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UNIVERSITÉ DE MONTRÉAL

DESIGN AND VALIDATION OF A REMOTE-CONTROLLED INTERNAL LENGTHENING PLATE FOR DISTRACTION OSTEOGENESIS IN PEDIATRIC PATIENTS

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DESIGN AND VALIDATION OF A REMOTE-CONTROLLED INTERNAL LENGTHENING PLATE FOR DISTRACTION OSTEOGENESIS IN PEDIATRIC PATIENTS

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en vue de l'obtention du diplôme de : Maîtrise ès sciences appliquées

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DEDICATION

À Louis Brown, mon charmant filleul.

À ma très chère famille : Vincent Gaudreau, Margaret Engelberts, Élyse Gaudreau.

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One is hard-pressed to think of any person's achievements, no matter how trivial, that have come about without the collaboration of others – this document is no exception.

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RÉSUMÉ

L'ostéogenèse par distraction est une technique couramment utilisée afin d'allonger les os longs chez les patients atteints d'une difformité osseuse dans un membre. Ce procédé chirurgical consiste à exécuter une ostéotomie partielle au niveau de la diaphyse de l'os et à séparer graduellement les deux morceaux à l'aide d'un fixateur extensible, qui maintient les deux segments osseux vis-à-vis l'un l'autre. Le fixateur le plus répandu est l'appareil Ilizarov qui, malgré son succès dans l'ostéogenèse par distraction, peut causer des infections ou de la cicatrisation excessive au niveau des broches de fixation. L'introduction des fixateurs télescopiques intramédullaires, tel le PRECICE, a résolu ces complications chez les patients adultes. Cependant, son implantation est impossible chez les patients pédiatriques. L'objectif du projet est de concevoir un fixateur extramédullaire dont l'implantation n'endommage pas les plaques de croissance des patients en croissance.

Un fixateur extramédullaire en acier inoxydable en forme de plaque osseuse extensible a été conçu afin de pallier le manque d'implants pour ostéogenèse par distraction chez les enfants. Cette plaque est fixée à l'aide de « locking screws », des vis qui maintiennent le dispositif au-dessus de la surface de l'os, préservant ainsi la vascularisation à la surface de l'os et favorisant la régénération. Le fixateur est composé de deux corps télescopiques accouplés, le premier desquels contient un aimant en rotation et une vis sans fin, qui sont responsables de l'extension, et le deuxième qui contient un filet de vis interne compatible avec la vis sans fin. Ces deux corps ont une fixation le long du côté où sont percés trois trous filetés afin de recevoir des « locking screws ». L'aimant est actionné par une manette magnétique externe au patient. Pour chaque rotation de l'aimant, le fixateur subit une extension de 0,025 mm, favorisant ainsi une distraction précise et contrôlée.

Afin de tester la force de distraction, un montage expérimental a été conçu pour simuler la force appliquée sur les segments osseux lorsque le fixateur est installé et en fonction. Le fixateur est fixé à une plate-forme coulissante sur laquelle est placé un poids. Des faux segments osseux ont été fixés à la plate-forme ainsi qu'à la base du montage expérimental, pour que la plate-forme coulisse en unisson avec la distraction une fois le fixateur vissé aux segments osseux. Plusieurs distractions complètes de 50 mm ont été exécutées, pour des poids variant de 10 à 70 kg avec un intervalle de 10 kg, ainsi qu'un test additionnel à 75 kg. Ces tests ont été effectués sur des segments cylindriques en bois et sur des os synthétiques.

Le fixateur a pu générer un effort de distraction jusqu'à 75 kg (735 N), ce qui dépasse la valeur maximale des forces de résistance des tissus mous dans un allongement osseux chez les patients pédiatriques (673 N) antagonistes à l'action du fixateur (Younger, Mackenzie et al. 1994). De plus, pour un poids donné, presqu'aucune variation n'a été mesurée au niveau de la vitesse de distraction, ce qui indique une relation essentiellement linéaire entre l'allongement et le temps de distraction. Par contre, un léger ralentissement a été noté aux poids les plus élevés.

Malgré le fait que ce fixateur cible une population pédiatrique, il présente une option moins invasive que les modèles intramédullaires qui sont actuellement en utilisation chez les adultes. Contrairement aux clous intramédullaires, le fixateur en forme de plaque ne nécessite pas de procédure de pré-perçage de l'os. Par contre, certaines améliorations sont nécessaires. Un sceau de caoutchouc ou de silicone devra être installé à l'interface entre les deux corps télescopiques afin d'empêcher la pénétration de liquides corporels, une source d'infection potentielle. Aussi, il sera nécessaire d'effectuer des tests de résistance mécanique et de fatigue sur le dispositif pour assurer son bon fonctionnement pour toute la durée de son implantation.

Durant les tests de distraction, il était important de s'assurer que les aimants en rotation dans la manette magnétique étaient en parfaite synchronisation avec l'aimant à l'intérieur du fixateur. Dans le cas d'un décalage de synchronisation, un « clic » se faisait entendre, ce qui pouvait échapper au responsable de l'expérience et ainsi fausser les résultats. En raison du coût élevé et de la complexité d'usinage des « locking screws », des vis filetées sur tout leur long (ISO M6 x 25 mm) ont été employées afin de simuler l'espace de 1 mm entre le fixateur et l'os. Bien que ces vis simulent avec justesse la position du fixateur vis-à-vis l'os, elles ne représentent pas bien la possibilité de bris de vis, bris de filetage ou de « pullout ».

Ce fixateur en forme de plaque télescopique ajoute beaucoup de valeur au traitement de l'allongement osseux puisqu'il diminue les complications chez les jeunes patients nécessitant une telle procédure. Les perspectives futures du fixateur comprennent une miniaturisation générale afin de réduire l'inconfort, des tests *in vivo* sur un modèle animal et éventuellement des tests cliniques. De plus, ce design pourrait facilement être adapté pour traiter des patients de tous âges, enfants et adultes.

ABSTRACT

Distraction osteogenesis is a technique widely used to treat limb length discrepancies due to congenital deformities, trauma, or infection. A cut is made to the affected bone, which is then incrementally lengthened with a fixation device used to hold both segments and to apply a distraction. For pediatric patients, the only available option is the Ilizarov external fixator, which is known to cause pin tract infections and scarring, as well as having a negative impact on the child's body image and social life. Recently, the introduction of implantable lengthening nails such as the PRECICE has solved these problems for adult patients. The objective of the project was to design an internal extramedullary and externally controlled fixator whose implantation would not damage the child's growth plates.

An extramedullary fixator was designed in the form of a stainless steel lengthening bone plate, screwed on the external surface of the bone. This device makes use of locking screws, which hold the device slightly above the bone surface, preserving the vascularization envelope on the surface of the bone and promoting faster bone regeneration. It is composed of two telescopic halves, the first containing a rotating magnet and a leadscrew, which drive the lengthening mechanism, and the other containing an internal thread compatible with the leadscrew's threads. Each half features a flange running alongside the length of its exterior shell, onto which three screw holes are evenly distributed on each side. This magnet can be activated from outside the patient's limb with a magnetic controller. For every rotation completed by the controller, it is calculated that the device extends 0.025 mm, resulting in a precise and controlled lengthening procedure.

To validate the lengthening plate's distraction mechanism, an experimental bench was designed to simulate a load applied on the bone segments while the fixator is installed. To do so, the fixator was attached to a vertically sliding wooden platform onto which weights were stacked. Mock bone segments were attached to the base and the platform, so that the weights would move in unison with the distraction. A series of full 50 mm distractions were performed on the experimental bench, with weights ranging from 10 kg to 70 kg in 10 kg increments, as well as a final test at 75 kg. Also, to measure possible changes in the device's distraction speed, measurements of the gap were taken every five minutes during the lengthening until the full 50 mm distraction was reached. These tests were performed on wooden bone segments and synthetic bones.

The lengthening plate was shown to generate distraction efforts of up to 75 kg (735 N), which exceeds the value of soft tissue resistance forces in pediatric limb lengthening (673 N) pushing back against the fixator's distraction (Younger, Mackenzie et al. 1994). Moreover, for a given weight added to the bench, very little change was observed in the lengthening speed, indicating a linear relationship between the lengthening and the distraction time. However, the speed was shown to decrease slightly with increasing weights.

Though its prime goal is to be designed for use in children, the lengthening plate can offer a less-invasive alternative to intramedullary nails in adults since it does not require a preliminary reaming procedure. However, a few improvements remain to be made to the device. A seal should be installed to prevent fluid ingress, and there are plans to miniaturize the device's diameter from 18 mm to 12 mm. To further validate the device's resistance, structural failure and fatigue tests should also be conducted to ensure that the device's body can withstand the patient's activities in a weight-bearing scenario for the duration of its 6-month distraction procedure.

During the distraction tests, it was important to ensure that the rotating magnets in the controller rotated in perfect synchronization with the magnet inside the lengthening plate. If not, a clicking sound was produced by the device, which could be missed by the experimenter. Due to the high cost and machining complexity of locking screws, it was decided that ISO M6 x 25 mm set screws would be used to simulate the gap between the lengthening plate and the mock bone segments. The set screws, threaded along their entire length, simulated the correct 1 mm gap between the device and the bone, but left out the possibility of testing screw pullout, breakage or thread back-out.This limb lengthening device finds great value in its extramedullary implantation, allowing young patients to avoid the extra complications normally associated with external fixators. Future perspectives for the device involve a general reduction in size to alleviate discomfort, *in vivo* testing using animal models, and clinical trials later down the line. Also, the design can be easily adapted to service patients of all ages, from infants to grown adults.

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CHAPTER 1 INTRODUCTION

Limb length discrepancy is a condition characterized by the difference in length between two limbs, such as one leg being longer than the other. This may be a congenital defect but does not preclude limb length discrepancy secondary to trauma, infection or long bone non-union. It is often negligible and does not cause a problem, but when the difference in length between two limbs is significant, a limb lengthening operation may be required. Distraction osteogenesis is the most common treatment for limb length discrepancy. It consists of separating the shorter bone in two segments, and gradually increasing the gap between the two over a period of many months in order to reduce the length difference between both limbs. The induced tension-stress action induces a regeneration of the bone inside the distraction gap (De Bastiani, Aldegheri et al. 1987).

For pediatric patients, the gold standard procedure in limb lengthening is currently the external Ilizarov fixator, where metal rings are affixed to the bone segments using percutaneous Kirschner wires to distract and stabilize the limb. Though this procedure has a high success rate, the bulky apparatus must be worn for extended periods of time, sometimes upwards of 6 months (Ilizarov 1989). The complications arising from this procedure include a 10-20% incidence of pin tract infection as well as pin breakage occurring in 23-27% of cases (Rogers, Bevilacqua et al. 2007; Aston, Calder et al. 2009). Additionally, children wearing the Ilizarov are prone to social isolation from their peers due to body image and anxiety (Paley 1990). The manual actuation required for distraction must be executed by the child's parent, which may lead to compliance issues and potential human error.

Fully implantable limb-lengthening devices address most of the problems associated with external fixators. For example, the PRECICE nail, which consists of a telescopic intramedullary rod powered by a rotating magnet, has been successful in treating adult cases of limb length discrepancy and congenital deformities. Internal limb-lengthening fixators present many clear improvements over the traditional Ilizarov external fixator, reducing the incidence of scarring and pin-site infection while improving mobility (Schiedel, Vogt et al. 2014; Paley 2015). However, as with all intramedullary devices, its implantation in the medullary canal through bone epiphyses renders it inaccessible to the pediatric population, because it would damage the growth plates, which are responsible for longitudinal bone growth, by piercing them. Once damaged, the growth plates are unable to function properly and hinder the child's normal physiological development.

Hence, there are currently no internal fixators for limb lengthening whose implantation does not damage the patient's growth plates, forcing pediatric patients to undergo the additional complications of external fixators.

CHAPTER 2 LITERATURE REVIEW

2.1 Limb lengthening

2.1.1 Long bone anatomy

In the human skeleton, long bones are characterized by an elongated shape, where one dimension is noticeably greater than the two others. This includes the femur, tibia, fibula, humerus, radius, ulna, and phalanges, among others. Long bones are typically the target for limb lengthening procedures, and their structure is divided into distinct parts. As seen in Figure 2.1, the middle part of the long bone, referred to as the diaphysis, has a consistent cross-section and is tubular in shape. At each end, there are irregular structures are called epiphyses, whose shape is built to accommodate the joints on either end of the bone. Separating these structures is an intermediate section, referred to as "metaphysis" (Drake, Vogl et al. 2014; OpenStax 2016). All bone is made up of cortical and spongious bone (Figure 2.1). Cortical bone, mainly found in the most solicited areas of the bone, is the dense outer shell that protects the bone from impact and gives it structural stability. On the other hand, spongious bone is a porous tissue structure that is found in the epiphyses and metaphyses of the long bones. It is less dense and less rigid than the cortical bone, and the alignment of the bone fibers in the spongy network are aligned with the load distribution. Due to its high surface area, it is optimized for nutrient transfer, such as calcium ion exchange, and contains much of the bone's vascularization (OpenStax 2016).

Longitudinal bone growth in children takes place at the epiphyseal growth plates (Figure 2.2), which are located between the epiphyses and the metaphyses (Figure 2.2). While a child is growing, the growth plates are "open" and still active. Any damage to the growth plates at this point can result in major problems with the child's normal development. As the child achieves skeletal maturity, the growth plates "close" and the natural growth ends (OpenStax 2016).

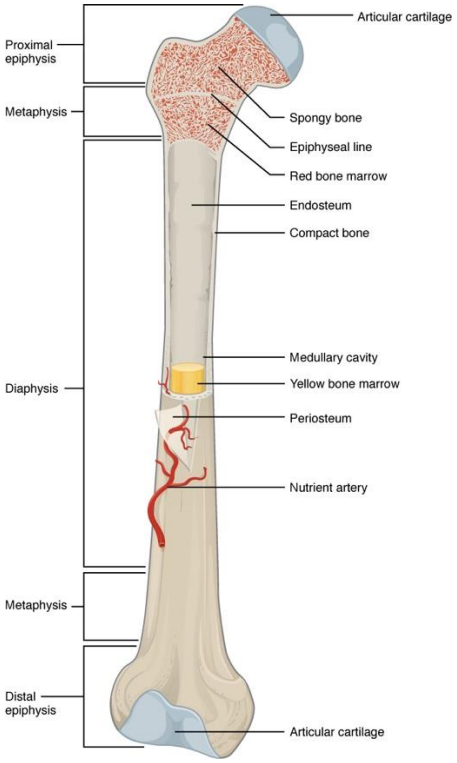


Figure 2.1: Long bone anatomy (OpenStax 2016)

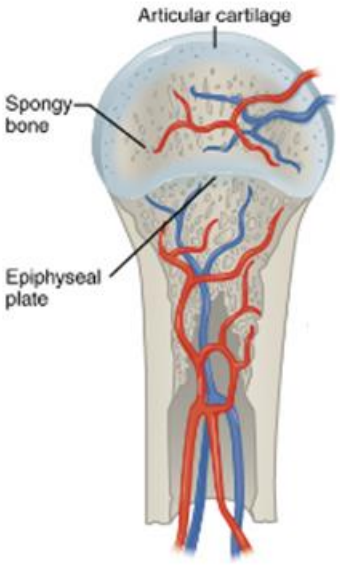


Figure 2.2: Anatomy of epiphyses and epiphyseal growth plates (OpenStax 2016)

2.1.2 Limb lengthening procedure

Distraction osteogenesis is a technique that allows for treatment of limb length discrepancies, limb deformities and long bone non-unions. It can also be used to treat bone loss secondary to infection, trauma and malignancies. This reconstructive technique allows for the lengthening of a bone without resorting to bone grafts. In short, the bone is separated into two segments, which are pulled away from one another in very small increments; this is referred to as distraction.

The surgical procedure is summarized in Figure 2.3. The limb is first stabilized with an extensible fixator, firmly attached to either end of the bone. This device serves a double purpose: it maintains the limb's alignment during the distraction procedure, and performs the controlled extension once the bone has been cut. To separate the affected bone, a corticotomy is then executed on the bone's midsection. This preserves the vascularization inside, favoring bone regrowth. A Gigli saw is used to perform the corticotomy on the patient. Distraction osteogenesis is characterized by three phases: latency, distraction/activation, and consolidation. Once the bone has been stabilized by a fixator and undergone a corticotomy, a period of time is provided in the *latency* phase to allow for the bone callus to begin forming at the corticotomy site (Figure 2.3a). This can last up to two weeks, depending on the patient's age and the location of the corticotomy Once an acceptable timespan has passed, the bone segments are subjected to a gradual distraction during the *activation* phase, inducing tension stresses in the intersegmentary callus and leading to formation of new bone fibers (Figure 2.3b). A distraction that occurs too rapidly may cause non-union between the two bone segments, generating only fibrous tissue in the distraction gap. Conversely, an insufficient distraction increment can lead to premature consolidation, where the bone fully repairs itself before the full distraction length has been obtained. Once the bone has attained its desired length, the fixator is left on the bone to maintain its stability during the *consolidation* phase, which allows the bone callus to strengthen over time and fully adopt the characteristics of healthy bone (Figure 2.3c) ((De Bastiani, Aldegheri et al. 1987)).

