can simplify the construct whilst improving stability using a rod to provide a stable platform for distraction and the force of distraction given by the spring. The rod can be pre-formed to a prescribed patient specific shape Figure 6-1.
By de-coupling the actuator and shape guide the rod brings stability to the distraction device in accordance with Ilizarov’s founding principles, thereby providing a framework that is robust enough to withstand the in-vivo environment of the mandible. The prototype is small in size; can be fully buried and is potentially biocompatible depending on material selection; can distract in multiple planes simultaneously according to the shape of the rod; removes the need for patient involvement as it is fully buried, and thereby has the potential to fulfil many of the requirements of the ideal mandibular distractor. The prototype introduced will here be further developed.

6.2 DEVICE DESIGN AND MANUFACTURING

A Computer aided design programme (Rhinoceros 5.0, McNeel, Seattle, WA) was used to design a novel distractor. Multiple iterations were designed, rapid prototyped, inspected and assessed empirically by hand and then improved upon (some of which can be seen in Appendix 1) to attain a final design. The final design comprises a fixable portion, a movable portion, a distractor arm which defines a movement path of the movable portion relative to the fixable portion, and a nitinol spring provided between the fixable portion and the movable portion to, in use, move the movable portion relative to the fixable portion along the movement path defined by the distractor arm, Figure 6-2. The distractor arm can define a 3-dimensional movement path. The coil spring may then move the movable portion along
the movement path defined by the distractor arm from an initial position proximal to the fixable portion to a final position distal to the fixable portion.

Both the fixable and movable portions are designed with apertures to allow bone screws to allow them to be connected to bone. In the current design 6 screw holes were chosen to allow fixation though any combination could be used. The screw holes are sited in a lateral extension to the fixable and movable portions.

The distractor arm extends from the fixable portion through an aperture of the movable portion. The distractor arm and movable portion are provided with complementarily shaped formations configured to guide the movable portion along the path defined by the distractor arm. The complementarily shaped formations comprise projections of the movable portion and recesses of the other of the distractor arm.

The distractor arm is provided with a stop so as to limit the movement of the movable member on the distractor arm, this limit can be pre-programmed to be within the quasi-constant force region of the nitinol.

![Figure 6-2 Prototype Top View](image)

**Figure 6-2 Prototype Top View**

10: Mandibular Distractor, 12: Fixed Portion, 14: Moveable Portion, 16: Distractor Arm, 18: Spring
**Figure 6-3 Prototype Perspective View**

10: Mandibular Distractor, 12: Fixed Portion, 14: Moveable Portion, 16: Distractor Arm, 18: Spring

**Figure 6-4 Prototype Side View**

10: Mandibular Distractor, 12: Fixed Portion, 14: Moveable Portion, 16: Distractor Arm, 18: Spring
Referring to the accompanying Figures 6-2 to 6-5, the mandibular distractor is designated 10. The distractor 10 comprises a fixable portion 12 and a movable portion 14. The fixable portion 12 includes a distractor arm 16 which, in use, guides the movement of the movable portion 14 of the distractor 10 relative to the fixable portion 12 of the distractor 10. Disposed between the fixable portion 12 and movable portion 14 of the distractor 10 there is provided a spring 18. The fixable and movable portions 12, 14 and distractor arm 16 may be formed from metal, for example Titanium. The spring 18 is formed from nitinol.
**Figure 6-6 Prototype Engineering Design Top View**


**Figure 6-7 Prototype Engineering Design Side View**

FIGURE 6-8 PROTOTYPE ENGINEERING DESIGN END VIEW

FIGURE 6-9 PROTOTYPE ENGINEERING DESIGN CROSS SECTIONAL VIEW OF DISTRACTING ARM

16: Distractor Arm, 26: Distractor Arm Channels
The fixable portion 12 comprises a body 20 having a pair of lateral extensions 22, each of which extends from an opposite side of the body 20. Each extension 22 is provided with a number of holes for bone fixation 24, Figures 6-6 – 6-10. In the embodiment shown, each extension 22 is provided with three circular holes 24 aligned in a direction which is parallel to the axis of the distractor arm 16.

