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DESIGN OF A NEW INTRAORAL MANDIBULAR DISTRACTOR DELIVERING CONTINUOUS FORCE OVER 24 HOURS

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BDS (London)

A thesis submitted in partial fulfillment of the requirements for the degree of Master of Dental Science (Orthodontics)

Discipline of Orthodontics
Faculty of Dentistry
University of Sydney
Australia
2001
DEDICATION

To my husband Arash, for his love, encouragement and enthusiasm, which have continually inspired me during my Masters Programme.

To all my family, in appreciation of their endless love and support throughout my life.
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DECLARATION OF AUTHORSHIP

This is to certify that the work presented in this thesis was carried out by the candidate in the Discipline of Orthodontics, Faculty of Dentistry, University of Sydney, and has not been submitted to any other university or institution for a higher degree. I agree that the library shall make it freely available for inspection.
### ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>A-P</td>
<td>Sagittal Plane</td>
</tr>
<tr>
<td>⁰C</td>
<td>Celsius</td>
</tr>
<tr>
<td>2D</td>
<td>Two Dimensional</td>
</tr>
<tr>
<td>3D</td>
<td>Three Dimensional</td>
</tr>
<tr>
<td>ASO</td>
<td>Australian Society of Orthodontics</td>
</tr>
<tr>
<td>cm</td>
<td>Centimeter</td>
</tr>
<tr>
<td>CT</td>
<td>Computerized Tomography</td>
</tr>
<tr>
<td>DCI</td>
<td>Distraction Consolidation Index</td>
</tr>
<tr>
<td>FIZ</td>
<td>Fibrous Interzone</td>
</tr>
<tr>
<td>H &amp; E</td>
<td>Hematoxylin and Eosin</td>
</tr>
<tr>
<td>IAN</td>
<td>Inferior Alveolar Nerve</td>
</tr>
<tr>
<td>IGF-1</td>
<td>Insulin – like Growth Factor 1</td>
</tr>
<tr>
<td>KPa</td>
<td>Kilopascals</td>
</tr>
<tr>
<td>LHS</td>
<td>Left Hand Side</td>
</tr>
<tr>
<td>mm</td>
<td>Millimeter</td>
</tr>
<tr>
<td>Mpa</td>
<td>Megapascal</td>
</tr>
<tr>
<td>Mpa s</td>
<td>Megapascal / Second</td>
</tr>
<tr>
<td>N</td>
<td>Newton</td>
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<tr>
<td>Pa s</td>
<td>Pascal / Second</td>
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<tr>
<td>Pa</td>
<td>Pascal</td>
</tr>
<tr>
<td>PCNA</td>
<td>Proliferating Cell Nuclear Antigen</td>
</tr>
<tr>
<td>PIT</td>
<td>Pin – in – tube</td>
</tr>
<tr>
<td>PMF</td>
<td>Primary Mineralization Front</td>
</tr>
<tr>
<td>QTS</td>
<td>Quantitative technetium scintigraphy</td>
</tr>
<tr>
<td>RHS</td>
<td>Right Hand Side</td>
</tr>
<tr>
<td>ROD</td>
<td>Razdolsky Oral Distractor</td>
</tr>
<tr>
<td>TMD</td>
<td>Transmandibular Distractor</td>
</tr>
<tr>
<td>TMJ</td>
<td>Temporomandibular Mandibular Joint</td>
</tr>
<tr>
<td>Tvse</td>
<td>Transverse Plane</td>
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**ABSTRACT**

Distraction Osteogenesis is a biological process utilized within the field of craniofacial surgery to lengthen bone and its surrounding soft tissue. The literature describes certain principles and procedures associated with this technique, which if followed optimize the success of this procedure. Consequently research has expanded into developing distraction devices, which incorporate mechanisms that enable distraction to proceed at a desired rate and frequency, and is readily accepted by the patient.

The aim of this study was to design and engineer an intraoral mandibular distracting device, which produces continuous distraction at a rate of 1mm per 24 hours and to assess its effectiveness in, in-vitro studies.

The device consisted of a piston, housed within a cylindrical case, loaded by a spring to 70N +/- 5N. The action of the piston was regulated by the incorporation of a high viscosity material within the cylindrical case. Unilateral and bilateral distraction procedures were assessed, with the new intraoral distractor on an acrylic model of a sheep’s mandible, which was kept in a water bath at a temperature of 37°C for seven days.

The study found that the new intraoral mandibular device, distracted continuously in the sagittal plane, when the distractors were orientated parallel to the axis of distraction, loaded to 70N. An average daily distraction of 0.87mm was achieved over a seven day period. However, a consistent daily distraction could not be obtained, possibly due to the non-linear nature of the internal and external resistant forces.

Further studies should focus on reducing the size of the distractor for in-vivo use and the production of a more reliable optimal (1mm / day) daily distraction rate.
1. INTRODUCTION

Distraction Osteogenesis (also known as callostatic – stretching of the bony callus, as in a fracture) is a biological process generating new bone formation between the surfaces of bone segments that are gradually separated by incremental traction (Samchukov et al., 1998). Bony reconstruction in the lengthened segment is provided by the osteogenic capability of the periosteum and the endosteal mesenchyma (Aldegheri et al., 1989).

Distraction Osteogenesis is a unique biological process as both the bone and the associated surrounding soft tissues increase in volume. Clinically this is advantageous over conventional surgery techniques on two accounts, first it appears to minimize skeletal relapse and secondly it eliminates the need for bone grafting (Grayson, 1999).

The technique of distraction osteogenesis has been employed in the specialty of orthopedics since 1905 (Codivilla), but recognition and worldwide acknowledgement for the discovery of distraction osteogenesis was bestowed on Gavriel Ilizarov, a Russian surgeon in the 1950’s (Ilizarov GA, et al., 1992). Ilizarov researched the biology of limb lengthening extensively; his work enabled him to establish some basic principals, which facilitated successful osteogenesis.

After documented success of distraction osteogenesis within long bones, the specialty of craniofacial surgery embraced this technique to gain increased bone and soft tissue mass in patients with craniofacial deformities (Razdolsky et al., 1998).
2. **HISTORY**

In 1905, Codivilla first described a method of lengthening both bone and soft tissue by gradual traction. The procedure involved the intermittent application of a 25-75 kg force to an osteotomized femur bone thorough a large nail inserted thorough the heel bone. A lengthening of 3 to 8 cm was documented for 22 cases. Abbott (1927) modified this technique, by designing a device that applied direct traction and stabilized the osteotomized bone segments. Abbott was the first to demonstrate lengthening of the tibia.

These early distraction osteogenesis techniques were often associated with a high level of morbidity, complications included; local oedema, skin necrosis, pin tract infection, and unpredictable ossification of the expanded zones (Davies et al., 1998).

In 1951 Gavriel Ilizarov, a Russian orthopedic surgeon accidentally stumbled across the lengthening of a limb by distraction while treating patients with fractures and nonunions in Siberia following World War II. Ilizarov was utilizing a primitive ring fixator to treat a non-union fracture by external compression, when he found that a patient had accidentally turned the screw for distraction rather than compression. Radiographs from this case revealed the formation of new bone at the fracture site.

Investigation into the biology of limb lengthening led Ilizarov to publish some basic principles, which if adhered to, decreased the incidence of complications with this technique (Ilizarov, 1988, 1989a, b).

The literature, which Ilizarov published, provided the foundations for other researchers to embark on both animal and human studies to ascertain if the process of distraction osteogenesis could be successfully applied to 'the craniofacial complex'.

Snyder *et al.*, (1973) were the first to report on the application of distraction osteogenesis in the craniofacial skeleton. In the initial study, a canine mandible was
surgically reduced by 1.5 cm unilaterally and then allowed to heal to produce a crossbite. Ten weeks later the crossbite was corrected by lengthening the mandible by distraction osteogenesis using a Swanson external fixators (Snyder et al., 1973).

Michieli and Miotti in 1977 repeated Snyder’s work utilizing an intra-oral device to distract the mandible in a canine model. The study was designed to lengthen the mandibular body of two dogs by an experimental orthodontic appliance after a bilateral reverse-step osteotomy. Post operative microscopic examination of the lengthened site, revealed active formation of new cortical and cancellous bone tissue. Polarized light, found evidence of directional changes within the interlacing collagenous fibres. Observation of the new bone tissue revealed that it eventually changed into lamellar organized bone. On the basis of the results, it was proposed that this technique using an intra-oral device attached to the dentition could be used for the correction of cases with excessive mandibular retrusion due to decreased mandibular length.

Further research continued on the application of intra-oral devices with distraction osteogenesis and in 1984 Kutsevliak and Sukachev documented lengthening of a canines’ mandible by 1.2 cm with an intra-oral device based on Ilizarov’s distraction principles.

McCarthy and his team of researchers in 1992 were the first to report on four clinical cases following distraction osteogenesis utilizing an extra-oral device. Mandibular lengthening with a range of 18 to 24 mm was documented. This paper is historical, as it was the first publication providing evidence that mandibular distraction could be successfully performed on a human, without significant risks of infections or complications.

This historical review identifies the pioneers associated with the adaptation of distraction osteogenesis from orthopedics to the craniofacial complex.
3. **THE PROCEDURE AND PRINCIPLES OF DISTRACTION OSTEOGENESIS**

In 1989 Ilizarov introduced his own technique for limb lengthening (Ilizarov 1989a, 1989b, 1990). The procedure involved performing a corticotomy for the surgical division of the bone. Initially the bony cortex was divided into two thirds with a narrow osteotome, with bony separation completed by a rotational osteoclasis (osteoclasis - therapeutic surgical fracture of a bone). The Ilizarov distraction protocol consisted of a latency period of five to seven days, after which the bone segments were gradually separated at a rate of 1mm per day in four increments of 0.25mm. Once the distraction phase had been completed, the consolidation period commenced and continued until newly formed bony tissue in the distraction gap had remodeled.

Ilizarov explored the factors, which influence the quality and quantity of the bone produced during limb elongation. He found that the quality of osteogenesis is dependent on; the stability of the external fixation, the daily frequency and rate of distraction, the degree of preservation of the periosteal and marrow tissues and the nutrient blood vessels at the level of the osteotomy and an adequate consolidation period. (Ilizarov 1952, 1969, 1989a, b.).

3.1. **The Corticotony**

A corticotomy is a low-energy cortical osteotomy with transection of only the bone cortex. The periosteum, the endosteum, the bone marrow with its blood supply, as well as the muscles and soft tissues surrounding the bone are maximally preserved. (Schwartzman *et al.*, 1992).

Ilizarov’s research (1984) illustrates improved quality of the bone regenerate in the shortest period of time, if the blood supply to the bone is preserved during the osteotomy. The success of the regenerative process is dependent on the amount of
injury sustained by the bone, and the damage extended to the periosteum, endosteum and the surrounding soft tissues, blood vessels, muscles and fascia. Preservation of the endosteal blood supply and the periosteal sleeve, which acts as a guide for new bone formation, is important for the reparative process of the bone (Ilizarov 1984).

The reparative process in bone is most pronounced when a fracture is undisplaced, these fractures are low-energy injuries in which the periosteum, endosteum and bone marrow are all preserved. Ilizarov, attempting to maintain these osteogenic bone elements performed numerous different shaped osteotomies. He later successfully produced a methodology to create subperiosteal nondisplaced fractures by controlled osteoclasis. In controlled osteoclasis, the fracture occurs within the periosteal sleeve, causing minimal damage to the structures responsible for osteogenesis (Schwartzman et al., 1992).

In 1990, Ilizarov studied the effects of three types of osteotomies on the preservation of bone marrow and osseous blood supply on osteogenesis. The osteotomies were performed on canine tibia, which were stabilized with a four ring fixator configuration. The first procedure consisted of an open transverse osteotomy with transection of the bone marrow and nutrient vessels. The second procedure involved an open transverse osteotomy with transection of only one third of the bone marrow. The third technique was a closed osteoclasis, which used the apparatus and a curved wire to crack the bone without damaging the marrow. After a latent period of 5 day’s distraction commenced at a rate of 0.5mm day. The results showed that the closed osteoclasis procedure, preserved more bone marrow and the quality of the bone formation within the distraction gap was more superior to that produced with the other techniques.

The transverse or oblique corticotomy is the most commonly performed, it is used to lengthen a bone, correct an angular or rotational deformity, or eliminate a bony defect by transporting a bone segment. The longitudinal corticotomy is used to widen a bone to overcome a large bone defect in one or two bones; it is used when either strength or
shape needs to be improved in an atrophic limb. A splinter corticotomy is the technique used to bridge a non-union site or eliminate a partial bone or skin defect. The splinter is produced by fracturing off small pieces of bone with attached periosteum, soft tissue and skin. (Schwartzman et al., 1992).

Other important considerations for the success of the distraction procedure are the surface area of the corticotomy and its location. It has shown that the local regenerative process is more pronounced as the surface area of the corticotomy increases (Schwartzmann et al., 1992). The optimal location for the corticotomy has been demonstrated within the metaphyseal area; here the bone is wide and mainly cancellous in origin providing a wide cross-sectional area in comparison to the diaphysis. This area also has a nutrient artery, which has already branched making it easy to preserve the blood supply (Schwartzmann et al., 1992).

In 1994 Frierson and his coworkers compared three different methods of bone division for distraction osteogenesis and looked at their effects on the regenerative bone produced. The three methods included: (I) a corticotomy, (II) an osteotomy with multiple drill holes and (III) an osteotomy with an osteotome and an oscillating saw. This study found no differences histologically, radiographically, or clinically between techniques I & II. The vascular perfusion studies also showed equal amounts of vessels across the distraction sites for these two groups. The oscillating saw group (III) showed distinct differences, with increased numbers of delayed consolidations and a decreased amount of vessel bridging when compared with the other two groups. In conclusion, they found successful bone lengthening occurred irrespective of whether the medullary canal was completely transected as in the simply performed osteotomy or whether it was preserved in the technically more difficult corticotomy. However the use of an oscillating saw in distraction osteogenesis was discouraged because of the increased number of observed delayed consolidations.