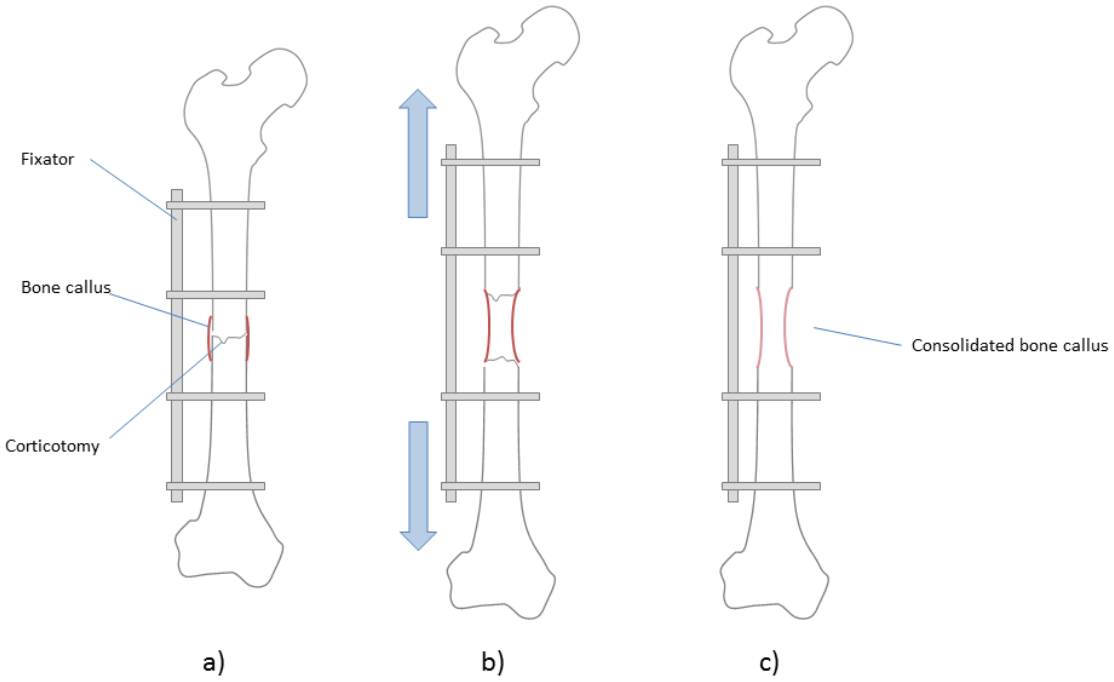


Figure 2.3: Limb lengthening by distraction osteogenesis steps: a) latency phase; b) distraction/activation phase; c) consolidation phase

As the bone segments are separated, the stresses at the site of the corticotomy provoke the regeneration of bone cells. A bony envelope, or callus, surrounds the gap between the bone segments. However, as the callus is not strong enough to withstand full weight-bearing, an additional span of time is necessary to ensure that the bone callus has fully consolidated. During distraction, the fixator must generate sufficient forces to overcome the resistance of soft tissues which stretch as the limb undergoes gradual distraction. In adult patients, this force can reach magnitudes in excess of 1000 N (Wolfson, Hearn et al. 1990; Simpson, Cunningham et al. 1996). Lengthening forces in children have been recorded up to 673 N (Younger, Mackenzie et al. 1994).

2.1.2.1 Early limb lengthening techniques

The early days of limb lengthening bear the hallmarks of any surgical technique in its infancy. At first, the procedure consisted of immediately stretching the affected limb to its final length, which resulted in significant damage to the surrounding soft tissues, vessels and nerves.

2.1.2.1.1 Codivilla

Codivilla is credited in 1904 with the first example of a present-day limb lengthening procedure, pictured in Figure 2.4. The idea behind his technique was to drive a calcaneal pin in the patient's heel, perform an oblique osteotomy, and apply a one-time traction to the limb. The elongated limb was then encased in plaster for 30 days and left to heal. While this technique enjoyed marginal success, it was weighed down by the serious complications and shock that came with abrupt lengthening of a limb (Codivilla 1994; Birch 2017).

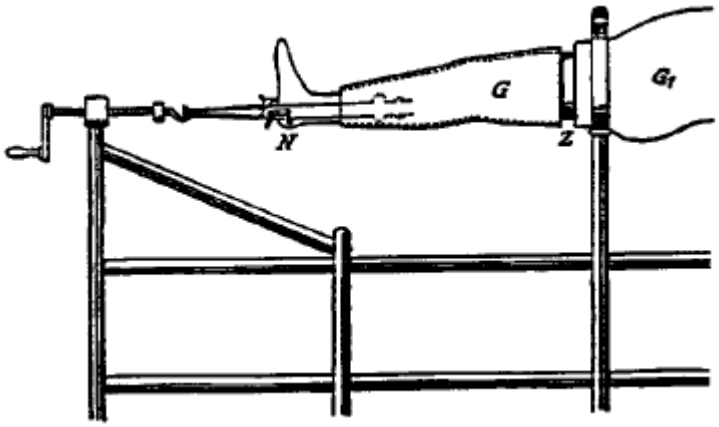


Figure 2.4: Codivilla apparatus (Codivilla 1994)

2.1.2.1.2 Putti

Intent on improving Codivilla's technique, Vittorio Putti developed a procedure in 1918 to lengthen the limb without severe soft tissue stretching. Putti ventured that a low-trauma osteotomy and a slower, measured distraction would decrease the instance of complications following the lengthening. In this embodiment of the limb lengthening procedure, a unilateral telescopic device (Figure 2.5) is affixed to the proximal and distal ends of the bone to be lengthened, and a gradual distraction is applied for 30 days. This lengthening corresponds to 2-3mm per day (Putti 1990).

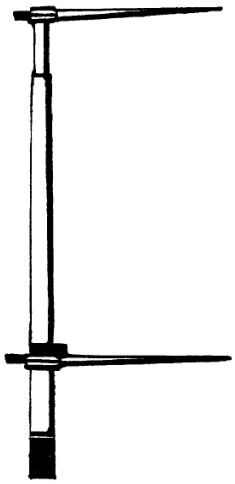


Figure 2.5: Putti lengthening device (Paterson 1990)

2.1.2.1.3 Abbott

Inspired by Putti's design, Leroy Abbott set out to reduce the complications associated with the limb lengthening procedure. To further stabilize the design, Abbott designed a fixator with drill wires secured to the bone at different angles, as seen in Figure 2.6. In contrast with Putti's unilateral design, this newer device held the bone in a more rigid fashion. In addition to the improved fixator, Putti pioneered the now-common practice of waiting up to two weeks after the osteotomy before beginning the distraction process. However, many complications remained and the surgery was discontinued (Abbott and Saunders 1939).

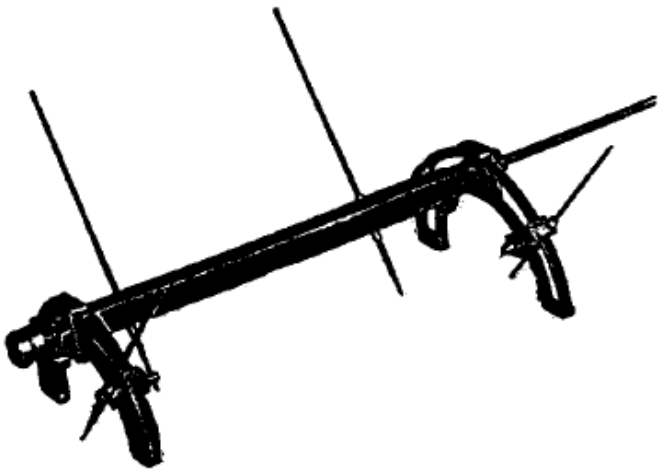


Figure 2.6: Abbott lengthening device (Abbott and Saunders 1939)

2.1.2.1.4 Ilizarov

First used in 1951, the Ilizarov technique addressed many of the previous limb lengthening surgeries' shortfalls by carefully characterizing the procedure's variables. After much testing, Ilizarov formulated limb lengthening principles that are still followed to this day. For example, he was a strong advocate for a simple corticotomy to separate the bone, instead of a full osteotomy to preserve the vascularization present in the bone marrow (Ilizarov 1989). He was also instrumental in defining the optimal lengthening rate per day, and encouraged patients to apply weight on the affected limb. The Ilizarov ring fixator (Figure 2.7) allows for a controlled and predictable distraction of about 1mm per day, which greatly reduced the complication rate when compared to the previous limb lengthening techniques (Ilizarov 1989). The Ilizarov fixator can also be used for a lengthening procedure, which includes a nail inserted in the patient's medullary canal, guiding the distraction and reducing the chance of axial deviation. This method is referred to as "lengthening over nail", which reduces the duration of external fixation and reduces complications, but adds a high risk of deep intramedullary infection (Paley, Herzenberg et al. 1997; Chaudhary 2008; El-Husseini, Ghaly et al. 2013).

Figure 2.7: Ilizarov ring fixator (Smith&Nephew 2018)

2.2 External fixators

During the nascent era of limb lengthening, patients relied on fully external fixators to stabilize the bone. Some of these fixators are still in use nowadays for patients whose intramedullary canals are

too thin for the more modern distraction nails or for younger patients whose growth plates are still open.

2.2.1 Monoaxial external fixators

Monoaxial external fixators can only correct limb deformity along the long axis of the bone. No rotational corrections or movements in the horizontal plane are possible.

2.2.1.1 Ilizarov device

Widely used to treat limb length discrepancies, the Ilizarov external fixator is typically composed of two metal rings that encircle the affected limb (Figure 2.8). These rings are affixed to both bone segments with percutaneous Kirschner wires. Longitudinal threaded rods connect the two rings together, and can be manually turned by the patient or physician, increasing the distance between both rings and thereby distracting the bone segments.

The Ilizarov fixator was developed in 1954 for distraction osteogenesis of long bones. Patient weight-bearing on the limb is allowed immediately after surgery, due to the high strength of the frame. Complications may arise in procedures involving the Ilizarov fixator due to a variety of factors. The percutaneous Kirschner wires can cause pin tract infections in patients, as well as muscle stiffness occurring due to pin transfixion. There are also reports of muscle contracture and damage to the patient's nerves and veins secondary to the distraction process. Moreover, there is a chance of knee subluxation and limb misalignment in an unsuccessful procedure. In some cases, mechanical failure can occur, causing a loss of stability in the limb (Paley 1990). Another study mentions the frequent occurrence of a decreased range of motion in the Achilles' tendon, and the inability of one patient to psychologically tolerate the Ilizarov fixator (Vargas Barreto, Caton et al. 2007). The Ilizarov fixator is a popular choice due to its low cost, but its large build is inconvenient for patient movement and body image (Spiegelberg, Parratt et al. 2010). This apparatus is FDA-approved and is distributed by many companies, including Smith & Nephew, Meditech, Carefix, and more.

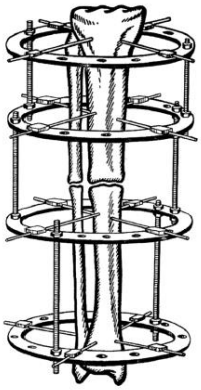


Figure 2.8: Ilizarov ring fixator (Paterson 1990)

2.2.1.2 Orthofix fixator series

Another style of uniaxial external fixator manifests itself in the Orthofix series. The Orthofix Procallus 9000 is shown in Figure 2.9. In contrast with the Ilizarov, which encircles the patient's limb, the Orthofix rail fixators are installed to one side and driven by a single telescopic rail system. The system is fixed to the patient's bone through percutaneous pins, which are attached to the Orthofix fixator clamps, which can be pivoted to accommodate the bone's shape. This device is FDA-approved. (Sakkers 2010)

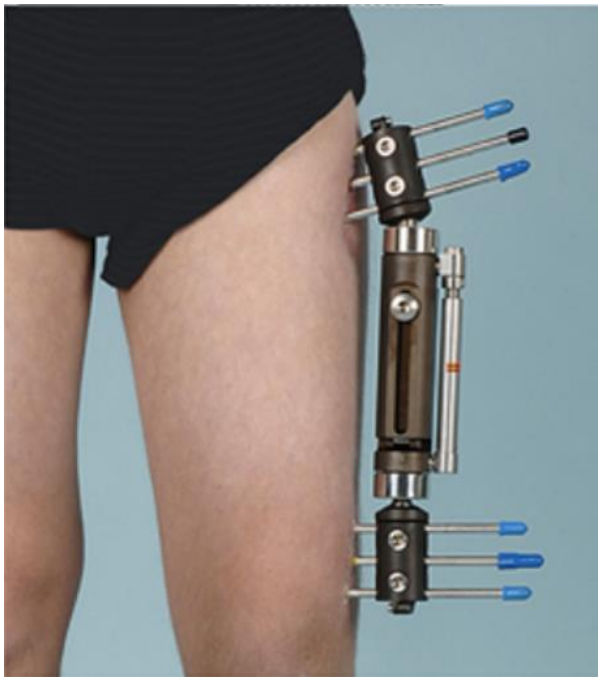


Figure 2.9: Orthofix ProCallus 9000 fixator (Sakkers 2010)

2.2.2 Polyaxial external fixators

In contrast to monoaxial fixators, polyaxial fixators can correct limb deformities in all directions, including rotation in all three planes(Eidelman and Chezar 2005).

2.2.2.1 Taylor Spatial Frame

The Taylor Spatial frame borrows the Ilizarov device's basic concept of the metal rings attached to each bone segment, also attached using Kirschner wires. However, instead of threaded rods connecting the two rings, the Taylor Spatial Frame makes use of the "hexapod" concept, and uses six telescopic struts, arranged in a triangular configuration, to link the rings (Figure 2.10). While the Ilizarov fixator allows distraction in one direction only, the Taylor Spatial Frame's "hexapod" struts allow for axial, angular, and rotational corrections. Each strut is color-coded and manually distracted according to the required correction.

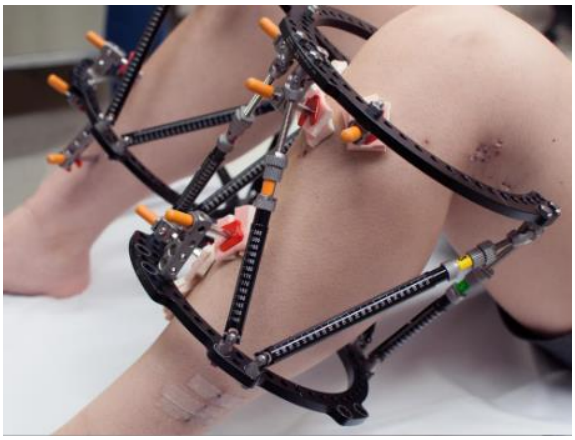


Figure 2.10: Taylor Spatial Frame (AboutKidsHealth 2015)

Used on long bones, this device has been commercially available through Smith & Nephew since 2002, and is FDA-approved. Patient weight-bearing is allowed immediately after surgery, and no notable difference in complications has been observed when compared to the Ilizarov fixator. Owing to the lack of interference with the bone's growth plates, the Taylor Spatial Frame has often been used in limb lengthening procedures in children. Like the Ilizarov fixator, the Taylor Spatial Frame is inexpensive to manufacture, but bulky and cumbersome for the patient (Dammerer, Kirschbichler et al. 2011).

2.3 Internal fixators

External fixators for limb lengthening procedures are subject to a wide range of complications due to the necessary piercing of the skin. These complications can include pin tract infections, muscle stiffness, and psychological problems linked to body image due to their bulky nature. Initially developed in the 1990s, internal fixators offer a solution to the aforementioned device-related complications (Cole, Justin et al. 2001; Paley 2015; Accadbled, Pailhe et al. 2016).

2.3.1 Intramedullary nail fixators

The most common type of internal fixator adopts the shape of an elongated telescopic nail, installed in the intramedullary cavity of the long bone, fastened with bone screws that lock the fixator in place. The nail's extension can be driven by a variety of mechanisms (Guichet, Deromedis et al. 2003).

2.3.1.1 Mechanically-actuated intramedullary fixators

2.3.1.1.1 Guichet/Albizzia nail

Reportedly the earliest internal limb-lengthening device, the Guichet/Albizzia nail consists of a telescoping rod that is surgically inserted into the long bone's intramedullary cavity and fastened with bone screws, as shown in Figure 2.11. Also commercialized in Germany under the moniker "Betzbone," this fixator requires a 20-degree rotation of one half of the nail to achieve an incremental axial distraction of the limb, yielding an audible "click". In other words, the patient must rotate the affected limb several times a day to achieve lengthening, which is measured by counting the number of "clicks". Patients can resume normal weight-bearing immediately after the surgery, and the complication rate, found to be 29% in one study (Guichet, Deromedis et al. 2003), is considerably lower than with external fixators. Because of its intramedullary nature, this fixator is unsuitable for limb lengthening in children, as its insertion pierces the patient's growth plate. Since the lengthening is controlled by the number of incremental "clicks," the elongation can be slowed or accelerated based on the patient's situation. Furthermore, the recovery time is shorter than with the external fixators. That being said, the necessary rotations required to lengthen the nail can be quite painful for the patient, who must perform multiple rotations 1-4 times per day. This

device was first used in 1994, but is not FDA-approved (Guichet, Deromedis et al. 2003; Paley 2014).

Figure 2.11: Guichet/Albizzia nail (X-os 2014)

2.3.1.1.2 Intramedullary Skeletal Kinetic Distractor

The intramedullary ISKD nail (Figure 2.12) borrows the concept of the Guichet/Albizzia nail, relying on axial rotations to trigger the incremental lengthening. In this case, the 3- to 9-degree rotations happen automatically with the patient's normal physical activity. Weight-bearing is allowed during the lengthening phase, as instructed by the physician. According to the literature, complications were found to occur at a rate of up to 60%, which included delayed bone healing, muscle cramping, and lengthening rate control problems among other factors (Paley 1990; Thonse 2005; Lee, Ryu et al. 2014).