The distractor arm 16 comprises a rod having a generally circular cross-section, Figure 6-9. The distractor arm 16 extends initially from the body 22 of the fixable portion 12 in the same direction as the extensions 22.
Figure 6-11 shows the distractor arm 16 in the initial position where upon it is straight and extends along a single axis. As will be described below, before attachment to the mandible of a patient the distractor arm 16 requires realignment so as to define a travel path for the movable portion 14.

The distractor arm 16 is provided along its length with a pair of recesses or channels 26, Figure 6-9. The channels 26 are provided on opposing lateral sides of the distractor arm 16. In use, the channels 16 receive guide projections (described below) of the movable portion 14 of the distractor 10. The interaction of the guide projections with the channels 26 ensures that the movable portion 14 of the distractor 10 follows an intended path. The
interaction of the guide projections with the channels 26 further counteracts unwanted
torquing and/or rotational forces that may be experienced by the distractor after
attachment to the mandible of a patient.

The distractor arm 16 has a pair of through apertures 28,30, Figure 6-6. A first distal
aperture 28 is located at the end 31 of the distractor arm 16 which is distal to body 20. A
second proximal aperture 30 is provided substantially at the midway point of the distractor
arm 16 between the body and the end 32 of the distractor arm 16. In use, the apertures
28,30 may be utilised to define stopping points on the distractor arm for the movable
portion 14 of the distractor 10 to correspond to the area of quasi-constant force of the
nitinol spring.

Stopping of the movable portion 14 on the distractor arm 16 may be effected by, for
example, a formation of the movable portion 14 which is received in one of the apertures
28,30. In such an embodiment, the movable portion 14 may require manipulation to
release the formation from an aperture 28,30 and thus allow the movable portion 14 to
move along the distractor arm 16.

In an alternative embodiment, stopping of the movable portion 14 on the distractor
arm 16 may be effected by, for example, an insert or pin received in each aperture 28,30.
In this case, a pin may require removal from an aperture 28,30 so as to allow the movable
portion 14 to move along the distractor arm 16.

The position of the distal and proximal apertures 28,30 of the distractor arm 16
define, respectively, the final and initial positions of the movable portion 14 of the distractor
10 on the distractor arm 16.

The movable portion 14 comprises a body 32 having a pair of lateral extensions 34,
each of which extends from an opposite side of the body 32. Each extension 34 is provided
with a number of holes for fixation 36.
The apertures 36 are sized and shaped to receive a fastener, such as a threaded fastener or bone screw, so as to enable the movable portion 14 of the distractor 10 to be fixed to a location on the mandible of a patient.

The body 32 of the movable portion 14 is provided with a through bore 38 through which the distractor arm 16 passes, in use. The wall 40 of the through bore 38 is provided with two pairs of opposed projections 42,44 which define the aforementioned guide projections of the movable portion 14 as seen in Figures 6-12 – 6-15. As described above, the interaction of the guide projections 42,44 with the channels 26 ensures that the movable portion 14 of the distractor 10 follows an intended path as defined by the distractor arm 16. The interaction of the guide projections 42,44 with the channels 26 further counteracts unwanted torqueing and/or rotational forces that may be experienced by the distractor 10 after attachment to the mandible of a patient.

**Figure 6-12 Prototype Engineering Design Side View Movable Portion**

14: Moveable Portion, 32: Body of Moveable Portion, 34: Paired Extensions of Moveable Portion
**Figure 6-13 Prototype Engineering Design End View of Movable Portion**

**FIGURE 6-14 PROTOTYPE ENGINEERING DESIGN TOP VIEW MOVABLE PORTION**

14: Moveable Portion, 32: Body of Moveable Portion, 34: Paired Extensions of Moveable Portion, 36: Drill Hole of Moveable Portion Extension
The spring 18 is a coil spring that is located around the distractor arm 16 and is constrained axially between the fixed and movable portions 12,14 of the distractor 10. The spring 18 is formed from a shape-memory material such as a shape-memory alloy or polymer.