Complications associated with the corticotomy technique include; incorrect technique
and displacement of the bone. The procedure should maximally preserve the vascularity of the bone and surrounding soft tissues, to provide the optimal conditions for the bone to regenerate to form. Incomplete corticotomy due to poor technique is also problematic as it leads to premature consolidation. This may be suspected when the initial distraction gap is asymmetric or disproportionately small in relation to the time of distraction (Schwartsmann et al., 1992).

Displacement after corticotomy is another dilemma that usually arises from incorrect placement of the fixators. This produces asymmetrical forces on the bone, which in turn causes displacement of the bone fragments, inducing poor bone regeneration with the possibility of non-union (Schwartsmann et al., 1992).

3.2. The Types of Distraction

There are three main types of distraction (Dr M Chin ASO Melbourne1999), these are:

Unifocal (or Monofocal)

![Diagram of Unifocal Distraction]

The two fragments of bone are distracted away from one another so there is only one area of new bone formation. (i.e. for small bony defects)

Bifocal

![Diagram of Bifocal Distraction]

Bone deposition is occurring in the gap (A) behind the advancing bone disc (1) as well as between the disc segment and the other bone segment (B). (i.e. for a large bony defect)
Bone deposition occurs at sites (A), (B), and (C), so discs (1) and (2) advance towards one another. {This type of distraction bridges a severe defect in the middle}

3.3. The Latency Period

Latency period is defined as the time elapsed from the corticotomy to the onset of distraction (Schwartsmann et al., 1992).

In 1974 Shtin and Nikitenko determined the optimal latency period after an osteotomy to be 7-10 days. Their study observed the effect of a latent period of 1, 3, 5, 7-10 and 14 days post-osteotomy. If distraction commenced on the first day after the osteotomy, the gap became completely filled with young connective tissue and bone trabecular layers of 1.5-2mm in height were formed in limited regions at the ends of the osteotomized fragments. When the distraction commenced three days post-osteotomy, the distraction gap was filled mainly with connective tissues and a bone trabecular layer height of 4mm was documented. Five days post-osteotomy, osteogenesis was more pronounced and the height of the newly formed bone was 5-6mm. Seven to ten days post-osteotomy a bone regenerate height of 8-9mm was observed, with new bone filling almost the entire gap between the osteomized fragments, leaving only a very thin layer of collagenous fibres in the middle of the regenerate bone. Fourteen days post-osteotomy after the commencement of distraction, Shtin and Nikitenko discovered that the bone regenerate at each of the osteotomized fragments was no greater than 7mm in height, with an irregular and wide shaped intermediate zone. It was also noticed that if distraction was not commenced within fourteen days post-osteotomy, the narrow osteotomy gap was almost entirely filled with bony trabeculae and in some areas a
primary bone union had formed. If the onset of distraction commenced once primary union had occurred the outcome was usually deleterious with disruption of the union, haemorrhage and retardation of the osteogenic process.

Ilizarov (1989a) as part of his distraction protocol (associated with limb lengthening) advised a latency of 5 days, enabling healing and re-establishment of the soft tissues, periosteum and marrow across the distraction gap. The literature reveals a large variation on the recommended magnitude of the latency period for limb lengthening with a range extending from 36 hours (de Pablos et al., 1986), to 10-15 days (Debastiani et al., 1987) and to 15 days (Aldergheri et al., 1989). It has been advocated that the surgeon should determine the length of the latency period based on, the type of bone chosen for distraction, the site of the osteotomy, the degree of soft tissue trauma and the age of the patient (White and Kenwright, 1991).

The length of latency period associated with the craniofacial complex is also controversial within the literature, it appears that most researchers within the field of mandibular distraction adhere to a latency period from 4 to 14 days (Perrot et al., 1993, Klein and Howalt, 1995; Rachmiel et al., 1995, Molina and Monasterio, 1995, Takato et al., 1993; Havlik and Barlett, 1994).

Aronson and Shen in 1994 compared latency periods of 0, 7, 14 and 21 days in both metaphyseal and diaphyseal sites in adult canine tibias. It was observed that the most reliable bone production occurred after a 0-day latency in both sites, contrary to other findings (White and Kenwright, 1991), indicating that a latency period may not be necessary.

In 1988, Tavakoli and his coworkers observed the effects of distraction on Wethers sheep after a latency period of 0, 4 and 7 days. The results indicated that there were no significant differences between the different groups. Tavakoli et al., (1988) concluded that a change in latency does not alter the properties of the regenerative bone in mandibular distraction osteogenesis and an elimination of the latent interval may be
possible with craniofacial distraction.

In agreement with Tavakoli et al., 1988 and Aronson et al., 1990, Troulis and coworkers (2000) confirmed that a 0-day latency produced an equivalent clinical healing, stability and radiographic density to a 4-day latency after performing mandibular distraction on Yucatan minipigs.

3.4. The Distraction Rate and Frequency

In 1989, Ilizarov designed a study to determine how the rate and frequency of distraction affect bone and soft tissue formation. Canine tibias were distracted at rates of 0.5mm, 1.0mm or 2.0mm per day with frequencies of 1, 4 and 60 steps per day. When the daily distraction rate was 0.5mm in 4 steps, Ilizarov found premature consolidation of the bone and concluded that osteogenesis was occurring at a faster speed than distraction. Retarded osteogenesis was observed with a rapid distraction rate of 2mm in 4 steps per day, this appeared to cause detrimental changes in the soft tissues surrounding the distraction site. Distraction of 1mm per day in 4 steps resulted in more favourable results than either a slower or faster rate. The study also found that a distraction rate of 1mm in 60 steps was more beneficial to the bone regenerate than a 4-step frequency. Illustration of this effect was observed in the elongating fascia. Normal fascia in its resting state has a wavy appearance with distinct collagen bundles, at a distraction rate of 1mm per day in 1 step every 24 hours, the fascia became stretched in appearance and many areas of homogenization, indicating structural damage were noted. At 1mm per day in 60 steps, the fascia retained its wavy appearance despite histological evidence of growth (fibroblast proliferation and ultramicroscopic evidence of collagen production, Ilizarov et al., 1983) (Fig 1A and 1B). These changes were also observed in other tissues (eg. nerve and muscle tissue). The cellular activity (proliferative, metabolic, and biosynthetic changes) observed, resembled histogenesis during embryonic, fetal and postnatal limb growth (Ilizarov 1989b).
THE FASCIA: Day 14 of Distraction (Ilizarov 1989b)

A: Control limb; normal wavy nature of normal fascia
B: 1mm in 1 step every 24 hours
   {Upper arrow identifying uneven staining}
   {Lower arrow identifying focal homogenization}
C: 1mm / day in 4 steps
   {Upper arrow identifying fiber swelling}
   {Curved arrow identifying accumulations of fibroblast like cells}
D: 1mm / day in 60 steps in the autodistractor.
   {The wavy fascial structure is almost normal}.
   {Curved arrows identifying new fibroblasts}
   {Straight arrow identifying minimal fibrous swelling}
THE FASCIA: Day 28 of Distraction (Ilizarov 1989b)

A: 1mm / day in 1 step every 24 hours
   {Collagen fibers are rectilinear, stretched out and orientated to tension vector.}
   {Large arrow identifying much homogenization}
   {Small arrow identifying few fibroblasts}
B: 1mm / day in 4 steps
   {The fibers are orientated longitudinally}
   {There are many young fibroblasts}
C: 1mm / day in 60 steps.
   {The fascial structure retains its wavy shape during distraction}
   {Large arrow identifying slight fiber swelling}
   {Small arrow identifying numerous fibroblasts}
Ilizarov (1989b) resolved that a 1.0mm per day off distraction in 4 steps produced osteogenesis within the distraction gap, in which new bone forms in parallel columns extending in both directions from a central growth zone.

Ilizarov's (1989b) principle of performing distraction at a daily rate of 1mm in four 0.25mm increment is now widely accepted in clinical practice.

In agreement with Ilizarov (1989a, 1989b, 1992), Aronson (1989) found distraction osteogenesis occurred at rates of 0.5mm to 2mm per day, with a 1mm per day being optimal. Aronson (1989) demonstrated successful distraction with a rhythm of two increments per day in animal models. Sporadic rhythms were found to inhibit bone formation.

Stewart et al., (1998) distracted two groups of rabbit mandibles, the first at a rate of 0.5mm twice daily for 15 days and the second at a rate of 1.5mm twice daily for 5 days. The total distraction length for both groups was 15mm. No differences in bone formation was observed between the two rates, although histological examination revealed the frequency of non-unions appeared to be substantial higher in the rapidly distracted group.

Distraction rates of 1mm, 2mm and 4mm in Yucatan minipigs revealed that the most uniform bone formation and the greatest stability by a bimanual examination occurred with a distraction rate of 1mm (Troulis et al., 2000).

The use of quasi-continuous distraction has been recommended (Ilizarov 1989b), although the experimental proof to enhanced osteogenesis, until 2001, was limited to Ilizarov's own work with motorized devices (Ilizarov, 1989b).

Wiltfang et al., 2001 utilized a microhydraulic cylinder to perform both intermittent and continuous distraction at a rate of 1.5mm / day for 10 days in minipigs. Both rates
of distraction were shown to produce a similar histological structure, but accelerated bone healing was evident from ultrasonography and scanning electron microscopy, after continuous distraction.

3.5. The Importance of Stable Fixation

Stable fixation of the bone fragments is one of the most important principles in the clinical application of the technique of transosseous osteosynthesis with external fixation. Secure fixation limits micro-motion between bone fragments, a movement, which inhibits union, damages local circulation and leads to the formation of callus thorough fibrocartilage (Ilizarov, 1990).

Ilizarov (1990) performed a series of experiments on canine tibias, which were distracted utilizing three configurations of circular external fixators of increasing stability. In the first configuration, a two-ring frame was applied with a pair of wires attached without tension at each ring level. In the second configuration, a two-ring frame was also used, but a pair of crossed wires were fixed with tension to each ring. The third (most stable) fixation consisted of a four-ring frame, each affixed to bone with a pair of tensioned crossed wires. Observations of the different fixators revealed that the least stable fixators (first configuration) resulted in a fibrous nonunion with a full shaft displacement at the osteotomy site. The more stable two-ring configuration of fixators produced patchy areas of bone and cartilage formation by endochondral ossification with delayed regeneration within the distraction gap. The most stable configuration of fixators (four rings) led to direct osteogenesis without intervening cartilage formation.

Stable fixation is important for adequate formation of microcolumns of bone during distraction osteogenesis. Bending or shear forces seem to induce fractures of the microcolumns with local haemorrhages and resultant histologic cartilage interposition (Aronson, 1994). Stable fixation, which allows controlled axial compression or distraction, is optimal (Paley et al., 1990).
3.6. The Consolidation Period

The consolidation period may be defined as the time required for the remodeling of the regenerate tissue. It commences post distraction, continuing until the newly formed bony tissue in the distraction gap has remodeled and the distraction device is removed (Cope et al., 1999).

During the consolidation period the newly formed collagenous tissue mineralizes to form parallel oriented bony trabeculae within the distraction gap. Remodeling of the woven bone then begins simultaneously at the host bone margins (Cope et al., 2000).

It appears from the literature (Smith et al., 1999) that little is known with the respect to the appropriate length of the consolidation period. It has been suggested that bone formation patterns during the distraction osteogenesis depend strongly on tissue morphology, external loading conditions, distraction device design parameters and device material properties, which in turn may effect the length of the consolidation period (Goldstein et al. 1994). It has been demonstrated that prolonged consolidation periods may lead to a weakening of the regenerate as a result of disuse atrophy (Ilizarov, 1990), whereas a prematurely short consolidation period may lead to fibrous nonunion, late buckling, bending or fracture of the regenerate (Aronson, 1994).

In 1994 Fishgrund et al., developed the distraction-consolidation index (DCI), this represents the approximate number of days of consolidation (fixation) needed per centimeter of distraction gap. This may vary depending on; the specific bone being distracted, the rate and rhythm of distraction, the age and health of the patient and the site of the corticotomy. It was found that the DCI is not constant, even if these variables are kept constant (Fishgund et al., 1994). For limb lengthening approximately 2 days of consolidation is needed per 1mm of distraction in order to allow complete mineralization of the regenerate tissue (Aronson et al., 1994).
Regenerate tissue mineralization and remodeling has been investigated by radiography (Rachmiel et al., 1995, Gantous et al 1994, Cope et al 1999), ultrasound (Carls et al., 1999, Eyres et al., 1993), computed tomography (Smith et al., 1999, Smatt et al., 1999, Roth et al., 1997), light microscopy (Cope et al., 1999, Farhadieh et al., 1999, Michieli et al., 1997, Komuro et al., 1994) and electron microscopy (Karahrju-Suvanto et al., 1992), although currently plain film radiographs and clinical evaluation are standard methods for determining the appropriate time for device removal. Panjaba et al., 1985, 1989 and Fishgund et al., 1994 found a poor correlation between the plain film radiographic density and the biomechanical properties of newly formed bone. Tjernstrom et al., 1992 demonstrated significant variations in the appearance of the regenerate bone on axial CT scans, hence plain radiographic images were considered comparable.

Smith et al., 1999, using quantitative computed tomography assessed three different consolidation times (4, 6 and 8 weeks post-distraction) of regenerate bone, produced in dogs whose mandibles were distracted bilaterally by 10mm. The results indicated that there was a significantly lower mean bone density of the regenerate 4 weeks post-distraction, when compared with either the 6 or 8 week groups. However there was no significant difference in mean bone density between the 6 and 8 week groups.

4. THE HISTOLOGY AND BIOCHEMISTRY OF DISTRACTION OSTEOGENESIS

Living tissue when subjected to slow steady traction becomes metabolically activated in both the biosynthetic and proliferative pathways, a phenomenon dependent on vascularity and functional use (Ilizarov 1989a, 1989b).