Figure 2.12: Intramedullary Skeletal Kinetic Distractor (AKVA-Surgical 2018)

Though unsuitable in children, this fixator has seen success in adult patients as compared to external fixators, reducing the likelihood of infections and shortening recovery time. However, the dependence on the patient's activity makes lengthening unpredictable; slower lengthening has resulted in early consolidation, and accelerated lengthening resulted in non-union (Cole, Justin et al. 2001). This nail was first used in 2001, but has since been discontinued and was never FDA-approved (Laubscher, Mitchell et al. 2016).

2.3.1.2 Magnetically-actuated intramedullary fixators

2.3.1.2.1 PRECICE

Developed by Ellipse Technologies, the PRECICE intramedullary nail is a telescopic rod that lengthens by using a rotating magnet, located inside the nail, as seen in Figure 2.13. To do so, an external remote control generates a magnetic field using built-in magnets, and the rotating permanent magnet drives a threaded leadscrew that can extend or retract the rod, depending on the direction of the field (Paley 2015).

Figure 2.13: PRECICE (Nuvasive 2018)

The first iteration of the PRECICE nail was developed in 2011, and the PRECICE 2 followed in 2013, improving on the device's structural shortfalls. This FDA-approved fixator allows for weight-bearing only during the consolidation phase, once sufficient bone regrowth has occurred. According to some clinical studies, the PRECICE nail yields an implant-related complication rate of 4-8%. The PRECICE's complications include non-union, where the bone segments do not consolidate to bridge the distraction gap with bone tissue but remain separated while fibrous tissue fills the gap. In some cases, there are reports of nail breakage where an additional surgery had to be executed to remove the offending nail. Furthermore, compartment syndrome was observed in several patients, where the pressure induced in the soft tissue by the lengthening procedure caused

a lack of blood supply in parts of the limb. (Kirane, Fragomen et al. 2014; Schiedel, Vogt et al. 2014). This device, as well as all the advantages associated with intramedullary nails, does not require painful actuation by the patient; lengthening happens in a very gradual manner. Also, the nail's bidirectional control allows for adjustments in treatment to prevent accelerated elongation. However, full weight-bearing is only possible an average of 4 months later than with mechanically-actuated intramedullary nails, which can support full weight-bearing immediately (Paley 2015).

2.3.1.2.2 Phenix M2

Much like the PRECICE nail, the Phenix M2 is an intramedullary extensible rod driven by a rotating magnet, which in turn drives a threaded shaft (Figure 2.14). Developed in 2011 by Phenix Medical, this device was never fully commercialized nor FDA-approved and was controlled by rotating an external magnet around the affected limb. This device produced good results on a small scale despite the absence of FDA clearance and reports that the nail was unable to generate enough force to lengthen the bone. Work has stopped on developing the Phenix M2 nail due to the untimely death of its inventor, but it is now contracted to Smith & Nephew (Paley 2014; Thaller, Furmetz et al. 2014).

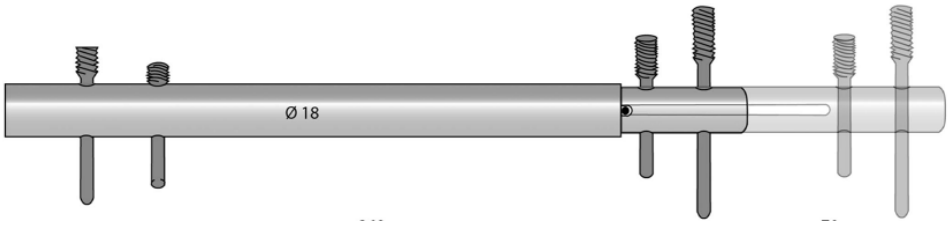


Figure 2.14: Phenix M2 (Thaller, Furmetz et al. 2014)

2.3.1.2.3 Patent US 6336929

Granted in 2002, this patent outlines an intramedullary rod whose telescopic extension is powered by the normal torsions occurring in the patient's daily life (Figure 2.15). Rotational increments as small as one degree cause a clutch mechanism to force apart the two telescopic halves, which renders this device prone to uncontrolled distraction and leaves the patient at a high risk of non-union or premature consolidation. It is noted in the patent that this device can be adapted to be controlled by an externally applied magnetic field (Justin 2002).

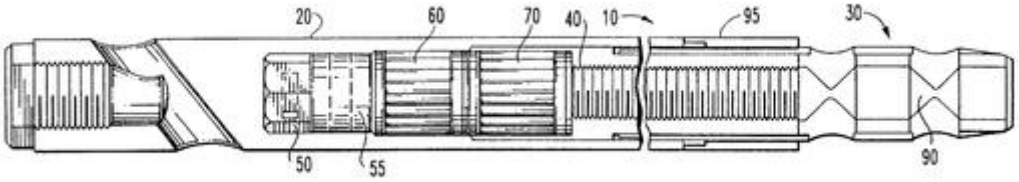


Figure 2.15: Automatic lengthening nail (Justin 2002)

2.3.1.2.4 Patent US 8777947

Patent US 8777947 describes a magnetically-actuated lengthening nail, similar to the PRECICE in that a rotating magnet powers the extension of the nail. While the magnet in the PRECICE rotates the leadscrew, in this case the magnet (Figure 2.16, label 24) rotates the body with the internal threading in one of the telescopic halves, while the leadscrew remains fixed to the other telescopic half. This action converts the magnet's rotation to a linear movement, conductive to distraction (Zahrly 2014).

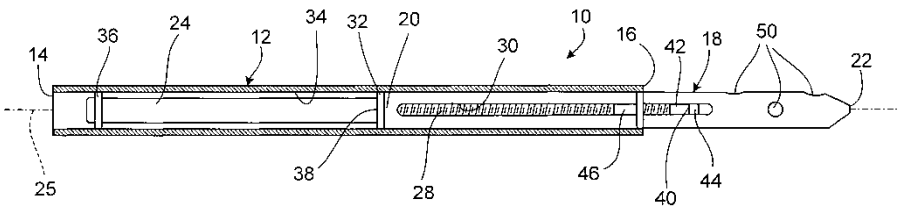


Figure 2.16: Magnetic lengthening nail (Zahrly 2014)

2.3.1.3 Electrically-actuated intramedullary fixators

2.3.1.3.1 Fitbone

The Fitbone provides an alternative to magnetically-actuated internal fixators. Lengthening is driven by a threaded rod, powered by a small motor lodged in the device. A subcutaneous receiver, connected to the telescopic nail by a wire, communicates with a remote control to extend the device (Figure 2.17). Like the PRECICE nail, full weight-bearing is not allowed until appropriate bone consolidation has been achieved. The Fitbone is subject to a 12.5-15.4% implant-related complication rate (Krieg, Lenze et al. 2011; Accadbled, Pailhe et al. 2016). As with other intramedullary solutions, the Fitbone cannot be used on skeletally immature patients. Although

there have been rare instances of corrosion with the receiver and connecting wire, this device minimizes scarring and patient discomfort compared to external fixators and mechanical nails. This telescopic intramedullary nail, first produced by Wittenstein Company in 1997, is not FDA-approved (Baumgart, Thaller et al. 2006).

Figure 2.17: Fitbone (Wittenstein 2018)

2.3.1.4 Other intramedullary fixators

2.3.1.4.1 Patent US 7135022 B2

Another patent (US 7135022 B2), filed in 2002, consists of a telescopic rod also inserted in the patient's medullary canal. One of the telescopic halves is made of a biocompatible metal, whereas the other is made from a ferromagnetic material. A coil placed around the patient's limb generates a magnetic field strong enough to displace the magnetic half of the nail, thereby extending the member (Figure 2.18). An internal ratchet system ensures that the nail does not retract after the magnetic field has ceased to act on the device. Like other intramedullary nails, this device reduces scarring and recovery time, but is not suitable for use in children since it damages the patient's growth plates upon implantation. Also, this nail cannot be retracted in case of accelerated distraction, and may result in non-union (Kosashvili and Robinson 2006).

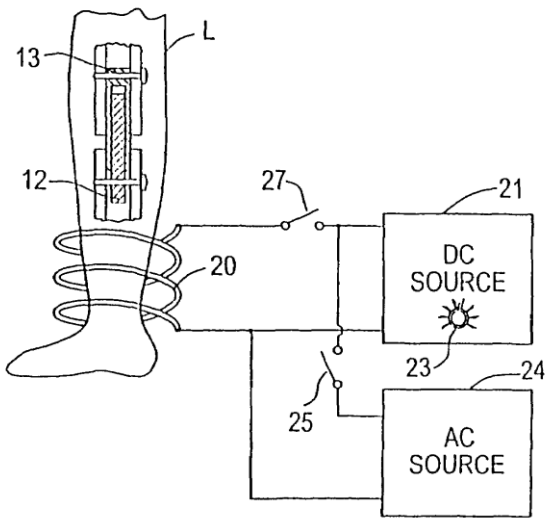


Figure 2.18: Magnetically-actuable intramedullary device (Kosashvili and Robinson 2006)

2.3.1.4.2 Patent US 6918910

Some noncommercial patents explore other mechanisms for limb lengthening. For instance, patent US 6918910, filed in 2003, is an intramedullary telescopic nail that acts as a hydraulic piston. The nail is connected to a subcutaneous valve by a small tube, into which a syringe can percutaneously transfer a fluid (e. g. saline solution) (Figure 2.19). The addition of fluid increases the volume in the hydraulic cavity and distracts the device. This device can be used on long or rib bones, and is not suitable for children. The lack of mechanical parts reduces the likelihood of part failure, and the system can act in two directions by adding or removing fluid. That being said, the hydraulic system introduces the possibility of leakage of fluid inside the patient, rendering useless the device and posing health risks at the device site (Smith 2005). Patent US 8632544 B2

Similarly, patent US 8632544 B2 makes use of a magnetorestrictive material to achieve distraction. Filed in 2009, this device relies on the material's special properties. This telescopic nail features a sample of magnetorestrictive material that increases in length when an appropriate magnetic field is applied. As it expands, the material pushes the telescopic rod outwards, and a ratchet mechanism secures the nail once the desired length has been reached. This nail presents similar strengths and weaknesses to the patent US 7135022 B2 (Haaja 2014).

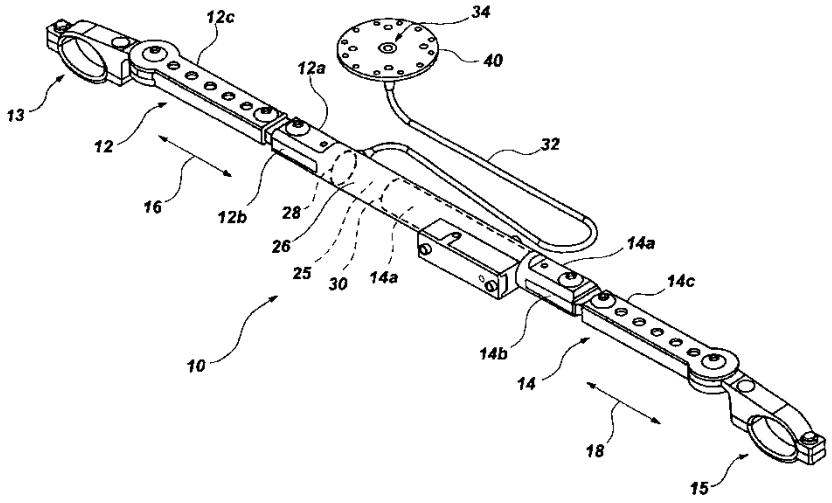


Figure 2.19: Implantable distraction device with hydraulic actuation (Haaja 2014)

2.3.1.4.3 SMALL (Shape Memory Alloy Limb Lengthening) nail

The SMALL (Shape Memory Alloy Limb Lengthening) intramedullary nail is currently in development, and is based on the thermal properties of a shape memory alloy element. When the element is thermally activated, it changes its shape and can initiate a distraction. A spring-loaded locking mechanism extends the telescopic device incrementally in 0.5-mm steps each time the element is activated (heated). As shown on Figure 2.20, a subcutaneous induction receiver is connected to the nail by a wire, and warms a heating cartridge inside the nail when actuated by an external controller. This particular strain of the device cannot be used in children. While this device presents all advantages of internal fixators, research has shown poor success rates in terms of limb lengthening steps attempted versus the number of steps achieved The target length was not achieved in many cases, and an unsuitable cooling period is suspected to be the reason (Dunnweber, Rodl et al. 2016).

Figure 2.20: SMALL nail (Dunnweber, Rodl et al. 2016)

2.3.2 Extramedullary plate fixators

While intramedullary lengthening nails offer a solution to many of the external fixators' complications, their implantation necessarily entails the piercing of the pediatric patient's growth plates in the epiphyses of the long bone. This is fine for adult patients, but damaging the growth plates in pediatric patients undermines the child's normal physiological development. Hence, the concept of a lengthening plate attached to the outside of the bone is an attractive option for pediatric patients in need of limb lengthening without resorting to an external fixator, which bears the risk of additional complications.

2.3.2.1 Monoaxial plate fixators

2.3.2.1.1 Patent US 8758347 B2

Currently, there are no commercially-available plate fixators for distraction osteogenesis on long bones. However, some existing patents illustrate similar concepts. US 8758347 B2, filed in 2011, illustrates an extensible bone plate. Both interlocking plate segments can slide relative to each other, and are linked to a central gear using a rack-and-pinion system (Figure 2.21). When the gear is turned, both plates are linearly distracted from one another. This method can be used on jaw or long bones. While this method is usable on children, testing remains to be done on the device's weight-bearing properties. Furthermore, the patent does not discuss an energy source to power the distraction, and the device relies on manual actuation. (Weiner 2014)

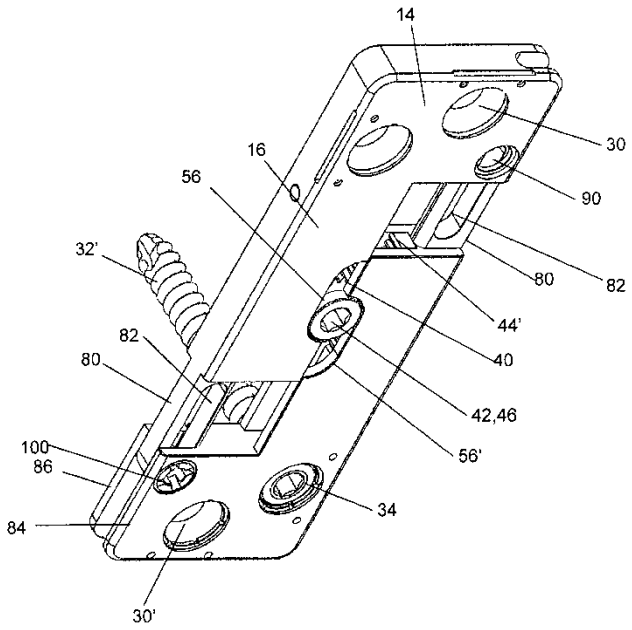


Figure 2.21: Dynamic bone plate with rack and pinion mechanism (Weiner 2014)

2.3.2.1.2 Patents US 20150025587 A1 and US 20090192514

A few records of plate fixators exist for jawbone distraction osteogenesis. Patent applications US 20150025587 A1 and US 20090192514, filed respectively in 2012 and 2008, outline the concept of a periosteal plate, fixated to either bone segment using bone screws. The device's elongation is driven by a threaded rod, which is controlled by a small motor. The threaded rod fits into the device's other segment, which is held into place by two guiding rods (Figure 2.22). An external controller and monitor interact with the device by way of a small transmitter implanted in the fixator. This device is suitable for children and can operate in two directions. This is useful to correct over- or under-distraction, which can lead to complications such as non-union or early consolidation, respectively. However, this has been specifically designed for a patient's jaw, which is subject to very small loads when compared to a femur or tibia; the design must be amended to bear the appropriate loads (Feinberg 2009; Kim 2015).

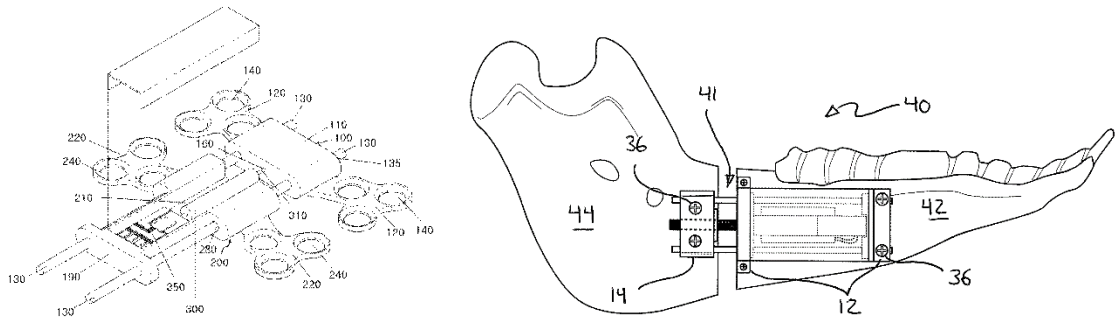


Figure 2.22: Plate fixators for jawbone distraction osteogenesis (Feinberg 2009; Kim 2015)

2.3.2.1.3 Patent US 5902304 A

Another example of a plate fixator is described in patent application number US 5902304 A, filed in 1996. Figure 2.23 shows two interlocking plates that slide one over the other and a threaded worm gear that is placed between the plates and fits into each plate's appropriate groove. The patent features the device as used in craniofacial and long-bone scenarios, and only deals with manual actuation to distract the device. As with the previous devices, the periosteal nature of this device makes it a good choice to treat children with limb length discrepancies. However, no allowance has been made in this particular embodiment of the device to allow for a power source, and no evidence exists to show that it could be used successfully in a long-bone scenario (Walker 1999).

