T.C.
DOKUZ EYLUL UNIVERSITY
INSTITUTE OF HEALTH SCIENCES

DEVELOPMENT OF LIMB LENGTHENING MECHANISMS USED IN ORTHOPEDIC SURGERY

By

BORA UZUN

DEPARTMENT OF BIOMECHANICS
BIOENGINEERING DOCTORAL PROGRAM
DOCTORAL THESIS

IZMIR-2015

THESIS CODE: DEU.HSI.PhD-2008970001

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Dokuz Eylul Umversity, Inst1tue of Health Science, Department of Biomechanics Bioengineering Doctoral Program; The thesis entitled **" DEVELOPMENT OF LIMB LENGTHENING MECHANISMS USED IN ORTHOPEDIC SURGERY "** successfully completed by **Bora UZUN** for the degree of Doctor of Philosophy on 2015

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ABBREVIATIONS

LLD ……………………….Leg Length Discrepancy

LBP …………………… Low Back Pain

OA ……………………Osteoarthritis

SLLD …………………..Structural Leg Length Discrepancy

FLLD …………………..Functional Leg Length Discrepancy

TSFs …………………...Taylor Spatial Frames

LON.…………………...Lengthening Over Nail

GEN.…………………...Gradual Elongation Over Intramedüllery Nail

ISKD…………………...Intramedullary Skeletal Kinetic Distractor

SAA……………………Slide Active Actuator

TAA…………………...Telescope Active Actuator

ERC……………………External Remote Control

FDA…………………... Food and Drug Administration

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ORTOPEDİK CERRAHİDE KULLANILAN BOY UZATMA MEKANİZMALARININ GELİŞTİRİLMESİ

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ÖZET

Ekstremitede değişik nedenlere bağlı kısalık insan hayatını fonksiyonel ve psikolojik olarak kötü yönde etkileyebilecek bir sorundur. Bu tip hastaların estetik ve fonksiyonel bir ekstremiteye sahip olabilmeleri için ortopedik cerrahide kullanılan bir çok yöntem bulunmaktadır. Yakın zamana kadar, ekstremite uzatmalarında intramedüller çiviler tek başına kullanılamamakta ve bir eksternal fiksatör yardımı ile uzatma işlemi gerçekleştirilmekte idi. Ancak eksternal fiksatörlerin kullanılmasında çeşitli komplikasyonların varlığından dolayı, eksternal fiksatör kullanımına gerek duymadan uzatma sağlayabilecek intramedüller çivilerin geliştirilmesi üzerine bir çok çalışma yapılmıştır.

Bu çalışmada, daha önce yapılan çalışmalar doğrultusunda mevcut sorunların ve komplikasyonların ortadan kaldırılması ve mümkün olduğu müddetçe , ikinci bir cerrahi müdahale yapılmadan, söz konusu ekstremitede kullanılan intramedüller çivinin boyu uzatılarak, mevcut olan ve daha sonra da ortaya çıkacak boy farkının ortadan kaldırılması amacıyla, uzamayı sağlayacak yeni bir sistemin geliştirilmesi amaçlanmıştır. Bu amaçla, electromekanik olarak aktive olan yeni bir intramedüller çivi tasarlanmış ve üretilmiştir.

Bu intramedüller çivi sistemi, ekstremite uzatmasını ihtiyaca göre hem mekanik, hem de elektronik olarak gerçekleştirebilecek şekilde tasarlanmıştır. Klinik koşullara göre çalışma şekli değiştirilebilmektedir. Ayrıca bu durum, sistemin biri arızalandığında (mekanik veya elektromik) diğeri ile uzatmaya devam edilebilmesi açısında avantaj sağlamaktadır.

Sonuç olarak, geliştirdiğimiz sistemin, halen kullanılmakta olan boy uzatma sitemlerine göre, çalışma prensibi, uygulama kolaylığı, kontrollü uzama, hasta mobilitesi ve tedavi süresinin kısalığı gibi avantajları olduğu görülmektedir. Sistemin uygulamadaki başarısı, yapılması planlanan *in-vivo* hayvan deneylerinde irdelenecek ve alınacak sonuçlara göre gerekli iyileştirmeler yapılarak insan üzerinde uygulamaya hazır hale getirilecektir.

Anahtar Kelimeler: Boy uzatma, İntramedüller çivi, Bacak boyu eşitsizliği

DEVELOPMENT OF LIMB LENGTHENING MECHANISMS USED IN ORTHOPEDIC SURGERY

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ABSTRACT

Shortness of an extremity due to different causes is an issue that may adversely affect human life functional and psychologically. There are many methods used in orthopedic surgery for such patients in order to have a functional and aesthetic limb.

Until recently, intramedullary nails could not be used alone and limb lengthening was being performed with the help of an external fixator. However, due to the presence of various complications in the use of external fixators, alot of studies have been performed on the development of intramedullary nail which can provide extension without the need of external fixators.

In this study, in the light of previous studies, it is aimed to develop a new expandable intramedullary system, providing lengthening in order to remove previous problems and complications and to annihilate leg length discrepancies at present and future without second surgical intervention as far as possibble by lenghtening the intramedullary nail. To this end, a new electromechanically active intramedullary nail has been designed and generated.

The intramedullary nail system was designed to perform extremity lengthening both mechanically and electronically according to the requirement. The function status can be changed at any time depending on the clinical conditions. This also provides an advantage that if any one (mechanic or electronic) fails, the lengthening process can continue with the other.

Consequently, it is evident that the system we developed have advantages in respect of the present leg lengthening systems, like operation princible, easiness of application, controlled lengthening, patient mobility and shortness of treatment duration. The success of the system at practice will be examined with *in-vivo* animal experiments and according to the results, it will be ready for use on human by performing necessary restorations.

Keywords: Limb lengthening, Intramedullary nail, Limb length discrepancy

1. INTRODUCTION AND PURPOSE

Shortness of an extremity due to different causes is an issue that may adversely affect human life functional and psychologically. There are many methods used in orthopedic surgery for such patients in order to have a functional and aesthetic limb.

In this study, in the light of previous studies, it is aimed to develop a new expandable intramedullary system, providing lengthening in order to remove previous problems and complications and to annihilate leg length discrepancies at present and future without second surgical intervention as far as possibble by lenghtening the intramedullary nail. To this end, a new electromechanically active intramedullary nail has been designed and generated.

2. GENERAL INFORMATION

2.1. Limb Length Discrepancy (LLD)

Limb length discrepancy, or anisomelia, is defined as a condition in which paired limbs are noticeably unequal (Figure 1). When the discrepancy is in the lower extremities, it is known as leg length discrepancy (LLD). LLD is a relatively common problem found in as many as 40 % [1] to 70% [2] of the population. In a retrospective study, it was found that LLD of greater than 20 mm affects at least one in every 1000 people [3,15]. And about one-third of the human population have 0.5–1.5-cm inequalities and five percent of them are more than 1.5 cm [3-5,15].

Studies have investigated the effects of LLD on low back pain (LBP) [6], osteoarthritis (OA) of the hip [7], stress fractures [8], aseptic loosening of hip prostheses [9], standing balance [10], forces transmitted through the hip [11], running economy [12] and associated running injuries [13,14].

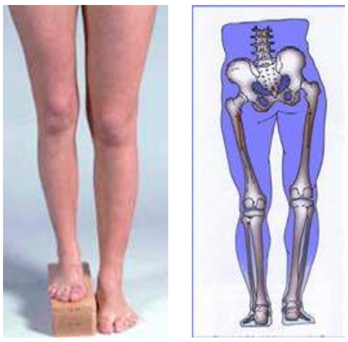


Figure 1. Leg length discrepancy.

LLD can be subdivided into two etiological groups: a structural LLD (SLLD) and a functional LLD (FLLD)

2.1.1. Etiology of Structural LLD

SLLD, also known as true LLD is defined as differences in leg length resulting from inequalities in bony structure. The etiology of SLLD may be congenital or acquired. The most of common congenital causes, include congenital dislocation of the hip, and congenital hemiatrophy or hemihypertrophy with skeletal involvement. Acquired causes can be as a result of infections, paralysis, tumors, surgical procedures such as prosthetic hip replacement, and mechanical such as slipped capital femoral epiphysis [14].

2.1.2. Etiology of Functional LLD

Functional, or apparent LLD is a result of muscle (tightens/weakens) or joint tightness across any joint in the lower extremity or spine. Some of the more common causes can be pronation or supination of one foot in relation to the other, hip abduction/adduction tightness/ contracture, knee hyperextension due to quadriceps femoris weakness, and lumbar scoliosis [14].

In addition, persons with LLD can be classified into two categories, those who have had LLD since childhood, and those who developed LLD later in life. In terms of functional outcomes such as gait, persons who have developed a LLD later in life are more debilitated by LLD of the same magnitude when compared to persons who have had LLD since childhood [16].

Difference in length of lower extremities is much more than a cosmetic problem, causes functional orthopedic disorders. Orthopedists are closely related to the treatment of this pathology because of both walking pattern changes due to balance disorder in the frontal plane and degenerative abnormalities occurring at the axial skeleton like knee osteoarthritis [17].

Despite the acceptable leg length discrepancy is 2 cm, this assumption may change depending on the anatomic parameters like muscle force, pelvic width, absolute leg lentgh and etc.

2.2. Indications For Leg Lengthening

Over the last 100 years, indications have shifted from leg length discrepancies and deformities due to poliomyelitis, war wounds, osteomyelitis and malunited fractures to congenital problems such as femoral deficiencies, simple femoral hypoplasia, fibular hemimelia and tibial aplasia, hemihyper- and hemihypotrophy, and a long list of acquired problems, such as post-traumatic growth arrest, post-infectious issues, avascular necrosis, Perthes' disease, Blount's disease, skeletal dysplasia, rickets, syndromes, Ollier's disease, enchondromatosis etc. [18-23]. The composition of causes varies [24-30].

The restoration of any complex deformities can be realized with recent techniques in deformity correction. But unfortunately, there are still considerable biological limitations and challenges. The patient and his psychosocial, medico-economic, logistic and legal environment must be consented, educated and prepared for a potentially longlasting journey paved with hazards such as delayed consolidation, pseudarthrosis, malalignment, joint contractures and dislocations, pain, infection, prolonged inability to work and refrain from school and sports activities [18-20,24,25,31-44].

All current methods of gradual leg lengthening rely on distraction osteogenesis by incremental 1-mm/day fragment separation and consolidation [45–49]. During this process, the bone is extended gradually by surgically cutting and new bone formation is observed at the extension region. In this way, bone can be extended 15 to 100 % of its length.

Until recently, intramedullary nails could not be used alone and limb lengthening was being performed with the help of an external fixator. However, due to the presence of various complications in the use of external fixators, alot of studies have been performed on the development of intramedullary nail which can provide extension without the need of external fixators.

In all these studies, several complications has appeared like difficulties in patients mobility, lack of mechanism for the extension, implementation challenges and infection.

However, concurring implants and techniques for mechanical bone guidance such as Taylor Spatial Frames (TSFs), traditional Ilizarov ring and wire constructs, various methods for unilateral external fixation and intramedullary mechanical or motor-driven nails offer space for individual application given by the skills and preferences of the surgeon, the affordability, the patient's needs and wishes, and the medical problem defined as a mixture of bony deformity and the condition of the joint, muscle and soft tissue compound adjoining the segment to be corrected.

2.3. History of Leg Lengthening

The history of surgical leg lengthening started about 100 years ago, probably when the German visionary surgeon Bernhard von Langenbeck 1869 claimed that 2–4-cm leg shortening causes significant impairment of function and that it should be equalised surgically by stretching of the bone. However, it lasted until 1903, when pioneer Alessandro Codivilla (Rizzoli Institute Bologna/ Italy) performed femoral osteotomies in patients with coxa vara. Traction (25–75 kg) was applied by a cast and a transcalcaneal wire [13, 50, 51] (Figure 2).

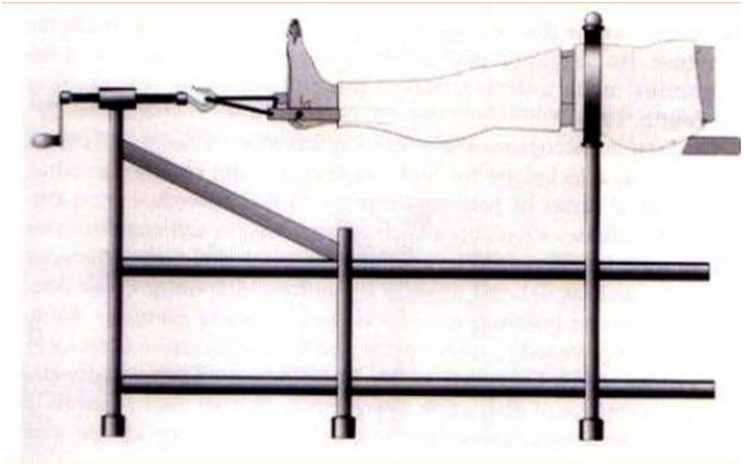


Figure 2. Codivilla's device for limb lengthening by traction.

Louis Ombre´danne 1913—first gradual (5-mm/day) lengthening on a femur using an external fixator with one pin above and one pin below the osteotomy— achieved an additional 4 cm [52]. Vittorio Putti conjoined the former ideas of external fixation, Z-shaped osteotomy and continuous but slower distractions (2–3-mm daily) for up to 8-cm lengthening, which resembles modern unilateral methods [53]. August Bier recognised and practised the importance of delaying lengthening after the osteotomy in 1923 [54]. Leroy Abbott St. Louis further developed the method of callus distraction in the mid-1920s (Figure 3).

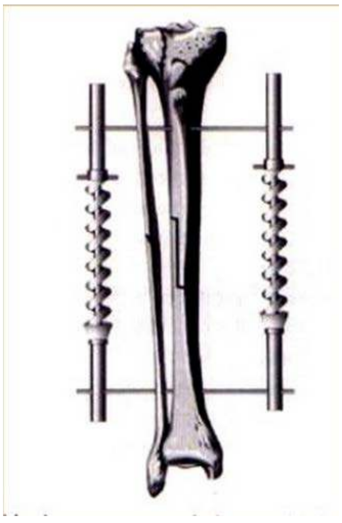


Figure 3. Leroy's distraction system.

The oldest and most widely used method of distraction osteogenesis is the Ilizarov method, developed by Gavriel Ilizarov Russian orthopedist in 1951. Ilızarov's Technique is consist of rings, rods ve Kirschner [55] wires (Figure 4).