4.1. The Bone Regenerate

After the initial corticotomy, an inflammatory reaction ensues, as occurs in normal bone healing.
Karp et al., in 1992 defined four zones in the area of distraction;

1. A fibrous central zone, which initially appears as a radiolucent area on radiographs.

2. A transition zone where bone formation commences along the stretched fibrous tissue

3. A bone remodelling zone where the bony spicules are lined by osteoblasts and osteoclasts.

4. A mature bone zone

Well-vascularized granulation tissue, with the proliferation of endosteal and periosteal osteogenic cells appear within the gap leading to callus formation. Once distraction commences, the local histology changes from a mixed endochondral – intramembranous ossification to a well organized longitudinal intramembranous ossification (Aronson, 1994). The distraction gap becomes filled with fibroblast like cells, orientated with their long axes parallel to the vector of elongation (Ilizarov, 1990) (Fig 2). Karaharju et al., (1993) studied the distraction gap (radiolucent zone) and found it was composed of a scattered heterogeneous cell population (fibroblasts, endothelial cells and large pleomorphic cells).

Electron microscopic studies of these cells have demonstrated, abundant endoplasmic reticula, prominent nucleoli with nuclei and other changes characteristic of Type 2 collagenoblasts (a cell found in embryonic and fetal tissue development). Collagen synthesized by these metabolically and biosynthetically active fibroblast like cells is so rapid that the Golgi apparatus is often bypassed, so the protocollagen fibres are transported by large excretory vacuoles into the pericellular environment (Ilizarov, 1990).

Peltonen et al., (1992) postulated that the cells in the central part of the distraction gap have the capacity for new collagen synthesis, whereas Vauhkonen et al., (1990) and Karaharju et al., (1993), demonstrated that the organic matrix formed in the distraction area is mainly composed of Type I collagen, which is an indicator of normal bone formation.
Histological Sections of Mandibular Distraction in Wethers Sheep
(Tavakoli K et al., 1988)

A: Cut end of bone cortex merging with longitudinal orientated new bone within distraction zone. (H&E x 20)

B: Demonstrates combination of woven and lamellar bone in distraction site. Original cortical bone is entirely lamellar in nature. (Polarization microscopy x 40)

C: Distraction zone consists of ongoing ossification of fibrocartilagenous matrix. (H&E x 40)

D: High power view of (C) demonstrating ongoing osteoclastic and osteoblastic activity. (H & E x 100)
Radiographically throughout the distraction phase, a transverse undulating central zone of 4-6mm thickness is observed. Histologically, this fibrous interzone (FIZ) is identified as a longitudinal arrangement of spindle cells, producing large quantities of collagen, parallel to the distraction force (Aronson, 1994).

A primary mineralization front (PMF) becomes evident at both ends of the FIZ, in the regions of the newly formed capillaries and vascular sinuses. In the primary mineralization zones, staining for fibroblast growth factor is dense and the osteoid surface of each new bone column exhibits vast quantities of plump osteoblasts. The collagen bundles and osteoblasts simultaneously become incorporated longitudinally into the microcolumns of bone, which expand up to diameters of 150-200 micrometers. These bone columns do not contain Haversian systems, as they are surrounded by large thin-walled blood vessels. The bone microcolumns span the entire cross section of the cut bone on both ends of the distraction gap, including the periosteum, cortex, and medullary spongiosa (Aronson, 1994).

After a week of distraction, the distraction area starts to organize (Karajarju et al., 1993). The collagen fibres condense to form bundles proximal and distal to the distraction gap and capillary formation commences between the bundles. Both the collagen bundles and capillaries display an orientation parallel to the vector of elongation (Ilizarov, 1990). The central part of the distraction gap is mainly composed of collagen producing fibroblasts, with the capillaries near the osteotomized bone ends, yielding a relatively avascular central zone (Karajarju et al., 1993). In the study of Delloye et al., (1990), vascularity was noted across the interfragmentary defect, whereas according to Aronson et al., (1990); capillaries in the distraction area do not extend the fibrous interzone.

Concurrent with capillary synthesis is the emergence of osteoid-producing osteoblasts, which characteristically line up along the collagen fibres. These osteoblasts have demonstrated a high level of biosynthetic activity with the presence of enlarged mitochondria with tightly packed cristae and an abundant amount of endoplasmic
reticulum evident by electron microscopy. As the elongation process continues, the newly formed osteoid turns into lamellar bone containing osteocytes, which eventually reach and merge with the cortical bone at both ends of the distraction space (Ilizarov, 1990). Osteogenesis proceeds centripetally toward the center of the distraction gap (Karaharju et al., 1993, Aronson et al., 1990, Delloye et al., 1990, Monticelli et al., 1983, Peltonen et al., 1992, Vauhkonen et al., 1990). Bone formation in the distraction area primarily resembles membranous ossification, as Type II collagen is absent from the matrix. This indicates that the fibrocartilaginous phase (even though cartilage islets are found) is not induced during distraction osteogenesis (Karaharju et al., 1993). Cartilage has however been identified in the interfragmentary space of canine lengthened bone, after corticotomy during the first two months by Kawamura et al., (1968). Delloye has also reported on the presence of areas of endochondral bone and residual cartilage nodules in bone regenerate, of a human bone specimen lengthened with the Ilizarov’s technique. Nevertheless, membranous ossification remains the main mechanism of bone formation during distraction osteogenesis (Delloye et al., 1990).

After distraction ceases the PMF advance toward each other, bridging the FIZ. During this phase, transverse bone bridges form in the longitudinal microcolumns of bone – giving it a honeycomb appearance (Aronson, 1994).

During the fixation period, the central growth zone slowly ossifies, while the bone regenerate forms a cortex, which blends in, eventually becomes indistinguishable from the bone’s original cortex (Ilizarov, 1990). A solid union across the distraction gap in animal models mandibles was noted radiographically 16 weeks after the distraction period. Complete bony union and remodeling occurred at 35 weeks and at one year the bone was undistinguishable from the control histologically (Karaharju et al., 1993).

At the end of the consolidation period, the bone bridging the distraction gap all had a honeycomb appearance. After six weeks of full weight bearing on the regenerate bone, it completely remolds to form mature lamellar bone with bone marrow present in the
medullary region. Radiographic and histological examination identified the reestablishment of the cortical structure (Aronson, 1994).

Decalcified and non-decalcified histological sections, taken after cessation of the consolidation period from a distracted adult canine tibia, confirmed the presence of well-organized collagen bundles and normal bone formation. Quantitative biochemical analysis measured an increase in calcium and phosphate in relation to collagen synthesis until mature ratios were achieved (Aronson, 1994).

Histological assessment of osteogenesis appeared to directly parallel that of the periosteum surrounding a growth plate at the zone of Ranvier. In this situation the cartilage physis is believed to “push” the epiphysis away from the bony metaphysis, leading to the stretching of the peripheral periosteum. In distraction the fixators stretches the FIZ, creating the push of the bone fragments away from one another (Aronson, 1994).

Cope et al., (2000) evaluated newly formed bone during the consolidation period following 10mm of bilateral mandibular distraction in seventeen dogs. The bone regenerates after a consolidation period of 0, 2, 4, 6 and 8 weeks were analyzed using quantitative histology. At the end of the distraction period, mineralization was found to be occurring at the host bone margins. This was accompanied by a progressive increase in trabecular bone and a decrease in the amount of fibrous tissue. In the 4 – 6 week interval of the consolidation period, mature bone regenerates of three different types were observed. Type I was characterized by the classical three zonal regenerate, seen as two mineralizing zones separated by an intervening fibrous zone (Aronson, 1991). Type II regenerate was characterized by the presence of the crestal part of the interzone and the obliteration of the central and cortical interzone areas (Aronson, 1991). Type III regenerate was characterized by almost complete obliteration of the interzone with a few isolated islands of fibrous or cartilage tissue (Aronson, 1991). Mineral apposition was shown to gradually increase from the end of the distraction period to the fourth week of consolidation period. This rate of apposition was maintained until sometime
before the eighth week, after which it tapered off slightly, as the remodeling increased.

4.2. The Blood Supply

Quantitative technetium scintigraphy (QTS) has been used to measure the blood supply to the distracted zone. Findings indicated blood supply levels of up to seven times that of the normal contralateral side during the distraction process which then remained at approximately three times normal for the next three months of remodeling. This relative increase in blood flow appears to exceed that usually measured for simple fracture healing (Aronson 1994). In 1983, Ilizarov reported an increase of 330% in the blood supply to a distracted limb.

Several researchers have investigated the importance of the preservation of the blood supply in performing the osteotomy. Inhibiting the medullary, the cortical or the periosteal blood supply, distinguished that the periosteal blood supply is one of the most essential structures required for successful regeneration of bone (Delloye et al., 1990, Yasui et al., 1991).

Choi et al., (2000) used a rat model to examine the spatial and temporal features of proliferating vessels of the regenerating bone tissue and the blood supply with a scanning electron microscope. Vascular casting was performed pre-operatively and on days 7, 14, 21, 28 and 42 days after a 14 day tibial distraction period. Periosteal vessels and distinct subperiosteal bone formation was evident on the osteotomized surfaces on days 7 and 14. On day 21, vascular branches from the medullary canal of the host bone formed a vascular network, which gave rise to multiple axial and straight vascular branches running parallel to the direction of distraction, toward the interzone, in accordance with the progress of mineralization. On day 28, the periosteum provided vascularization to the peripheral side of the interzone whereas the center of the interzone was still relatively avascular. On day 42, the periosteal and medullary vascular channels were completely connected at the distraction site including the interzone, which was occupied by developing and mature trabeculae. In
conclusion, vascular proliferation was found to be actively occurring in both the latency and distraction periods. Post-distraction, this proliferation was shown to gradually decrease over time. Consequently a close temporal and spatial relationship was found to exist between the formation of regenerated bone and vascular proliferation of the periosteum and medullary canal.

In 1994, Aronson analyzed histological sections of specimens in which distraction osteogenesis had failed. He found that these preparations consistently lacked a local blood supply and concluded that each bone segment must contain viable osteocytes in their bony lacunae with an intact blood supply for successful distraction to occur.

4.3. The Rate and Frequency

Histochemical studies on the distraction zone, confirmed that the quantity and quality of osteogenesis during limb lengthening is dependent on the rate and frequency of distraction (Ilizarov, 1989b).

Succinyl dehydrogenase activity was measured as an indicator of the level of aerobic metabolism (reflecting the osteogenic activity). The intensity of the reaction was assessed by the amount of Phormasan blue within the cellular cytoplasm of the regenerative zone. The greater the stain present in the cell and the more area occupied by cells containing Phormasan blue, the higher the osteogenic activity (Ilizarov, 1989b). A low level of osteogenic activity was demonstrated in two groups of animal models (the groups were divided according to their osteotomy technique i.e. open osteotomy or closed osteoclasis), in which distraction proceeded at a rate of 1mm with a one step frequency in 24 hours. Osteogenic activity was shown to increase as the frequency of distraction increased from four 0.25mm increments to 0.017mm increments every 24 minutes (for a 1mm per day rate) with the intensity of the staining increasing from the middle of the regenerate zone towards the ends (Ilizarov 1989b). If the rate of distraction was increased to 2mm per day, the intensity of the staining was shown to decrease (Ilizarov 1989b).
Levels of alkaline phosphatase were used to assess mineralization of the osteoid, as alkaline phosphatase participates in the mineralization of the osteoid. A low level of mineralization was demonstrated when the daily distraction rate was 1mm in one step, this activity increased as the 1mm was performed in four increments. The distribution of the mineralization was uneven, increasing from the middle part of the regenerate towards both ends. Mineralization was even and continuous (indicating rapid osteogenesis) throughout the distracted zone in the autodistractor group (0.017mm per 24 minutes), (Ilizarov 1989b). The level of mineralization was shown to be lower when the daily distraction rate was 2mm in four increments as compared to a daily distraction rate of 1mm in four increments. Interestingly however, the mineralization rate was higher than that observed when the daily distraction rate was 1mm in one step (Ilizarov 1989b).

ATPase activity was used to assess the rate of osteoblastic formation in the primary bone matrix, with its activity demonstrated by the intensity and saturation of staining in the cells. The results were found to parallel those of the succinyl dehydrogenase activity, with a distraction rate of 1mm per day with the autodistractor producing a high level of activity (indicative of complete rapid osteogenesis) along the entire length of the distraction zone (Ilizarov, 1989b).

Light microscopy of fascia in its normal state has a wavy appearance. Observation of the fascia following a daily distraction rate of 1mm in one step revealed that it lost its normal wavy structure, demonstrating swelling and focal homogenization, evident from silver staining. A daily distraction rate of 1mm in four increments illustrated slight swelling of the fibres and less waviness of the fibres when compared to the ‘norm’. Along the periphery of the second order bundles, small accumulations of undifferentiated fibroblast like cells appeared indicating a stimulation of tissue growth. Distraction with the autodistractor at 1mm / day produced almost a normal appearance of the fascial structures. Greater accumulations of undifferentiated fibroblast like cells were evident (Ilizarov, 1989b).
At a daily distraction rate of 1mm in one step the collagen fibres were shown to be rectilinear shaped with an orientation corresponding to the vector of distraction. Dense collagen fibres lacking a wavy appearance with young fibroblasts accumulating along the periphery of the bundles were observed after a distraction rate of 1mm / day in four increments. Fascial tissue at the end of the distraction period utilizing the autodistractor with a daily rate of 1mm, had an appearance similar to that of the control undistracted limbs. Swelling of the fibres was minimal and the tissue maintained a wavy appearance (Ilizarov, 1989b).

Capillaries within the fascia demonstrated similar dependency on the frequency of distraction. A daily distraction rate of 1mm / day in four increments produced capillaries which had terminal directional cells on their blind ends, with no formation of a common capillary network. Numerous newly formed capillaries were visualized growing deeply into the distracted zone from all directions in the autodistractor group; the capillaries were close enough to one another to form anastomoses (Ilizarov, 1989b).