The described invention utilises a nitinol coil or helical spring 18 which reverts from a compressed state to an extended state. The nitinol spring 18 is martensitic below human body temperature to allow for easy manipulation and application during the surgical procedure but becomes austenitic when warmed to human body temperature. The hysteresis of the nitinol forming the spring 18 is required to be low (ideally within 10-15°C) for ease of working. The nitinol spring 18 delivers sufficient force which is relatively constant over a displacement that is compatible with mandibular DO.
It will be appreciated that, depending upon the surgical requirements of a particular patient, a differing quasi-constant force over a different range may be required. A spring can be thus produced by changing such features as the wire diameter, spring diameter, pitch, transition temperature and number of active turns to achieve the desired spring characteristics.

Referring to Figure 6-11 there is shown a mandibular distractor 10 according to the present invention in an initial extension condition (Top) and a final extension condition (Bottom). For the sake of describing the operation of the distractor 10, the distractor arm 16 is shown in its straight configuration and not in the curved condition necessary for a successful surgical outcome.

The initial extension condition of the distractor 10 corresponds to the condition of the distractor 10 prior to and during implantation. The spring 18 is in its deformed state, i.e. where its length is shortest. The spring 18 is positioned between the fixed and movable portions 12,14 of the distractor 10 and may exert minimal or no force on the portions 12,14. Additionally, the movable portion 14 may be stopped or retained in position on the distractor arm 16 by interaction with the proximal aperture 30 of the arm 16.

The final extension condition of the distractor 10 corresponds to the condition of the distractor 10 prior to removal of the device from a patient. The spring 18 is positioned between the fixed and movable portions 12,14 of the distractor 10 and may exert quasi-constant force on the portions 12,14. Additionally, the movable portion 14 may be stopped or retained in position on the distractor arm 16 by interaction with the distal aperture 28 of the arm 16.

6.3 INDEX PATIENT AND SHAPE ANALYSIS

A patient was chosen from the craniofacial database at Great Ormond Street Hospital for Children who presented with a significant asymmetry of the mandible, the geometry of which would be challenging to correct completely with standard distraction techniques.
The patient is a 14-year-old male diagnosed with craniofacial microsomia (CFM) with no previous surgical history.

A medical CT (SOMATOM, Siemens, Germany) was performed and demonstrated a Pruzansky class IIa mandibular deformity as shown in Figure 6-16. Reconstruction of the images was performed using the commercially available post-processing software Mimics (Materialise, Materialise Inc., Leuven, Belgium). Following data capture, Digital Imaging and Communications in Medicine (DICOM) files from CT were imported into Mimics. A Multi-Planar Reconstruction (MPR) is reviewed in 2 dimensions in coronal, axial and sagittal sections. Thresholding is performed by defining the Hounsfield range appropriate for bone and creating a segmentation mask. To remove unwanted structures and artefact a region-growing algorithm is used, manual editing functions were used to edit single pixels. The ramus is shortened, the condyle is present though of small size and there is a rotational deformity of the body of the mandible. The skull base and midface deformities are demonstrated in Figure 6-17 and show ipsilateral midface hypoplasia, loss of anatomical structure of the glenoid fossa and relative hypoplasia of the pterygoid process demonstrating involvement of the temporal and sphenoid bones.
6.4 Virtual Surgical Planning

In this case, simple mirroring of the contralateral side of the mandible would not provide a suitable surgical plan due to the asymmetry of the cranial base and the facial scoliosis which makes a facial midline in the sagittal plane difficult to define. Rhinoceros (Rhinoceros 5.0, McNeel, Seattle, WA) was used to carry out the virtual procedure using the previously described postprocessed CT data. A single osteotomy was made, this was chosen as this is the standard approach used clinically and it is important that the device reflects
continuity with clinical practice. The proximal and distal fragments were then manipulated to correct rotational and length discrepancies, whilst ensuring the TMJ/Glenoid relation was maintained, to achieve the optimum outcome as judged empirically as shown in Figure 6-18.