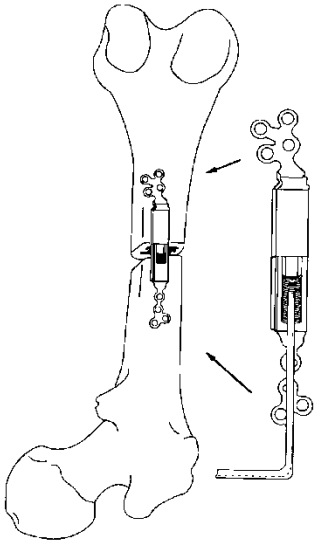


Figure 2.23: Telescopic bone plate (Walker 1999)

2.3.2.1.4 Patent US9949772B2

Patent US9949772B2, granted in 2018 to Texas Tech University, illustrates a telescopic fixator affixed periosteally (beside the bone). Both halves are distracted by using a worm gear, which is turned by a small motor. The patent claims that its smooth design (Figure 2.24) enables surgeons to install it using minimally-invasive techniques. Furthermore, finite element analysis has been conducted on a simulated model of the device and has rated it with a 1.71 safety factor regarding failure at high loads. Like other similar patents, this fixator can be used for limb lengthening in children (Abdelgawad 2018).

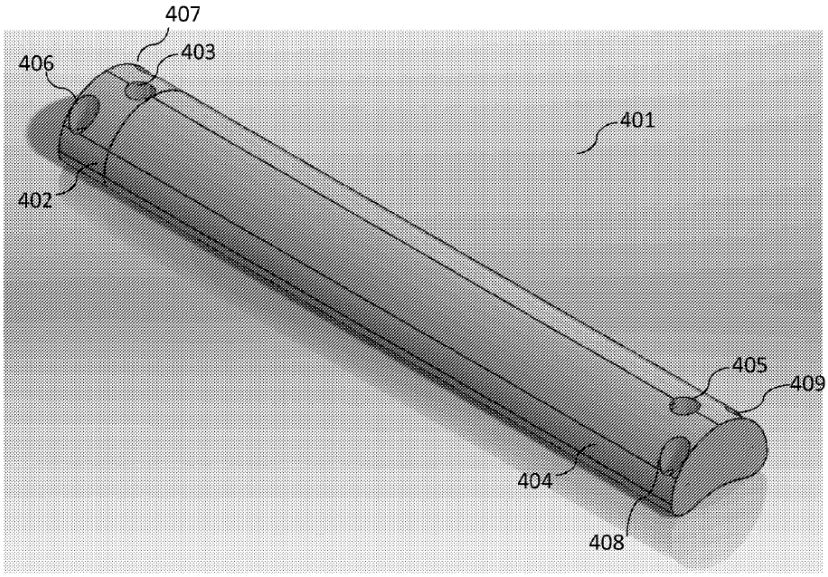


Figure 2.24: Texas Tech lengthening plate

2.3.2.2 Polyaxial plate fixators

2.3.2.2.1 Patent US 20050234448

This fixator, also known as the McCarthy device, ventures an extramedullary solution that allows for patient weight-bearing. It was filed in 2004. It is built like a rail, on which a plate segment can slide freely. Moved by a worm gear, the plate elongates the device and distances the bone segments from one another (Figure 2.25). This fixator is designed to be used on long bones. Since this device does not go through the bone's intramedullary canal, it can be used to treat skeletally immature patients. Moreover, the device is designed as to provide angular corrections in all translational and

rotational planes. This device has not been tested, and the weight-bearing properties have not yet been validated (Mccarthy 2005).

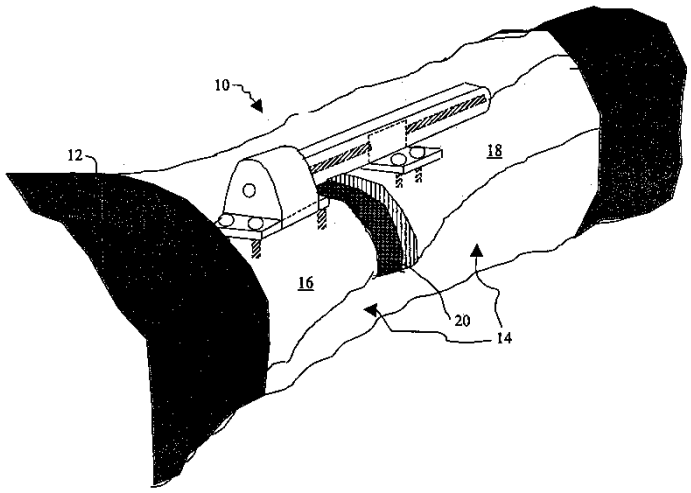


Figure 2.25: McCarthy lengthening plate (Mccarthy 2005)

2.4 Comparative synthesis of fixators

The following table summarizes the existing devices designed for a limb lengthening procedure using distraction osteogenesis. It outlines which devices are commercially available, and categorizes them into main subsections related to the device's shape or power source (i.e. mechanically-actuated, magnetically-actuated, etc.), and gathers the relevant information pertaining to the device's validity in the field of limb lengthening, such as distraction method, weight-bearing capacity, complication rate, and suitability in pediatric patients.

Table 2.1: Comparative synthesis of existing external limb lengthening fixators

	Device/Reference	Graphic	Year	Distraction method	Weight-bearing	Implant-related complication rate (%)	Suitable for children	Critique
External fixators	Ilizarov Fixator (Spiegelberg, Parratt et al. 2010)		1954	Circular plates, affixed to either bone segment by percutaneous Kirschner wires, are manually distracted by turning threaded rods, thereby linearly increasing the distance between the two plates.	Yes, immediately after surgery	60.1 ((Dammerer, Kirschbichler et al. 2011))	Yes	Bulky construction High complication rate High likelihood of scarring
	Taylor Spatial Frame (Dammerer, Kirschbichler et al. 2011)		2002	Circular plates, affixed to either bone segment by percutaneous Kirschner wires, are manually distracted by turning six threaded rods. These rods are oriented in a "hexapod" configuration, which enables the user to correct limb deformities with six axes of movement (linear, angular, rotational)	Yes, immediately after surgery	59.3 (Dammerer 2011)	Yes	Bulky construction High complication rate High likelihood of scarring
	Orthofix ProCallus series		1995	One-sided rail system attached to bone using percutaneous pins. Manual distraction.	Yes	N/A	Yes	Bulky construction High likelihood of scarring

Table 2.2: Comparative synthesis of commercial mechanical intramedullary nails

	Device/Reference	Graphic	Year	Distraction method	Weight-bearing	Implant-related complication rate (%)	Suitable for children	Critique
Commercial mechanically-actuated nails	Guichet/Albizzia Betzbone (Guichet, Deromedis et al. 2003)		1994	An axial rotation of the patient's limb (20°) causes the nail to extend, and produces an audible "click".	Yes, immediately after surgery	29 (Guichet 2003) 20.8 (Garcia-Cimbrelo 2002)	No	Lengthening requires painful rotations of the limb, at times intolerable for the patient
	ISKD (Cole, Justin et al. 2001)		2001 (discontinued)	Natural rotations of the patient's foot (3°-9°) cause the device to naturally lengthen. Length is monitored with the help of magnets inside the nail.	Yes, during lengthening phase, as instructed by physician	11 (Cole 2001) 30 (Simpson 2009) 47 (Schiedel 2011) 33 (Kenaway 2011) 50 (Mahboubian 2012)	No	Expensive Automatic, uncontrolled lengthening can lead to serious complications (e.g. non-union or early consolidation)

Table 2.3: Comparative synthesis of commercial magnetic and electric intramedullary nails

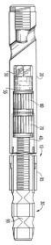
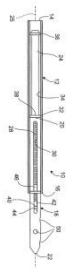
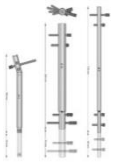
	Device/Reference	Graphic	Year	Distraction method	Weight-bearing	Implant-related complication rate (%)	Suitable for children	Critique
Commercial magnetically-actuated nails	Patent US 6336929 B1 (Intramedullary skeletal distractor and method) (Justin 2002)		Filed 2000	1) Rotating magnet inside nail actuated by external magnetic field, drives worm gear that extends the device. 2) (Alternate) Natural rotations of the affected limb (1°) cause the nail to extend naturally with the patient's movements.	N/A	N/A	No	Untested and non-commercial
	Patent US 8777947 B2 (Telescoping IM nail and actuating mechanism) (Zahrly 2014)		Filed 2011	Rotating magnet inside nail actuated by external magnet drives worm gear that extends the device. An external controller, equipped with two magnets, is placed around the limb and generated a magnetic field strong enough to rotate the internal magnet.	N/A	N/A	No	Untested and non-commercial
	Phenix M2 (Thaller, Furmetz et al. 2014)		2011	Rotating magnet inside nail actuated by external magnet (rotated by hand around limb), drives worm gear that extends the device.	Not during lengthening phase When physician has deemed bone strong enough	N/A	No	No full weight-bearing until consolidation phase Development discontinued after death of inventor
	PRECICE/PRECICE 2 (Paley 2015)		2013 (previous model 2011)	Rotating magnet inside nail actuated by external magnetic field, drives worm gear that extends the device.	Not during lengthening phase After adequate consolidation	4 (Kirane 2014)	No	No full weight-bearing until consolidation phase
Commercial electrically-[illegible]	Fitbone (Baumgart, Betz et al. 1997)		1997	Small motor inside the nail drives a worm gear that extends the device. An external remote communicates with a subcutaneous receiver, powering the motor.	Not during lengthening phase After adequate consolidation	13 (Baumgart 2006) 12.5 (Krieg 2008) 13.3 (Dincyurek 2012)	No	No full weight-bearing until consolidation phase

Table 2.4: Comparative synthesis of non-commercial intramedullary nails

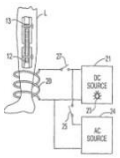
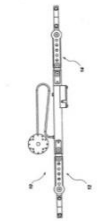
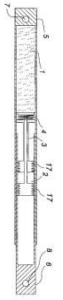
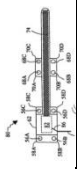
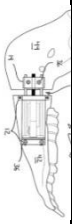
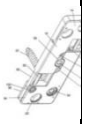
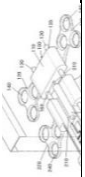
	Device/Reference	Graphic	Year	Distraction method	Weight-bearing	Implant-related complication rate (%)	Suitable for children	Critique
Non-commercial intramedullary nails	Patent US 7135022 B2 (Magnetically-actuable intramedullary device) (Kosashvili and Robinson 2006)		Filed 2002	A telescopic rod is comprised of two concentric cylinders, one of which is made from ferromagnetic material. The application of a magnetic field (via a coil) generates a force on the ferromagnetic portion, extending the device, which is then held in place by a ratchet system.	N/A	N/A	No	
	Patent US 6918910 B2 (Implantable distraction device) (Smith 2005)		Filed 2003	The injection of a hydraulic fluid inside a piston cavity extends the nail. A subcutaneous valve is connected to the nail via a small tube, through which the fluid is injected percutaneously with a syringe.	N/A	N/A	No	Risk of leakage
	Patent US 8632544 B2 (Internal osteodistraction device) (Haaja 2014)		Filed 2009	The telescopic rod is extended though the action of a magnetorestrictive material inside the device. When this material is subjected to an appropriate magnetic field, it extends its shape and generates a force sufficient to distract the device. A locking system ensures that the movement happens in one direction only.	N/A	N/A	No	
	SMALL Nail (Dunnweber, Rodl et al. 2016)		Article published 2015	A heating cartridge in the telescopic nail heats a shape memory alloy, which changes its length. A spring-loaded locking mechanism distracts the nail in 0.5-mm increments following the heating of the element.	N/A	N/A	No	

Table 2.5: Comparative synthesis of non-commercial plate fixators

	Device/Reference	Graphic	Year	Distraction method	Weight-bearing	Implant-related complication rate (%)	Suitable for children	Critique
Non-commercial plate fixators	Patent US 5902304 A (Telescopic bone plate for use in bone lengthening by distraction osteogenesis) (Walker 1999)		Filed 1996	A worm gear placed between two superimposed bone plates fits into each plate's appropriate grooves. Turning the threaded worm gear extends or retracts the two plates relative to each other.	N/A	N/A	Yes	Weak fixation to bone
	Patent US 2005/0234448 A1 (implantable bone-lengthening device) (Mccarthy 2005)		Filed 2004	Two interlocking plates can be separated or brought closer by a worm gear, which can be controlled by a small motor and externally actuated by a remote control (in one embodiment of the device).	N/A	N/A	Yes	Weak fixation to bone
	Patent US 20090192514 A1 (Implantable distraction osteogenesis device and methods of using same) (Feinberg 2009)		Filed 2008	A worm gear is driven by a small motor, extending or retracting the device. A controller and monitor are used to control and record the distraction. A wireless transmitter is built into the device.	N/A	N/A	Yes	Electric motor/battery,
	Patent US 8758347 B2 (Dynamic bone plate) (Weiner 2014)		Filed 2011	In this embodiment of the dynamic bone plate, both sliding plate segments are linked to each other using a rack-and pinion system. When the gear is manually turned, both segments are separated.	N/A	N/A	Yes	Requires manual actuation
	Patent WO 2013162107 A1 (US 20150025587 A1) (Jawbone distraction system and a control method thereof capable controlling operation using a remote control) (Kim 2015)		Filed 2012	A worm gear is driven by a small motor, extending or retracting the device. A controller and monitor are used to control and record the distraction. A wireless transmitter is built into the device.	N/A	N/A	Yes	Fixation unsuitable for long bone lengthening, designed to withstand small stresses in jaw
	Patent WO2015184397A1 (Internal bone lengthener device and method of use thereof) (Abdelgawad 2018)		Filed 2015 Granted 2018	A telescopic curved device can extend or retract through the action of a worm gear, controlled by an external remote control.	N/A	N/A	Yes	Fixation at either end of device – less stability at site of osteotomy

While all these devices are implicated in the field of limb lengthening, the fixators that are relevant to the design of a lengthening plate can be narrowed down to the models that do not damage the growth plates and that are thus usable with pediatric patients. The external fixators, encompassing the Ilizarov device, Taylor Spatial Frame and Orthofix Procallus, are all commercially available for use in young patients and are particularly appealing options since most of the device's body remains outside the patient's body, minimizing skin tenting and facilitating actuation, which can be done manually from the outside. Also, immediate weight-bearing is allowed for patients wearing these fixators. Despite these advantages, the percutaneous fixation used by all three external devices introduces additional complications when compared to a fully internal fixator. No other lengthening devices that are suitable for children have been successfully commercialized, but in some cases, they have been filed as a patent. Patents 20090192514 A1 and 20150025587 A1 exhibit an interesting mechanism for a leadscrew-driven lengthening plate, but are designed to distract the patient's jawbone, and may not be suited to lengthen long bones. On the other hand, patent US 5902304 features a fixation at either end of the device's body, which is disadvantageous in keeping with the principles of stable bone fixation. This form of extremity fixation is also found in patent US 20050234448, published by Texas Tech University, but with a smoother and thicker body in this embodiment. Finally, patent US 8758347 B2's rack-and-pinion plate system requires an incision for every distraction increment, which can increase the incidence of infection. As it stands, the only viable option for pediatric patients remains external fixators.

2.5 Locking plates

For decades, dynamic compression plates have been the typical choice for the fixation of bone fractures. To promote healing, these plates exert a compressive force between both bone segments and are affixed to the bone with screws designed to hold the plate in place. However, the direct contact between the plate and the bone's surface causes damage to the periosteum, a sleeve of vascularization that supplies the bone with nutrients and oxygen. The fracture's healing process is consequently impeded. The locking plate, an innovative device developed in the last few decades, seeks to remedy this shortfall of the typical compression plate and leave the periosteum intact (Kubiak, Fulkerson et al. 2006).

The novel concept offered by the locking plate introduces the idea of threaded screw holes, compatible with specialized screws whose heads are similarly threaded. When the screws are

engaged in the plate's holes, the construct is afforded angular stability and does not rely on compressive force between the plate and the bone. This allows the plate to be installed in such a way as to leave a gap between the plate and the bone (Figure 2.26), thereby preserving the periosteum and improving fixation stability. This type of plate conforms to the behavior of an external fixator, in that the stiffness of the construct is totally independent of the bone. This allows more freedom for the plate's shape, as it does not have to follow exactly the bone's shape (Herford and Ellis 1998).

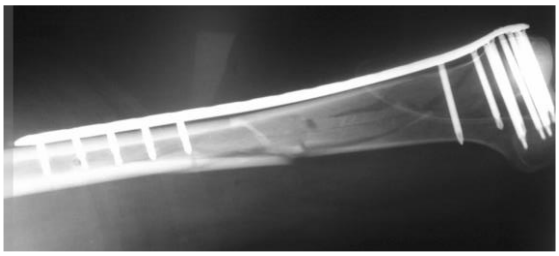


Figure 2.26: X-Ray of a locking plate (Kubiak, Fulkerson et al. 2006)

Locking plates can be fixated using unicortical or bicortical screws (Figure 2.27), the latter achieving better results in high-torsion scenarios, and the former causing less damage during insertion. Also seen in Figure 2.27, a combination of locking and non-locking screws can be used in the event where special circumstances warrant the insertion of screws at an angle. This is the case for unusual fractures that need to be stabilized (Kubiak, Fulkerson et al. 2006).