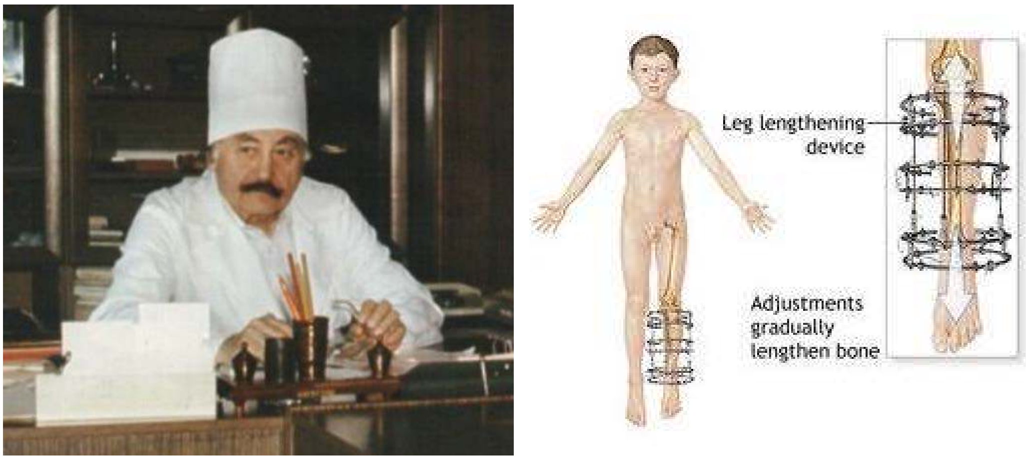


Figure 4. Gavriel Ilızarov and his technique.

At the beginning of the 1990s, modern web-based hexapod platform technology (1994, Taylor Spatial Frame [TSF]) and motorised, fully implantable, solid intramedullar nails have lifted them to better predictability, more comfort and lower risk [56, 57].

2.4. History of Intramedullary Nails

The first information regarding the therapeutic use of intramedullary nails is based on the 16th century. In this period, there are informations related to that Incas and Aztecs have used resin-coated wooden nails in to the medullary canal for treatment of non-union long bone fractures.[58]

Later in 1886, Birch et al, have provided fixation by hammering ivory nails into the medullary canal and after that in 1913 Koning was also used ivory nails in the treatment [59,60].

During the 1890s, Gluck recorded the first description of an interlocked intramedullary device consisted of an ivory intramedullary nail that contained holes at the end, through which ivory interlocking pins could be passed [61,62]. The medullary canal nail insertion method was used by Lambot for clavicle in 1907 in Belgium and by Schöne for radius and ulna in 1913 in Germany for the treatment of fractures [63]. At the same time period, Nicolaysen has published the intramedullary nailing principles [64].

During World War I, Hey Groves reported the use of metallic rods as in intramedullary nail for the treatment of gunshot wounds [62,65]. In 1931 Smith-Petersen reported the successful use of stainless steel nails for the treatment of femoral neck fractures [62,66]. That was the beginning of rapid increase of using metallic intramedullary implants.

Küntscher is considered as the father of today's standard intramedullary nail. During World War II, he first used V shaped and then Y shaped intramedullary nails for the treatment of femoral neck fractures [63,67,68]. In 1945, Küntscher and Richard Maatz have written a book named “Technik der Marknagelung” which describes the principle of the stabilization of his cloverleaf shaped slotted nail in the intramedullary canal of long bones (Figure 5), [63].

Figure 5. Cloverleaf shaped slotted nail.

During the 1940s, different intramedullary nail designs were reported such as in 1944 by Westerbon, in 1946 U-shaped nail by Soeur and in 1947 a nail by Hansen-Street [62,69-71].

In 1953, Modny and Bambara introduced the transfixion intramedullary nail which was cruciate-shaped, having multiple holes to allow for placement of screws at 90° angles from each other [62,72].

In the 1960s, Kaesman described the compression nailing technique [63].

The Zickel nail was introduced In 1967 . The nail has a hole in the proximal portion to allow a screw to be placed into the femoral cortex into the femoral neck and head to prevent backout of the nail [73].

Ender and Simon-Weidner reported the use of flaxible nails for the fixation of intertrochanteric and subtrochanteric fractures in 1970 (Figure 6), [63,74].

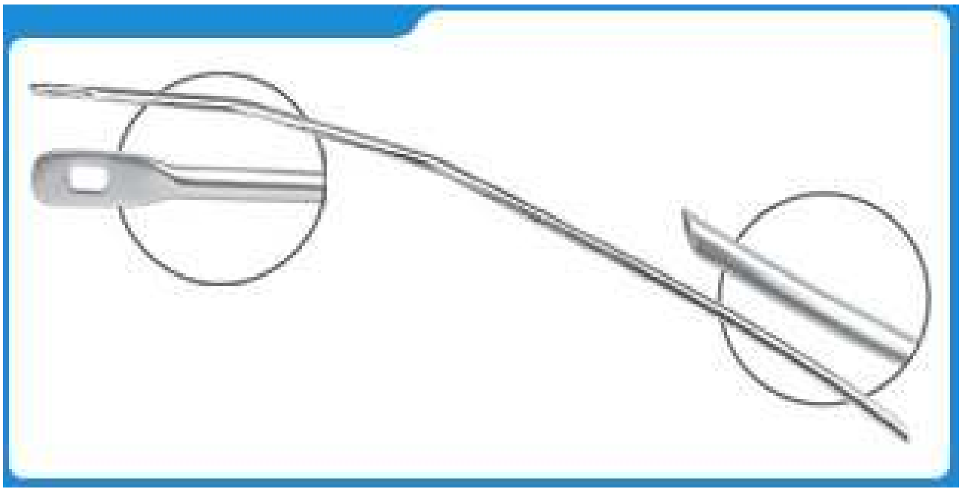


Figure 6. Ender nail.

In 1980s, the dominant design was the slotted cloverleaf shaped interlocked nail like AO and Grosse Kempf nails [62,63].

2.5. Bone Lengthening Techniques

The common pathway of all leg lengthening methods is 1-mm/day distraction after an initial latency period. Technical options comprise external unilateral or ring fixation (Ilizarov, TSF), intramedullary solid nails as a mechanical or motorised standalone technology or in combination with an external device during the distraction phase (lengthening over nail) (Table 1), [24].

Table 1. Systems to perform distraction osteogenesis at the lower limb.

External systems			Fully implantable systems		
Without intramedullary nail		With intra-medullary nail	Mechanical systems		Motorised systems
Ring fixator	Monolateral fixator	Lengthening over nail	Albizzia	ISKD	Fitbone

2.5.1. External Fixators

External fixator is a device placed outside the body. Pins and screws are used to secure the bone passing through the skin, muscle and soft tissue.

There are various types of external fixators:

- Unilateral
- V-Shape
- Circular

2.5.1.1. Unilateral External Fixators:

Unilateral external fixators are placed longitudinally on one side of the limbs (Figure 7). External fixator is placed in the lateral aspect of the femur and on the inner or medial side of the lower leg. The main body of external fixator is mounted to the bone with 4-6 mm diameter pins or screws.

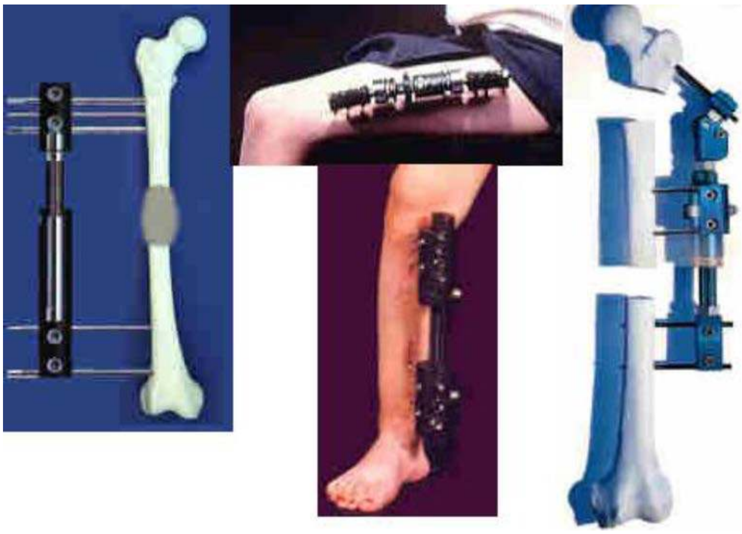


Figure 7. Unilateral external fixators.

2.5.1.2. V-Shape External Fixators:

V-Shape external fixators are formed by two unilateral external fixator placed in an angle (Figure 8).

Figure 8. V-Shape External Fixators.

2.5.1.3. Circular External Fixators:

Circular External Fixators can solve any three-dimensional, multi-plane, 6-axes deformity problem including fragment translation and contractures at any age with a custom-made frame (Figure 9). Ring constructs, usually with hybrid wire and screw bone fixation to reduce the number of soft tissue transfixations, provide the greatest versatility and best mechanical control [24]. The first external fixator was designed by Ilizarov in 1951 [55].

Figure 9. Circular external fixator.

2.5.2. Lengthening Over Nail (LON, monorail method)

A different strategy for the distraction and consolidation phases aims at reducing the total fixator time by simultaneously placing an intramedullary solid nail at the time of osteotomy and by removing the external device at the end of distraction [15,23, 75]. This concept was introduced in 1956 by Bost and Larsen [24]. LON is technically more demanding than the placement of a ring or unilateral fixator: after reaming, the nail is temporarily placed, then the pins and wires beneath and distally beyond the nail, followed by nail removal, placement of the external fixator, osteotomy and definitive nail insertion (Figure 10). After the distraction phase, the nail is locked to stabilise the gained length and axis before removal of the fixator [15].

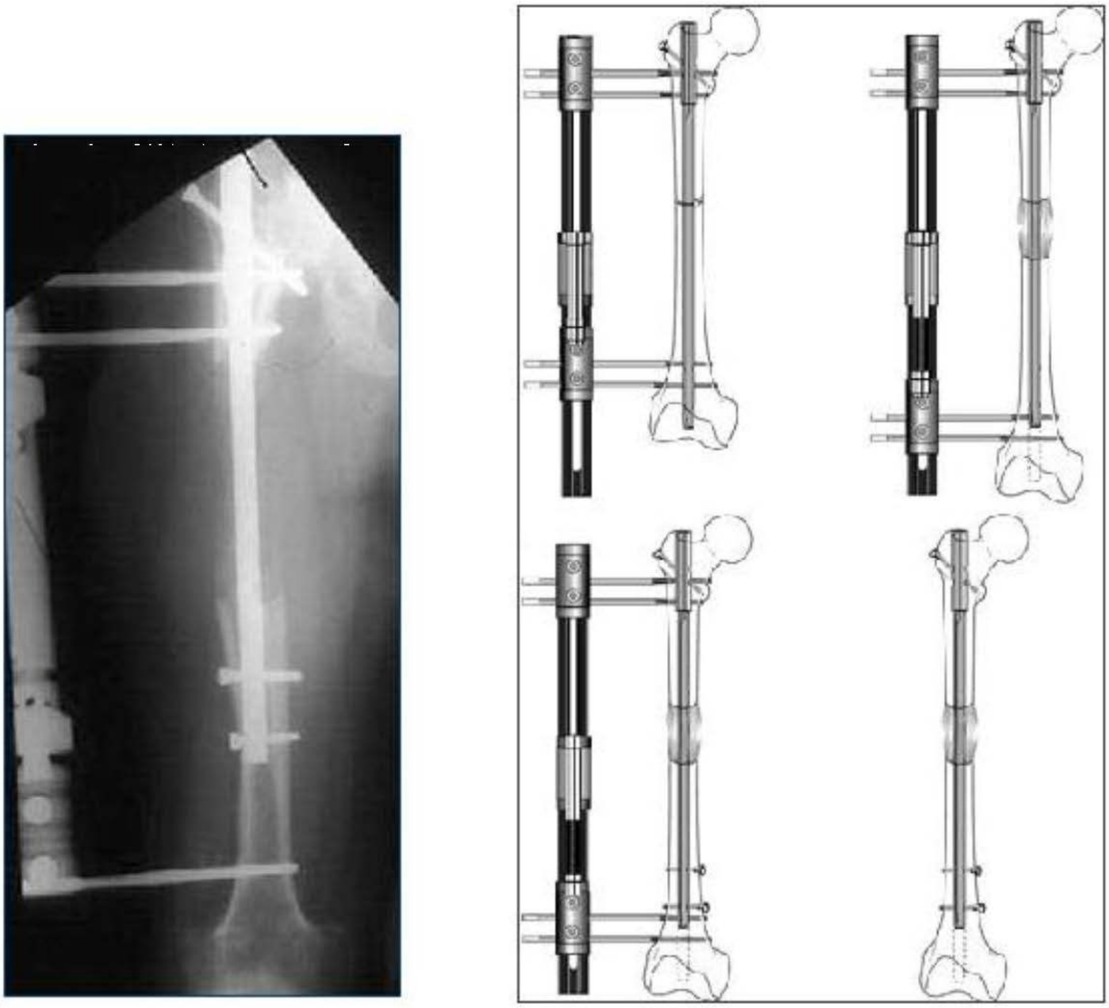


Figure 10. Example of LON application.

After Ilizarov's fundamental appreciation of regenerate biology and guided three-dimensional bone moulding, the development of expanding intramedullary nails formed the next milestone. They apply to more simple deformities after the end of growth and require appropriate medullary canal sizes and bone lengths [15]. At the end of the 1970s and the beginning of the 1980s, the first intramedullary lengthening devices appeared: in 1975, a hydraulic pressure system and a nail to lengthen the femur [76] and in 1977, an extension nail with external driver passed through the soft tissues in a canine experiment [77]. Bliskunov used the patient's own energy source (movement between the femur and iliac wing) to generate length. All these open-source devices with external components directly linked to the nail and medullary canal failed due to infections and unbearable pain [15,77, 78].

2.5.3. Intramedullary Lengthening Nails

The first intramedullary lengthening devices appeared: in 1975, a hydraulic pressure system and a nail to lengthen the femur [76] and in 1977, an extension nail with external driver passed through the soft tissues in a canine experiment [77]. Bliskunov used the patient's own energy source (movement between the femur and iliac wing) to generate length [15]. Bliskunov developed a telescopic lengthening nail that used a crankshaft connected to the pelvis to drive his mechanism and lengthen the femur (Figure 11). Rotational motion of the femur produced lengthening of the nail. The rotation was through the hip joint and not through the osteotomy. His technology was not available outside of the Soviet Union. Even today it is only used by a few in Ukraine [79].

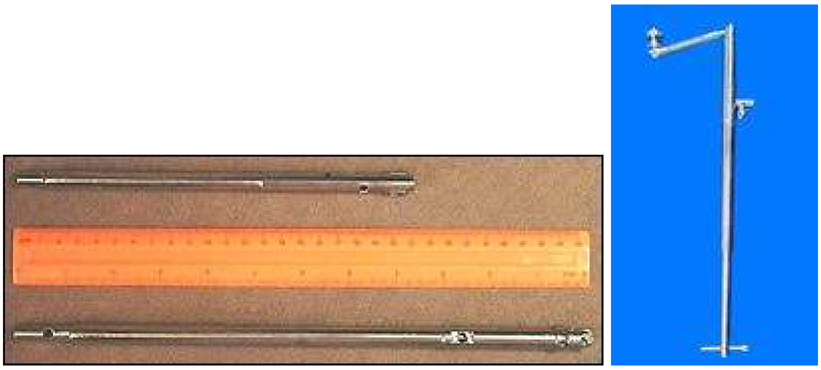


Figure 11. Bliskunov's telescopic lengthening nail.