5. **THE HISTOLOGY AND ULTRASTRUCTURE OF ARTERIES, VEINS PERIPHERAL NERVES, MUSCLES AND SKIN**

5.1. **The Arteries & Veins**

Histological sections, following a distraction rate of 1mm / day in one step revealed arteriolar damage of the paraosseous tissues had occurred (Ilizarov, 1989b). At the end of the distraction period, electron micrographs of the arteriolar endotheliocytes revealed disturbances of the inner mitochondrial structures with an abundance of micropinocytic cells forming straight intracellular contacts. These changes are indicative of extensive arteriolar dilation (Ilizarov, 1989b). A daily distraction rate of 1mm in four increments found these changes to be less pronounced. At this rate and frequency, the inner structure of the mitochondria showed mild dysplasia. All the tissues under the tension-stress effect displayed increased biosynthetic cellular activity paralleling that of growth, (the appearance of smooth muscle cells within the arteriolar walls is indicative of
tissue growth). At a distraction rate of 0.017mm every 24 minutes, active growth of the arteriolar tissue was more pronounced characterized by marked hypertrophy of the organelles within the cytoplasm of vascular smooth muscle cells. There was an increase in the cytoplasmic volume of the endotheliocytes and an increase in length and complexity of the intracellular contacts between them (Ilizarov, 1989b). Distraction rates of 2mm in four increments per day led to decreased biosynthetic activity of the arterioles (Ilizarov, 1989b).

Ippolito et al., (1994) studied the effect of lengthening the metacarpal bone on blood vessels in 8 calves. They found no alteration in the vein structure at 1cm of lengthening (8% of initial length). At 2.5 cm (20% of initial length) the smooth muscle cells of the tunica media lost their typical scalloped contour of their plasma membrane, these cells became thinner and longer than normal and showing a decrease in cytoplasmic content of actin and myosin undergoing fibrous metaplasia, plus thinning of the subintimal elastic layers. These ultrastructure changes led to thinning of the wall of the vein and enlargement of its lumen. It is possible that circulatory disturbances could be caused in part by a venous insufficiency due to the structural alterations. Two months after the end of the lengthening procedure, the veins recovered their normal structure almost completely, although remnants of the previous degenerative phenomena were still present in the tunica media.

Ippolito et al., (1994) found that arteries are much more resistant than veins to gradual stretching. The first alterations in the arteries appeared at 2.5cm of lengthening. At 4 cm lengthening (33% of the initial length), some smooth muscle cells degenerated and died, the subintimal elastic layer was duplicated and some endothelial cells were detached from the basal membrane. All of the alterations completely disappeared 2 months after the end of the lengthening procedure. Ischaemic disturbances are not usually encountered in clinical practice although minor alterations in circulation identified with a Doppler laser have been documented in limb-lengthening procedures (Peretti et al., 1989).
5.2. The Peripheral Nerve Tissue

Nerve tissue at a daily distraction rate of 1mm in one step demonstrated uneven axon diameters within the nerve fibres and the formation of irregular accumulations of cytoplasm. A 1mm in four increments per day distraction rate revealed minimal changes within the axons. Normal axon structure was maintained in the lengthening produced by the autodistractor (Ilizarov, 1989b).

Ippolito et al., (1994) demonstrated from his study that peripheral nerves are vulnerable to stretching. Alterations of the myelinated nerve fibres were present at 1cm lengthening. The myelin sheath lost its compact structure, with separation of the mellae from each other and consequent fragmentation, but the axons remained unaffected. As the distraction procedure progressed the myelin swells strangulating the axon, causing the disappearance of microtubules and neurofilaments. At 4cm lengthening smaller myelinated fibres still remained unaffected. Unmyelinated fibres were always spared. Once the distraction process had ceased, the fibres tended to recover their normal structure in a relative short time. The severity of sensory or motor nerve loss usually appears to be dependent on the magnitude of the lengthening procedure (Ippolito et al., 1994, Cattaneo et al., 1990, Dal Monte et al., 1988, de Bastiani et al., 1987, Kawamura et al., 1968, Mastragostino et al., 1990, Mastragostino et al., 1988, Monticelli et al., 1990, Peretti et al., 1989).

5.3. The Muscles

Muscle growth by myofibrillogenesis in existing muscle fibres and the formation of new muscle tissue with active formation of myofibrils and sacromeres (indicated by increased numbers of muscle satellite cells, the appearance of myoblasts and their fusion into myotubules) has been demonstrated to occur under the influence of tension-stress (Ilizarov, 1989a). The tension–stress effect also influenced growth of the smooth muscle tissue within the walls of blood vessels. Canine tibiae at the end of the first week of distraction, at a rate and frequency of 0.125mm every six hours, demonstrated
activated arterial smooth muscle cells within the subendothelial intima spaces Ilizarov (1989a). By day fourteen of distraction, activated smooth muscle cells were found in the middle layer of the vessel walls. These cells differed from contractile myocytes by the significant development of mitochondria, ribosomes, endoplasmic reticulum and other cytoplasmic organelles. They also differed from normal arterial wall myocytes by the hypertrophy of their nuclei and by the appearance of finely dispersed, functionally active euchromatin in the nuclei. This intensified smooth muscle cell biosynthetic activity and proliferation were accompanied by an increase in the extent and number of intracellular contacts and by the formation of new elastic structures. The smooth muscle cells changed their orientation from their usual circular configuration to a longitudinal one, with cellular formation taking place near the inner elastic membrane (Ilizarov, 1989a).

The morphological changes in the ultrastructure of arterial wall smooth muscle cells are similar to the changes found in walls of arteries elongating during active prenatal and postnatal growth (Ryvkind, 1962). The morphological features common to elongating smooth muscle cells under the influence of either tension-stress or normal growth include:

1. Biosynthetic activation of smooth muscle cells and an increased number of contacts between them (Clark, 1979, Gabbiani, 1981).
2. New formation of elastic structures in the arterial walls (Kader et al., 1979).
3. Longitudinal orientation of smooth muscle cells (Lavrishcheva et al., 1983).

Castano et al., (2001) unilaterally distracted the mandibles of 16 Yucatan minipigs at a rate of 1, 2, or 4mm / day following a 0-day latency to determine whether elongation by distraction induces myocytes proliferation. Proliferation of myocytes was estimated using immunohistochemical localization with antibodies against proliferating cell nuclear antigen (PCNA). The results revealed that the distracted mandible had a 6-fold more PCNA-positive myocytes than the contralateral control side and that the sham controlled animals had a low index of PCNA-positive myocytes on both the osteotomy and contralateral sides. Consequently it was concluded that this proliferative
response (as seen in the masseter myocytes of the porcine) might contribute toward the long-term stability of mandibular expansion by distraction osteogenesis.

5.4. The Skin

Cellular elements of the skin have demonstrated signs of activation as a result of the tension-stress effect, these alterations have mainly been observed in the basal cell layer of the epidermis (Ilizarov, 1989a). By day 21 out of a 28 day distraction period on canine tibiae, Ilizarov (1989a) found the basal cells had acquired a highly cylindrical shape with numerous mitotic figures, with their long hyperchromatic nuclei orientated toward the long cellular axis, perpendicular to the basement membrane. As a result of this proliferative activity, the number of basal cell layers and consequently the thickness of the skin increased considerably (up to 10 layers compared to 3-5 layers in controlled limbs). Four distinct subdivisions; growth, granular, squamous and corneous zones can be observed within the thickened basal cell layer (Ilizarov, 1989a).

The skin appendages were also activated by tension-stress effect. By day 21 of distraction the number of hair follicles along with their associated sebaceous and sweat glands has also increased. Hair roots became closer to one another rather than being isolated structures and were parallel to the surface. As the distraction process continued, the number of hair follicles per cross-sectional area continued to increase. Hairs within the follicles of the distracted limb were of greater diameter than those of the control limb (Ilizarov, 1989a).

Ilizarov (1983, 1989a, 1989b) concluded that the tension-stress effect on the tissues under optimal conditions produces a special type of growth plate within the elongated bone, with histological and functional adaptive changes within the perosseous tissues that recreate the conditions of normal growth. The success of this technique is dependent on stability, soft-tissue and marrow preservation, and the rate and frequency of distraction.
6. **COMPLICATIONS OF DISTRACTION OSTEOMESIS**

Distraction osteogenesis can fail in at least four ways (Aronson, 1994):

6.1. **Ischaemic Fibrogenesis** occurs from inadequate local blood supply during distraction. Although fibrous tissue forms in the distraction gap, it appears loose and bone columns do not form from the avascular host bone surface (Aronson, 1994).

6.2. **Cystic Degeneration** seems to occur when there is blockage of venous outflow from the system. The large vascular channels contain a fluid more like lymph than blood and the distraction gap is filled either completely, or in part, with a cystic cavity and cyst-like fluid (Aronson, 1994).

6.3. **Fibrocartilage Non-union** occurs usually with unstable external fixation where microfractures, haemorrhage and cartilage interposition occurs histologically (Aronson, 1994).

6.4. **Buckling or Bending of the Regenerate Bone** occurs when the fixation device is destabilized or removed prematurely. Plain radiography is helpful to determine the maturity of regenerate bone. If new bone has a radiodensity equivalent to the host bone surfaces and a macrostructure resembling host bone with equivalent cross-sectional area and formation of cortex and medullary canal, the fixators can be removed (Aronson, 1994).
7. **MANDIBULAR DISTRACTION**

7.1. **Introduction**

After the success of distraction osteogenesis in limb lengthening, researchers commenced experimental studies to determine if the principles of distraction osteogenesis could be applied to the craniofacial complex (Synder et al., 1973, Michieli et al., 1977, McCarthy et al., 1992).

Recent reports indicate that distraction osteogenesis is becoming a viable treatment option for the correction of mandibular deformities, with many authors reporting on successful corrective results following osteotomies and gradual bone distraction for mandibular lengthening, (Synder et al., 1973, Michieli et al., 1977, Bell et al., 1996 and Sawaki et al., 1996) widening (Bell et al., 1996, Perrott et al., 1993, Bell et al., 1997 and Block et al., 1996) and alveolar ridge augmentation (Block et al., 1996).

Mandibular distraction can occur in three planes of space; Anterior-Posterior, Vertical and Transverse by utilizing either extraoral or intraoral appliances. The extraoral appliances are attached to the mandible by percutaneous pins connected to fixation clamps, which in turn are, joined by a linear distraction bar (distractor). So when the appliance is activated the bar pushes the clamps apart, generating new bone in its path. The intraoral appliances are contained entirely within the oral cavity. They are attached only to the bone (bone-borne), only to the teeth (tooth-borne) or both to the teeth and bone (hybrid). A linear distractor similar to an orthodontic expansion device is used to push the bone segments apart irrespective of the method of intraoral attachment (Samchukov et al., 1998).
8. MANDIBULAR DISTRACTION STUDIES IN THE ANIMAL MODEL

8.1. Extraoral Appliances

Snyder et al., (1973) were the first to perform and report on successful mandibular distraction using external fixation in a canine model. In 1990, Karp unilaterally distracted the mandibles of 6 growing dogs by 2cm. The procedure involved unifocal distraction, utilizing an external distractor. Karp concluded from the study that bone deposition occurred by intramembranous ossification.

Karaharju-Suvanto et al., (1990) reported on a new mandibular external fixator, which was tested in 17 growing sheep. The results found the device to be very stable facilitating easy distraction for up to 16 days for 8mm elongation. It was concluded that this device could provide mandibular lengthening by distraction osteogenesis without the need for additional bone grafting and after further experimental investigation may be suitable for the correction of facial deformities.

Furthermore, the ability to close a 2.5cm defect by bifocal distraction (Ganey et al., 1994, Klotch et al., 1993 and Costantino et al., 1990) and symphyseal defects by trifocal distraction (Annio et al., 1994) in the canine model has been demonstrated.

8.2. Intraoral Appliances

8.2.1. Bone Borne

As the success of mandibular distraction eventuated, research expanded to designing devices small enough that may be used intra-orally to avoid the scarring associated with external devices (Guerrero, 1992).

Michelle and Miotti (1977) repeated Snyder’s canine model (Synder et al., 1973) using
an intra-oral distraction device. They demonstrated that the mandibular teeth could be used to anchor a distraction device.

In 1995, 10mm of distraction was achieved at the level of the body of the mandible in two monkeys utilizing an intra-oral distractor. Although 10mm of distraction was successfully performed in both monkeys, one of the monkeys suffered secondary bone sequestration due to exposure of one of the bone plates (Altuna et al., 1995). In the same year McCarthy et al achieved 20mm of distraction utilizing an intra-oral device in a canine’s mandible.

Sawaki et al., (1996) in the canine model demonstrated mandibular lengthening by distraction osteogenesis using osseointegrated implants and an intra-oral device. The procedure involved five adult dogs in which osseointegrated implants were placed in the left mandibular premolar and molar extraction sites. Three months after implantation, the osteotomy, abutment connection and attachment of the intraoral distraction device were performed. The mandible was distracted 10mm at a rate of 1mm / day. The dogs were sacrificed on weeks two, three and four post-distraction. The results from histological and radiological examination found that the uniformity of the new bone improved as the post-distraction time interval increased. Assessment of the titanium implants found that they remained stable thorough out the whole procedure. Consequently it was concluded that, titanium implants provide rigid anchorage against a continuous distraction force and also provide an efficient mechanism for securing the distractor.

In 1999, Seldin et al., reported the on the success of a recently designed intraoral distraction device. The new semiburied, fixed-trajectory, curvilinear distraction device was constructed to determine its effects on mandibular distraction within the animal model. The design of the distractor was such that each device was capable of a single specific trajectory of distraction, which follows a path with radii of curvature in 1, 2 or 3 orthogonal planes. Incorporated within the device is a rack and worm-gear drive mechanism like that found in hose clamps used within the automotive industry. The
distractor itself consists of two parts, each incorporating a foot-plate with screw holes that allow fixation to the proximal and distal bone segments. The essential feature of this device is its curved track, which incorporates a radial arrangement of slots with an offset angle that matches the pitch of threads of the caged worm-drive mechanism. The cage couples the two halves of the distractor to allow only movements, which conform to the curvature of the track. It is activated through a universal joint by a percutaneous wire. The results showed a curvilinear distraction, with angulation of the margins of the wedge-shaped distraction gap conforming to the calculated angulation of the fixed radius of curvature of the distractor.

8.2.2. **Tooth Borne**

Hollis and Block (1998) assessed the amount of mandibular skeletal and dental widening achieved, to distract the parasymphysis of a canine model by 10mm using a tooth-borne distraction device. Findings indicated that the canine teeth (to which the device was anchored) moved 95% of the distraction movement, whereas the bone widened 55% of the distraction device movement. Histology of the distraction gap identified woven bone formation occurring within the regenerate. It was concluded that a tooth-borne device would move the teeth significantly more than the bone.