Although placed further away from the bone, the locking plate does not compromise the fixation's stiffness. Its behavior in bending and torsion is like that of a compression plate when the gap is 0-2mm wide. However, for a gap value of 5mm, high displacement in bending and torsion is observed, which makes for a weaker fixation (Ahmad, Nanda et al. 2007).

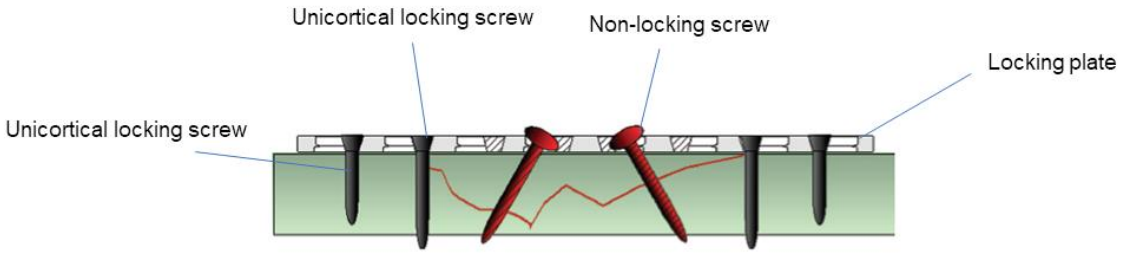


Figure 2.27: Combination of unicortical, bicortical, locking and non-locking screws for an unusual fracture (Kubiak, Fulkerson et al. 2006)

Usually, conventional plate failure occurs due to screw loosening or breakage (Figure 2.28) since the screws are susceptible to toggling because of the lack of angular fixation. This is addressed by locking plate technology, which minimizes screw toggling and loosening, but does not eliminate the risk altogether (Lill, Hepp et al. 2003). Failure can be observed on the plate itself, near the screw holes close to the bone gap. Furthermore, bone resorption around the screws can cause loosening and subsequent failure of the fixation. It is important to note that these failure modes are not specific to locking plates, and also occur in dynamic compression plates. The only failure mode particular to locking plates is the thread failure at the screw-plate threaded engagement, characterized as screw back-out failure (Figure 2.29) (Ahmad, Nanda et al. 2007). Moreover, stress concentrations are highest in locking plates at the screws near the bone gap, and in the screw threads due to the acute geometry (Ahmad, Nanda et al. 2007).

Figure 2.28: Locking plate failure (Ahmad, Nanda et al. 2007)

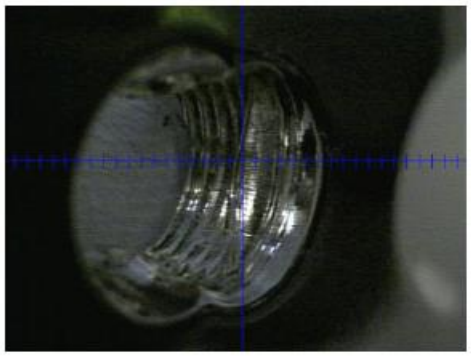


Figure 2.29: Thread damage due to screw back-out in a locking plate (Ahmad, Nanda et al. 2007)

CHAPTER 3 PROJECT RATIONALE

Following the literature review, the rationale of the project can be explained as follows:

- The Ilizarov external fixator is currently the gold standard for limb lengthening in pediatric patients. External fixators can cause unnecessary complications for the patient. Internal fixators have been shown to eliminate the implant-related complications associated with external fixators.
- Currently available internal fixators are only suitable for adult patients who have reached skeletal maturity since their implantation damages the pediatric patients' growth plates.
- There are currently no internal fixators for pediatric patients in need of a limb lengthening procedure.

3.1 Main objective

The objective of the project is to design a remote-controlled implantable extramedullary device for limb lengthening procedures in pediatric patients. The device should be fully programmable to avoid compliance issues with the patient.

3.2 Research question

This research work aims to answer the following research question:

- Can an internal lengthening plate be designed for a pediatric patient's physiological dimensions and generate a distraction force that is sufficient to perform a limb lengthening procedure?

3.3 Specific Objectives

To achieve the project's main objective, the following five specific objectives have been completed:

1. establish the device design specifications and constraints;

2. generate possible design options and choose an option based on the device specifications and constraints;
3. create a 3D model for the device using a modeling software;
4. fabricate a functional prototype based on the 3D model generated;
5. complete an *ex vivo* validation of the device's distraction performance on synthetic bones.

This thesis is divided in six chapters, beginning with a literature review in Chapter 1. Chapter 2 outlines the project rationale as well as the objectives that guide the project in answering the research question, also detailed in this section. Chapter 3 is a complementary section, which includes the lengthening plate's design specifications and the concept selection based on the specification criteria. Chapter 3 also addresses specific design features that were incorporated into the device's creation. In Chapter 4, a scientific paper details the lengthening plate's innovative function, and provides validation results. Finally, Chapters 5 and 6 cover the project's discussion and conclusions and offer a glance at future work. Figure 3.1 shows a summary of the thesis layout.

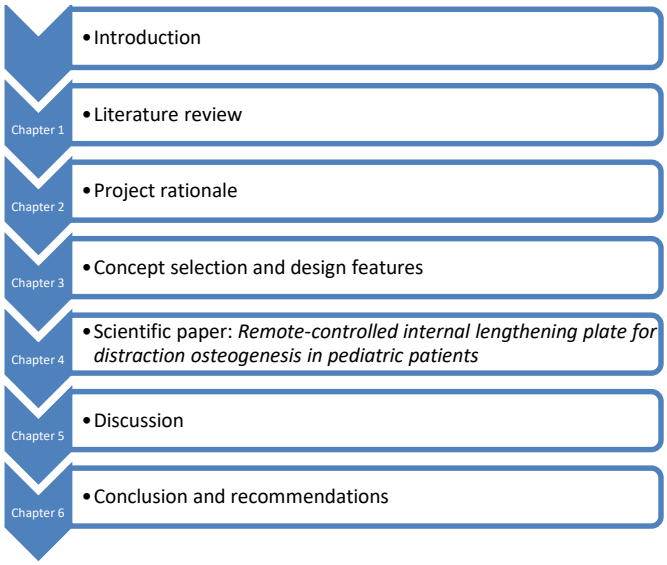


Figure 3.1: Summary of the thesis layout

CHAPTER 4 CONCEPT SELECTION AND DESIGN FEATURES

4.1 Device specifications

To guide the brainstorming process, it was important to properly outline the specific needs to be met by the lengthening plate. All specifications are presented in detail in Appendix A.

The main functional requirements indicated that the lengthening plate should be implanted outside the medullary canal of the bone but remain totally internal to the patient. In accordance with the distraction osteogenesis parameters defined by Ilizarov, the lengthening plate had to be able to apply a precise distraction length of 1 mm per day, divided into 0.25 mm increments applied four times daily (Ilizarov 1990). Also, it had to be able to generate a distraction force greater than 673 N, which is the peak reported antagonist force in pediatric limb lengthening literature (Younger, Mackenzie et al. 1994).

The lengthening plate's stability is highly valued in order to produce a high-quality bone callus. To promote device stability, it is important that the body is sufficiently rigid and that a suitable number of screws are used to affix each half of the lengthening plate to the bone segments. In keeping with the principles of optimally stable bone fixation, the innermost screw holes must be as close to the osteotomy as possible, while the outermost screw holes must be as far away from it as the lengthening plate permits. Any screw holes in between must be evenly distributed (Evans, Kenwright et al. 1979).

The implantation location of the lengthening plate was chosen to be the diaphysis of the long bone, with emphasis on minimizing the device's height to avoid tenting of the skin and patient discomfort.

4.2 Preliminary concepts

Since this project was earmarked for commercialization and for a patent application, the concept generation for the lengthening plate was fast-tracked by decreasing the amount of possible solutions generated. The potential fallout of this rapid concept generation process was weighed against the time savings considering the milestone requirements of the project in the interest of gaining a competitive edge in the market. To mitigate the risk, the generated concepts were largely based on existing mechanisms with proven functional success.

Three lengthening plate concepts were drafted in accordance with the defined specifications. For all concepts, the sliding half with the power source was defined as the “barrel” and the sliding passive half was defined as the “piston”. At this stage, the details for the power source were not yet formulated, and it was unclear whether a rotating magnet or an electric motor was to be used. A cavity capable of housing either of these options was planned on each of the concept drawings to allow for a clearer idea of the lengthening plate’s proportions.

Concepts were first hand-drawn and scanned, and digital drawings were made subsequently.

4.2.1 Concept 1: Telescopic fixator with fixation at each end

The first concept, illustrated in Figure 4.1, followed the principle of a simple telescopic structure with the piston of the device fitting into a corresponding cavity in the other half. For this design, a leadscrew originating from the barrel is coupled to an inner thread in the piston. The leadscrew’s rotation drives the linear motion of the piston relative to the barrel and is responsible for generating the required distraction force. The leadscrew design can also prevent back driving of the mechanism, meaning that when a compression force is applied to the device, the mechanism will not move in reverse. This is caused by the friction between the leadscrew and the internal threads in the piston, acting in conjunction with an appropriately small lead angle of the screw. The device is screwed to the bone using screw holes that are positioned at either end of the device, because the fact that the parts nest into one another prevents the placement of holes along the body of the device.

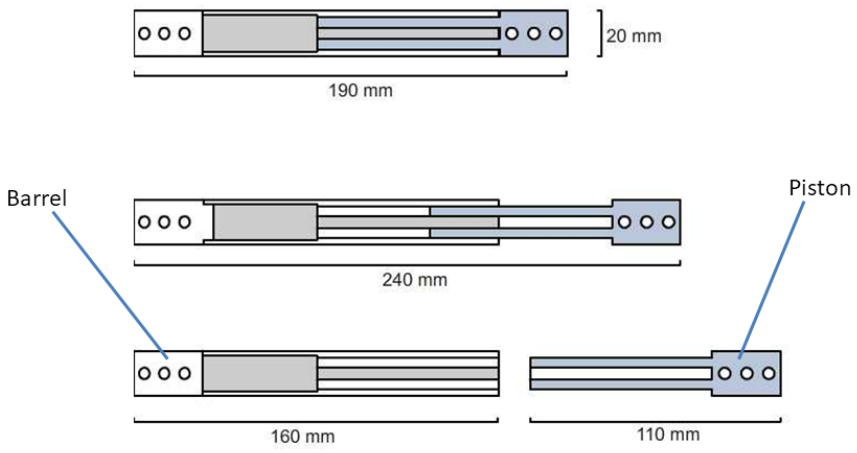


Figure 4.1: Concept 1 - Telescopic fixator with fixation at each end

4.2.2 Concept 2: Telescopic fixator with fixation along the side

Like the first concept, the second concept makes use of a leadscrew to power the sliding movement of the piston relative to the barrel. However, a fixation that was more widely distributed is more desirable, since it boasts an increased stability in accordance with the principles of external fixation. To achieve this, the fixation runs along the side of the device on a flange that extends radially from the device's body (Figure 4.2).

Furthermore, it was ideal to have both flanges at the same length. For this reason, the second concept consists of a barrel with a step down in diameter, whose tubular extrusion fits into an annular cavity in the piston, exposing an equal amount of surface area for both the barrel and the piston. Because of this, the flanges running alongside the device's body can have equal lengths, offering a high level of stability to the lengthening plate by ensuring even force distribution on both halves. However, the eccentric fixation increases the distance between the lengthening plate and the bone, rendering the lengthening plate's body more prone to high bending stresses, since bending is a product of the compressive force applied coaxially with the bone and the radial distance separating the device's and the bone's central axes. .

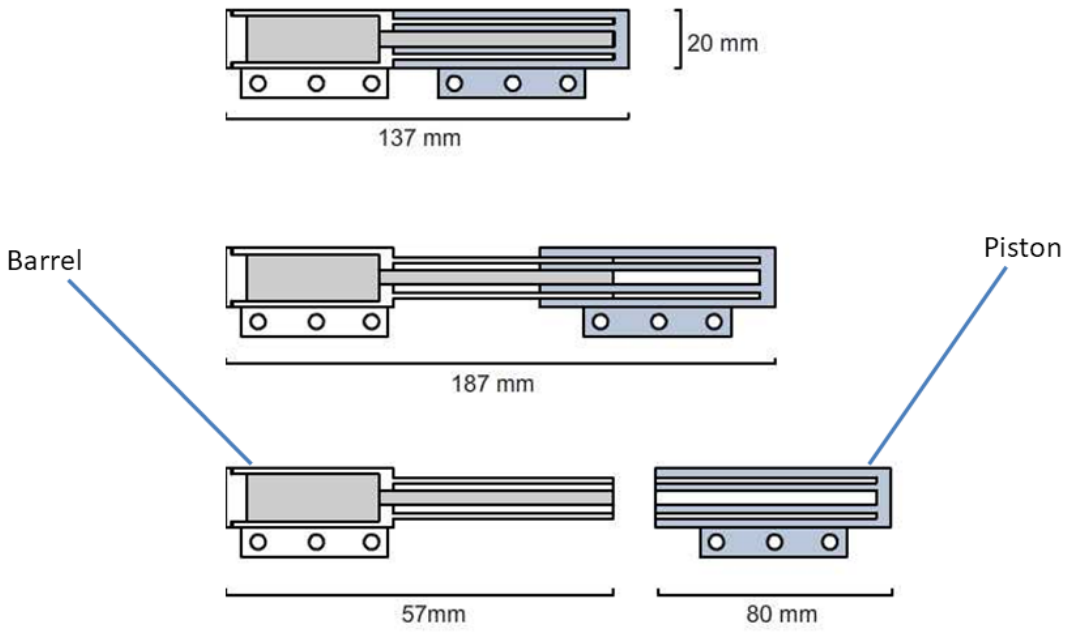


Figure 4.2: Concept 2 - Telescopic fixator with fixation along the side

4.2.3 Concept 3: Rack and pinion fixator with fixation at each end

The third concept deviated from the first two in that it omitted the leadscrew mechanism altogether in favor of a rack and pinion system (Figure 4.3). The barrel contains a rotating cog, onto which is coupled a linear gear, dubbed “rack”, which can move laterally upon rotation of the cog. The magnet/motor cavity, which restricted the placement of the leadscrew, minimally constrains the position of the rack in this model, since the rack can glide alongside the device. This way, the device benefits from a potential decrease in length, albeit at the expense of an increase in width. For this concept, the fixation is located at each end of the device.

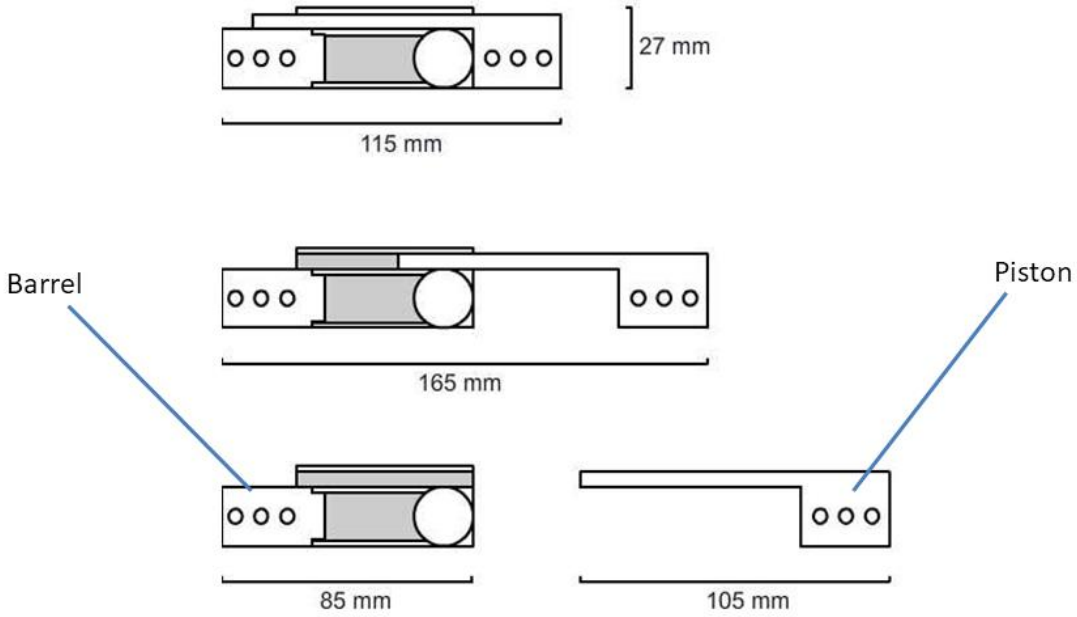


Figure 4.3: Concept 3 – Rack and pinion fixator with fixation at each end

4.2.4 Chosen concept: Concept 2

After a weighted evaluation of all the criteria, it was determined that the second concept, featuring a fixation flange running along the side of the plate’s body, was chosen (Figure 4.4). While concepts 1 and 3 outpaced it in one category by having a center of mass slightly closer to the bone, concept 2 scored points with its stable fixation according to the theoretical principles of fracture fixation, edging out the other two options. Concept 3, on the other hand, suffered from the lower load capacity and inability to prevent back drive of the rack and pinion mechanism, over which the leadscrew had a significant advantage. Antagonist pressure on the rack risks turning the pinion in

the opposite direction – this problem can be solved by the installation of a ratchet system on the sliding body, but this adds unnecessary complexity to the device and restricts its ability to execute a sliding movement in both directions.