2.5.3.1. Albizzia Nail

Albizzia, also called GEN (gradual elongation over intramedüllery nail) was also developed by Dr. Jean-Marc Guichet in France in 1987 [81,82]. It is made of two sliding tubes. The alternative rotation of the device allows the lengthening (multiple alternate rotations of 20° inwards and outwards) (Figure 12). The nail is inserted into the bone canal after bone section from the inside, without any added scars, and is then fixed with screws. ost-operatively, the patient turns himself his leg or arm, with alternate rotatory maneuvers. 15 go-and-forth clicks per day represent 1 mm of gain. It takes 10 days to gain 1cm [83]. Many reports exist of patients suffering from severe pain and discomfort, which limit their ability to independently perform the lengthenings. In some cases, these patients required readmission to the hospital with general anesthesia and closed manipulation [44,79,82,84]. In other reports, 12% of the lengthenings remained incomplete because the patients were simply unable to tolerate the pain of the manipulation [82].

Figure 12. Albizzia Nail and working principle.

2.5.3.2. ISKD - Intramedullary Skeletal Kinetic Distractor

Using the same concept of lengthening by rotation through the callus, Cole developed a double-clutch mechanism to cause distraction (Figure 13). Only 3 to 9 degrees of rotation was required to cause the nail to lengthen. The intramedullary Skeletal Kinetic Distractor (ISKD) (Orthofix Inc., McKinney, TX) was Food and Drug Administration (FDA) approved in 2001 [79,85,86]. The system consists of a telescoping internal limb lengthener, locking screws, instrumentation and an external hand-held monitor. As the patient performs small rotational oscillations of the limb, the ISKD internal limb lengthener gradually distracts. The rate of distraction can be varied by changing the patient’s activity level or by manually manipulating the limb. The hand held monitor contains a magnetic sensor that detects the small magnet sealed inside the lengthener (Figure 14). As the lengthener distracts, the magnet inside rotates. When positioned correctly over the magnet, the monitor tracks and records the poles of the magnet; then converts pole changes into millimeters of distraction.

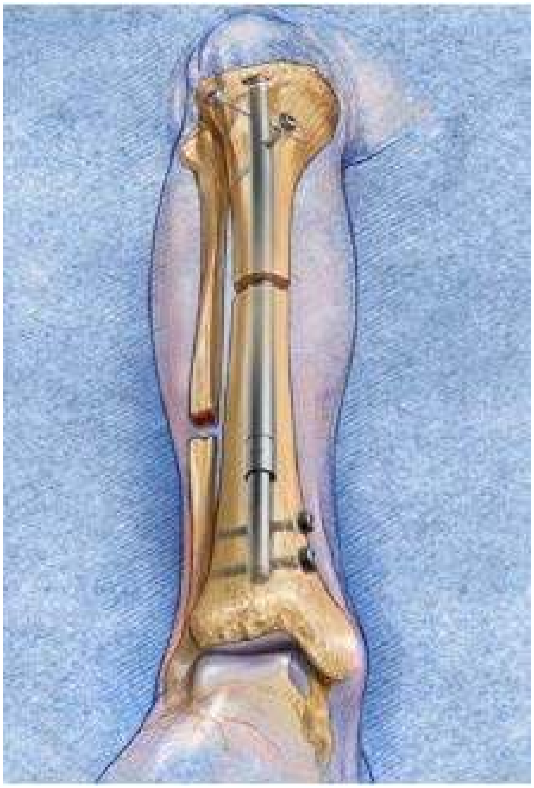


Figure 13. Intramedullary Skeletal Kinetic Distractor.

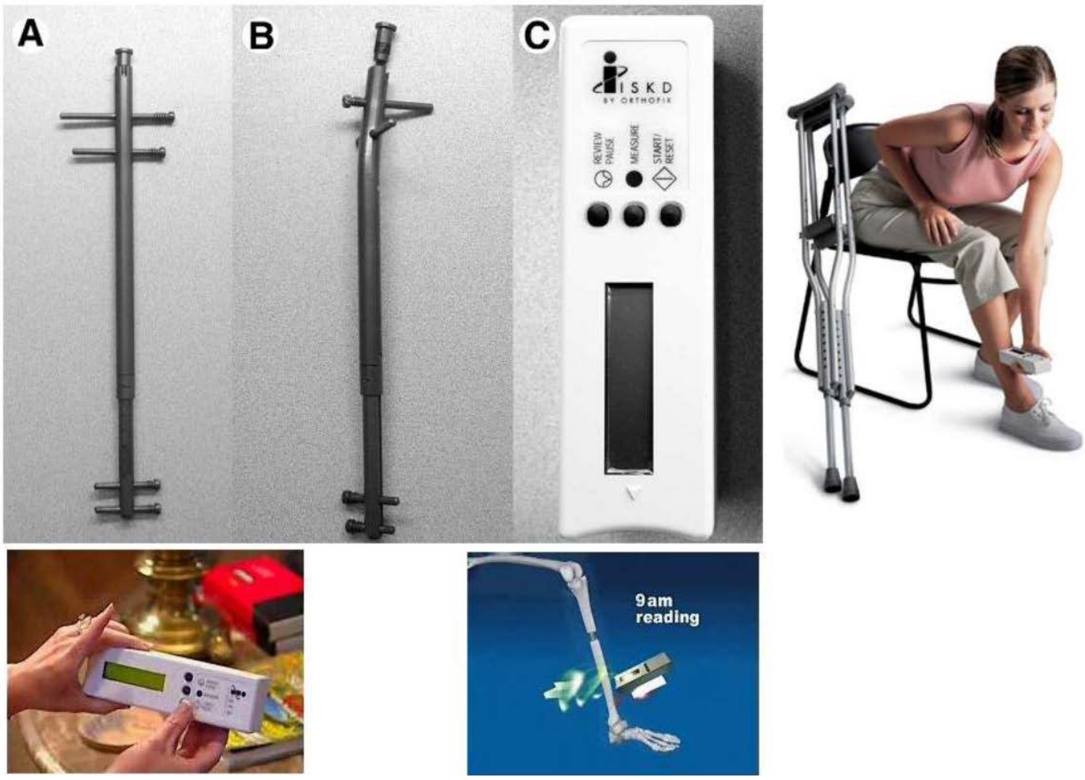


Figure 14. ISKD and it’s monitor.

2.5.3.3. Fitbone

Baumgart and Betz from Germany developed a motorized nail in 1991 (now called Fitbone). The Fitbone (Wittenstein, Igersheim, Germany) is a fully implantable lengthening nail whose mechanism is driven by an internal motor that requires an external transmitter (Figure 15). An antenna comes out of one end of the nail and is implanted subcutaneously. It is powered and controlled by radiofrequency and the lengthening is performed at night when the patient is in bed to mimic natural growth [56, 57, 79].

Electromechanical parts, are located in the proximal part of the intramedullary nail. In this section a 10 mm diameter motor is situated. The engine converts the torque to axial movement with the aid of gear wheel and the shaft. The power produced by 10 mm was tested as 1000 N force and after technical modifications that power was raised up to 1800 N which is almost twice the power required for the femur distraction [87, 88].

Extension process is carried out by, high-frequency signals from the external control unit reaching to the receiver under the skin, the transmission of signals to the electronic module by the receiver, and activating the electromechanical part of the telescopic intramedullary the nail (Figure 16).

There are two types of nails available: the Fitbone SAA (Slide Active Actuator) straight nail for antegrade femoral placement has a slide hole, an external diameter of 13 mm and is available in lengths between 260 and 520 mm. Lengthening of up to 85 mm and bone transport of up to 200 mm are possible. The Fitbone TAA (Telescope Active Actuator) nail is a telescopic version with a diameter of 11 mm in the shaft and 12 mm near the joint. There is a straight 24.5-cm-long version for retrograde insertion into the femur and a curved 22.5-cm-long version with Herzog angulation for anterograde placement into the tibia. Lengthenings of up to 80 mm in the femur and 60 mm in the tibia may be achieved [15].

After surgery, patients are rested for the healing of the incision at the first 5-7 days then extension is started. Weight bearing is provided on the patient's foot in the extension period.

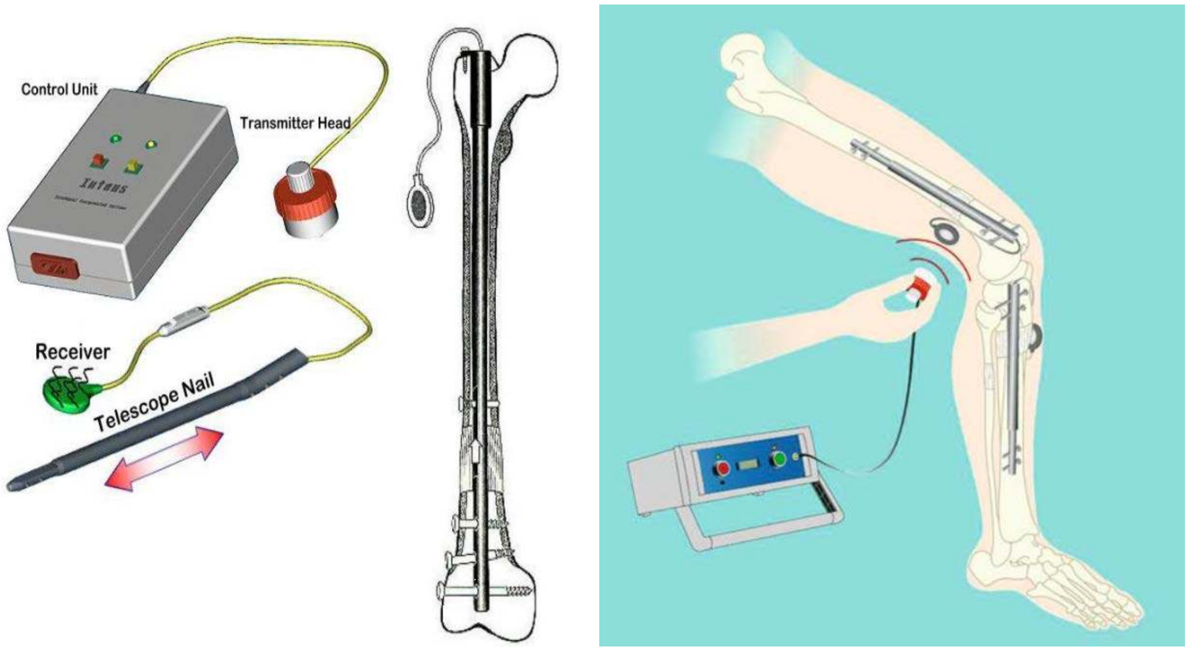


Figure 15. FITBONE

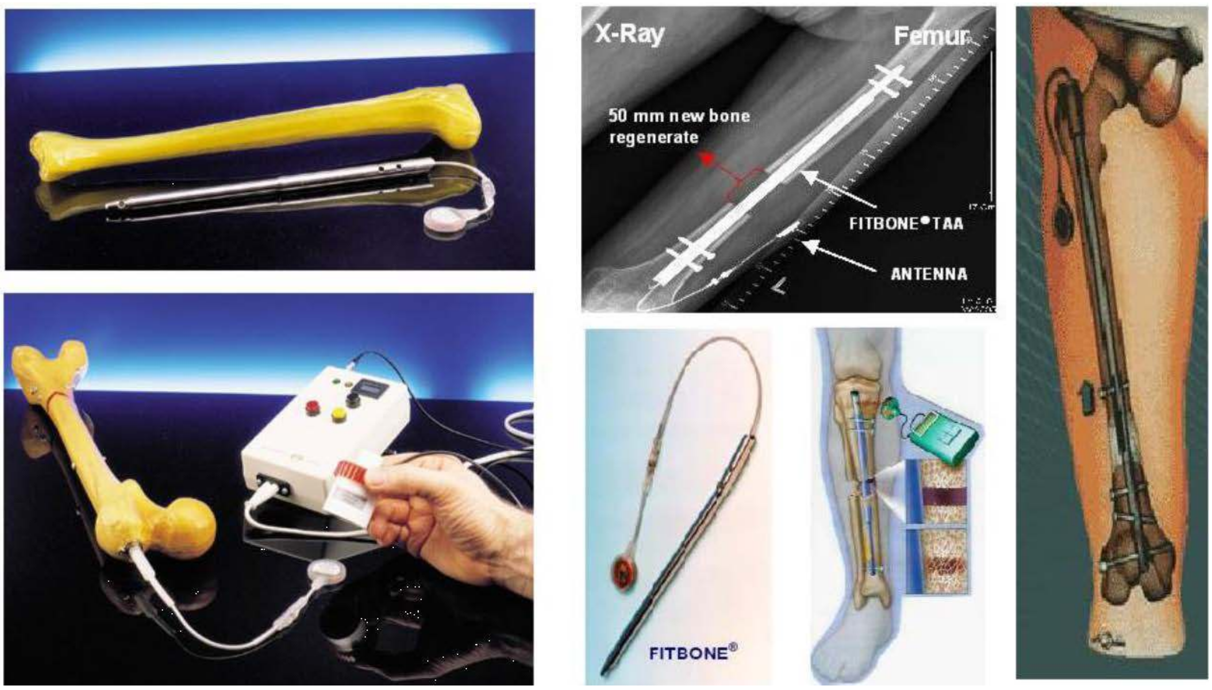


Figure 16. FITBONE application.

2.5.3.4. Precice (Phenix) Nail

Arnaud Soubieran from France developed the Phenix nail. The Phenix has a mechanism activated by a large external, hand-held magnet. By rotating the magnet around the leg an internal crankshaft mechanism in the nail was rotated. This lead to traction on a wire pulley, which caused distraction of the nail. The mechanism for the Phenix was first used in a spinal distractor, and, in a lengthening prosthesis manufactured by the same company. Rotating the magnet one direction leads to lengthening, whereas rotating it the other way leads to shortening [79].

Ellipse Technologies (Ellipse Technologies, Irvine, CA) developed the Precice nail. There is a magnetic metal spindle that is connected to a series of gears. The gears are connected to a coupling, which is connected to a threaded drive shaft. The mechanism is activated by an external remote control (ERC) device (Figure17). The ERC employs 2 motor-driven rotating magnets to magnetically couple to and rotate the magnetic metal pins. The ERC performs 30 revolutions per minute. It takes 7 minutes and 210 revolutions to achieve 1mm of lengthening. Facing the ERC 1 direction causes the nail to lengthen, whereas facing it the other direction would go in the reverse (shortening) direction. The Precice is the second FDA cleared implantable lengthening nail device (July 2011) and the first one that have bidirectional control (lengthening and shortening) [79].