**Figure 6-18 3DCT Reconstruction of Patient’s Mandible**

*Demonstrating deformity before (Left) and after (Right) virtual surgery with single osteotomy*

### 6.5 Shape of the Distractor Arm & Cutting Guides

In order to effect change in 3 dimensions it is important that the distractor arm is shaped according to the pre-prescribed geometry. The virtual operation thus dictates the prescription for the distractor arm shape. Rhino 3D (Rhinoceros, McNeel, Seattle, WA, USA) was used to design the shape of the distractor arm using the properties of the distractor arm as discussed in the device design above. The distractor arm shape is designed by taking
a smooth path from the start-point to the endpoint. A smooth path is a requirement in order to prevent obstruction of the spring as it opens, and this path can be found using a thin-plate-spline command in the CAD software. Thin-plate-spline is a technique for data smoothing which gives an interpolation function that passes through set points whilst minimising ‘bending energy’. The name comes from the technique used by draughtsmen when drawing curves, a physical analogy to better understand this concept would be bending a sheet of metal which is constrained by set points, Figure 6-19.

The yaw and roll of the path are guided by the path of the rail along the distractor arm whilst the pitch is guided by the path of the distractor arm itself, Figure 6-20.
FIGURE 6-20 SIDE AND FRONT VIEWS OF THE MANDIBLE WITH PROTOTYPE DEVICE

Single Osteotomy Surgical Plan Front View (Top Left) and Side View (Bottom Left). With Prototype in Front View (Top Right) and Side View (Bottom Right)
**Figure 6-21 Side and Front Views of Mandible with Prototype**

**Side view (Left) and Front view (Right) showing distractor in initial extension condition.**


**Figure 6-22 Side and Front Views of Mandible with Prototype**

**Side view (Left) and Front view (Right) showing distractor in final extension condition.**

Figure 6-21 and Figure 6-22 again show the distractor in its initial and final extension conditions while located on a mandible. The distractor is located to the mandible on opposing sides of mandibular osteotomy. The distractor arm is shaped so as to define a desired movement path for the portion of the mandible connected to the movable portion of the distractor. The distance over which the portion of the mandible connected to the movable portion is moved by the spring is defined by the position of the stops on the distractor arm.

Cutting guides were designed using Rhino 3D and rapid prototyped using 3D printing. The cutting guide is a negative of the mandible and can be sited easily into the correct position and includes indications for the location of the osteotomy and siting holes for the location of the bone plates. This allows for confident placement of the device. The guides were designed using Rhino 3D (Rhinoceros, McNeel, Seattle, WA, USA) and are shown in Figure 6-23.

![Figure 6-23 Cutting Guides](image)

**Figure 6-23 Cutting Guides**

*Designed in Rhino 3D with mandible (Left) and showing negative impression of mandible to allow accurate locating (Right)*

### 6.6 Proof of Concept Study

The scope of this thesis does not include in-vivo experimentation however, through the use of rapid prototyping a suitable model can be produced and tested as proof of
The ability of the device to re-create the prescription of the virtual surgical procedure will define its success.

Assessment of change in shape can be carried out in a variety of ways. Robins 3D is a software that provides a set of tools for examining 3D volumetric data. A stereolithographic (STL) file format gathers data on surface geometry of a three-dimensional object. In order to compare differences in surface geometry, STL files for comparison are loaded into the software and the function ‘Differences of Surfaces’ is used. This function shows a map of the shortest distance from each point on one surface to a homologous point on another surface and displays this as a colour map. Where surfaces are congruent, they will appear uniformly blue, where they differ in geometry the colour will change with larger differences becoming more different in colour according to a registered scale. This is a useful technique that allows for a rapid and intuitive understanding of shape difference. For accurate comparison, the two objects must be correctly registered to ensure they are in the same position and this is performed by landmarking the two STL objects. Landmarking maps a specific point on one surface to a homologous point on another, for example the medial canthus. When multiple points are appropriately landmarked, the surfaces can be said to be correctly registered and the difference of surfaces can be assessed.

A study was carried out to review to what extent the novel device recreates the prescribed geometrical change following a virtual surgical procedure.