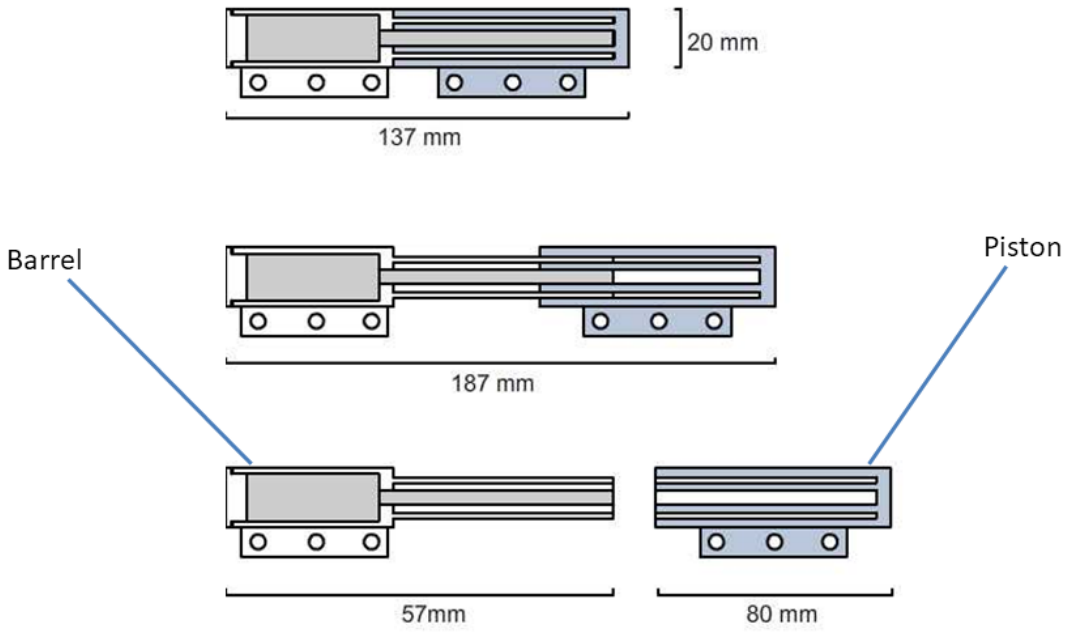


Figure 4.4: Chosen concept - Telescopic fixator with fixation along the side

Criterion	Weight	Option 1	Score 1	Weighted Score 1	Option 2	Score 2	Weighted Score 2	Option 3	Score 3	Weighted Score 3
Range of lengthening	4.13	50mm	1	4.13	50mm	1	4.13	50mm	1	4.13
Distraction increments	3.31	1mm/day	1	3.31	1mm/day	1	3.31	1mm/day	1	3.31
Distraction direction	**1.65**	**Both**	**1**	**1.65**	**Both**	**1**	**1.65**	**Single**	**0**	**0**
Load range	**3.31**	**Med**	**1**	**3.31**	**Med**	**1**	**3.31**	**Lower**	**0.5**	**1.655**
Type of load	3.31	Tension	1	3.31	Tension	1	3.31	Tension	1	3.31
Resistance to torsion and bending	**3.31**	**High**	**1**	**3.31**	**High**	**1**	**3.31**	**Med**	**0.5**	**1.655**
Resistance to screw pull-out	3.31	Med	1	3.31	Med	1	3.31	Med	1	3.31
Allowable movement	4.13	None	1	4.13	None	1	4.13	None	1	4.13
Number of fixations per bone segment	1.65	3	1	1.65	3	1	1.65	3	1	1.65
Distance between the fixation's screw holes	**1.65**	**Small**	**0**	**0**	**Far**	**1**	**1.65**	**Small**	**0**	**0**
Distance between each fixation location and the distraction gap	**1.65**	**Far**	**0**	**0**	**Small**	**1**	**1.65**	**Far**	**0**	**0**
Contact with periosteum	4.13	None		0	None		0	None		0
Position of device wrt bone anatomy	3.31	Diaphysis	1	3.31	Diaphysis	1	3.31	Diaphysis	1	3.31
Length of device in initial configuration (mm)	3.31	190	1	3.31	137	1	3.31	115	1	3.31
Total weight of device	1.65	Adequate	1	1.65	Adequate	1	1.65	Adequate	1	1.65
Center mass localisation	**2.48**	**Med**	**1**	**2.48**	**Far**	**0**	**0**	**Med**	**1**	**2.48**
Mechanical Energy	1.65	No	0	0	No	0	0	No	0	0
Electrical Energy	2.48	Undetermined	1	2.48	Undetermined	1	2.48	Undetermined	1	2.48
Magnetic Energy	2.48	Undetermined	1	2.48	Undetermined	1	2.48	Undetermined	1	2.48
Location	2.48	Inside leg	1	2.48	Inside leg	1	2.48	Inside leg	1	2.48
Electrical insulation	4.13	Adequate	1	4.13	Adequate	1	4.13	Adequate	1	4.13
Mechanical insulation	3.31	Adequate	1	3.31	Adequate	1	3.31	Adequate	1	3.31
Reading of measurement	3.31	On controller	1	3.31	On controller	1	3.31	On controller	1	3.31
Distraction activator location	3.31	On controller	1	3.31	On controller	1	3.31	On controller	1	3.31
Emergency stop location	3.31	On controller	1	3.31	On controller	1	3.31	On controller	1	3.31
Time reaction for stopping	3.31	1 sec	1	3.31	1 sec	1	3.31	1 sec	1	3.31
Corrosion rate	4.13	None	1	4.13	None	1	4.13	None	1	4.13
Resistance to pH	4.13	Adequate	1	4.13	Adequate	1	4.13	Adequate	1	4.13
Component materials	4.13	Titanium	1	4.13	Titanium	1	4.13	Titanium	1	4.13
Lifetime	3.31	7.5 months	1	3.31	7.5 months	1	3.31	7.5 months	1	3.31
Operating temperature	4.13	36.1-37.8	1	4.13	36.1-37.8	1	4.13	36.1-37.8	1	4.13
Weight-bearing	4.13	Toe-touch	1	4.13	Toe-touch	1	4.13	Toe-touch	1	4.13
Price of device	3.31	15000	1	3.31	15000	1	3.31	15000	1	3.31
				90.94			**95.07**			**89.29**

Figure 4.5: Concept selection table

4.3 Power source

Once the general shape and function of the lengthening plate was chosen, a power source had to be selected to rotate the leadscrew from the outside without performing any invasive procedures. Existing power sources for internal lengthening devices were found as follows:

Mechanical ratchet: This concept can be borrowed from the earliest intramedullary lengthening nails, such as the ISKD (see section 2.3.1.1.2), which were powered by manually rotating the patient's limb. This motion triggered a ratchet mechanism and achieved a small distraction length

increment. The mechanically-actuated nails are the strongest, as they allow full weight-bearing, but are prone to runaway lengthening, which happens when the mechanism is triggered unknowingly by the patient and results in excessive lengthening, as in the ISKD (Lee, Ryu et al. 2014).

Rotating magnet: Powering the plate's leadscrew can be done by a rotating permanent magnet inside the device. The magnet is driven by an external controller comprising its own rotating magnets, which alternately attract the negative and positive poles of the magnet inside the lengthening plate. This is found in the PRECICE nail, and consists of a very simple mechanism with no electronic parts (Paley 2015).

Electric motor: The German-made Fitbone employs an electric motor to power the leadscrew's rotation. This lengthening nail features a battery to power the motor for the device's lifetime, as well as an RF receiver that is implanted sub-dermally and connected to the nail by a wire (Baumgart, Thaller et al. 2006).

For the lengthening plate, the rotating magnet was chosen. Mechanically-actuated nails have fallen out of favor due to their high incidence of runaway nails (Lee, Ryu et al. 2014) and the fact that the pain caused by self-actuated lengthening devices causes enough pain to greatly discourage patient compliance (Garcia-Cimbrelo, Olsen et al. 1992). Though an electric motor was considered, the introduction of extra parts, such as a battery and a subdermal receiver, was deemed to be riskier for the patient. The simplicity of the rotating magnet system was an attractive prospect, especially given the success of the PRECICE lengthening nail, which also makes use of a rotating magnet.

CHAPTER 5 ARTICLE I REMOTE-CONTROLLED INTERNAL LENGTHENING PLATE FOR DISTRACTION OSTEOGENESIS IN PEDIATRIC PATIENTS

5.1 Article presentation

The scientific article presented in section 4.2 details the design and testing of an internal limb lengthening plate fixator for distraction osteogenesis procedures on young children. This addresses the objectives and research question provided in Chapter 3.

This article, titled «Remote-controlled internal lengthening plate for distraction osteogenesis in pediatric patients» was submitted to the following journal: «The Bone & Joint Journal» in October 2018. The first author contributed roughly 85% of the writing of the article. The authors' contribution is outlined below.

Jérémie Gaudreau: design and fabrication of the device, validation of the device, interpretation of results, writing the article, responsible for the integrity of the work.

Mina Mekhail: management of the project, technical support, article review.

Reggie Hamdy: project inception, technical support, article review.

Isabelle Villemure: project inception and management, technical support, interpretation of results, article review and correction.

5.2 Abstract

Limb lengthening by distraction osteogenesis is a technique widely used to treat limb length discrepancy resulting from trauma, congenital limb defects and long bone non-union. A partial osteotomy is performed on the bone, which is then lengthened by daily increments until the desired length has been reached and new bone has fully formed in the gap. For decades, patients have resorted to the Ilizarov apparatus to complete this procedure, prone to pin tract infections and scarring, among other complications. Although implantable lengthening nails, such as the PRECICE, have made great strides in reducing the incidence of complications, they are not applicable in pediatric patients whose growth plates have not yet closed. The proposed device has the form of an internal remote-controlled telescopic lengthening plate, screwed to the lateral side of the bone. This is appropriate for use with pediatric patients, as it leaves the growth plates untouched. This internal lengthening plate has been shown to generate distraction forces of over 700 N on wooden and synthetic bones (Sawbones^{TM}). This device maintained a constant distraction speed over the course of the procedure at a given weight, but the distraction speed was found to slightly decrease with increasing weights. This device represents a major advancement in the field of pediatric limb-lengthening, effectively addressing a demographic gap left open by current implantable devices.

5.3 Introduction

Limb length discrepancy affects a significant portion of the population, with most cases going unnoticed. Often, these cases can be treated simply with a shoe insert (Guichet, Spivak et al. 1991). For the most extreme cases, surgical lengthening by distraction osteogenesis is required to equalize the length of the limbs. As part of this technique, an osteotomy is first performed on the long bone. Bone segments are thereafter incrementally distracted over the course of a few months. A distraction corrective apparatus is affixed to either bone segments to perform the lengthening. The distraction phase stimulates the growth of new bone in the gap and the subsequent consolidation phase eventually achieves permanent bone formation leading to the desired limb length (De Bastiani, Aldegheri et al. 1987).

The gold standard in limb lengthening is currently the external Ilizarov fixator, which consists of metal rings installed around the affected limb, affixed to the bone by Kirschner wires that pierce through the skin. By manually rotating long threaded rods connected to the rings, incremental distraction can be achieved with success (Ilizarov 1990). However, the pins can lead to complications such as pin site infection in 10-20% of cases , pin breakage in 23-27% of cases (Rogers, Bevilacqua et al. 2007; Aston, Calder et al. 2009), as well as scarring and muscle stiffness due to transfixion by a pin (Paley 1990). Due to the bulkiness of the Ilizarov, which is worn for a prolonged time, children wearing this device are also prone to numerous social, psychological and medical complications. These complications include social isolation due to body image and anxiety (Paley 1990). Compliance to the distraction procedure is another issue, since the children or their parents must perform the distraction manually twice to four times a day. Moreover, since it is a manual distraction, there is possible human error involved.

The Taylor Spatial Frame uses a similar fixation as the Ilizarov combined with Kirschner wires but features a hexapod multiaxial distraction system. Contrary to the Ilizarov, which distracts the bone segments in one direction, the Taylor Spatial Frame can make corrections in all directions, including rotations (Eidelman and Chezar 2005).

Fully implantable limb-lengthening was pioneered by the Albizzia nail. It consists of a telescopic rod inserted in the medullary cavity of the bone, maintained in place with screws on either end and is activated by mechanically twisting the patient’s limb to perform the distraction (Guichet,

Deromedis et al. 2003). Though this internal system solves the problem of pin site infection and scarring found in the external Ilizarov and Taylor Spatial Frame systems, the patient is subjected to extreme pain during lengthening and complications due to inconsistent lengthening rates. The ISKD (intramedullary Skeletal Kinetic Distractor) follows suit as another mechanically-actuated intramedullary rod, with many similar problems (Cole, Justin et al. 2001).

Most prominent in the implantable limb-lengthening field, the PRECICE nail is a telescopic intramedullary rod powered by a rotating magnet. The PRECICE has been successful in treating adult cases of limb length discrepancy and congenital deformities. However, as with all intramedullary devices, its implantation in the medullary canal through bone epiphyses renders it inaccessible to the pediatric population, because it would damage the growth plates, which are responsible for longitudinal bone growth. This nail is currently the only implantable limb-lengthening solution to be approved by the FDA since the ISKD, or *Intramedullary* Skeletal Kinetic Distractor, another intramedullary rod, was removed from the market (Schiedel, Vogt et al. 2014; Paley 2015; Laubscher, Mitchell et al. 2016). The Fitbone, powered by an electric motor and an RF transmitter, is another commercially-available intramedullary lengthening nail. Though it is not FDA-approved, it can achieve adequate lengthening with the advantages of a fully internal device but retains the shortfalls of the nail's design principles, which necessarily entail the implantation through the patient's growth plates (Baumgart, Thaller et al. 2006).

Internal limb-lengthening fixators discussed above present many clear improvements over the traditional Ilizarov external fixator, reducing the incidence of scarring and pin-site infection while improving mobility. These benefits are nonetheless limited to fully-developed adult patients, whose growth plates have closed, leaving no choice for pediatric patients who must shoulder the additional complications brought on by the external Ilizarov fixator. Therefore, there is a clear need to improve patient care and deliver superior clinical outcomes for children undergoing limb lengthening. This was the main motivation behind this project, which resulted in the development of an internal extramedullary plate fixator that can be distracted remotely. This design allows successful distraction without the physical and psychological complications of external fixators, and without affecting the growth plates of children undergoing lengthening.

5.4 Materials and Methods

5.4.1 Device Design

In the interest of protecting the lengthening plate's intellectual property, the standard parts' specifications were withheld.

Main Concept: The proposed device combines the principles of a telescopic intramedullary limb-lengthening nail and the geometry of locking plates but would be installed on the bone shaft in an extramedullary manner (Figure 5.1). It is composed of two halves, the first containing a rotating magnet and a leadscrew, which drive the lengthening mechanism, and the other containing an internal thread compatible with the leadscrew's threads. Each half features a flange running alongside the length of its exterior shell, onto which three screw holes are evenly distributed on each side. The screw holes are threaded to allow for locking screws. This type of fixation creates a 1-2 mm gap between the device and the bone, preserving the periosteum and promoting faster healing (Herford and Ellis 1998). The internal lengthening plate is screwed to the bone's diaphyseal segments, and its telescopic halves move relative to one another.

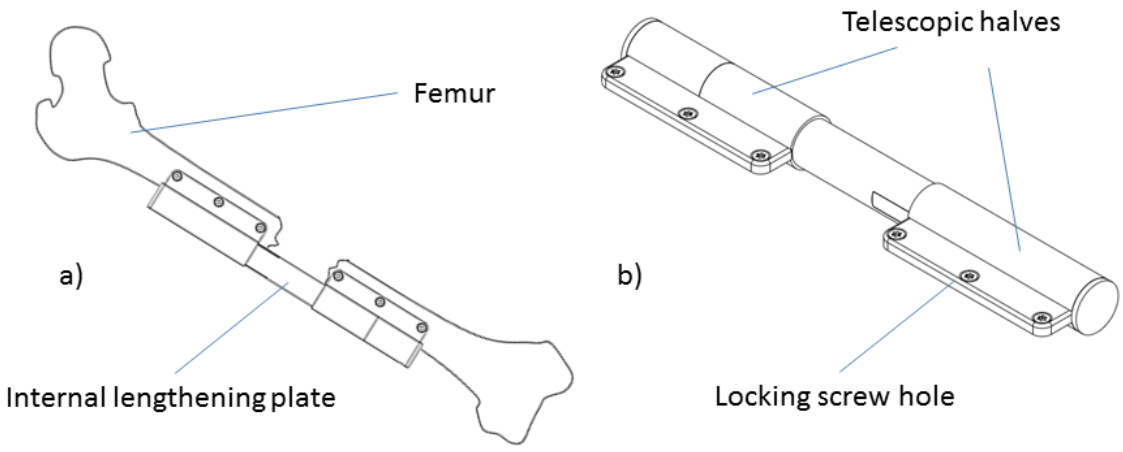


Figure 5.1: a) Lengthening plate attached to bone; b) Isometric view of lengthening plate

Geometry and Biomaterial: Since the fixator's demographic target is 8- to 9-year-old patients the diameter of the device must be minimized to a value that is approximately the same as the diameter of the patient's femur, which is considered a suitable size to avoid tenting of the skin and

interference with the muscles of the limb. The plate's cylindrical body's diameter is 18 mm, which was considered close enough to the measured femur diameter of 15 mm. This measurement was obtained from the reconstructed scan of a pediatric patient's femur. In addition, the center of each screw hole is 9 mm from the cylinder wall, which is optimal to fit the fixator body snugly against the bone when screwed in. The internal lengthening plate must have the ability to perform a full 50 mm distraction, with the permanent magnet rotating at a rate lower than 1000 rpm to ensure proper synchronization with the magnetic drive between the controller and the magnet inside the device. For biocompatibility issues, the device's body and screws are made of medical-grade 316 stainless steel, which can be sterilized before use with gamma-ray sterilization processes. Although the parts are currently joined using a metal-to-metal glue, further replicates would be welded using electron-beam welding.