Figure 17. The Precice nail and external remote control device (ERC).

2.5.3.5. Axial Mechanical Loading Nail 1

In 2007, Havıtçıoğlu et al. have developed and patented a mechanical intramedullary system to be used for limb lentghening and to correct limb inequalities with tumor prosthesis [110]. The system can be activated mechanically by applying axial load on it and after each loading, the system extends 1mm (Figure18). The system has U shape shaft with 1mm pins on it and also a tube having 1.2mm holes where the pins gets in. There is a spring set in the system in order to give the mechanical movement for lengthening. When the load applied on the system, the U shape shaft becomes narrow by the inner pressure of the pins on outer tubular part. Then, pins on the shaft get out of the holes on the tube by the force of the spring and gets in the next holes. So, the system extends 1mm by each laoding.

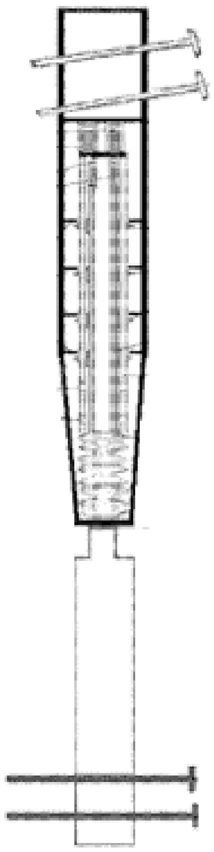


Figure 18. Axial mechanical loading nail 1.

2.5.3.1. *Axial Mechanical Loading Nail 2*

In 2008, Havıtçıoğlu et al. have developed a different mechanically activated intramedullary lengthening nail (Figure 19) and it is described in Master Thesis of Bora UZUN in detail [80]. The system is also mechanically activated and if an axial load applied to the system, it performs 0.1 mm extension after each loading and it can be easily controlled to get the optimum distraciton rate which is 1 mm/ day. When the desired lengthening is reached, the system stops automatically. So, no complications due to over distraction occur.

There is no rotational movement on this system so, the complications which are caused by rotational movements are eleminated with this system. After the implantation of the intramedullary nail, following the formation of the required biological conditions, the system is activated by the patient's sudden loading on the operated leg, without interrupting the contact with the ground.

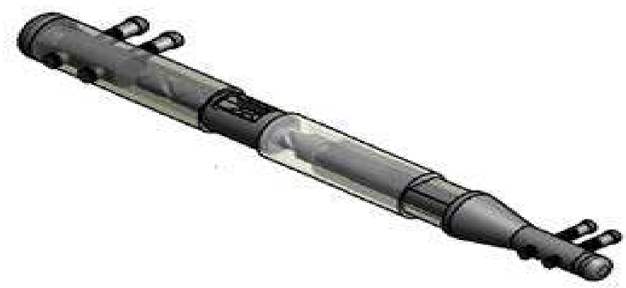


Figure 19. Axial mechanical loading nail 2

2.5.3.2. *Motorised Extraskeletal Lengthening Plate*

In 2010, Havıtçıoğlu et al. have developed a new motorised lengthening plate system [111]. The system includes a motor, specifically programmed circuit board and a battery. The system can be used like standard fracture plates and implanted on the surface of bone extraskeletally. It is designed to be extend 0.1 mm at each activation (Figure 20).

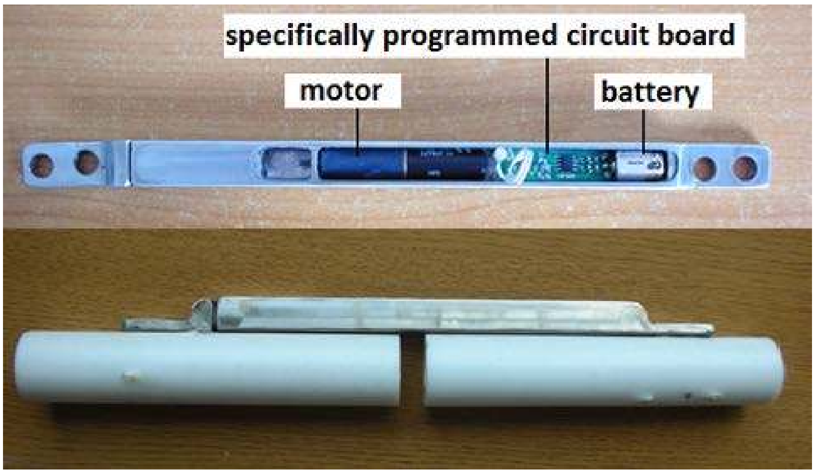


Figure 20. Motorised extrasketal lengthening plate.

All lengthening systems have their own extension mechanism and distraction rate. Also, their power supplies are different (Table 2).

Table 2. Comparison of working principle, distraction rate and power supply of intramedullary lengthening systems

Nail system	**Working principle**	**Distraction rate**	**Power Supply**
Bliskunov Nail	Mechanical	18 mechanism clicks – 1 mm for femur 56 clicks – 1 mm for tibia	Mechanical motion input by the patient
Albizzia	Mechanicalal	20 degrees of rotation to move the ratchet one notch. Each notch is 1/15 of a millimeter.	Mechanical motion input by the patient
ISKD	Mechanical	The clamps are activated in rotation from 3 to 9°; 1 mm of distraction is achieved after 160 extremity rotation movements	Mechanical motion input by the patient
Axial mechanical loading nail 1	Mechanical	1 mm/each stimulation	Mechanical motion input by the patient
Axial mechanical loading nail 2	Mechanical	0.1 mm/each stimulation	Mechanical motion input by the patient
Fitbone	Motorised	90 seconds x 4 times stimulation for 1mm distraction	External impulse power unit
Phenix (PRECICE)	Magnetic motorised	Concentric movement of the master magnet by 180°, 0.1 mm distraction	External magnetic power unit
The system developed in this thesis	Mechanical and motorised	0.1 mm/each stimulation for both mechanic system and electronic system	Mechanic movement and battery within the system

3. MATERIAL AND METHOD

3.1. Type of Study

Type of this study is development of a new medical implant which is used for extremity lengthening.

3.2. Place and Time of Study:

This study was performed at Dokuz Eylül University, The Laboratory of Department of Biomechanics between 2010 and 2015.

3.3. Research Universe and Sample/ Study Groups:

There is no human study on this research and so, there is no need to identify the research universe and sample or study groups.

3.4. Study Material:

The study material is newly developed intramedullary nail which is used for extremity lengthening. The nail is made of 316L stainless steel. 3D designing software is used to design the system. Testing equipments are used for the determination of mechanical and functional features of the newly developed system.

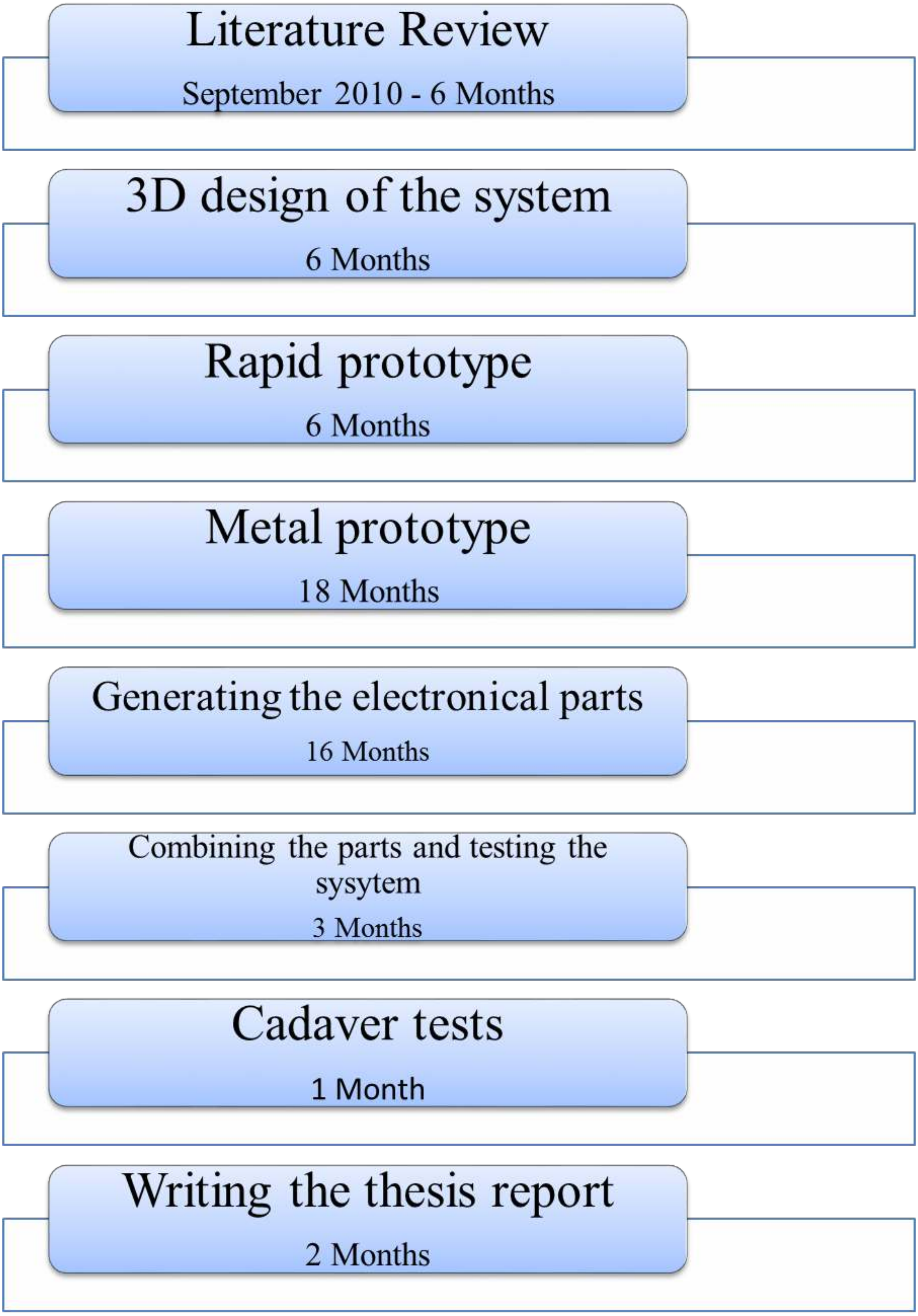
3.5. Research Variables:

There is no research variables.

3.6. Data Collection Tools:

For the compression and distraction tests of the system, a mechanical testing device (Shimadzu AG-10, Autograph, Kyoto, JAPAN) and a dynamometer (Chatillon DVE-200, Amatek, NY, U.S.A) is used. This is a new device prototype development study and there are no animal and clinical trials. So, no data have been collected on livings yet. In the future, animal and clinical trails will be performed as a continuation of this study.

3.7. Research Plan and Shedule



3.8. Evaluation of Data:

The working principle of the new developped intramedullary lengthening nail system was evaluated both mechanically and electronically. For the mechanical evaluating, appropriate loads are applied to the system and working and the lengthening mechanism were examined. For the electronical evaluating, the system was stimulated and the electronical lengthening mechanism was examined. Distraction forces of electronic lengthening are measured. Both lengthening subsystems of the system (electronic and mechanic) have worked as it is predicted. Compression tests of all critical parts of the system are performed.

3.9. Limitations of The Study

The new developped system was only examined *in-vitro* in this study. In the future, animal and clinical trails will be performed as a continuation of this study to get results and the potential complications in human body.

3.10. Ethical Committee Approval:

Ethical committee approval no: 2011/32-06 and date: 29.09.2011

3.11. Preliminary Study:

Knowing the force required to provide distraction during lengthening process with intramedullary nails is extremely important to design and determine the working principles of developed systems for this purpose. If the distraction force is known, it will be possible to design a mechanism strong enough to overcome these forces and establish the working principle according to these forces.

To this end, distraction forces in cadaver leg amputee above the knee were measured at our laboratory. While the leg was at horizantal and vertical position, the minumum forces needed for 1mm distraciton were calculated. As a result of these measurements, it was found that the average force required for distraction at horizontal position is 220N and at vertical position position is 70N (Figure 21).

In the light of these data, the design of our new intramedullary nail system is regulated to provide the necessary forces to carry out the extension process.

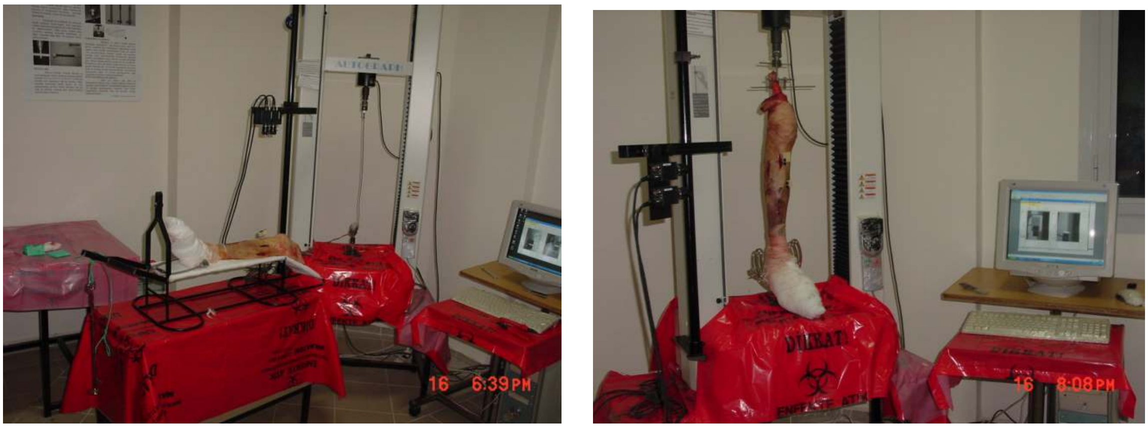


Figure 21. Test set up for measuring the distraction forces.

3.12. Design of The Intramedullary Nail

The intramedullary nail was designed to perform extremity lengthening electro-mechanically. The 3D design of the system is performed with computer software (Solidworks Premium 2012,USA) (Figure 22).

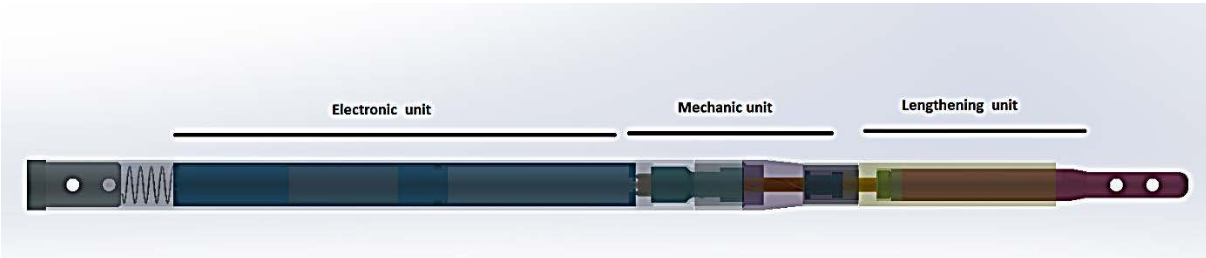


Figure 22. 3D design of the system

After designing the system, rapid prototype has been produced to perform the necessary regulations like size and the shape of the system (Figure 23).