6.6.1 METHODS

The postprocessed data of the deformed mandible was used to reconstruct the three-dimensional bony surface (Mimics, Materialise, Belgium) and an STL file was then generated, STL files were also generated of the cutting guides described in above. Rapid prototyping with a 3D printer (Makerbot, Makerbot Industries, Brooklyn, NY, USA) was then performed to produce a model of the deformed jaw and cutting guides. Using the cutting guides, the ‘osteotomy’ was made in the printed jaw using a fine saw blade and drill holes for fixation of the device sited.
The device prototype as described in above was printed in Titanium by Direct laser metal sintering (3D Systems Ltd, High Wycombe, UK). A body temperature nitinol spring of wire diameter 1.25mm, pitch of 5mm, length of 51mm and total number of coils of 12, as described in Chapters 4 & 5, was then placed in the device and steel wire was used to constrict its activation start-point and end-point as described in the design specifics above. The device was then fixed to the model using 5mm screws inserted through the pre-made screw holes. The device was then activated by removing the constricting wire and the geometry of the final construct was evaluated by cone beam computed tomography (CBCT) scan (PaX-Zenith 3D, Valtech). The resulting DICOM data was postprocessed (Mimics, Materialise, Belgium) in the manner described above to reconstruct the surface. An STL was then created and the shape of the novel construct was compared to the pre-designed ‘virtual operation’ by means of a colour difference map (Robins 3D) created by landmarking the unmodified portion of the construct to the corresponding portion of the ‘virtual operation’ prescribed shape.

6.6.2 RESULTS

The final construct can be seen in Figure 6-24 with the device fitted to the ‘osteotomised’ 3D print. The colour difference map in Figure 6-25 demonstrates the prescribed shape was successfully replicated.
The colour difference chart shows the two scans to be well registered as demonstrated by the uniform blue of the unaffected portion of the mandible. Empirical assessment of the distracted portion shows good correlation with the prescribed position in the medial/lateral dimension as evidenced by the blue colouring inferior to the coronoid notch to the osteotomy. The anterior/posterior position is reasonably correlated though shows some anterior displacement relative to the prescribed position.
6.7 **Discussion**

An iterative design process was employed using rapid prototyping to refine the initial sketch of the device described in Chapter 2. Fixed and movable plates were added with six screw holes for each with bevelled edge to permit standard screws. The distractor arm is novel such that it has guiding rails along which the movable part can run, guided by the projections housed within the body of the movable part. Through the distracting arm two apertures dictate the prescribed start and end points corresponding to that distance at which the spring has a plateau and acts with relatively constant force. Either wires, screws or small rods could be placed through these apertures to contain expansion. With regards to the proximal aperture this obstruction could be removed to allow for a period of latency if required, and with regards to the distal aperture, this ensures that expansion is maintained within the plateau region of relative constant force. The shape of the distracting arm can be linear, curvilinear or multiplanar as required. The roll of the movable part is modified by the angle of the guide rail to the distracting arm whereas the pitch and yaw of the movable part is dictated by the shape of the distracting arm. A smooth path must be traversed from the prescribed start point to the prescribed end point so as not to obstruct the path of the movable plate and this is estimated using the computer aided design software. Accurate cutting guides are key to the success of this technique and small variations in accuracy can lead to large discrepancies between the prescribed endpoint and actual endpoint. The proof of concept was demonstrated with a virtual operation, which demonstrated a good correlation of outcome to prescribed position.

Weaknesses of this study include an incompletely corrected mandible. Increasing the number of osteotomies could improve upon this by, for example, allowing the rotational deformity in the dentoalveolar segment to be corrected. However, this would increase the surgical complexity and potentially the morbidity of the procedure. In addition, whilst the correlation between prescribed position and experimental position was good, it was not perfect, this could potentially be improved upon with more accurate cutting guides though
is a limitation of this process. The lack of in-vivo study in this thesis is a further weakness and these studies will be important in order to demonstrate safety and efficacy should this approach be considered in a human model.
CHAPTER 7 CONCLUSIONS AND FUTURE WORK
7.1 OVERVIEW

The aim of this thesis was to develop a novel mandibular distraction device which satisfies the following criteria:

- *small in size, fully-buried and biocompatible*
- *programmable to distract to a patient specific shape*
- *distract continuously without the need for patient involvement*
- *provide sufficient force generation*
- *robust enough to withstand the in-vivo environment*

These criteria are key in order to provide a patient specific approach to the management of complex craniofacial deformity in a clinically acceptable format which minimises complications and patient anxiety. In this context, the presented research combined clinically acquired image datasets with empirical data, computational modelling and rapid prototyping to develop a workable device that aims to fulfil the above criteria.