Distraction Mechanism: Driven by the telescopic halves' relative motion, the bone segments are distracted and tension is applied to the bone gap area, effectively applying the principles of the tension-stress effect on bone regrowth (Ilizarov 1990). The device's extension is powered by the rotation of a cylindrical magnet (Figure 5.2c), fitted into two magnet housings (Figure 5.2b & d) and coupled to a multi-stage planetary gearbox (Figure 5.2e). Friction is minimized by a radial bearing (Figure 5.2a) press-fit to the outermost magnet housing. The gearbox has a reduction ratio of 1:64 and fulfils the function of multiplying the magnet's torque. The output is coupled to an ISO M6 coarse thread leadscrew (Figure 5.2h), which is engaged to an internal thread in the second telescopic half of the device and controls the device's extension. The 12 mm coupling between the gearbox and the leadscrew is flexible (Figure 5.2g) to prevent the leadscrew from locking up in the internal threads when the device experiences bending due to the off-center loading caused by the fixation, which is offset with respect to the device's centerline.

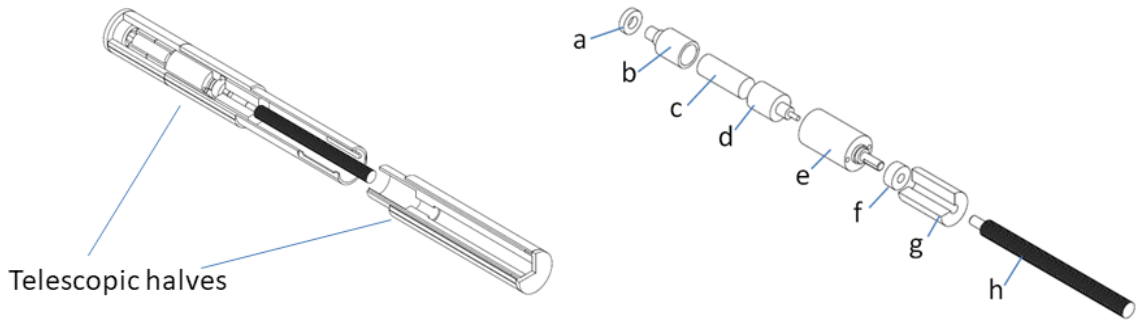


Figure 5.2: Exploded view of the internal components of the lengthening plate: a) radial bearing; b) proximal magnet housing; c) magnet; d) distal magnet housing; e) gearbox; f) thrust bearing; g) flexible coupling; h) leadscrew.

The device must be able to generate a sufficient force to counteract the soft tissue resistance forces in pediatric patients. Indeed, as the distraction is applied, the surrounding muscles, tendons, ligaments, and other soft tissues exert a force working against the distraction motion. Although there is variation between published pediatric limb lengthening studies, the literature reporting these forces cites 673 N as the peak lengthening force in the most extreme case (Wolfson, Hearn et al. 1990; Younger, Mackenzie et al. 1994). The high axial forces felt by the device are supported by a thrust bearing at the base of the leadscrew. The 9 mm thrust bearing can withstand loads of up to 912 N and protects the reducing gearbox, whose delicate components cannot withstand forces of high magnitudes.

Bone Fixation: The distribution of the screw holes is of great importance for the stabilization of the bone segments. In keeping with the principles of stable fixation of a limb, the screws of a fixator must be spread as far apart from each other as possible, while the innermost screws must be as close to the distraction gap as possible (Evans, Kenwright et al. 1979). The screws feature a threaded head as well as a bicortical thread along the length of the screw body. The threaded head is compatible with the device's screw holes and holds the device 1-2 millimeters above the bone. The screws for the lengthening plate were dimensioned based on the recommendations of Dr. Reggie Hamdy, the orthopedic surgeon spearheading the idea.

External Controller: To power the device, the cylindrical magnet encased in the device's body is activated by an external controller via magnetic drive. In the controller, there is a "cross" of

magnets alternating between positive and negative charges. A 100-rpm stepper motor executes precisely the correct amount of rotations. When in rotation, this magnetic arrangement moves in such a way that the cylindrical magnet inside the device performs two full rotations every time the controller's magnets complete one full turn (Figure 5.3). For every rotation completed by the controller, it is calculated that the device extends 0.025 mm, resulting in a precise and controlled lengthening procedure. For a daily lengthening increment of 1 mm, the controller's magnet should then rotate 40 times. A motor at 100 rpm (low angular speed) would thus take 24 seconds to complete a full daily distraction.

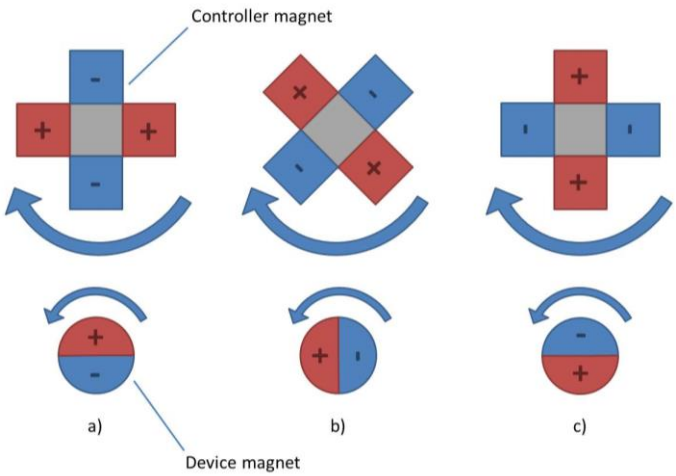


Figure 5.3: Magnetic drive between the controller and the device's magnet: a) initial position; b) eighth of a turn; c) quarter turn.

Precision in applying the correct distraction increment is paramount; errors can lead to premature consolidation or bone non-union (Paley 1990; Kenawey, Krettek et al. 2011). To reduce the incidence of errors, the controller includes an LCD screen and a keypad, which allows the user to input the desired distraction value directly into the system. Furthermore, the controller is password-protected, reducing the potential for human error which can occur if a button is accidentally pressed.

5.4.2 Device Validation

Validation was completed to: (i) verify if the distraction force generated by the device was sufficient to withstand typical limb lengthening forces for pediatric patients; (ii) measure any slowdown in the distraction procedure with increasing weight and distraction length; and iii)

confirm that no device failure of any kind takes place under increasing mechanical stress. Tests were carried out on simulated bone segments made from wood, and further repeated on a pediatric-sized synthetic bone.

To complete the validation steps, an experimental bench was designed and fabricated. The bench was composed of a wooden frame and a vertically sliding platform. The sliding platform includes four linear bearings to ensure stable vertical movement and frictionless contact, coupled to four vertical shafts fixed to the corners of the wooden frame (Figure 5.4), which were long enough to allow for a full 50 mm distraction. The two bone segments to be distracted were first simulated by vertically arranging two 15 mm x 15 mm wooden beams, one above the other in a coaxial fashion. The beams were dimensioned to match the diameter of a pediatric femur's diaphysis, as measured on the pediatric-sized synthetic bone. One of the beams was fastened to the base of the unmoving wooden frame, while the other was attached to the sliding platform. These beams were arranged so that when the platform was at its lowest position, the beams were just touching, and in perfect alignment. In this set-up, when a device-driven distraction occurred between the two beams, the sliding platform moved in unison.

To perform the distraction test, the device was screwed to both beams with 6x25 mm set screws. The set screws, threaded into the lengthening plate screw holes, simulated the action of a locking screw and allowed for a 1 mm separation between the plate and the beam.

To approximate the fixation conditions more accurately, the test was repeated on the same set-up with the pediatric-sized synthetic bone. This synthetic bone offered a realistic shape profile and physical properties more representative of an actual bone. To affix the synthetic bone to the experimental bench, each end of the bone was set vertically in a container filled with quick-setting cement. In a similar fashion to the wooden beams, the bone was placed between the wooden frame and the sliding platform, and then cut in half. The device, screwed to the synthetic bone, could then perform a 50 mm distraction movement.

Maximum Load: To measure the efficacy of the device undergoing typical limb-lengthening forces in pediatric patients, weights were added to the sliding platform to simulate increasing distraction forces as lengthening progresses. A series of full 50 mm distractions were performed on the experimental bench, with weights ranging from 10 kg to 70 kg in 10 kg increments, as well

as a final test at 75 kg. An initial distraction gap of 13 mm was applied to the fixator due to the screw holes being too close to the edges of the bone gap in the closed position.

Distraction Speed: To measure possible changes in the device's distraction speed, measurements of the gap were taken every five minutes during the lengthening until the full 50 mm distraction was reached. To ensure that the magnetic drive remained engaged between the controller and the device's rotating magnet, the test was monitored for signs of disconnect between the two magnets. This disconnect typically occurs when the magnet inside the device is unable to generate a moment that is sufficient to displace the weight, and as a result reverses its position quickly and audibly.

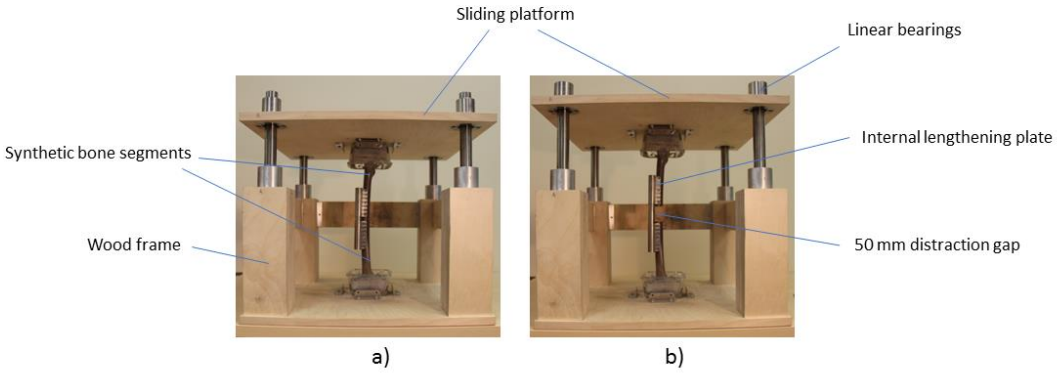


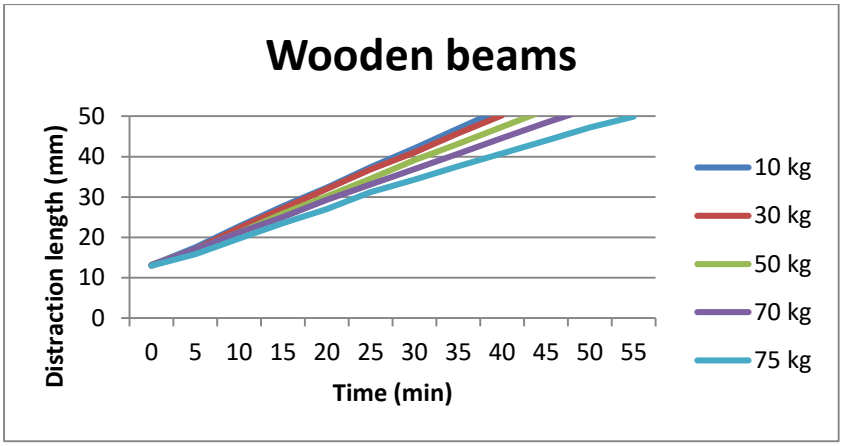
Figure 5.4: Experimental bench with the platform in the: a) lowest position; b) highest position.

5.5 Results

Maximum Load: With the wooden bone segment, 50 mm distractions were successfully achieved for weights ranging from 10 to 70 kg with 10 kg increments, and a maximum weight of 75 kg (735 N), exceeding the target weight of 700N. With the synthetic bone, all 50 mm distractions were similarly met at the same weights.

Distraction Speed: Considering a given weight added to the wooden bone segment, very little change was observed in the lengthening speed, indicating a linear relationship between the lengthening and the distraction time (Figure 5.5). However, the speed was shown to decrease slightly with increasing weights. No evidence of clicking or disconnect was noticed in the magnetic drive between the controller and the device. Similar results were obtained for the synthetic bone.

a)



b)

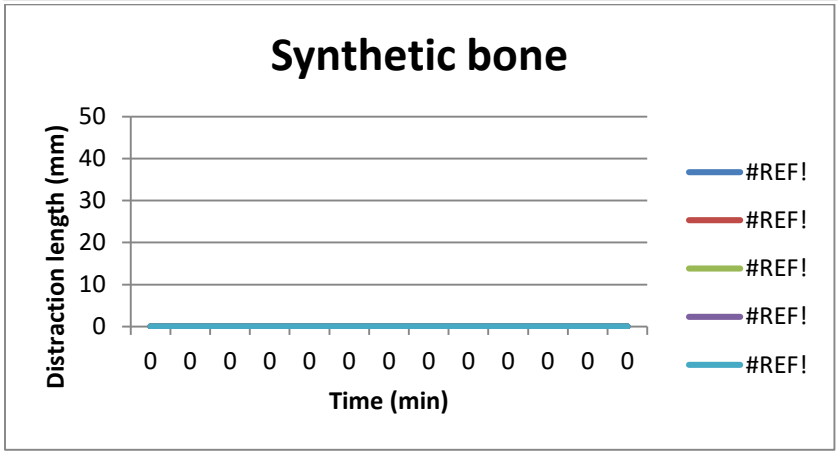


Figure 5.5: Distraction length over time for a) wooden bone segments b) synthetic bone segments

5.6 Discussion

This remote-controlled internal lengthening plate represents a significant improvement in the field of limb lengthening and caters to pediatric patients for which intramedullary nails are unsuitable. The lengthening plate is made up of two halves telescopically fitted into one another. Lengthening is powered by a rotating permanent magnet in one half of the device, coupled to a leadscrew engaged into a threaded nut portion in the second half. The fixation flanges running alongside the device's halves feature threaded screw holes to accommodate locking screws, which promote rapid bone healing. Hence, the lengthening plate avoids the intramedullary cavity altogether, mitigating damage to the growth plates, which renders it minimally-invasive as opposed to the implantation of internal lengthening nails such as the PRECICE.

Results show that the fixator, in a distraction procedure, could sustain loads normally generated during extreme cases of pediatric limb lengthening. The device was able to reach its maximum

extension of 50 mm distraction. However, the distraction tests were started at a partially distracted position of 13 mm, due to the screw holes being drilled into the mock bones further away from the distraction gap. This was done to ensure that the device was solidly fixed without risk of undue failure in the distraction gap. Nonetheless, stalling or failure is expected in the later stages of the distraction due to the overextension of the device, so a small initial length was deemed acceptable to test the generated force. Also, standard ISO M6 set screws (threaded along their entire length), instead of medical-grade locking screws, were used to fasten the device to the experimental bench. While these screws could simulate the 1 mm gap between the bone and the device, they do not approximate with accuracy the geometry and threading of the locking screws that would be used during *in vivo* studies. This renders the test suitable to assess the mechanical integrity of the device itself but confers little reliability with regards to testing failure by pullout or by thread breakage.

Furthermore, the device's lengthening position was shown to have a negligible impact on the speed and did not appreciably slow down as the lengthening approached the end of the 50 mm distraction. However, a decrease in lengthening speed was noted with increasing weight on the platform, which is ascribed to the increase in the load on the controller's motor. However, typical signs of "skipping" or disconnection were not observed in the magnetic drive between the controller and the device. In other words, the relationship between the controller's rotation and the rotation of the device's leadscrew remained unaffected, even at slower rate. Consequently, the next iteration of the controller's design should prescribe the daily increment as a specific number of rotations, instead of a given time interval.

To further validate the device's resistance, structural failure and fatigue tests should also be conducted to ensure that the device's body can withstand the patient's activities in a weight-bearing scenario for the duration of its distraction procedure, which can take many months. Indeed, this device is expected to accommodate full patient weight-bearing in the future. For *in vivo* testing and subsequent commercialization, a seal made of rubber or silicone should also be designed and installed at the telescopic interface between the two sliding parts of the lengthening plate. This seal would prevent fluid ingress into the device's cavities, which could cause bacterial growth and present a potential for patient infection.

5.7 Conclusion

In this paper, we presented an innovative internal fixator design that will significantly improve patient care for children undergoing limb lengthening. The fixator and remote controller designs were presented, and the ability of the fixator to withstand loads up to 750N without any signs of mechanical failure was demonstrated. Next steps involve in vivo testing in a big animal model using medical locking screws. Moreover, adapting the fixator to be used in a wider age range is part of future development.

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CHAPTER 6 DISCUSSION

According to the literature on pediatric limb lengthening fixators, children do not have access to the up-to-date devices that have been shown to decrease complications (i.e. lengthening nails). The aim of this project was to design a remote-controlled internal lengthening plate for use in pediatric patients.