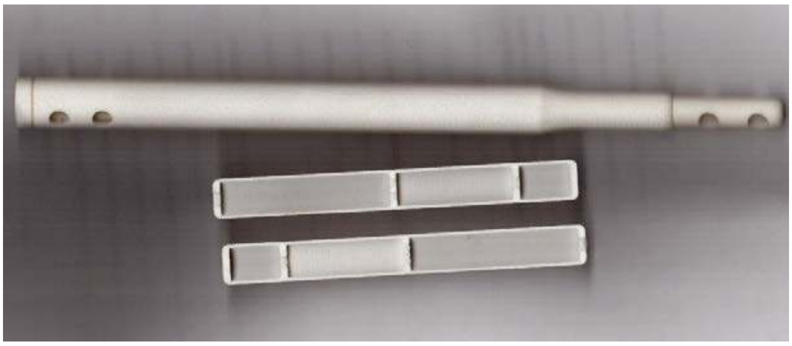


Figure 23. System parts produced by rapid prototyping technique.

The intramedullary nail system is comprised of three main units.

1. Mechanical transmission unit
2. Electronic unit
3. Lengthening unit

This system is under patent application process, so some parts are not going to be described in detail.

3.12.1. Mechanical Transmission Unit:

During the previous master's thesis study, a novel mechanical intramedullary lengthening nail was designed and developed [80]. It consists two units; lengthening unit and mechanical movement unit (Figure 24).

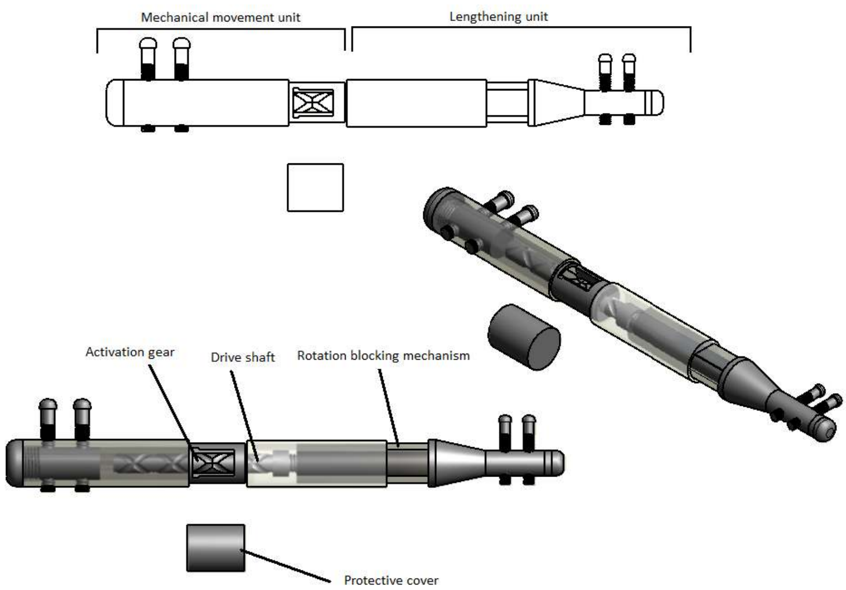


Figure 24. Previously designed axial mechanical loading nail 2.

Mechanical movement unit includes a drive shaft and an actvation gear positioned on this shaft, control switch that controls the gear, a spring and a protective cover.

The mechanical transmission unit of the new designed intramedullary nail acts as same as the nail mentioned above.

Working Principle:

The system has two main parts. When load applied on part A where the movement exists, the elastic material transfers the load to the activation gear and it activates the drive shaft. The rotation movement occured at the top of the drive shaft provides the rotaion of the worm gear at the lower part of the shaft. Thus, the drive shaft exits the threaded part B. Situation 1 indicates no loading and in situation 2, the system in compressed by loading and the lengthening is occured. Situation 3 shows that unloaded and distracted nail. To prevent rotation of parts A and B during extension, cornered edges are arranged instead of cylindrical structure (Figure 25).

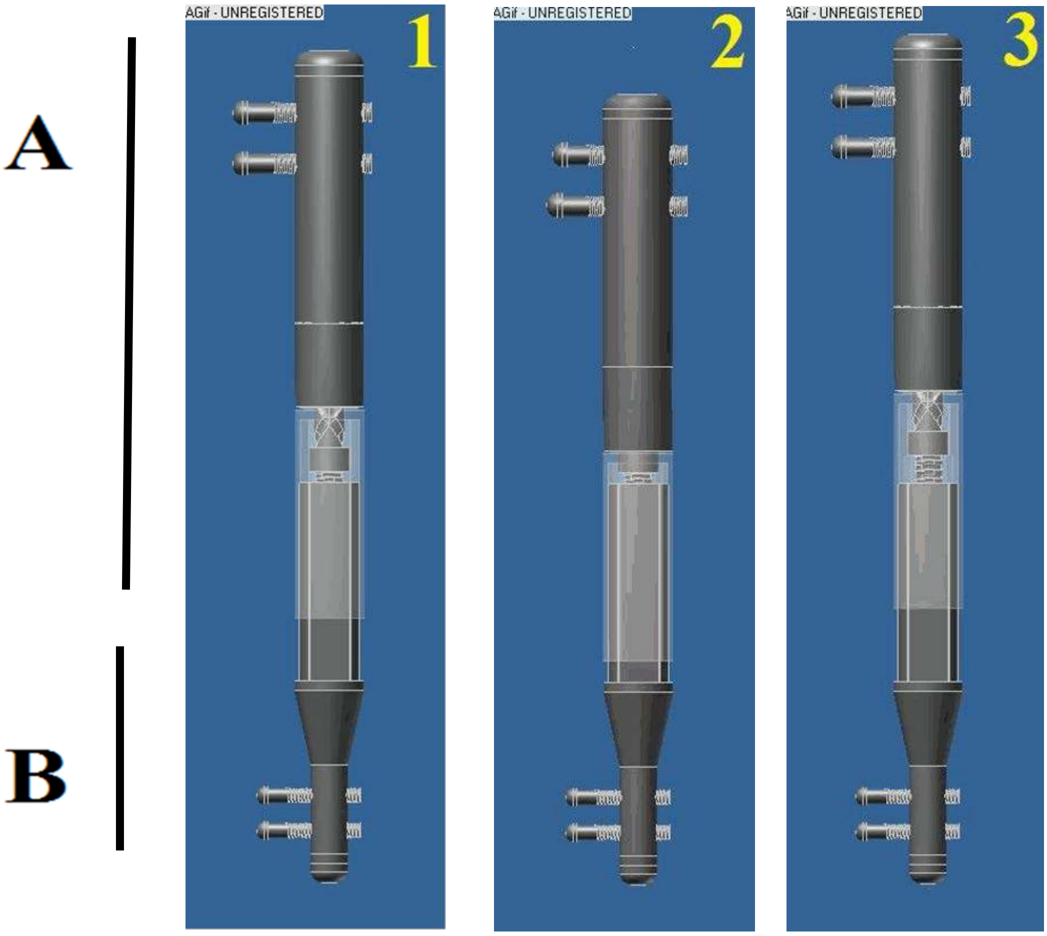


Figure 25. Working principle of the mechanical intramedullary nail.

After the implantation of the intramedullary nail, following the formation of the required biological conditions, the system is activated by the patient's sudden loading on the operated leg, without interrupting the contact with the ground.

In this way, the system performs 0.1 mm extension after each loading and it can be conviniently controlled to get the optimum distraciton rate which is 1 mm/ day. When the desired lengthening is reached, the system stops automatically. So, no complications due to over distraction occur.

Produced intramedullary nail prototype was inserted into synthetic femur (Saw-bone) and nail system was subjected to cyclic loading with testing device (Shimadzu AG-10, Autograph, Kyoto, JAPAN) and the load is limited to 300N (Figure 26).

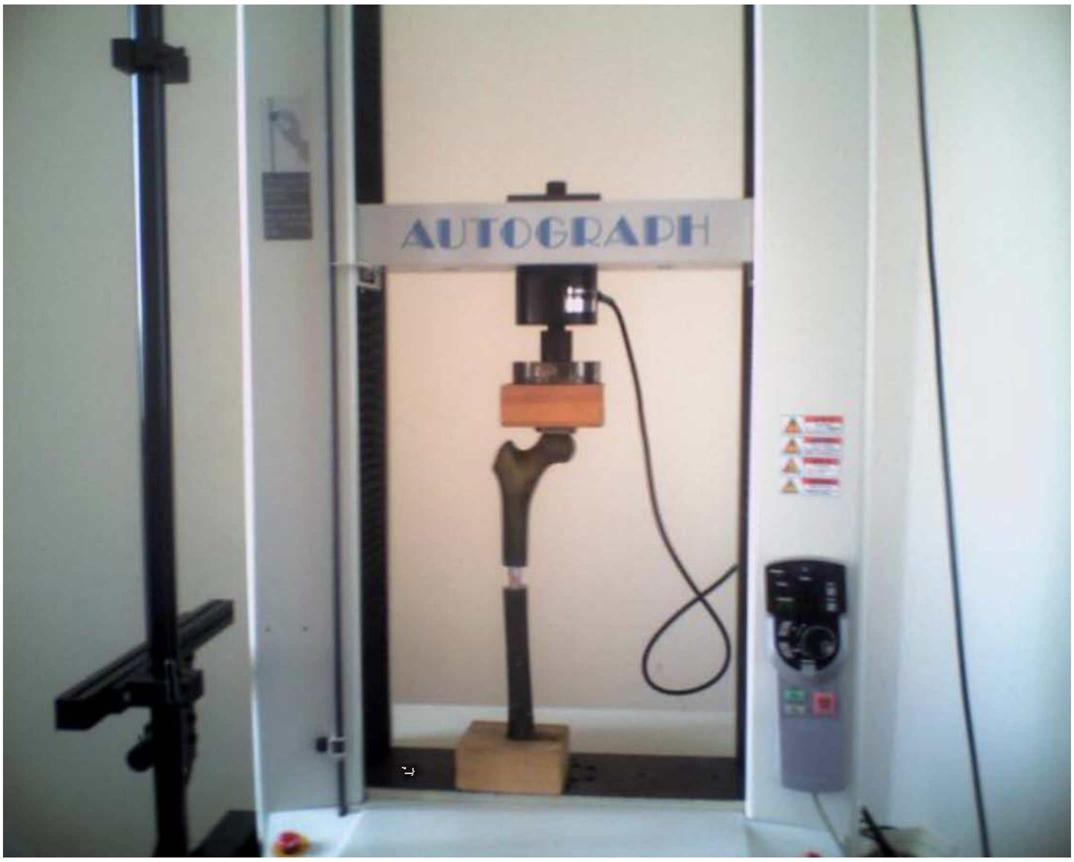


Figure 26. System operation test and the testing device.

3.12.2. Electronic Unit:

Electronic unit includes an electronic circuit board, a battery and an electric motor with a reduction gear (Figure 27). The electronic circuit board can be programmed to different operational durations and frequencies between operations.

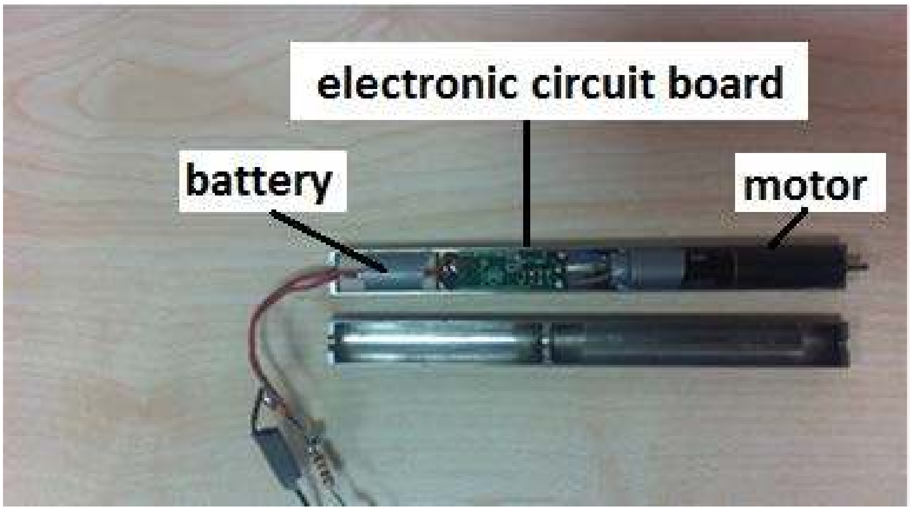


Figure 27. Electronic unit

3.12.3. Lengthening Unit:

Lengthening unit is comprised of a threaded rod which is connected to the drive shaft also and an anti-rotating telescopic lengthening part (Figure 28).

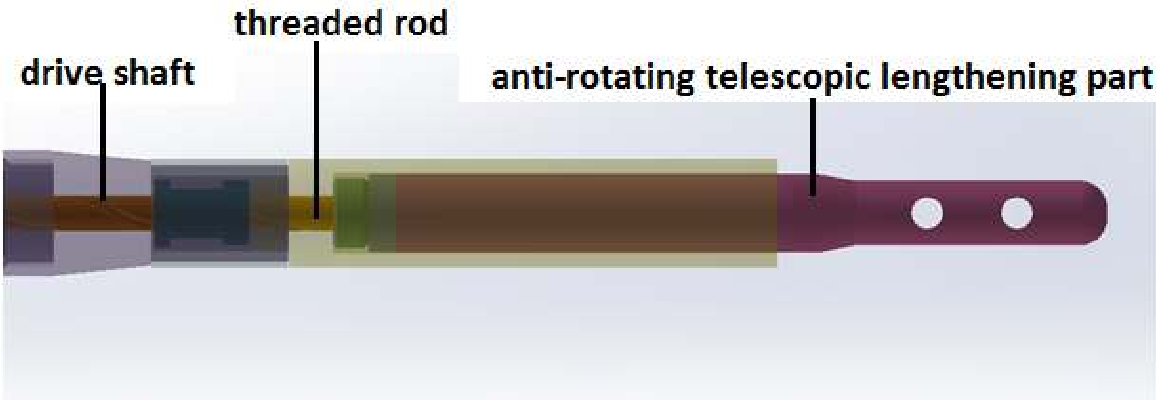


Figure 28. Lengthening unit

3.13. Distraction Force Test of the System

For the loading test of the new intramedullary system, an experimental setup was developed (Figure 29). The intramedullary nail was fixed on a board through the fixation points (proximal screw holes) with two screws in order to prevent rotation. The distal end of the nail was not fixed to the board so as to extension can take place. A dynamometer (Chatillon DVE-200, Amatek, NY, U.S.A) was fixed on the board at fixation points to measure the tension load. A C-ring is connected to the dynamometer with a connector and a pre-load adjausting tool was attached to this connector. Two springs were attached to the distal screw hole of the nail from one side, and attached to the connection rods from the other sides. The connection rods are fixed on the C-ring.