8.2.3. **Tooth and Bone Borne (Hybrid)**

Successful distraction of a bone and tooth-anchored intraoral distraction appliance, known as the “pin-in-tube” (PIT) appliance, has been demonstrated as an effective method to produce mandibular lengthening within the animal model (Douglas *et al.*, 2000).

8.2.4. **Designed to Achieve Continuous Distraction**

While internalizing the distraction devices, researchers also attempted to incorporate mechanisms within the design to enable distraction to proceed at a continuous rate
and rhythm.

Schmelzeisen et al., (1996) reported on 13mm of mandibular lengthening in a pig model utilizing a motor driven plate. The motor driven plate was operated by a power unit, consisting of lithium batteries and a timer module, which was inserted into a subcutaneous pocket within the animal’s neck at the time of surgery.

Ploder et al., (1999) reports on a maximum mandibular lengthening of 13.6mm in sheep utilizing a fully implantable electromechanical device secured to the mandible, with the power and control unit inserted subcutaneously in the neck region.

However, the electric motor-driven devices as presented by Schmelzeisen et al., 1996 and Ploder et al., 1999, both share a common disadvantage in so far as they have no means of measuring the distraction forces applied.

8.2.5. Designed to Determine the Forces Required to Distract the Mandible

Kessler et al., (2000) were the first to utilize an intraoral microhydraulic osteodistractor to record the pressures necessary to discontinuously distract the mandible of mini-pigs at a rate of 1.5mm (in one increment) per day for 2 weeks and then use the data obtained to perform continuous bone distraction at a rate of 1.5mm (in one increment) per day by a hydro-pneumatic injector system. Discontinuous distraction was shown to produce pressure peaks of $25 \times 10^5$Pa, these peaks were shown to fall after 30 minutes reaching a basic level of $8.9 \times 10^5$Pa after 4-6 hours. In continuous distraction a mean pressure level of $12-15 \times 10^5$Pa was found to be sufficient to move the piston constantly over 1.5mm in 24 hours. The volumetric, pressure controlled, continuous thrust displayed considerable variations in pressure monitoring caused by the masticatory action. It was concluded that the microhydraulic cylinder was a reliable device in continuous and discontinuous bone distraction.
Cope et al., (2000) placed distraction devices parallel to the mandibular body and then parallel to the axis of distraction in five unembalmed human cadaver mandibles to assess the force level and strain patterns on the mandible during bilateral osteodistraction. The mandibles were placed in a specifically designed apparatus for stabilization of the proximal during distraction and a force transducer was attached to the lateral aspect of the inferior ramus. Strain gauges were also attached to the bone segments proximal and distal to the distraction device. The results showed that greater lateral forces were seen when the devices were orientated parallel to the mandibular body. This device orientation was found to increase tensile strains at the labial symphysis and medial ramus and to increase compressive strains at the lingual symphysis and lateral ramus. However, these forces and strains were not detected when the devices were orientated parallel to the axis of distraction. The study concluded that device orientation has important biomechanical effects on lateral forces and strain patterns during mandibular osteodistraction.

8.3. **Animal Studies for Alveolar Distraction**

Block et al., (1996) performed 10mm of vertical distraction in edentulous mandibular quadrants of four dogs. An average vertical augmentation of 8.85 +/- 1.05mm was achieved after 10 weeks of healing. Serial sections revealed that bone had formed between the distracted segments, creating an augmented alveolar ridge.

9. **MANDIBULAR DISTRACTION STUDIES IN THE HUMAN MODEL**

9.1. **Extraoral Mandibular Distraction**

McCarthy et al., (1992), reported the first experience of extraoral mandibular distraction for congenital deformities on the human mandible. The publication described unilateral lengthening of the mandible in three cases of hemifacial microsomia and one bilateral lengthening case of a patient with Nager’s Syndrome. An
average of 18 to 24mm of bone lengthening was achieved in these four cases. The procedure utilized a Hoffman Mini Lengthener (Howmedica Co., Rutherford, NJ) attached to the osteotomized bone segments with two pairs of pins. A series of drill holes were placed along the osteotomy line and bone division occurred when these were connected with a narrow osteome. After a latency period of 7 days, distraction commenced at a rate of 1mm per day. External fixation was maintained for an average of 9 weeks (range 8-10 weeks) post- distraction.

In 1992, Aytemiz and Sengezer described their experiences in fourteen cases, in which distraction osteogenesis was performed on hypoplastic mandibles secondary to temporomandibular joint ankylosis.

Perrott et al., (1993) reported on a case of hypoglossia-hypodactyly syndrome in which the mandible was symmetrically widened 10mm without any increase in the intercondylar distance. The procedure involved a symphyseal osteotomy with a distraction device fixed by extraoral pins to mobilize the mandibular arches. Distraction proceeded at a rate of 0.33mm / day for 30 days, after which the device had to be removed for social reasons. A bony graft was placed at the time of distractor removal.

In 1995, Molina and Oritz-Monasterio utilized a corticotomy technique in which the medial cortical plate was left intact and only one fixation pin was inserted on either side of the corticotomy to secure the distraction device. This was called a semi-rigid extraoral fixation system. Molina and Oritz-Monasterio (1995) stated that the muscles exert constant forces over the appliance, slightly bending it and reflecting externally the bone remodeling taking place internally.

The initial reports and studies performed demonstrated extraoral appliances, which were only capable of unidirectional (i.e. horizontally or vertically) mandibular distraction. It soon became obvious that multi-directional osteodistraction was a necessity for severe deformity cases in which simultaneous distraction of the ramus, corpus, and angle of the mandible would be required (Cope et al., 1999).
Molina and Oritz-Monasterio (1995) were the first to use a bi-directional osteodistraction device in the mandible. The procedure generated two distraction sites via double-level corticotomies (horizontal in the ramus and vertical in the corpus); this enabled the mandible to be lengthened in both regions simultaneously. Modifications of this device provided an adjustment in the angular relationship between the two distraction vectors during the lengthening, thereby allowing augmentation of the gonial angle. Later multi-directional extraoral devices were designed providing manipulation of the bone segments in multiple planes in space.

9.2. **Intraoral Mandibular Distraction**

9.2.1. **Lengthening of the Mandible in the Sagittal Plane**

In 1995 McCarthy *et al.*, developed a miniaturized bone-borne Uni-guided Mandibular Distraction Device (Howmedica, Leibinger Inc) suitable for intraoral placement. The device consisted of two clamps attached to the bone via pairs of pins connected by a telescopic distraction rod.

In 1977, Wangerin designed a similar appliance, the Intraoral Titanium Mandibular Distraction Device (Medicon Instrumente, Tuttlingen, Germany). The device consists of mini-plates for bone fixation connected by a square-shaped distraction cylinder, which eliminates the tendency to rotational movement.

Diner *et al.*, (1997) developed two types of intraoral bone-borne devices for mandibular lengthening based on the anatomic location of distraction of the horizontal corpus or ascending ramus.

In 1995 Guerrero *et al.*, presented different tooth-borne, bone-borne and hybrid intraoral devices for mandibular lengthening and widening. The appliances can be modified and attached to orthodontic bands or to pairs of bendable arms having fork
shaped ends. The bendable nature of the device allows intraoperative adaptation, which minimizes the possibility of mandibular damage as a result of screw placement. The device can also be removed at the end of the consolidation period by cutting the metal arms and pulling the fork ends of the appliance, leaving the fixation screws in the bone.

Razdolsky, in 1977 introduced a preprogrammed tooth-borne distraction device (Razdolsky Oral Distractor (ROD), Oral Osteodistraction, LP, Buffalo Grove, III) for mandibular distraction in patients with retrognathic mandibles. The device consists of a broad surface precision attachment soldered to preformed stainless steel crowns and a matching female component soldered to a specialized expansion screw. Anchorage struts were placed on teeth adjacent to planned surgical sites to provide added dental anchorage for the appliances. Each device is customized according to the patient’s requirements. This system sets bilateral expansion screws parallel to each other and to the vector of distraction.

Dessner et al., (1999) reported on five patients with mandibular retrognathia, who underwent intraoral mandibular distraction with the preprogrammed tooth-borne device. The results revealed that only 3 out of the 5 cases distracted occur along the planned vector, with the other 2 cases showing opening rotations of the mandibular anterior segment along with advancement.

Razdolsky et al., (1988) developed a series of tooth-borne and hybrid distraction devices (ROD 1,2 and 3) (Oral Osteodistraction, LP, Buffalo Grove. III) (Fig 3) in which the distraction mechanism can be attached to stainless steel crowns or miniplates. A special laboratory instrument was also designed to allow preprogrammed fabrication of the device along a predetermined axis of distraction based on preoperative records.
Fig 3
Razdolsky’s Toothborne ROD Appliances
(Oral Osteodistraction, LP, Buffalo Grove, III)

The ROD Appliances

ROD 1

ROD 2
Bone plate on lateral or medial side of the coronoid process

ROD 3
A new technique for using the Leibinger multiplanar mandibular distractor (Howmedica Leibinger, Inc., Rutherford, NJ) (Fig 4) was described by Gateno et al., (2000) in an attempt to overcome the difficulties associated with the three dimensional distraction of the mandible. The technique involves the production of a 3D computerized scan of the facial skeleton, from which a 3D wire mesh model is built using animation software. With the software, a virtual distractor is built and installed on the wire-mesh model. The osteotomies and the distraction process are then simulated, hence a plan for sequencing the linear and angular changes of the distractor are calculated. Next a wire mesh model of the angle of the mandible is created to allow correct transfer of the pin position. An aluminum template is finally constructed to allow transfer of the information to the patient at the time of surgery. Gateno et al., (2000) also designed a fully adjustable custom-made drill guide with four drilling cylinders that relate all the pins to each other. The distractor and the drill guide can then be pre-bent to allow correct pin orientation as determined by the pre-surgical planning process. Initially the authors performed mock surgery on the stereolithographic models and the results were compared with those predicted by the computer. The results found the difference between the predicted position for the condylar marker was 0.6mm +/- 1.1mm on the X-axis, -0.9mm +/- 2.6mm on the Y-axis and 0.04mm +/- 0.8mm on the Z-axis. It was concluded that if the results of the study were validated in clinical practice, the outcomes of patients undergoing distraction osteogenesis would improve. In a later report the author documents 7 successfully treated cases as predicted by the pre-planning process (Gateno et al., 2000).

Van Strijen et al., (2000) published a report on fourteen cases with mandibular hypoplasia (with a mean age of 14.1 years) treated by bilateral intraoral mandibular distraction, following unsuccessful treatment with functional orthodontic treatment. All cases achieved the planned mandibular lengthening and a class I occlusion was achieved. Additional elastic traction to close a mild (1-3mm) open-bite in seven patients was required directly after active distraction. Twelve cases finished their orthodontic treatment within six months after distraction.
Fig 4

Multi-Guide Mandibular Distraction Device
(Howmedica Leibinger, Inc., Rutherford, NJ)
Unilateral mandibular distraction followed by hybrid functional appliance therapy and fixed orthodontic appliance therapy has been successfully used to treat four cases of mandibular asymmetry. The surgical procedures included both body and ramal mandibular lengthening. Once the desired skeletal position was achieved a consolidation of period of 2 to 3 months was employed. After distraction, functional appliance therapy was initiated during growth to correct the cant of the occlusal plane by the extrusion of teeth on the affected side for improved facial symmetry. Fixed orthodontic therapy was used for the final occlusal adjustments (Tehranchi et al., 2000).

9.2.2. Widening of the Mandible

Guerrero et al., (1997) performed symphyseal distraction, followed by non-extraction decompensating orthodontic treatment, on 10 patients with a mandibular transverse deficiency and significant dental crowding. The procedure utilized either an intraoral tooth-borne Hyrax appliance or a new custom-made bone-borne distractor following a vertical interdental symphyseal osteotomy, allowing the mandible to gradual widen. The appliances were activated for 7 days after the symphyseal osteotomies, at a rate of 1mm (in a single increment) per day. The consolidation period ranged from 30-60 days post distraction, during which the symphyseal distraction gaps became bridged with new bone regenerate. Non-extraction orthodontic alignment of the mandibular teeth was accomplished in the post distraction period. It was concluded that, distraction osteogenesis could provide an alternative to orthognathic surgery for widening the mandible and the treatment of transverse mandibular deficiency without the extraction of teeth.

Long-term evaluation of fifteen patients after mandibular midline symphyseal distraction revealed that no patients experienced any worsening or development of a new TMJ symptom. Improved TMJ symptoms occurred in 5 patients and 3 patients experienced complete resolution of symptoms. No periodontal bone loss or soft tissue recession were evident. Tooth vitality was maintained in 13 patients, while class II
mobility of a single lower incisor was recorded in two patients. One patient experienced simultaneous tooth pain and widening of the periodontal ligament adjacent to the osteotomy / corticotomy site and one patient experienced mental nerve paresthesia. Consequently it was concluded that transverse distraction osteogenesis could be used to treat mandibular transverse discrepancies with limited morbidity (Kewitt et al., 1999).

Mommearts (2001) describes a new titanium intraoral expansion device for symphyseal widening by callus distraction, the Transmandibular Distractor (TMD) {TMD – Surgitech NV, L. Bauwensstraat 20, 8200 Brugge, Belgium}. The TMD consists of two vertical footplates for osteosynthesis, each provided by an offset extension that pierces the mucosal incision. The footplates are placed close to the vertical osteotomy line. Two threaded parallel distraction rods, the middle part of which is helical, connect the extensions. The device is activated with a screwdriver that can be inserted at either end of the rod; every full turn equals 1mm expansion. Both rods should be activated at the same rate and rhythm. Orthodontic closure of the diastema is commenced after 1-½ months consolidation. The appliance should be removed 2 months, after calcification of the callus is confirmed radiographically. The advantages of TMD include limited surgical exposure, skeletal anchorage and expansion along the arch segment together with proportional and differential widening in the frontal plane.