Chapter 2 sets out the clinical background to this thesis giving an outline of craniofacial microsomia and reviewing currently available techniques and devices used for distraction osteogenesis and provides an understanding of requisite forces. The limitations of devices in clinical use were discussed and no device was found which fulfils the desired criteria outlined above. The potential advantages of experimental devices including continuous distraction with springs was reviewed. Initial research focussed on understanding the current clinical use of springs, I retrospectively reviewed 100 cases of spring assisted cranioplasty, describing the surgical technique and adding to the body of literature that has demonstrated that the use of springs for calvarial distraction osteogenesis is physiologically acceptable and provides acceptable results.

Chapter 3 provides a technical background to this thesis describing the stress-strain pattern of currently used spring materials and highlighting the potential drawback of using materials with Hookean properties for mandibular distraction osteogenesis due to the rapid
dissipation of force. The advantages of the non-linear properties of nitinol were discussed, in particular the stress-strain curves, which demonstrate a plateau effect, were highlighted and this effect was found to be true in a nitinol helical spring in both compression and tension.

In Chapter 4, the nitinol helical spring was further developed, and tensile testing was performed to select the most appropriate pitch, mandrel size, wire diameter and number of coils to deliver relevant force for mandibular distraction in adults. Multiple springs were tested and an ideal spring for mandibular distraction with an appropriate plateau phase was selected.

In Chapter 5, a finite element model was developed. The model used CAD software to design the spring shape and was optimised using empirical data such that the design of a spring with predictable force generating characteristics could be simulated for any case.

In Chapter 6, an iterative design process was undertaken to develop the rod and spring prototype. Computer aided design software in combination with rapid prototyping was used to refine the design following manual inspection. A clinical case of craniofacial microsomia was identified to use as a foundation for prototyping the potential device. Rapid prototyping was used to generate 3D models of the craniofacial skeleton and virtual surgical planning was used to develop a desired end point. The shape of the distracting arm was reviewed and cutting guides constructed. Lastly, a proof of concept study was carried out by performing a virtual operation on a model and assessing with a colour difference map which demonstrated an acceptable outcome.

7.2 Future Works

The work in this thesis has focussed on the construction of a workable prototype. I believe that the prototype holds real promise for improving the outcomes and patient experience for those who require mandibular distraction osteogenesis. At this stage
however, the device is not suitable for use in clinical practice and several hurdles remain to be overcome.

7.2.1 **PROCESS AUTOMATION**

For patient-specific medicine and surgery to be able to affect the improvements it promises it is vital that the transition from patient specific modelling to clinical practice be seamless. To achieve this with regards to this device, automated tools must be developed that remove the need for the multiple manual tasks outlined in this thesis from the post-processing of imaging data to the design and generation of a suitable model. Workflows are already in place in many maxillofacial departments whereby much of the manual work is outsourced to third parties and teleconferencing allows for the surgeon and technician to decide together on the surgical plan, this could be a potential avenue available to manage this workflow.

7.2.2 **ANIMAL MODEL**

This device, although building on currently available distraction devices, represents a new category of distractor as a fully buried unit. In order to justify the use of this device in humans it may therefore be necessary for an animal model to be demonstrated to be viable. The literature available, as discussed in Chapter 2, suggests that a continuous, fully buried distractor of this design will be likely to generate positive results and a minipig would be an appropriate model in which to demonstrate this, given the comparative forces and anatomy to humans. In addition, an animal model would give an appreciation of the benefits or otherwise of a latency period however, as discussed in Chapter 2 a latency period may not be required.