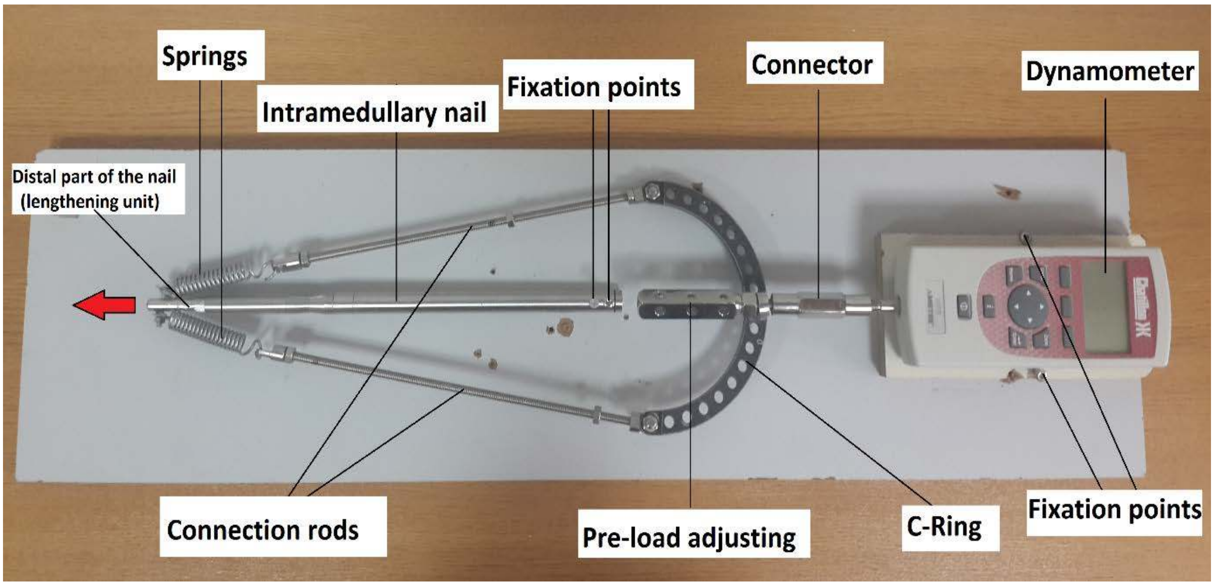


Figure 29. The experimental set-up of the distraction force test

When the sysem is activated, the distal part of the nail moves to direction of the arrow. The pushing force is transmitted to the dynamometer through the springs, connection rods and C-ring. So, the magnitude of the pushing force can be seen on the dynamometer. With the pre-load adjusting tool, it is possible to set pre-loads to the system. In this study, we set 0N, 30N and 50N pre-loads to the system.

In order to determine the constant k value of the springs, tension force at velocity of 20mm/min was applied to the spring with the testing device (Shimadzu AG-10, Autograph, Kyoto, JAPAN), as shown in Figure 30.

Figure 30. Tension test to determine the k constant value of the spring

The constant k value of the springs are calculated according to Hook's Law.

Hooke's law is a principle of physics that states that the force *F* needed to extend or compress a spring by some distance x is proportional to that distance.

That is:

$$F = kx \tag{3-1}$$

where k is a constant factor characteristic of the spring, its stiffness.

$$k = \frac{F}{x} \tag{3-2}$$

3.14. Mechanics of Screws Used in Mechanic Lengthening Unit

There are two screw mechanisms in the lengthening system for mechanically lengthening. In order to perform suitable screw system and loading conditions for activation of mechanical lengthening unit, knowing the working principles of screw systems is needed.

Referring to the figre 31, some terms from geometry that relate to screw threads are defined as follows [112].

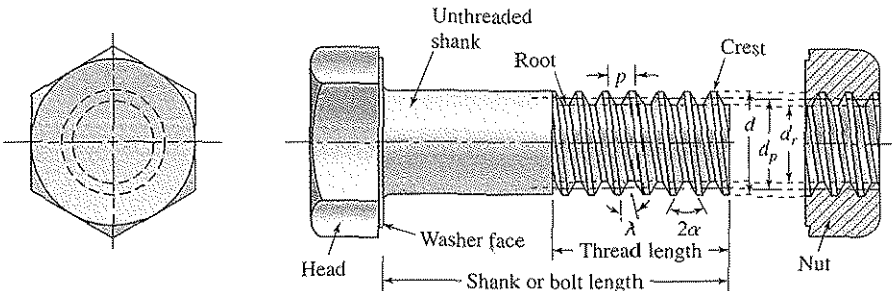


Figure 31. Illustration of Hexagonal bolt and nut [112]

Note: p = pitch, λ= helix or lead angle, α= thread angle,

d= major diameter, d_p = pitch diameter, d_r = root diameter.

Pitch p is the axial distance measured from a point on one thread to the corresponding point on the adjacent thread. *Lead L* represents the axial distance that a nut moves, or advances, for one revolution of the screw. *Helix angle, λ,* also called the lead angle, may be cut either right-handed (as in Figure 31) or left-handed. All threads are assumed to be right-handed, unless otherwise stated [112].

A single-threaded screw is made by cutting a single helical groove on the cylinder. For a *single thread,* the lead is the same as the pitch. Should a second thread be cut in the space between the grooves of the first, a double-threaded screw would be formed. For a *multiple (two or more)-threaded screw,*

$$L = np \qquad (3\text{-}3)$$

in which L = lead, n = number of threads, and p = pitch. The standard geometry of screw thread shown in Figure 32 is used. The *thread angle* is 60° and the crests and roots of the thread may be either flat or rounded [112]. Metric thread specification is given in Table 3.

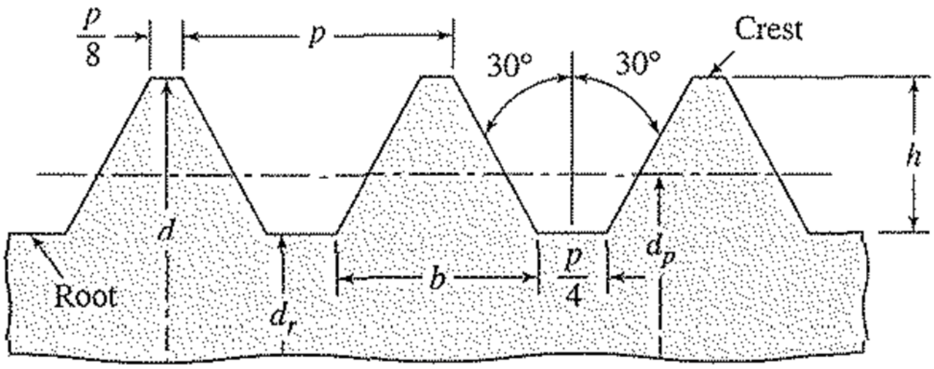


Figure 32. Unified and ISO thread forms [112].
The portion of basic profile of the external thread is shown
h = depth of thread, b = thread thickness at the root.

Table 3. Dimensions of ISO (metric) screw threads

Nominal diameter, d (mm)	Pitch, *p (mm)*	Tensile stress area, A_1 (mm^2)
4	0.7	8.78
5	0.8	14.2
6	1	20.1

Root or minor diameter $d_r \approx d - 1.227p$

A power screw, sometimes called *the linear actuator* or *translation screw,* is in widespread usage in machinery to change angular motion into linear motion. A simplified drawing of a screw jack is shown in Figure 33. The load W can be lifted or lowered *by* the rotation of the nut that is supported by a washer, called a *thrust collar* [112].

We see from Figure 33 that turning the nut forces each portion of the nut thread to climb an inclined plane [112]. This plane is depicted by unwrapping or developing one revolution of the helix in Figure 34a, which includes a small block representing the nut being slid up the inclined plane of thread. The forces acting on the nut as a free-body diagram are also noted in the figure. Clearly, one edge of the thread forms the hypotenuse of the right triangle, having a base as the circumference of the mean-thread-diameter circle and as the lead [112].

Therefore,

$$tan\lambda = \frac{L}{\pi\, d_m} \tag{3-4}$$

Where

λ = helix or lead angle

L = lead

d_m = mean diameter of thread contact surface

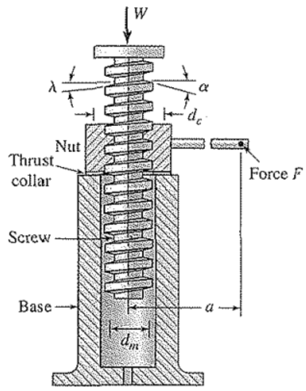


Figure 33**.** Schematic representation of power screw used as a screw jack [112]. Note: Only the nut rotates in this model: d_m = mean thread diameter, d_c = mean collar diameter.

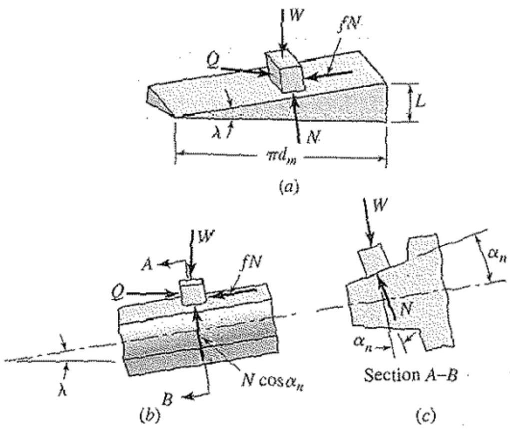


Figure 34. Forces acting on an Acme screw-nut interface when lifting load W [112].

(a)a developed screw thread;

(b) a segment of the thread;

(c) thread angle measured in the plane normal to thread, α_n

The conditions of equilibrium of the horizontal and vertical forces give,

$$\sum F_h = 0: \qquad Q - N\,(f \cos\lambda + \cos\alpha_n \sin\lambda\,) = 0$$
$$\sum F_u = 0: \qquad W + N\,(f \sin\lambda - \cos\alpha_n \cos\lambda\,) = 0$$

Where α_n is the normal thread angle and the other variables are defined in the figure. Inasmuch as we are not interested in the normal force *N*, we eliminate it from the foregoing equations and solve the result for *Q*. In so doing, we have

$$Q = W\,\frac{f + \cos\alpha_n \sin\lambda}{\cos\alpha_n \cos\lambda - f\,\sin\lambda} \tag{3-5}$$

The screw torque required to move the load up the inclined inclined plane after dividing the numerator and denominator by $\cos\lambda$, is then

$$T = \frac{1}{2}\,Qd_m = \frac{Wd_m}{2}\,\frac{f + \cos\alpha_n \tan\lambda}{\cos\alpha_n - f\,\tan\lambda} \tag{3-6}$$

But, the thrust collar also contributes a friction force. That is, the normal reactive force acting on contact surface due to *W* results in an additional force $f_c\,W$. Here, f_c is the sliding coefficient of the collar friction between the thrust collar and the surface that supports the screw. It is assumed that this frictional force acts at the mean collar diameter d_c (Figure 33) [112]. The torque needed to overcome collar friction is,

$$T = \frac{W\,f_c\,d_c}{2} \tag{3-7}$$

The required *total torque* T_u *to lift the load* is found by addition of Eqs. (3-6) and (3-7):

$$T_u = \frac{Wd_m}{2}\,\frac{f + \cos\alpha_n \tan\lambda}{\cos\alpha_n - f\,\tan\lambda} + \frac{W\,f_c d_c}{2} \tag{3-8}$$

The analysis of lowering a load is exactly the same as that just described, with the exception that the directions of *Q* and *f* N (Figure 34b) are reversed [112]. This leads to the equation for the total required *torque* T_d *to lower the load* as

$$T_d = \frac{W d_m}{2} \frac{f - \cos\alpha_n \tan\lambda}{\cos\alpha_n + f \tan\lambda} + \frac{W f_c d_c}{2} \tag{3-9}$$

A relationship between normal thread angle α_n, thread angle α , and helix angle λ can be obtained from a comparison of thread angles measured in axial plane and normal plane [112]. Referring to Figures 33 and 34c, it can readily be verified that,

$$\tan\alpha_n = \cos\lambda \tan\alpha \tag{3-10}$$

In most applications, λ is relatively small, and hence $\cos\lambda \approx 1$. So, we can set $\alpha_n \approx \alpha$ and Eq. (3-8) becomes,

$$T_d = \frac{W d_m}{2} \frac{f + \cos\alpha \tan\lambda}{\cos\alpha - f \tan\lambda} + \frac{W f_c d_c}{2} \tag{3-11}$$

A self-locking screw requires a positive torque to lower the load. This is a useful provision, particularly in screw jack applications. *Self-locking* refers to a condition in which the screw cannot be turned by applying an axial force of any magnitude to the nut [112]. If collar friction is neglected, Eq. (3-9) shows that the *condition* for self-locking is,

$$f \geq \cos\alpha_n \tan\lambda \tag{3-12}$$

For a square thread, the foregoing equation reduces to

$$f \geq \tan\lambda \tag{3-12a}$$

Overhauling or back-driving screw is one that has low enough friction to enable the load to lower itself, by causing the screw to spin. ln this situation, the inclined plane in Figure 34b moves to the right and force Q must act to the left to preserve uniform motion [112]. *It* can be shown that the *torque* T_o *of overhauling* screw is

$$T_0 = \frac{W d_m}{2} \frac{-f + \cos\alpha_n \tan\lambda}{\cos\alpha_n + f \tan\lambda} + \frac{W f_c d_c}{2} \tag{3-13}$$

A negative external lowering torque must now be maintained to keep the load from lowering.

Values of Frjction Coefficients:

When a plain *thrust collar* is used, as shown in Figure 33, values of f and f_c, vary customarily between 0.08 and 0.20 under conditions of ordinary service, lubrication, and the common materials of steel and cast iron or bronze [112].

Fastener Materials and Strengths:

The SAE class (metric series) of steel threaded members are numbered according to tensile strength. The *proof strength* S_p corresponds to the axial stress at which the bolt or screw begins to develop a permanent set. The *proof load* F_p is defined by

$$F_p = S_p A_t \tag{3-14}$$

Here the *tensile stress area* A_t represents the minimum radial plane area for fracture through the threaded part of a bolt or screw [112]. Numerical values of A_t, are listed in Table 3. The proof strength is obtained from Table 4.

Table 4. Metric specifications and strengths for steel bolts [112].