9.3. **Alveolar Distraction**

Vertical alveolar distraction was performed in a seventeen-year-old girl who required alveolar ridge augmentation before the placement of implants. The procedure involved, a segmental osteotomy of the healthy bone beneath the atrophied superior aspect of the ridge. The distractor was placed and distraction at a rate of 1mm per day for 9 days proceeded a latency period of 5 days. The period of consolidation was 10 days after which the device was removed. The osseointegrated implants were placed six weeks later into the augmented ridge (Chin et al., 1996).
Schierle et al., (2000) reports on a case of a 16 year old patient who following a sporting injury at the age of 7 years had ankylosed upper incisors with subsequent underdevelopment of the frontal alveolar process. The report describes fabrication of a custom-made device, which was attached to the tooth-bearing segment following the osteotomy. Bone lengthening occurred at a rate of 0.5mm / day after a latency of 7 days. Distraction continued until the open bite was closed, after which the device was removed and the segment was fixed using an orthodontic arch wire. A retention period of 6 weeks was maintained until sufficient stability was detectable. One and a half years post treatment the lengthening appears stable with good consolidation of the bone fragments and a physiologically shaped gingivo-buccal sulcus.

Raghoobar et al., (2000) describes the use of a Groningen distraction device to distract severely resorbed anterior edentulous mandibles. The device consists of 2 distraction screws and one guide screw. The distraction screws are replaced by endosseous implants 2 months after the last day of distraction. Prosthetic treatment can commence 3 months after placement of the implants. The study reports on 3 patients with severely resorbed mandibles all of which are augmented in height between 5-7mm in the canine region to enable insertion of endosseous implants with a length of at least 12mm. Biopsies of the distraction site revealed formation of lamellar bone parallel to the distraction vector. Raghoobar et al., (2000) concluded that the Groningen vertical distraction device has the potential for reliable augmentation of the anterior segment of a severely resorbed edentulous mandible, to enable insertion of endosseous implants of adequate length and primary stability.

Chiapasco et al., (2001) reports on 8 patients who underwent augmentation of mandibular alveolar ridges to improve local anatomy for ideal implant placement. Two to three months after consolidation of the distracted segments, implants were placed within the distracted areas. Four to six months later, abutments were connected and prosthetic loading of the implants commenced. The study demonstrated a mean vertical bone gain of 8.5mm. Radiographic examination of the bone 12 months after functional
loading of the implants showed a significant increase in the density of newly generated bone in the distracted areas. Success rates of the implants, periodontal indices of peri-implant soft tissues were consistent with those reported in the literature regarding implants in the native bone (Chiapasco et al., 2001).

Consolo et al., (2000) performed alveolar distraction osteogenesis in 7 patients with ridge deformities to obtain the desired ridge augmentation for implant placement. Clinical and radiological evaluations were performed before implant insertion. Biopsies at 40 days post-distraction revealed soft callus commencing ossification. Sixty days post-distraction biopsies showed the soft callus converting into a network of trabecular woven bone; osteogenic activities were low; trabecular bone volume was about 50%. Eighty-eight days post-distraction biopsies revealed a reduced amount of bone with a more ordered structure, further reduction of bone formation activity, whereas osteoclast erosion was active. Consolo et al., (2000) concluded that bone deposition continued at a steady rate for up to 60 days post-distraction, after which it regressed with time, suggesting the possibility of an early implant insertion to avoid bone loss due to mechanical unloading.

Segmental alveolar distraction osteogenesis of the anterior alveolar process has been described as an alternative non-extraction therapy for patients with anterior tooth crowding in the mandible or with an unfavorable relation between the anterior dentoalveolar area and the skeletal base (Triaca et al., 2001). A report on twenty-five patients (with either Class I or II skeletal patterns with crowding or Class III skeletal pattern requiring decompensation before surgery), describes the successful use of a special hinge-joint bone plate for distraction of the anterior alveolar process, which allows rotation of the bone segment into the desired position. This study documents an average advancement at the incisal edge of 2-5mm (Triaca et al., 2001).
10. **THE BIOMECHANICS OF MANDIBULAR DISTRACTION**

Samchukov *et al.*, (1998) used a computer two-dimensional model to determine the biomechanical considerations of lengthening and widening on the mandibular distraction. Linear distractors were then assessed on their orientation, either parallel to the body of the mandible or parallel to the axis of distraction, for bilateral lengthening of the mandible and bilateral lengthening of the mandible in combination with midline mandibular widening (with the widening preceding the lengthening procedure). Findings indicated that distractors placed parallel to the body of the mandible caused lateral displacement of the posterior components of the distraction devices during mandibular lengthening, with a reduction of the midline distraction gap after widening during mandibular lengthening. Elimination of these effects occurred, when the device was orientated parallel to the axis of distraction. Midline symphyseal distraction caused an axial rotation of the condyles regardless of the orientation of the distractors. It was concluded that the distraction devices should be orientated parallel to the plane of distraction to exclude any adverse biomechanical effects during mandibular lengthening and hinged devices with ramus osteotomies may be required for angular correction of the rotated condyles, secondary to midline osteodistraction.

Distractors orientated parallel to the body of the mandible within an animal model have demonstrated an increase in the anterior width of the proximal segments. Lateral displacement of the proximal segments led to several complications, including screw fixation failure and bone resorption under the fixation plates. All of these effects were minimized when the device was orientated parallel to the axis of distraction (Cope *et al.*, 1999).

A 2D model of the human mandible was generated to enable computer simulation of mandibular osteodistraction and to evaluate the biomechanical effects of linear distractor orientation in the sagittal plane relative to the anatomic axis of the mandible (mandibular plane) and the maxillary occlusal plane. Positional changes of the distal mandibular segment were analyzed over a 10mm incremental lengthening based on
the distractor orientated parallel to the maxillary occlusal plane. Findings indicate that
distractors placed parallel to the inferior border of the mandible without regard to the
maxillary occlusal plane created a vertical translation of the distal bone segment
resulting in an anterior openbite. The magnitude of the anterior openbite appeared to be
proportional to the angle between the vector of distraction and the maxillary occlusal
plane and to the amount of distraction. Placement of the distractors parallel to the
occlusal plane eliminated the tendency for an anterior openbite. Consequently it was
concluded that the orientation of the distractors should be considered in relation to the
maxillary occlusal plane when planning mandibular osteodistraction (Samchukov et al.,
1999).

11. **THE PRINCIPLES OF MANDIBULAR DISTRACTION**

11.1. **The Importance of Stable Fixation**

Guerrisi et al., (1994) reported on a couple of different methods of external fixation
used in the distraction of a rabbit’s mandible, they concluded the stability of the
distractor was directly proportional to the success rate of distraction.

11.2. **The Latency Period**

Tavakoli et al., (1988) reported on their study, which aimed to establish the role of
latency in mandibular distraction of the sheep model. They found that a change in
latency from 0 through to 7 days does not alter the histological features, biomechanical
properties and bone density mass of the regenerate bone 20 days post-distraction.

Califano et al., (1994) studied the effect of a short latency period in 1994. Their
method involved distracting rabbit mandibles after a latency period of 12 hours.
Observation of the distraction gap utilizing bone scans, found an active inflammatory
process occurring at the osteotomy site for up to 7 days post-operatively.
11.3. **The Rate of Distraction**

Faradieh *et al.*, (2000) evaluated the effect of different distraction rates (1, 2, 3 and 4mm / day) on mineralization, biomechanical and histological properties of lengthened sheep mandibles. The mandibles were distracted 24 mm and then stabilized for 5 weeks. The specimens were analyzed with respect to mineralization using dual energy x-ray absorptiometry, biomechanical strength, through a modified three-point bending test, and histological properties with hematoxylin and eosin stains. Biomechanical, mineralization and histological analyses of the 1mm / day distraction samples were shown to be significantly superior to the 4mm / day distraction samples and although bone formation was achieved in all samples, the 1mm / day group demonstrated the strongest biomechanical and histological properties.

The effect of varying the rate of distraction osteogenesis in rabbit mandibles by the in the infusion of a local insulin-like growth factor-1 (IGF-1) found slow distraction (1.5mm/day) allowed a more reliable bony union than did rapid distraction at 3.0mm/day. Osteogenesis was not affected by the infusion of IGF-1 during the lengthening procedure (Stewart *et al.*, 1997).

12. **THE EFFECT OF MANDIBULAR DISTRACTION ON THE SURROUNDING TISSUES**

12.1. **The Inferior Alveolar and Mental Nerve**

Michieli and Miotti (1977) performed a corticotomy on two dogs in which every attempt was made to maintain the integrity of the nerve. Mandibular lengthening of 5 and 15mm by distraction osteogenesis was achieved utilizing an intraoral tooth-borne distractor. Light microscopy found that there was no alteration in the nerve fibres proximal or distal to the corticotomy site.
Block et al., (1993) constructed a study on four dogs to determine the effect of distraction osteogenesis on the ultrastructure of the inferior alveolar nerve (IAN). In one dog the IAN was completely severed during pin placement, however in the other three dogs the IAN were fully preserved. Light microscopy of the preserved nerves found signs of wallerian degeneration in a large quantity of both the large and small fibres. In two of the dogs the degeneration was extensive, whereas in the third dog, the degeneration appeared more peripherally. The transmission electron microscope revealed intact unmyelinated and thinly myelinated fibres.

Milner (1989, 1992) demonstrated in the rat model, that all nerve fibres undergoing expansion showed an increase in fiber length and that slow expansion over 15 days is better tolerated than rapid expansion over 3 days. A decline in conduction velocity was also noted on expanding nerve fibres, however this had completely reversed by 100 days post expansion. Histologically, segmental demyelination was evident in the expanded peripheral nerves (Endo et al., 1993).

Normal neurosensory function has been observed in the mental nerve in patients undergoing mandibular distraction at a rate of 0.5-1.5mm per day (McCarthy et al., 1992, Takato et al., 1993, Klein et al., 1995, Rachmiel et al., 1995 and Diner et al., 1997). However Diner et al., (1977) reported on a 28mm mandibular distraction case, in which the nerve underwent reversible dysesthesia.

Mararov et al., (1998) conducted a study to evaluate the function of the inferior alveolar nerve (IAN) during distraction osteogenesis of the canine mandible. Fourteen dogs (including 2 controls) were used in the study. Twelve dogs underwent a 10mm bilateral mandibular lengthening with an intra-oral bone borne device and a midbody osteotomy. IAN sensory function was evaluated utilizing sensory nerve action potentials, immediately before surgery, before and at the completion of distraction and before necropsy after 4, 6, or 8 weeks of fixation. Results demonstrated 12 of the 24 nerves showed a complete loss of evoked potential after surgery without recovery at any point throughout the study. Acute nerve injury caused by either osteotomy or
screw encroachment was identified at necropsy. The other twelve nerves showed reproducible responses after surgery. Eight of these nerves had significant amplitude attenuation of the evoked action potentials, which was identified at necropsy as a result of acute injury. The remaining four nerves did not show significant evoked potential abnormalities and appeared to be grossly normal at necropsy. During distraction, the amplitude of evoked potentials in all 12 nerves remained at the postoperative level, whereas latency showed a significant delay. In 7 of these 12 nerves, various degrees of evoked potential recovery were identified at the completion of the study. Mararov et al., (1998) concluded that, the high incidence of acute IAN injury in the study was due to device construction and osteotomy technique and if acute nerve injury is avoided at surgery, mandibular distraction of up to 10mm appears to produce minimal deleterious effects on IAN function.

12.2. The Masticatory Muscles

Fischer et al., (1997) performed biopsies on the masseter and digastric muscles after lengthening canine mandibles by distraction osteogenesis using an intra-oral distracting device. Findings indicated that the digastric muscle underwent a transient atrophy with the initiation of distraction but regenerated completely after 48 days of fixation. The masseter muscle was unchanged initially but showed evidence of atrophy after 20mm of distraction and it continued to exhibit evidence of atrophy during fixation. A significant decrease in protein synthesis (determined by quantitative assessment of RNA / DNA) was also observed during periods of atrophy in the masseter, but not in the digastric. Conclusions from this study indicate that, any muscle which lies in the same distraction plane or vector (e.g. digastric) adapts with compensatory regeneration and hypertrophy, whereas those muscles lying in a different plane (e.g. masseter) show persistent evidence of atrophy with decreased protein synthesis.
12.3. **The Temporomandibular Joint**

Histological studies of the temporomandibular joint after gradual distraction of the condyle in growing sheep revealed active biological interactions in the joint cavity at the cartilage and the bone interface. In unilateral distraction, osteoblastic and osteoclastic activity was observed on the contralateral TMJ, indicating a transmission of the effects of pressure to the nondistracted side. The function of the joint was not affected and no degeneration of the fibrous capsule was noticed. During a follow-up period (52 weeks), the area remodeled until it appeared similar to that in the control samples, although the cartilage remained thinner. No major disturbances in the condylar head were noted. (Karaharju-Suvanto et al., 1996)

Morphological changes in the fibrous and cartilaginous layers of the TMJ were observed in tooth-borne vertical midsymphyseal distraction in the monkey model (Harper et al., 1997, Bell et al., 1997).

12.4. **The Teeth and Periodontium**

Distraction of the mandible in the sagittal plane rarely causes damage to the teeth as the screws holding the bone plates in position are usually placed in the angle of the mandible. However in a developing child the permanent molar teeth form near this area and careful planning with tomograms, radiographs and 3D imaging is needed (Davis et al., 1998). If the corticotomy is to be placed near the teeth and supporting tissues, such as in a midline mandibular procedure, pre-operative orthodontics may be needed to increase the interradicular width (Guerrero, 1990).

13. **RETENTION AFTER MANDIBULAR DISTRACTION**

Schwestka-Polly et al., (2000) describes the use of a newly designed orthodontic appliance called “vario plates”, for retention following distraction osteogenesis of the
mandible. These plates consist of removable orthodontic appliances in the maxilla and
the mandible, which are fabricated out of self-curing resin with wire elements. The
plates are connected with telescoping maxillomandibular guidance rods, which have a
smoothly variable length, from the maxillary molar region to the mandibular premolar
region on each side. The telescope on both sides is adjustable in length by means of a
protrusion nut, thus it is possible to move the mandible forward an exactly controlled
amount. The "vario plates" are in function for 24 hours a day in the patient for 6
months after mandibular distraction osteogenesis and subsequently only at night.
Application of the "vario-plates" makes it possible to hold the mandible in a stable
position after distraction osteogenesis.
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DESIGN OF A NEW INTRAORAL MANDIBULAR DISTRACTOR
DELIVERING CONTINUOUS FORCE OVER 24 HOURS

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ABSTRACT

The aim of this study was to design and engineer an intraoral mandibular distracting device, which produces continuous distraction at a rate of 1mm per 24 hours and to assess its effectiveness in, in-vitro studies.