- An extramedullary lengthening plate was designed with a high-stability fixation in keeping with the principles of bone fixation.
- The lengthening plate was shown to generate a distraction force exceeding the maximum soft tissue resistance measured in pediatric patients, and an adequately consistent distraction speed over the 50 mm distraction interval.

This section addresses discussion points on the device design and validation that were not mentioned in the article and expound on some details that require additional information.

6.1 Device design

Although the lengthening plate's extramedullary disposition renders it usable in pediatric patients, it is not limited to the younger demographic. In theory, it could be implanted in a patient of any age. Intramedullary lengthening nails implanted in the medullary canal of the bone require a preliminary reaming procedure, in which the surgeon drills inside the medullary canal to clear the way for the nail and remove any tissue that may be in the way, such as bone marrow or other bony tissue. The internal lengthening plate does not require such a procedure and can be installed much like any conventional locking plate, requiring only the screwing of the locking screws inside the bone.

One of the lengthening plate's future improvements includes the addition of a seal at the telescopic interface between the barrel and the piston. During the distraction process, the lengthening plate expands and necessarily creates a void inside the device's body, which in turn could promote ingress of bodily fluids inside the lengthening plate's recesses. This can lead to bacterial growth and puts the patient at risk of infection. While the sliding fit between the barrel in the piston is machined with great precision, its tightness may not be enough to prevent the inflow of fluid. To do so, a seal made from a flexible biocompatible material (such as rubber or silicone) must be

designed and attached to the end of the piston that is in contact with the barrel, to seal off any communication between the lengthening plate's interior and the patient's body.

Furthermore, the lengthening plate's diameter was originally planned to be smaller (12 mm) but was increased (18 mm) due to the limited machining abilities of the available machine shop. Although the current diameter was deemed to be suitable based on its similarity to the diameter of a pediatric femur, patients can benefit from increased comfort with a smaller device. With that in mind, the lengthening plate was designed with internal components suitable for a version featuring a 12 mm diameter, obtainable by decreasing wall thickness. It should be noted that the parameter of patient comfort as a function of implant size is largely undefined due to the wide variety of factors that come into play (size, position, shape), so case-by-case clinical trials should be carried out to evaluate with greater precision the impact of the lengthening plate's size on patient comfort.

6.2 Device validation

During the validation trial using the experimental bench, the resistance forces applied to the fixator were simulated by adding weights to the frame's vertically-sliding platform. The bench thus restricted the forces to a single degree of freedom (tension-compression), which may be an oversimplification of the interaction between the patient's soft-tissue forces and the lengthening process. A more accurate appraisal of the device's behavior in lengthening will be portrayed in the animal and clinical trials to come.

During the lengthening validation, the success of the lengthening plate's magnetic drive was critical. In other words, it was important to ensure that the rotating magnets in the controller rotated in perfect synchronization with the magnet inside the lengthening plate. If not, this would have signaled a failure to adequately lengthen the plate at a given weight, hence invalidating the lengthening plate's good working order. When a disconnection between the magnets occurred, the magnet inside the device was unable to perform a full rotation and reversed its position, and the audible clicking sound produced was taken as the signal for the inadequacy of the device's magnetic drive. Since the plate's internal parts were enclosed in the device's body, it was impossible to verify whether the click was caused beyond all doubt by the reversing magnet. Conversely, while the clicking noise seemed definitive and difficult to mishear, it was possible that it could have been missed by the experimenter with no way to verify its incidence. Once the plate

is implanted inside the patient's body, it becomes very difficult to monitor this event – the patient must rely on X-rays to verify the distraction length. This is a problem encountered by the PRECICE as well, which has no solution to provide lengthening feedback to the user without medical imaging.

Additionally, the testing was done with a preliminary controller featuring a DC motor. This differs from the planned controller, which would have a way to program the specific number rotations of the lengthening plate's leadscrew, which can be translated to a defined lengthening increment. With the DC motor, there was no way to reliably assess the number of rotations performed by the motor to measure against the device's lengthening increment. While the distraction length could be measured, the extremely high number of rotations required for distraction made it very difficult to keep track of the number of rotations accomplished and thus impossible to measure the two data points against each other. This metric would be interesting to test in the future, since precise lengthening is paramount for a high-quality bone callus in limb-lengthening procedures.

Although the lengthening plate was planned to include locking screws for its fixation, these proved to be exceptionally difficult to obtain, and the double-start conical threading on the head nearly impossible for machine shop technicians to recreate. To test this device, it was then decided that ISO M6 x 25 mm set screws (which have a thicker body than the locking screws) would be used to simulate the gap between the lengthening plate and the mock bone segments. This way, the threading machined along the entire set screw's body engaged the threading in the lengthening plate's screw holes, as well as the threading that was cut into the experimental bone segments. The lengthening plate was installed by clamping the fixation flanges to the mock bones with a 1 mm spacer, screwing the set screws through the device's screw holes and the mock bone segments, and removing the spacers. This set-up tested the resistance of the device with the correct position regarding the bone, but left out the possibility of testing screw pullout, breakage or thread back-out. These parameters should be tested with the correct screws once these have been secured.

CHAPTER 7 CONCLUSION

This thesis outlines the design process of an internally-implanted lengthening plate for distraction osteogenesis procedures in children. It describes the overall structure of the lengthening plate, highlights its innovative features, and details its preliminary testing, which validates the distraction force generated the mechanism as well as its distraction speed that remained appreciably constant throughout the full distraction.

Usability in pediatric patients gives great value to this minimally-invasive lengthening plate, fixed to the outside of the bone shaft and avoiding damage to the growth plates. Typically, young patients with open growth plates rely on the use of external fixators and run a high risk of device-related complications. Avoiding complications, such as pin-tract infections, pin loosening, or deviations, as well as social isolation secondary to body image (Paley 1990), emphasizes the value of the proposed lengthening plate and removes the need for additional procedures to rectify problems.

The internal lengthening plate was designed with fixation holes distributed evenly along the side of the device. These screw holes utilize locking screw technology, which promotes faster bone healing due to the preservation of the vascularization present on the surface of the bone. It features a rotating magnet coupled to a leadscrew to drive its telescopic extension, as well as a reducing gearbox to multiply the rotating magnet's torque by a large factor. The device has been confirmed to successfully exert a lengthening force of over 700N, which is above the maximum value of the resistance forces in lengthening for pediatric patients (Younger, Mackenzie et al. 1994).

Additionally, a magnetic controller is planned to deliver predetermined password-protected distraction increments, eliminating the manual actuation required with the Ilizarov device and reducing the chance of human error. This will improve patient compliance, which is principal in ensuring the formation of high-quality bone regeneration.

The future of the device is expected to include a general miniaturization of the lengthening plate, the addition of a waterproof seal, further stress and fatigue testing, and accommodation for proper locking screws. Also planned is *in vivo* testing using animal models and eventually clinical trials. The highly adaptable design would also make it applicable to many patients, where different-sized versions could cater to patients from a few months old to fully adult.

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APPENDIX A – SPECIFICATIONS TABLE

Jérémie Gaudreau, Christophe Farley, Isabelle Villemure, Mina Mekhail, Reggie Hamdy

Targeted Patients: **8-9 years old**
Femur's deformation

#	Description		Criteria	Level	Flexibility	K	Weight	Flex.	Scale	%	Comment/Reference
1- Implant should lengthen the bone											
1	Correct length of the bone		Range of lengthening	Maximum 75 mm *(25% of mean femur's length of 300 mm)*	± 5 mm	5	4.13	0			According to Dr. Hamdy, the maximum allowed lengthening corresponds to 25% of a femur's length
2	Distraction settings		Distraction increments	1mm/24h	1-4 equally-distributed increments	4	3.31	0			Dr Hamdy says that there is not enough evidence that slow continuous distraction is better than discrete - Mina Mekhail
3	Distraction settings		Distraction direction	Device can distract in both directions		2	1.65	0			This is not necessary, but a good asset. Reference: Dr. Hamdy
2- Implant should generate a variable axial force											
1	Applied load		Load range	0 - 700 N	± 100 N	4	3.31	1			Forces Measured During Femoral Lengthening in Children by Alastair S. E. Younger. MB., ChB., Aberdeen University, 1985 Simpson, A. H. R. W., Cunningham, J. L., & Kenwright, J. (1996). The forces which develop in the tissues during leg lengthening. Bone & Joint Journal, 78(6), 979-983. Lauterburg, M. T., Exner, G. U., & Jacob, H. A. (2006). Forces involved in lower limb lengthening: an in vivo biomechanical study. Journal of orthopaedic research, 24(9), 1815-1822.
2	Nature of load transmitted to the bone		Type of load	Tension		4	3.31	0			

3- Implant should transmit the load to the bone											
1	Fixation in the bone (Rigidity of the fixation)		Resistance to torsion and bending	To be determined experimentally using Sawbones or cadaver bones		4	3.31	1			To be determined experimentally - bending and torsion tests with screws in bone
			Resistance to screw pull-out	Lower bound: 298 N (per screw) (7x16mm, cannulated, Synthes) Upper bound: 716 N (per screw) (6.5x32mm, non-cannulated, Zimmer)	Lower bound: ± 5 N Upper bound: ± 18 N	4	3.31	2			Assumed a 6.5mm - 7mm diameter screw Asumed a low density Chapman, J. R., Harrington, R. M., Lee, K. M., Anderson, P. A., Tencer, A. F., & Kowalski, D. (1996). Factors affecting the pullout strength of cancellous bone screws. Journal of biomechanical engineering, 118(3), 391-398.
2	Mobility allowed by the implant		Allowable movement between bone and device	None		5	4.13	0			
3	Fixation settings		Number of fixations on each bone segment	Minimum: 3		2	1.65	2			
			Distance between the fixation's screw holes	As far as possible		2	1.65				According to Dr. Hamdy, the screw holes in each fixation must be as far apart from each other as possible.
			Distance between each fixation location and the distraction gap	As close as possible		2	1.65				Dr. Hamdy mentioned that each fixation should be screwed in as close to the distraction gap as possible to ensure implant stability.
			Contact with periosteum	No contact - locking plate		5	4.13	2			According to Dr. Hamdy, avoiding interference with the periosteum is critical to favor callus formation. This can be achieved using locking-plate technology.
4- Implant should fit on the femur of a 8-9 year old child											
1	Implantation zone		Position of device w/r to bone anatomy	Diaphyseal zone		4	3.31	2			
			Length of device in intial configuration	150 mm	± 9mm	4	3.31	2			
			Device cross-section	18mm							Close to the measured diameter of a pediatric femur's diameter
2	Mass of the device		Total weight of the device	Its total weight must not be over 50% of ILizarov apparatus external fixator's weight (Waiting for the actual mass of the liizarov)		2	1.65	2			According to Mina, this number was arbitrarily picked to ensure good mobility for the patients.
			Center mass localisation	Device center mass should be the closest to femur center mass		3	2.48	1			

5- Implant should receive energy to make mechanical motions											
1	Energy source		Type of energy	Mechanical (Kinetic) energy		2	1.65	2			
				Electrical energy		3	2.48	2			
				Magnetic energy		3	2.48	2			
			Location	Inside the leg		3	2.48	1			
2	Safety		Electrical insulation	Perfect		5	4.13	0			
			Mechanical insulation	Best possible		4	3.31	1			
6- Implant should be able to activate and deactivate whenever necessary											
1	Activation settings management		Reading of the measurement	On an external controller		4	3.31	0			
			Distraction activator location	On an external controller		4	3.31	0			
2	Deactivation settings management		Emergency stop location	On an external controller		4	3.31	0			
			Time reaction for stopping	< 1sec		4	3.31	1			
7- Implant must resist the functional activities of a 8-9 year-old human being											
1	Corrosion resistance of the implant in its environment		Corrosion rate	No corrosion		5	4.13	2			Mina - Corrosion cannot occur during the device's lifetime.
			Resistance to pH	7.0 - 7.45		5	4.13	2			Waugh, Anne; Grant, Allison (2007). "2". Anatomy and Physiology in Health and Illness (Tenth ed.). Churchill Livingstone Elsevier. p. 22. ISBN 978-0-443-10102-1.
2	No infections or inflammations		Component materials	Biomaterials	Nitinol, Titanium alloy, Cr-Co, SS316L, MED610	5	4.13	0			Bio-compatible 3D print medical devices, PolyJet MED610, Stratasys
3	Mechanical stability of implant		Lifetime	7.5 months		4	3.31	2			Mina - The distraction and consolidation phases are approximated at 1 month/cm of distraction.
			Operating temperature	36.1° - 37.8°		5	4.13	0			T.R. Harrison (2011). Harrison's principles of internal medicine. (18th ed.). New York: McGraw-Hill. p. 142. ISBN 978-0-07-174889-6.
			Weight-bearing	Toe-touch (very little weight applied)		5	4.13	1			According to Dr. Hamdy, the preliminary device can be designed as toe-touch weight-bearing.
8- Implant should be produced at competitive prices											
1	Cost of fabrication and materials		Price of the device	15 000.00 $	± 1000.00 $	4	3.31	2			Reference: Univalor

	Criteria weight calculus				
	Number of functions/constraints	Relative weight	Importance	K	**Weight**
Number of 1k	0			1	**0.00**
Number of 2k	6	200	12	2	**1.65**
Number of 3k	4	300	12	3	**2.48**
Number of 4k	13	400	52	4	**3.31**
Number of 5k	9	500	45	5	**4.13**
		Total	**121**		100

Legend

Criteria importance : K
1 : Useful
2 : Desirable
3 : Important
4 : Very important
5 : Vital

Flexibility classes : Flex.
0 : None
1 : Low
2 : Negotiable
3 : High

APPENDIX B – CONCEPT SELECTION TABLE

Criterion	Weight	Option 1	Score 1	Weighted Score 1	Option 2	Score 2	Weighted Score 2	Option 3	Score 3	Weighted Score 3
Range of lengthening	4.13	50mm	1	4.13	50mm	1	4.13	50mm	1	4.13
Distraction increments	3.31	1mm/day	1	3.31	1mm/day	1	3.31	1mm/day	1	3.31
Distraction direction	**1.65**	**Both**	**1**	**1.65**	**Both**	**1**	**1.65**	**Single**	**0**	**0**
Load range	**3.31**	**Med**	**1**	**3.31**	**Med**	**1**	**3.31**	**Lower**	**0.5**	**1.655**
Type of load	3.31	Tension	1	3.31	Tension	1	3.31	Tension	1	3.31
Resistance to torsion and bending	**3.31**	**High**	**1**	**3.31**	**High**	**1**	**3.31**	**Med**	**0.5**	**1.655**
Resistance to screw pull-out	3.31	Med	1	3.31	Med	1	3.31	Med	1	3.31
Allowable movement	4.13	None	1	4.13	None	1	4.13	None	1	4.13
Number of fixations per bone segment	1.65	3	1	1.65	3	1	1.65	3	1	1.65
Distance between the fixation's screw holes	**1.65**	**Small**	**0**	**0**	**Far**	**1**	**1.65**	**Small**	**0**	**0**
Distance between each fixation location and the distraction gap	**1.65**	**Far**	**0**	**0**	**Small**	**1**	**1.65**	**Far**	**0**	**0**
Contact with periosteum	4.13	None		0	None		0	None		0
Position of device wrt bone anatomy	3.31	Diaphysis	1	3.31	Diaphysis	1	3.31	Diaphysis	1	3.31
Length of device in initial configuration (mm)	3.31	190	1	3.31	137	1	3.31	115	1	3.31
Total weight of device	1.65	Adequate	1	1.65	Adequate	1	1.65	Adequate	1	1.65
Center mass localisation	**2.48**	**Med**	**1**	**2.48**	**Far**	**0**	**0**	**Med**	**1**	**2.48**
Mechanical Energy	1.65	No	0	0	No	0	0	No	0	0
Electrical Energy	2.48	Undetermined	1	2.48	Undetermined	1	2.48	Undetermined	1	2.48
Magnetic Energy	2.48	Undetermined	1	2.48	Undetermined	1	2.48	Undetermined	1	2.48
Location	2.48	Inside leg	1	2.48	Inside leg	1	2.48	Inside leg	1	2.48
Electrical insulation	4.13	Adequate	1	4.13	Adequate	1	4.13	Adequate	1	4.13
Mechanical insulation	3.31	Adequate	1	3.31	Adequate	1	3.31	Adequate	1	3.31
Reading of measurement	3.31	On controller	1	3.31	On controller	1	3.31	On controller	1	3.31
Distraction activator location	3.31	On controller	1	3.31	On controller	1	3.31	On controller	1	3.31
Emergency stop location	3.31	On controller	1	3.31	On controller	1	3.31	On controller	1	3.31
Time reaction for stopping	3.31	1 sec	1	3.31	1 sec	1	3.31	1 sec	1	3.31
Corrosion rate	4.13	None	1	4.13	None	1	4.13	None	1	4.13
Resistance to pH	4.13	Adequate	1	4.13	Adequate	1	4.13	Adequate	1	4.13
Component materials	4.13	Titanium	1	4.13	Titanium	1	4.13	Titanium	1	4.13
Lifetime	3.31	7.5 months	1	3.31	7.5 months	1	3.31	7.5 months	1	3.31
Operating temperature	4.13	36.1-37.8	1	4.13	36.1-37.8	1	4.13	36.1-37.8	1	4.13
Weight-bearing	4.13	Toe-touch	1	4.13	Toe-touch	1	4.13	Toe-touch	1	4.13
Price of device	3.31	15000	1	3.31	15000	1	3.31	15000	1	3.31
				90.94			**95.07**			**89.29**