Class number	Size range diameter, d(mm)	Proof strength, S_p (MPa)	Yield strength, S_y (MPa)	Tensile strength, S_u (MPa)	Material carbon content
4.8	Ml.6-M 16	310	340	420	Low or mediuın
9,8	M1.6-M 16	650	720	900	Medium, Q&T
10.9	M5-M36	830	940	1040	Low, martensite, Q&T
12.9	Ml.6-M36	970	110	1220	Alloy, Q&T

SOURCE: Society of Automotive Engineers Standard J1199 (1979). O&T = quenched and tempered.

Referring the equations above, the load and the required torque values for the activation of lengthening unit are calculated.

Stresses In Screws:

In order to calculate the screw stresses due to the axial load acting on the system fallowing definition is given.

For *loading,* it is commonly assumed that the load carried by a screw and nut is about *uniformly* distributed throughout thread engagement. A rule of thumb for the length of full thread engagement is $1.0d\ in$ steel, where d is nominal thread size [112].

The axial stress σ is

$$\sigma = \frac{P}{A} \tag{3-15}$$

Where

P = tensile or compressive load

$$A = \begin{cases} A_t \; from\; Table\; 3\; (threaded\; fasteners) \\ \frac{\pi d_r^2}{4} \quad dr = the\; root\; diameter\; (power\; screws) \end{cases}$$

3.15. Compression Tests of The parts of Intramedullary Nail System.

Compression tests are applied to the critical parts (Table 4) which are exposed to load, in order to evaluate the strength of the nail system. 4000N compression load was applied at 20mm/min to the parts and the deformation values are observed. For the mechanical lengthening, the system needs 300N to be activated. So, the deformation values of the parts at 300N are also recorded (Figure 35).

Figure 35. Compression tests of part 1, part 2 and part 3.

4. RESULTS

The metal prototype of the system is produced (Figure 36). All the parts are made from 316 LVM stainless steel which is used for medical implants. The electronic unit (circuit board, motor and battery) is taken under protection with a liquid impervious metal capsule. The nail system is designed to function both mechanically and electronically complying with set the requirement. The function status can be changed at any time depending on the clinical conditions. This also provides an advantage that if any one (mechanic or electronic) fails, the lengthening process can continue with the other. If the patient cannot apply mechanic load because of pain or other complications, that will be mechanic failure. On the other hand, if the motor failures or the battery gets discharged, that will be electronic failure.

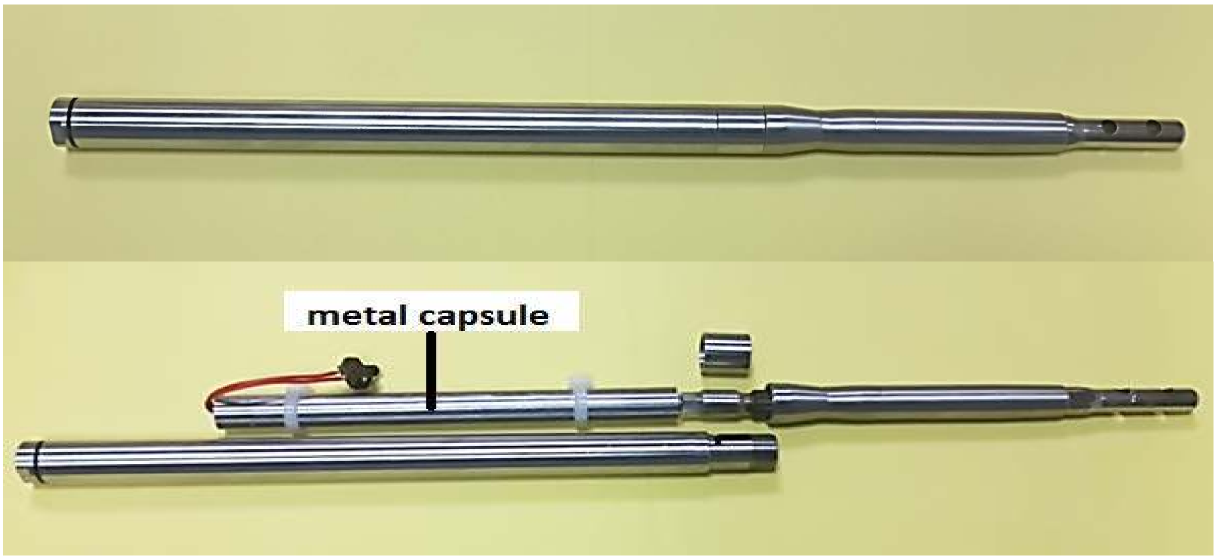


Figure 36. Metal prototype and parts of the nail system

Operation test results of the mechanical subsystem nail:

The system needs 7 mm free space for the activation of lentghening mechanism. The nail system includes a 120N preload (it depends on the patient) in order to be stretched. 120N is required to press the spring to the end of its stroke and activate the system. At each cycle, while loading, the system is compressed 7 mm at 120N first and after 7mm gap is closed, it begins to be fully loaded. At 300N, the loading is stopped and begins to be removed. After 7mm moving to opposite direction, the loading starts again.

Each loading, the system has shown 0.1mm distraction. After 10 cycles, the total distraction has become 1mm (Figure 37).

Name	Max Force	Max Disp	Min Force	Min Disp
Units	N	mm	N	mm
Cycle #1	310.781	-7.3938	-3.7500	0.17812
Cycle #2	308.438	-7.3406	-5.0000	0.26563
Cycle #3	305.313	-7.1969	-4.6875	0.39063
Cycle #4	292.500	-7.1250	-5.4688	0.51563
Cycle #5	272.656	-7.0500	-2.8125	0.61563
Cycle #6	303.594	-6.9500	-5.6250	0.70938
Cycle #7	315.469	-6.8438	-4.3750	0.80937
Cycle #8	297.188	-6.7344	-2.8125	0.81250
Cycle #9	330.469	-6.6344	-4.8438	0.84375
Cycle #10	338.438	-6.5406	-5.3125	0.99687
Cycle #11	314.063	-6.4094	-5.1563	1.09375

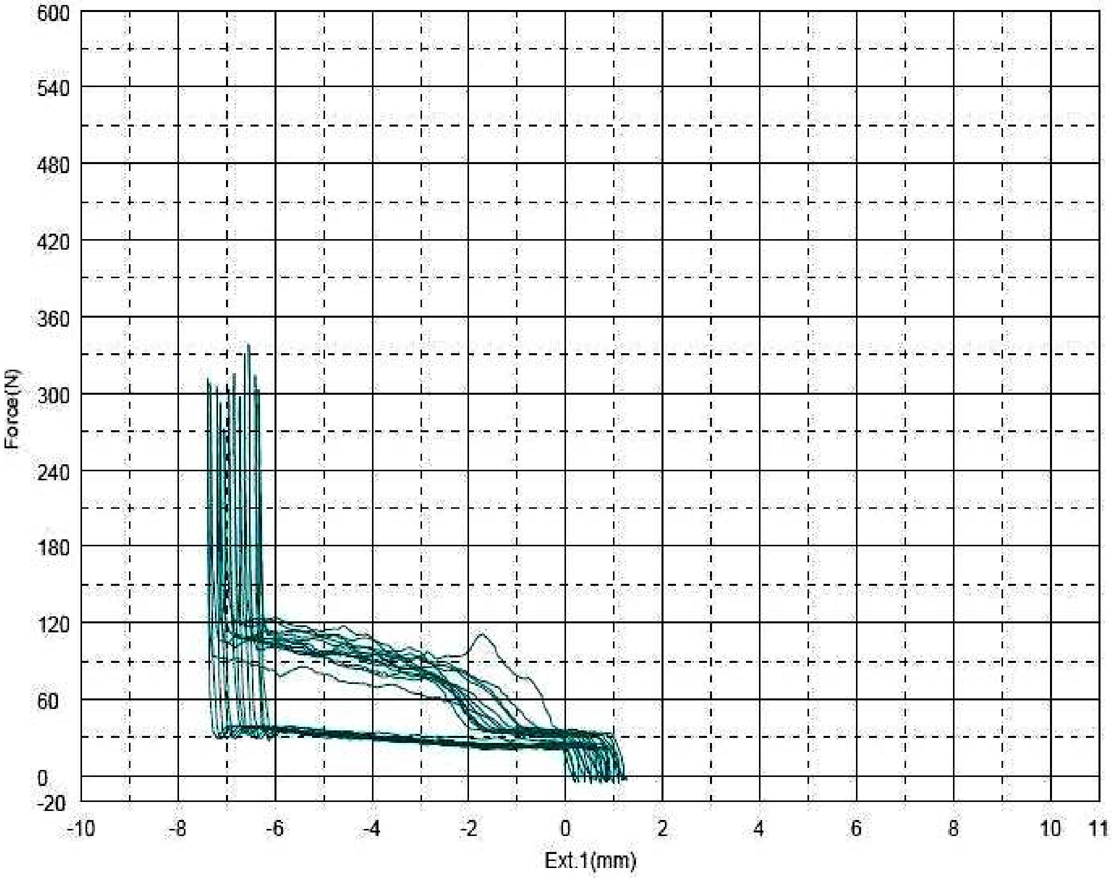


Figure 37. Operation test results of the mechanic nail.

Distraction force test:

In this study, we set 0N, 30N and 50N pre-load to the system. In each case, the maximum pushing force of the system is measured as 120N with a battery and 200N with a power supply. This is due to the power rating of the battery.

Tension test of the spring:

According to test results, the spring failed at 300N. So, 200N is taken as the maximum force and 40mm as the displacement value at 200N within the elastic region (Figure 38).

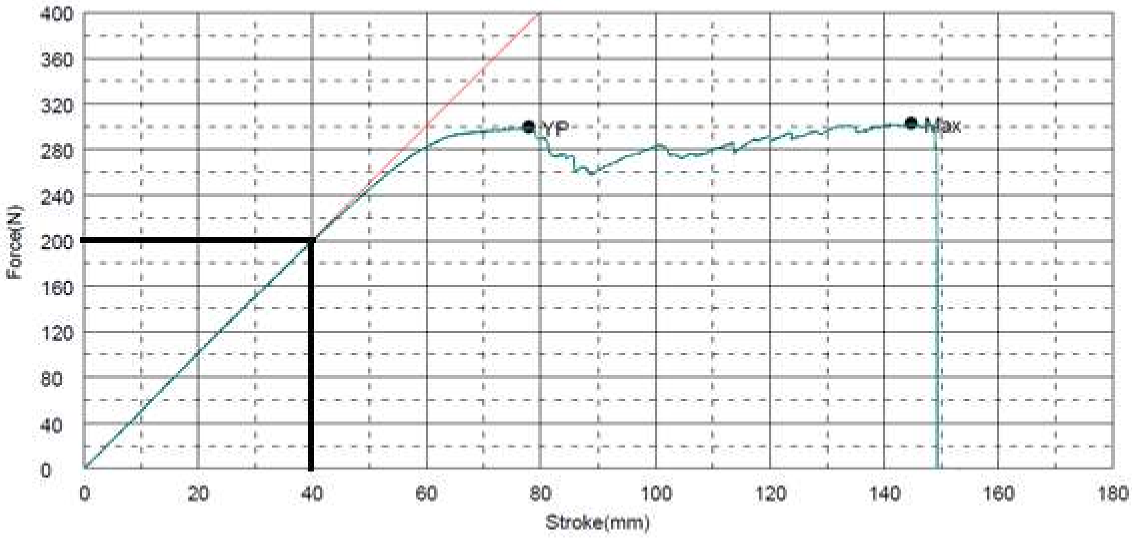


Figure 38. Tension test result of the spring.

According to Hooke's law :

$$k = \frac{F}{x} \tag{3-2}$$

$F = 200N$

$x = 40mm = 0.04m$ $k = \frac{200N}{0.04m}$ $k = 5000N/m$

During the distraction force test, we measured maximum 200N with the power supply and the spring was failed at 300N during tension test. The force value that we obtain from the loading test is in the borders of elastic region of the spring. That means, the springs which were used for the loading test were appropriate.

Compression tests:

According to compression test results, part 1 had 0.077 mm deformation at 300N and 0.697mm at 4000N (Figure 39). Part 2 had 0.06 mm deformation at 300N and 0.326 mm at 4000N (Figure 40). Part 3 had 0.087 mm deformation at 300N and 0.442 mm at 4000N (Figure 41).