The device consisted of a piston, housed within a cylindrical case, loaded by a spring to 70N +/- 5N. The action of the piston was regulated by the incorporation of a high viscosity material within the cylindrical case. Unilateral and bilateral distraction procedures were assessed, with the new intraoral distractor on an acrylic model of a sheep's mandible, which was kept in a water bath at a temperature of 37°C for seven days.

The study found that the new intraoral mandibular device, distracted continuously in the sagittal plane, when the distractors were orientated parallel to the axis of distraction, loaded to 70N. An average daily distraction of 0.87mm was achieved over a seven day period. However, a consistent daily distraction could not be obtained, possibly due to the non-linear nature of the internal and external resistant forces.

Further studies should focus on reducing the size of the distractor for in-vivo use and the production of a more reliable optimal (1mm / day) daily distraction rate.
INTRODUCTION

Distraction osteogenesis is a biological process generating new bone formation between the surfaces of bone segments that are gradually separated by incremental traction. Codivilla first described this method of elongating both bone and soft tissue in 1905, however it is Garvriel Ilizarov, a Russian orthopedic surgeon who is credited with rediscovering and developing the technique to successfully lengthen limbs.

Snyder et al. in 1973 were the first to document unilateral lengthening of the mandible in an animal model; this was the first time osteodistraction had been applied to the craniofacial complex. Several years later, McCarthy et al. published an inaugural report on four patients with congenital craniofacial abnormalities, in which augmentation of the mandible had been performed by distraction osteogenesis, utilizing extraoral appliances.

As the success of mandibular distraction eventuated, research expanded into designing devices, which would be small enough to be used solely intraorally, eliminating the scarring and psychological effects associated with extraoral devices.

As internalization of the devices became feasible, researchers attempted to incorporate mechanisms within the appliances, which would allow distraction to proceed at a continuous rate and rhythm. Quasi-continuous distraction at a rate of 1mm per day has been shown to produce proliferative, metabolic, and biosynthetic changes resembling histogenesis during embryonic, fetal and postnatal growth. An accelerated rate of bone healing has also been reported with continuous distraction at a rate of 1.5mm / day. Incorporation of these features would minimize the post-operative activation and maintenance of the device during the active phase distraction, for both the patient and the surgeon; at the same time providing the most optimal conditions for bone regenerate formation. To date most of these are electric motor driven devices, all of which share common disadvantages in that; firstly they require a power supply, which tends to make the appliance big and cumbersome and secondly they have no means of measuring the distraction forces applied.

Literature on the force levels required to distract the mandible is scarce, recently
however, Keßler et al., 10, reported successful mandibular distraction in mini-pigs employing a mean pressure level of 1.2-1.5 MPa using an intraoral microhydraulic cylinder to distract constantly over 24 hours at a rate of 1.5mm / day. Although this system is the first of its kind to allow continuous measurement and registration of the applied distraction forces, the device was not completely internalized, as the extra corporal steering unit was fixed to the animals’ back. Consequently, the aim of this research was to design and engineer an intraoral mandibular distracting device, which produces continuous distraction at a rate of 1mm per 24 hours. Assessment of the effectiveness of the new mandibular distractor would be ascertained from in vitro studies.

MATERIALS AND METHODS

A new intraoral mandibular distractor was developed (Fig 1A – 1B). The device consisted of a commercially available piston, housed within a cylindrical case (Pneumatic cylinders, Festo Pty Ltd, catalogue number DSNV – 8 – P- A), loaded by a spring to 70N +/- 5N (Fig 1C – 1D). The action of the piston was regulated by the incorporation of a high viscosity material within the cylindrical case (proximal to the piston). As force was applied to the piston, material extruded from the proximal to the distal section of the cylindrical case through a small hole cut longitudinally through the piston. This mechanism enabled the piston to move continuously over 24 hours, hence producing the required amount of distraction.

Initially, the maximum dimensions for the device were assessed as a length of 50mm, a height of 10mm and a breadth of 10mm; these measurements were recorded after examining a dry sheep’s mandible.

Preliminary calculations were then undertaken to estimate the size of the spring, suitable for incorporation within the device, yet able to produce a force level of 70N.

The following formulae was utilized to determine the diameter of the stainless steel necessary for fabrication of the spring to produce a force of 70N while maintaining the spring radii between a range of 1 to 3.5mm.
\[ F = \frac{\pi}{32} d^3 \sigma_y/R \]

F = Force (N)
\( d \) = Diameter (m)
\( \sigma_y \) = Yield strength (N/m²)
R = Coil radius (m)

The results showed that, the diameter of the stainless steel wire from which the coil is fabricated increased as the spring radii increased (Fig 2). However, the desired force level could also be obtained by altering the number of coils within the spring.

Next, three different sizes of the commercially available Minne Expander stainless steel springs (Ormco, Ca, USA, catalogue numbers; 670-0000, 670-0001 and 670-002) were tested on the Instron machine (Instron Universal Testing Machine {Instron Inc., Canton, Mass.}). Nine loading and unloading curves were obtained for each different spring size, as three springs of each type were obtained and each of these was tested three times. Graphical representation of the Minne Expander Spring 670-0000 revealed that these springs produced a 70N force when compressed by 4.53mm +/- 0.05mm (Fig 3). The unloading curve was characterized by the formulae:

\[ y = ax + b \]

y = Force (N)
a = Spring constant
\( x \) = Millimeters of activation
b = Intercept

So, the formulae for the unloading curve of this particular spring was \( F \) (N) = 15.45x.

The dimensions of this spring (20mm in length, comprising of 10 coils made from 1.25mm stainless steel wire with an internal and external diameter of 3.5mm and 6mm respectively) were also found to satisfy the requirements for its incorporation within the device.

To establish the viscosity of the material required to produce a flow rate of 1mm /
day the following formulae was utilized:

\[ V = \frac{P\pi R^4}{8L\eta} \]

\( P \) = Pressure difference
\( R \) = Tube radius
\( L \) = Length
\( V \) = Volume
\( \eta \) = Viscosity

The calculated viscosity of the material required to maintain a flow rate of 1mm / day against a 70N load, was shown to increase from 16 KPas to 66 MPas as radii of the hole within the piston increased from 0.2mm to 0.8mm (Fig 4). The piston radius (3.5mm), applied load (70N), duration of experiment (10 days) and the volume / day / \( m^3 / \text{sec} \) (4.45 x 10^{-13}) remained constant. \{Volume/day (m^3/sec) = \pi r^2 h, where the tube radius was 3.5mm and the flow rate was 1mm per day\}. The magnitude of the force decreased linearly with displacement of the piston necessitating the incorporation of a simple spring activating arrangement (Fig 3).

**Preliminary Study**

A preliminary study was performed to ascertain the effect of applying 70N of force with a stainless steel spring (type 670-0000) on the commercially available piston, housed within a cylindrical case, which was filled with glycerin and mounted on the Instron machine (Fig.5). The distal section of the cylindrical case was adapted to incorporate a readily available gas jet (Fig 6). Gas jets are manufactured with a hole of 0.15mm diameter in the center of the fixture. This hole allowed the glycerin (which for the preliminary study was contained within the distal section of the cylindrical case) to escape externally as the piston was loaded, hence controlling the rate of movement of the piston. The diameter of the hole in the gas jet was one of the variables, which could be altered in an attempt to achieve constant movement of the piston over 24 hours. Initially when the piston (incorporated with a gas jet of diameter 0.15mm) was filled with glycerin and loaded to 70N, a 0.25mm travel was recorded on the millimeter gauge within one hour. Extrapolation of this result, led to the assumption that a
6mm of travel would be obtained in 24 hours and hence a material with six times the viscosity of glycerin would produce a travel of 1mm in 24 hours. Once the preliminary test had been performed with glycerin in the cylinder, the system was then modified to incorporate; a small loading cell, a millimeter gauge and a digital signal amplifier (Fig 7 and 8). As an alternative to glycerin the distal section of the cylinder was filled with pink modeling wax, which was then loaded to 70N at 37°C. The movement of the piston was recorded every 24 hours from the millimeter gauge, as the diameters of the holes within the gas jets were changed (Fig 9). The movement of the piston over a 24-hour period, irrespective of the gas jet diameter was very inconsistent. Movements of less than or equal to 0.52mm in 24 hours were achieved in six out of ten tests, when the diameters of the jets varied from 150 to 1600 microns (Fig 10).

In an attempt to improve the inconsistencies in the results, the load cell system was modified in design to incorporate a fixed rigid arm to the millimeter gauge (Fig 11). Movement of less than or equal to 0.25mm / 24 hours were recorded for gas jet diameters up to 900 microns. At 1000 microns, readings ranging between 2.17 – 2.56mm were obtained. However, the inconsistencies of the readings were not found to improve after the addition of the fixed rigid arm to the millimeter gauge (Fig 12).

The next step in the preliminary study was to determine the force necessary to overcome the soft tissue resistance of an osteotomized sheep’s mandible. To do this, the mandible of a complete sheep’s head (excluding the skin) was osteotomized approximately 1cm proximal to the mental foramina. Both the distal and proximal segments were supported in the transverse plane by 4mm stainless steel schantz pins. A stress gauge was then applied to the distal segment and a reading was recorded, as the two fragments were distracted 10mm in the sagittal plane. The soft tissue resistance was found to increase with distraction rising to 10N on the osteomized sheep mandible for the 10mm of distraction.

Finally utilizing the data from the preliminary studies, the new distraction device was constructed. The device consisted of the commercially available cylinder (Fig 1C–1D), reduced in length to 44mm; a window 10mm in length and 6mm in breadth was cut into the cylinder case (this was to allow the proximal section of the cylinder to be filled with modeling wax). A hole of 1mm diameter was cut longitudinally through the piston,
which was 4mm in length; this allowed the wax to extrude back into the distal section of the cylinder as the piston moves. The total length of the piston arm was 27mm, 5mm of which was threaded to allow fixation of the device to the bone plates through a proximal screw cap. The distal end of the internal cylinder was threaded to accommodate a hexagonal screw, which enabled activation, insertion and removal of the spring. The force load applied to the piston by the spring was controlled by a torquing screwdriver (A device which was calibrated using the Instron machine which enabled the spring to be compressed within the desired range), which was inserted into the hexagonal screw. The device was attached to the mandible by two stainless steel bone plates, which were approximately 25mm in length, designed with three holes of 1mm diameter to enable the plates to be attached to the mandible with stainless steel screws. The distal bone plate was 7mm in length and incorporated a laterally offset cylindrical housing unit, into which the distractor would be seated at the time of surgery. The proximal bone plate incorporated a small lateral extension with a hole of a diameter of 3mm; this allowed the distractor to be screwed firmly into position by the piston arm. The distractor was tested in two different orientations; parallel to the body of the mandible and parallel to the axis of distraction. Before the distractor was attached to the mandible, the proximal section of the cylinder had to be loaded with pink modeling wax. To do this, the cylinder was first warmed in water for a few minutes, after which melted wax was poured through the window. As the wax cooled, the piston arm was pulled proximally so that the proximal part of the piston was level with the margin of the window in the cylinder; this marked the pistons starting position. Once the new mandibular distractor had been constructed, unilateral and bilateral osteotomies were performed on an acrylic replica of a sheep’s mandible. Elastics distributing 10N of force were placed lingually across the osteotomy site in an attempt to simulate the soft tissue resistance.

The method of attachment of the device to the mandible was as follows:

1. The bone plates are attached 7mm apart on the mandible, as determined by the use of a template.

2. The cylinder (without the spring and hexagonal screw) is inserted into the distal cylindrical housing unit.
3. The piston arm passes through the hole in the proximal plate enabling the screw cap to be secured to the threaded end of the piston arm, ensuring the stability and rigidity of the device.

4. After the spring and hexagonal screw have been inserted into the cylinder, the spring was loaded to 70N with the torquing screwdriver to start the distraction. Distraction of the acrylic mandible was tested over 7 days at a temperature of 37°C, during this period the spring was reloaded to 70N on a daily basis with the calibrated torquing screwdriver. Daily records were taken, which included photographs and measurements of the distraction gap with dial calipers to the nearest 0.1mm. Pre- and post-distraction radiographs were taken using a standardised radiographic technique. This involved the construction of an acrylic key on the x-ray table, into which the acrylic mandible could be seated. This ensured that the mandible was consistently relocated in the same position for each radiograph.

Initially the acrylic sheep’s mandible was designed incorporating intercondylar stainless steel pins, which maintained the intercondylar distance without rigidly fixating the proximal segments. In the present study this design feature was modified twice, first by incorporating two inter-rami rods (which facilitated lateral expansion of the rami) and secondly by incorporating an inter-rami block of acrylic (which rigidly fixed the rami at their pre-distraction position) instead of the intercondylar pins. These modifications were made to overcome “frictional resistances” that were occurring within the system, due to the lateral rotation of the proximal segments.

The final modification in the present study, involved the addition of five holes (of 1mm diameter) longitudinally through the piston within the distractor. These extra holes were placed to decrease the resistance associated with the wax extrusion, hence increasing the daily magnitude of movement of the distractor.

The in vitro studies performed were:
1. Unilateral distraction at 70N
2. Bilateral distraction, parallel to the body of the mandible at 70N with intercondylar pins.
3. Bilateral distraction, parallel to the body of the mandible at 70N with inter-rami rods.
4. Bilateral distraction, parallel to the body of the mandible at 100N with inter-rami rods.

5. Bilateral distraction, parallel to the axis of distraction at 70N with inter-rami rods.

6. Bilateral distraction, parallel to the axis of distraction at 70N with an inter-rami block of acrylic.

7. Bilateral distraction, parallel to the axis of distraction at 70N with an inter-rami block of acrylic and six holes through the piston.

RESULTS

Unilateral distraction at 70N produced a total sagittal movement of 1.2mm (Fig 13A) and a transverse movement of the distal fragment by a total of 1mm over the 7 day period (Fig 13B).