7.2.3 **SINGLE PLANE DISTRACTER**

There are two elements to this thesis, firstly the development of a fully buried continuous distractor and secondly the development of a programmable shape for correcting a defect in 3 planes. The majority of distractors used worldwide are single plane distractors and, if this novel device is to be used widely in practice, it is important for the
single plane distractor to be demonstrated to be effective. An animal model should therefore include the demonstration of the single plane distractor.

7.2.4 Defining the Ideal Nitinol Spring

There remains incomplete literature with regards to the standard forces required for distraction osteogenesis in the human mandible across age groups. There are many potential variables that could modify the ideal force for each patient however, the work performed on springs in cranioplasty is important to note here. Firstly, because history suggests that the surgeons experience can be relied upon to gauge an appropriate force – springs were used prior to their biomechanics being fully understood empirically. Secondly, the approach of creating several standardised devices that have a set plateau force would seem to be a practical solution. Further work should include the testing of multiple nitinol helical springs with variations of wire thickness, mandrel size, pitch and number of coils. This work was limited in this thesis due to cost considerations related to the bespoke nature of the springs.

7.3 Conclusion

In many ways, the rod and spring prototype represents a natural progression from currently used distraction devices having a fixed and a movable portion connected by a distracting arm. It is novel insofar that it allows for the device to be fully buried by incorporating the actuator within the device in the form of a spring and by allowing complex movements as the movable portion follows the rail of the distracting arm. The hypothesis behind this design is that a constant force continuous distractor is physiologically acceptable to allow for mandibular distraction osteogenesis, this is backed up by the available literature as discussed in Chapter 2. The refined device is the culmination of an iterative design process which was key to identifying issues that are not readily noticeable without the advantage of manual inspection following rapid prototyping. For example, it will be noted that both the fixed and movable plates have the same orientation. This is key to keep the total size of device to a minimum whilst allowing for the length of the
compressed spring to be contained. The completed prototype was demonstrated to regain the desired shape to a reasonable accuracy however, I believe this can readily be improved upon through the use of better cutting guides which have a better fit to the model. The addition of proximal and distal apertures on the distracting arm allow for the device to be constrained to only that portion corresponding to the plateau phase of the spring. It is therefore possible for a latency period to be incorporated, should this be desired, by obstructing the spring until the desired period when the obstruction can be removed thus allowing distraction to proceed until it reaches the prescribed distal obstruction. As highlighted in Chapter 2 however, it is possible that a latency period is not as key to distraction in the craniofacial skeleton as it is in the long bones and therefore may not be necessary though further research will be required to demonstrate this.

The proposed device fulfils many of the desired criteria for the ideal distractor. It is small in size compared with currently used devices and, as it is fully buried, is considerably less bulky, removes the need for an additional wound for the actuator, there is a reduced number of moving parts and it has the potential to reduce the risk of infection. The device is able to be used to distract in a straight line or through 3 dimensions thus allowing for the correction of complex geometrical deformity which allows for a patient-specific prescription to be made. Distraction in current clinical practice is often variable due to the difficulty in accurately judging hard tissue advancement when soft tissues are swollen. Due to the pre-determined start and end points of distraction in this device, the variability of distraction should be reduced. The endpoint could also incorporate a degree of over-distraction if required to allow for relapse. Current devices used in practice are discontinuous in nature, this device offers a continuous distraction. As discussed in Chapter 2 there is a convincing argument for the use of continuous distractors as they allow for swifter rates of distraction requiring a reduced maximal force whilst producing good bone quality.

By including the actuator within the fully-buried device the need for patient intervention is removed. This both improves the patient experience with their treatment
and removes the potential for incorrect distraction due to difficulty assessing bony distraction by eye in the peri-operative period.

The device holds potential and warrants further research to develop it to such a point that it can be used in clinical practice, Figure 7-1.

**Figure 7-1 Development of a Fully Buried Mandibular Distraction Device**

*Left: Pre-operative, Centre: At the end of distraction, Right: Final outcome*
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