Bilateral distraction, parallel to the body of the mandible at 70N with intercondylar pins produced a total sagittal movement of 0.1mm on the LHS and no movement on the RHS (Fig 14A). In the transverse plane the whole distal fragment moved a total of 2mm to the LHS (Fig 14B).

Bilateral distraction, parallel to the body of the mandible at 70N with inter-rami rods produced a total sagittal movement of 1.3mm on both the RHS and LHS (Fig 15A). The transverse movement showed the both the RHS and LHS of the distal fragment moving 1mm initially but returning back to zero by day five (i.e no lateral movement observable). The transverse measurements on the RHS varied from those on the LHS from days two to four (Fig 15B).

Bilateral distraction, parallel to the body of the mandible at 100N with inter-rami rods produced a total sagittal movement of 0.1mm and 2.2mm on the RHS and LHS respectively (Fig 16A). In the transverse plane the RHS of the distal fragment was seen to move laterally by 0.5mm on day one, returning to 0.1mm displacement on day seven. No lateral displacement was observable on the LHS throughout the experimental period (Fig 16B).

Bilateral distraction, parallel to the axis of distraction at 70N with inter-rami rods produced a total sagittal movement of 0.3mm and 1.6mm on the RHS and LHS.
respectively (Fig 17A). No transverse displacement occurred during the experimental period (Fig 17B).

Bilateral distraction, parallel to the axis of distraction at 70N with inter-rami block of acrylic produced a total sagittal movement of 1.5mm and 1.6mm on the RHS and LHS respectively (Fig 18A). No transverse displacement occurred during the experimental period (Fig 18B).

Bilateral distraction, parallel to the axis of distraction with an inter-rami block of acrylic and six holes through the piston, produced a total sagittal movement of 5.8mm and 6.4mm on the RHS and LHS respectively (Fig 19A) and an average daily movement of 0.87mm (Fig 19B). No transverse displacement occurred during the experimental period (Fig 19C).

DISCUSSION

The design of new mandibular distraction devices are concerned with, the internalization of the appliance and the incorporation of a mechanism to allow slow controlled continuous distraction.\textsuperscript{8-10, 12} Enforced limitations on intraoral appliance design are determined by the surrounding anatomy of the model and include; the dimensions of the appliance, the accessibility and the durability of the appliance in situ. Ilizarov\textsuperscript{11} from his experimental work on canine tibias, found that the cellular activity of the hard and soft tissues resembled that of histogenesis during embryonic, fetal and postnatal limb growth, as the frequency of activation increased from 1 to 60 steps, for a daily distraction rate of 1mm. Consequently, devices utilizing either an electric or a hydraulic system were constructed to produce continuous distraction.\textsuperscript{8-10} Incorporation of these mechanisms adversely affected the design of these devices making them “bulky” in size and necessitating an external power supply.

Keßler \textit{et al.},\textsuperscript{10} was the first to measure the pressures required for both discontinuous and continuous distraction. He reported, that pressures in the range of 1.2 - 1.5 MPa were required to continuously distract the mandible in minipigs. Furthermore, continuous distraction, at a rate of 1.5mm / day was found to accelerate bone healing.\textsuperscript{12} In the present study, a pressure of 1.8 MPa (70N) was set as the magnitude of force
required to achieve continuous distraction. This was achieved by controlling the unloading rate of the spring, {which from the Instron machine measurements was shown to produce a linear continuous force (Fig 3)} by utilizing an opposing resistance (the pink modeling wax).

The magnitude of force used in the present study was higher than that reported by Keßler et al., 10, this was to overcome both the internal resistance of the device (i.e. frictional forces within the cylinder and the force to extrude the wax) and the soft tissue resistance associated with the sheep’s mandible (assumed to be between 1.2 - 1.5 MPa, 10). Our preliminary studies found that the internal resistance of the device was variable, depending on the diameter of the gas jet used. A pressure of 1.8 MPa (70N) was shown to produce an average distraction of 2.4mm in 24 hours, with a 1mm gas jet diameter (Fig 12), hence it was believed that this pressure would be adequate to overcome the internal and external resistances within the system.

In the preliminary experiments, the piston moved 0.25mm / hour when the cylinder case was filled with glycerin. This rate of flow exceeded the optimal 1mm / day distraction rate11. Variation of the gas jet diameters after placement of the pink modeling wax (a higher viscosity material) within the cylinder produced inherent inconsistencies in the results over a 24 hour period. So, it was assumed (Fig 10 and 12) that the rate of movement over 24 hours did not have a linear relationship with gas jet diameter. Consequently a gas jet of 1mm diameter (with an average movement of 2.4mm and a range of 2.17 - 2.56mm) was used in the design of the device, as gas jet diameters smaller than 1mm recorded less than 0.5mm movement within 24 hours. Premature consolidation of the bone regenerate has been shown in distraction rates of less than or equal to 0.5mm per day, as osteogenesis overtakes the speed of distraction11.

An assessment of the soft tissue resistance was determined to give representation of this force in the in vitro study. The 10N measured on the stress gauge for 10mm distraction was of smaller magnitude than anticipated. It was hypothesized that the magnitude of force for distraction over the first 10mm was less than that required after this distance had been accomplished, due to the viscoelastic nature of biological soft tissues. It is known that the forces required to stretch soft tissues are initially small for a large
degree of lengthening\textsuperscript{12}. This is due to the straightening of the undulating pattern (crimp) of fibrils within the soft tissues, as demonstrated by the "toe" region on their stress strain curves\textsuperscript{13}. However, for further stretch, forces of larger magnitudes are required for the uncrimping and orientation of additional recruited fibres and for elongation of the actual fibrils\textsuperscript{13}. As muscle tonicity and function were not present in the osteotomized sheep's mandible, larger magnitudes of soft tissue resistance would be expected in-vivo. It was not possible to test soft tissue resistance in vivo at this stage of the study, as the University of Sydney requires that all new devices be evaluated in vitro before approval can be granted for in vivo studies.

The design of the new intraoral mandibular distraction device was based on the Maxwell viscoelastic fluid with a spring and dashpot linked in a series\textsuperscript{13}. As a result of this serial arrangement, the fluid when loaded will respond instantaneously and flow indefinitely\textsuperscript{13}.

The final size of the new device exceeded the original maximum length assessment, however once the device had been constructed it became apparent that the length of the device could be reduced from 62mm to 48mm, while maintaining a distraction distance of 15mm. This 14mm reduction in length of the device could be achieved by decreasing the piston arm by 7mm, leaving only 5mm (instead of 12mm) of the threaded piston arm external to the cylinder for attachment to the proximal bone plate and by reducing the length of the distal end of the piston cylinder by 7mm. Feasibility of this reduction appeared only after assembling the device, when it became evident that the hexagonal screw had to travel 7mm before loading of the spring commenced. Further reduction in the length of the device is possible, if either the length of the pistons arm (for distraction distances less than 15mm) or the spring is decreased.

Initial results from both the unilateral and bilateral distraction at 70N with the distractor orientated parallel to the body of the mandible, produced only a total sagittal movement of 1mm and 0.5mm respectively over the seven day period. The total transverse movement was 1.2mm for the unilateral and 2mm for the bilateral distraction procedures. From these results it was concluded that the intercondylar pins across the rami, although flexible, were unable to facilitate lateral expansion, thus inducing
increased resistances laterally and inhibiting the magnitude of sagittal movement. So, the intercondylar pins were replaced by inter-rami rods. These rods maintained the pre-
distraction intercondylar width, while facilitating the rami to expand laterally (increasing the intercondylar distance), enabling the forces of distraction to act more favorably over the mandible. Bilateral distraction at 70N with the inter-rami rods and the distractor parallel to the body of the mandible produced a symmetrical total sagittal movement of 1.3mm with minimal transverse movement. From this test it was concluded that the distraction process was occurring successfully in terms of direction, but unsuccessfully in terms of the magnitude of distraction, possibly due to an increase in the intercondylar width. Consequently the above test was repeated utilizing a daily activation force of 100N, in an attempt to overcome the resistances incurred and to improve the distraction rate. This test showed that, minimal total movement in the sagittal plane occurred on the RHS (0.1mm) and more movement (2.2mm) occurred on the LHS. It was assumed from this test that there must be some “binding” forces within the system preventing symmetrical distraction at a rate of 1mm per day. Another weakness of the system was related to the orientation of the distractors, parallel to the body of the mandible. Samchukov et al., 14 using a computer generated 2D model of a human mandible, found that the posterior component of the distractors were laterally displaced, when the distractors were orientated parallel to the body of the mandible. This displacement was not however apparent when the distractors were orientated to the axis of distraction. So a new test was commenced bilaterally at 70N maintaining the inter-rami rods, with the distractors orientated parallel to the axis of distraction. This test revealed that distraction in the sagittal plane was occurring without any lateral component, but at very low and uneven magnitudes, only a total movement of 0.3mm on the RHS and 1.6mm on the LHS was recorded. From this test it was concluded that simulation of the “live” intraoral situation was extremely difficult as it was almost impossible to reproduce the soft tissue (as associated with muscles, tendons and ligaments) and masticatory forces, while maintaining intercondylar width for the in vitro studies. This inability to reproduce the in vivo environment was also felt to hinder the distraction process, as the perturbations produced by oro-facial functions could possibly overcome the “binding” occurring within the system. In an attempt to increase
the magnitude of the sagittal movement the final test performed consisted of a design modification in which, the inter-rami rods were replaced with an inter-rami block of acrylic to securely fix the proximal segments. Bilateral distraction at 70N with the distractor placed parallel to the axis of distraction was then commenced. This test showed that symmetrical sagittal distraction was achieved but still the overall total movement obtained was of a much lower magnitude than expected (1.5mm on the RHS and 1.6mm on the LHS). In the final test, bilateral distraction was performed at 70N with the distractors orientated parallel to the axis of the distraction and with six holes in the piston. The results found the overall total sagittal movement (5.8mm on the RHS and 6.4mm on the LHS) to be within the optimal range\textsuperscript{11}. As the total amount of distraction obtained in this test varied on a daily basis, it was proposed that this was due to non-linear nature of the internal and external resistant forces.

CONCLUSION

1. A new intraoral mandibular distractor was designed and engineered.
2. The distractor was shown to produce an average daily distraction of 0.87mm in an acrylic replica of a sheep’s mandible.
3. A consistent daily distraction could not be obtained with the new distractor, probably due to the non-linear nature of the internal and external resistant forces.
4. Before in-vivo studies can be performed, further work is required in design modification, firstly to reduce the size of the distractor and secondly to produce a more reliable optimal (1mm / day) daily distraction rate.
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Fig 1A

Distraction device fixed on the acrylic mandible model

Fig 1B

Bilateral placement of the distractors on the acrylic mandible model
Fig 1C

The components of the distractor

Proximal screw cap
Proximal section of cylinder
Piston
Spring
Hexagonal screw cap
Distal section of cylinder
Window

Fig 1D

The external and internal parts of the distractor

Hexagonal screw cap
Spring
Piston
Proximal screw cap
Fig 2

Variation in the diameter of the stainless steel wire of the spring to produce 70N of force

Fig 3

Loading and unloading curves for the Minne Expander stainless steel spring size 670-0000

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Fig 4

Variation in viscosity for different gas jet diameters to maintain a constant flow rate for 70N of force application

<table>
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Fig 5

Piston and cylinder loaded to 70N on Instron

Piston and cylinder assembly

Millimeter gauge
Fig 6
Cylinder with gas jet

Fig 7
Cylinder, piston, load cell and digital signal amplifier
**Fig 8**

The parts of the assembly

- Millimeter gauge
- Load cell
- Spring
- Piston and cylinder
- Gas Jet

**Fig 9**

Wax extrusion through the gas jet

- Gas jet

**Fig 10**

Variation in the rate of movement with the change in gas jet diameter

![Graph showing rate of movement vs. gas jet diameter](image)
Fig 11
Fixed rigid arm incorporated into the assembly
to improve the millimeter gauge readings

Fig 12
Variation in the rate of movement with the change in gas jet diameter
Fig 13A
Total amount of unilateral distraction at 70N

Fig 13B
Post-distraction radiograph

Intercondylar pins
Proximal bone plate
Distal bone plate
Acrylic model of a sheep’s mandible
Distractor
Fixation pin of the standardization key
Acrylic standardization key
Fig 14A

Total amount of bilateral distraction at 70N, parallel to the body of the mandible, with intercondylar pins. RHS, right hand side; LHS, left hand side; A-P, sagittal plane; Tvse, Transverse plane

Fig 14B

Post-distraction radiograph
Fig 15A

Total amount of bilateral distraction at 70N, parallel to the body of the mandible, with inter-rami rods

Fig 15B

Post-distraction radiograph

Inter-rami rods
Fig 16A
Total amount of bilateral distraction at 100N, parallel to the body of the mandible, with inter-rami rods

Fig 16B
Post-distraction radiograph
**Fig 17A**

Total amount of bilateral distraction at 70N, parallel to the axis of distraction, with inter-rami rods

**Fig 17B**

Post-distraction radiograph
Fig 18A

Total amount of bilateral distraction at 70N, parallel to the axis of distraction, with an inter-rami block of acrylic

Fig 18B

Post-distraction radiograph

Inter-rami block of acrylic
Fig 19A
Total amount of bilateral distraction at 70N, parallel to the axis of distraction, with six holes in the piston

Fig 19B
Amount of daily bilateral distraction at 70N, parallel to the axis of distraction, with six holes in the piston
Fig 19C

Post-distraction radiograph
FUTURE DIRECTIONS

✓ PHASE I
   A. To adapt the new intraoral distractor to produce a continuous daily distraction rate of 1mm. This could possibly be achieved by either;
      i. Increasing the diameter of the holes cut longitudinal through the piston.
      ii. Increasing the number of holes in the piston.
      iii. Increasing the force applied to the piston.
      iv. Decreasing the viscosity of the material within the cylinder case.
   B. To reduce the size of the distractor for in vivo use

✓ PHASE II
   A. To test the effectiveness of the new intraoral mandibular distractor in vivo.
   B. To histologically analyze the hard and soft tissue regenerates.

✓ PHASE III
   A. To conduct human clinical trials.