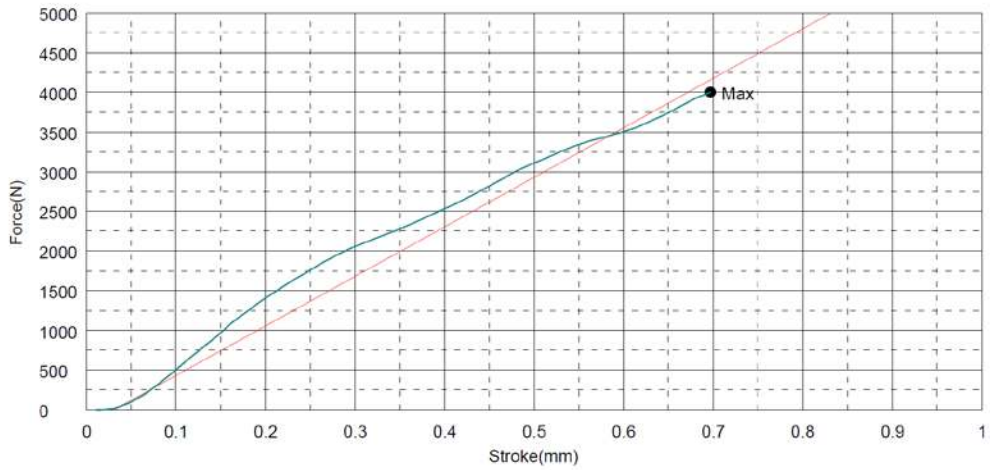


Figure 39. Force/stroke graph of Part 1

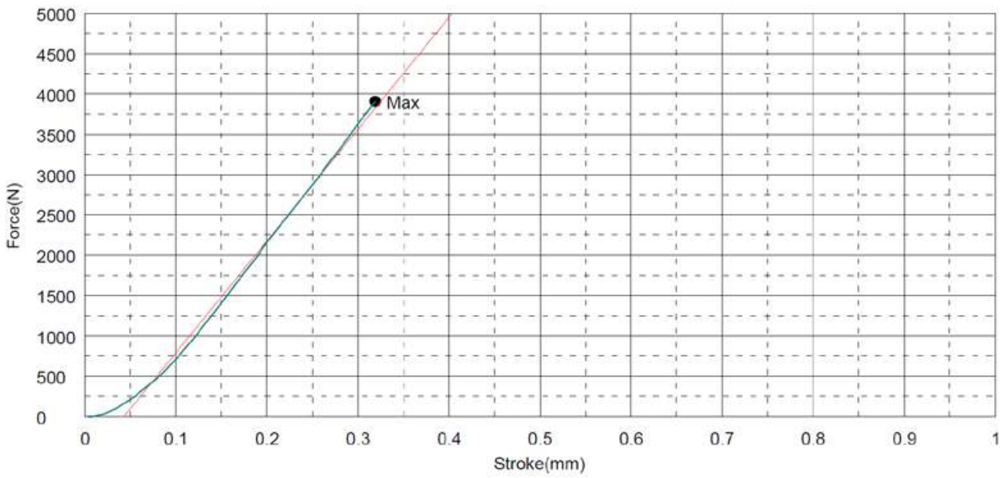


Figure 40. Force/stroke graph of Part 2

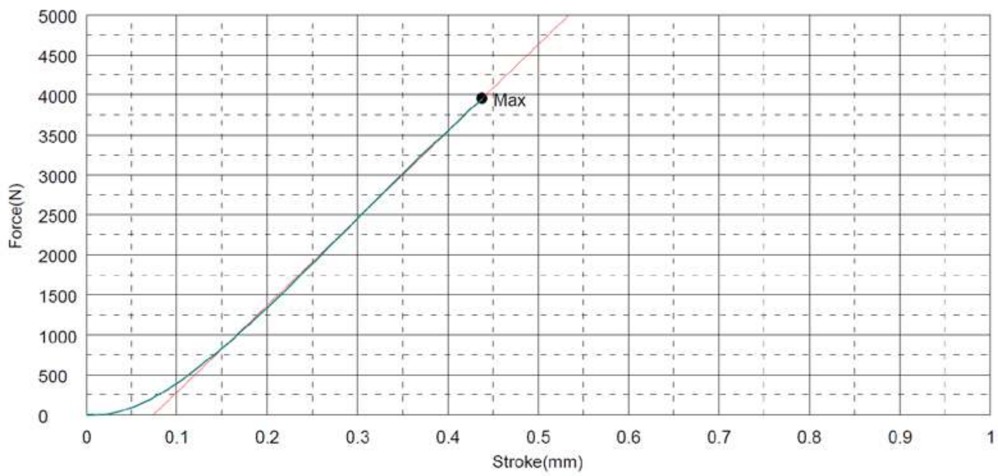


Figure 41. Force/stroke graph of Part 3

According to compression test results, deformation of those three parts under 300N and 4000N are observed. The stress values of each parts for 4000N were calculated (Table 5).

Table 5. Compression test results

Part	**Stress N/mm²** **(F=4000N)**	**Area** **mm²**	**Deformation (mm)**	
			F=4000N	**F=300N**
(1) 	86.69	46.14	0.697	0.077
(2) 	124.05	32.245	0.326	0.06
(3) 	78.35	51.05	0.442	0.087
Total			1.465	0.224

Screw mechanics:

The screw mechanisms in lengthening unit can be seen on schematic view in Figure 42.

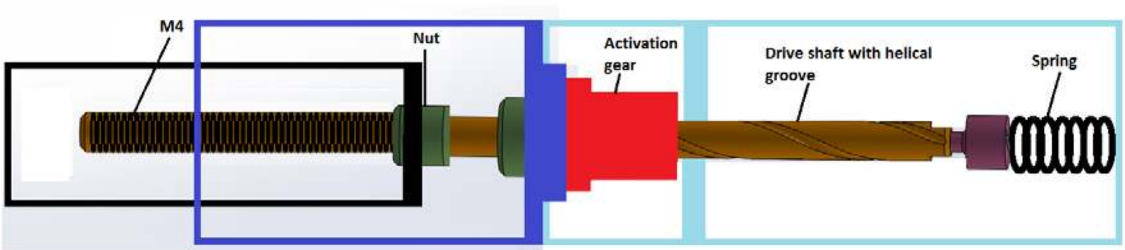


Figure 42. Schematic view of lengthening unit.

Data for drive shaft:

Nominal diameter d= 4mm

Pitch p= 11mm = Lead = L

Mean diameter d_m= 3.4 mm

Groove angle α= 45°

Friction coefficient f= 0.25

W=F_d = *drive force*

Helix or lead angle $\lambda = arctan\left(\frac{L}{\pi d_m}\right)$ from Eq: (3-4)

$$\lambda = arctan\left(\frac{14}{\pi\ 3.4}\right)$$

$$\lambda = 0.919\ rad$$

$$\lambda = 52.66^o$$

Normal groove angle $\propto_n = \arctan(cos\lambda\ tan\ \propto)$ from Eq: (3-10)

$$\propto_n = \arctan(cos\,52.66^o tan\,45^o)$$

$$\propto_n = 0.45 rad\ = 31.24^o$$

Torque $T_0 = \frac{W d_m}{2}\frac{-f+cos\propto_n tan\lambda}{cos\propto_n + f\ tan\lambda}$ from Eq: (3-13)

$$T_0 = \frac{F_d\ 3.4}{2}\frac{-0.25 + cos\,31.24^o\ \ tan52.66^o}{cos\,31.24^o + 0.25\ \ tan52.66^o}$$

$$T_0 = 1.25\ F_d\,Nmm$$

Self-locking condition $f \geq cos\propto_n\ \ tan\lambda$ from Eq: (3-12)

$$cos31.24^o\ tan\,52.66^o = 1.12$$

1.12 > f = 0.25 NO SELF-LOCKING

Data for M4:

Nominal diameter d= 4mm

Pitch p= 0.7mm

Tensile stress area A_t =8.78 mm^2 from Table (2)

Number of thread n = 1

Root diameter $d_r \approx d$ - 1.227p from Table (2)

$d_r \approx$ 4- 1.227 0.7

$d_r \approx$ 3.1411mm

Mean diameter $$d_m = \frac{d + d_r}{2}$$

$$d_m = 3.57mm$$

Lead $L=n .p = 0.7$ mm

Friction coefficient f= 0.25

Helix or lead angle $\lambda = arctan\left(\frac{L}{\pi d_m}\right)$ from Eq: (3-4)

$$\lambda = arctan\left(\frac{0.7}{\pi\, 3.57}\right)$$

$$\lambda = 0.0623\, rad$$

$$\lambda = 3.57^o$$

Thread angle $\propto\, = 30^o$

Normal thread angle $\propto_n = \arctan(cos\lambda\ tan \propto)$ from Eq: (3-10)

$$\propto_n = \arctan(cos\, 3.57^o\ tan\, 30^o)$$

$$\propto_n = 0.5228\ rad = 29.95^o$$

T_0 is applied to M4 rod to rotate. Torque to tuen M4 rod can be calculated as follows:

$$T_u = \frac{Wd_m}{2}\ \frac{f + cos\propto_n tan\lambda}{cos\propto_n - f\ tan\lambda}$$ from Eq: (3-8)

$$T_u = \frac{F_s\,3.57}{2}\,\frac{0.25 + cos29.95^o\ tan3.57^o}{cos29.95^o - 0.25\ tan3.57^o}$$

$$T_u = 0.637879\ F_s$$

M4 rod screw system and force acting on it can be seen on figure 43. Forces acting on main part of the system also can be seen on figure 44.

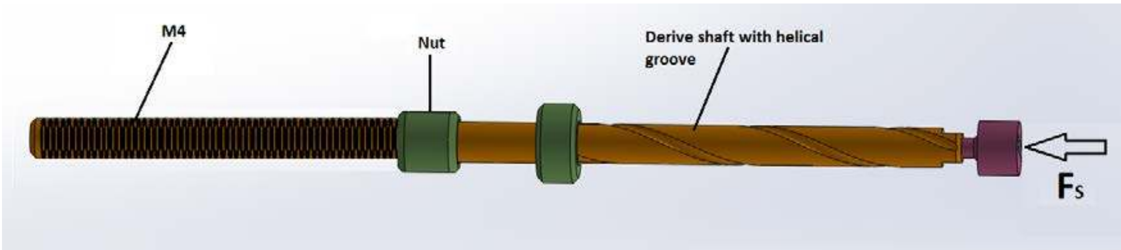


Figure 43. Schematic view of M4 rod screw system

$\Sigma T = 0$, $\quad T_0 + T_u = 0$

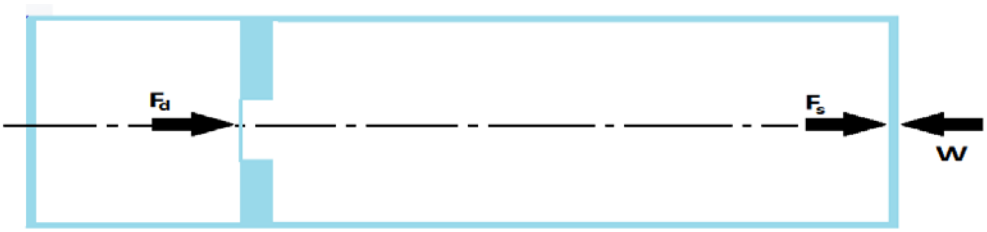


Figure 44. Schematic view of loads acting on the main part of the system

W= Weight necessary to activate sthe system

F_s = Spring force = $k\,x = k\,x_0 + k\,(x-x_0)$

F_d = Driving force which pushes the drive shaft

$\Sigma F = 0$; $-W + F_d + F_s = 0$

$F_d = W - F_s$ or,

$F_d = W - k\,x$ where k is coefficient of spring

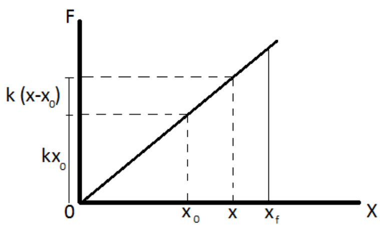


Figure 45. Spring diagram of the system.

The system needs 6 mm free distraction space to be activated. x_0 means initial length of spring, x is the preset displacement of the spring and x_f is maximum displacement of the spring (Figure 45). So, $x_f - x$ = 6mm *and* x_f = displacement at F_{max}

Torque $T_0 = 1.25\ F_d\ Nmm$ is applied to drive shaft with helical groove.

On the other hand, torque $T_u = 0.637879\ F_s$ is required to rotate against F_s for M4 rod screw.

Therefore;

$1.25\ F_d + 0.637879\ F_s = 0$

$1.25\ (W - kx) + 0.637879\ kx = 0$

$1.25\ W - 1.25\ kx + 0.637879\ kx = 0$

$1.25\ W = (\ 1.25 - 0.63879)\ kx$

$W = 0.49\ kx$

Selection of spring coefficient k and initial displacement X_0, depend on W and X_f.

Let's assume $W = 100\ N$ *and* $X_f = 10\ mm$

$W = 0.49\ kx$

$100 = 0.49\ k\ 10$

$k = 20.4$ N/mm

That means if the weight which will be applied on the system is 100N, we need a spring with k = 20.4 N/mm. It can be hard to find a spring by just telling the k value. So, we have to measure and calculate the force and size values of the spring that we get and try to find the best for our requirement.

Since X_f = 10 mm,

X_0 can be choosen as 4 mm becouse 6 mm displacement is enough for the activation. The weight will be changed depending on the patient and the spring will be changed also.

Stresses In Screws:

$$\sigma = \frac{P}{A} \quad (3\text{- }15)$$

Where

P = tensile or compressive load

$$A = \begin{cases} A_t \; from\; Table\; 15.2 \;\; (threaded\; fasteners) \\ \frac{\pi d_r^2}{4} \;\; dr = the\; root\; diameter\; (power\; screws) \end{cases}$$

A_t = 8.78 mm^2

σ = 970 MPa

$$970Mpa = \frac{P}{8.78mm^2}$$

P = 970 x 8.78

P = 8516.6 N

The system only needs 300 N to be activated. So, M4 threaded rod is very safe for this system. If safety factor is choosen 10, then P_{max} will be 851.66 N and it will be safe also for the system.

Application of the System in a Cadaver Leg

The prototype of the nail system is implanted to a cadaver leg and the surgical process is tested (Figure 46). We have demonstrated the appropriateness of the nail dimensions. After implantation of the nail, scopy and x-ray images were taken to verify the position of the nail inside the bone (Figure 47).

Figure 46. The cadaver leg that the nail system implanted.

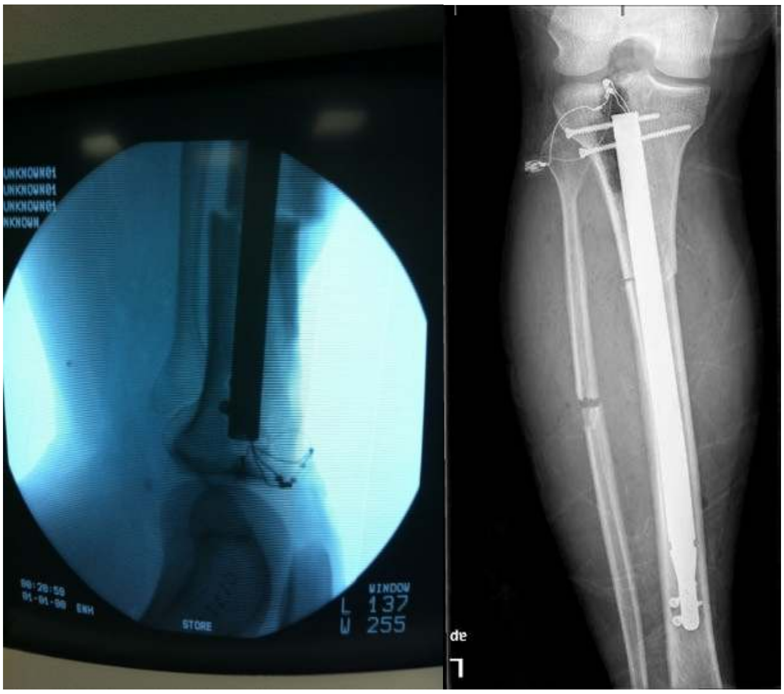


Figure 47. The scopy and X-ray images of the system in the cadaver.

5. DISCUSSION

External fixation and intramedullary nail applications are performed as a surgical method in extremity lengthening. Both methods are based on the principle of the callus distraction.

Callus distraction by external fixation has become a widely accepted treatment method for limb lengthening. However complications rates in this method are extremely high. Complication rates in external limb lengthening starts at 24% of patients, depending on the extension amount, the surgeon's experience and the patient's age [19,20, 23, 42, 89,90]. Pin tract infection, pain due to the fixation nails and wire are the most common cause of complications.

Removal of the external fixator at the end of extension process is a critical step. Even after removal of the fixator, additional complications such as displacement and fractures occur frequently again [19,23,42]. Many patients are not satisfied with the external fixation for reasons such as soft tissue transfixing with pain, decreased range of motion and taking a long time to return to normal daily activities [91,92]. At the same time, lentghening with external fixator can lead to secondary axial deformities and fractures on the newly formed bone [42,93,94,95].

Also, in the combination of intramedullary nails and external fixators (LON), high rates of complications are seen in adults [23,75,96,97,98]. Lower rates like 11% have been reported in children [70]. However, combination of temporary external fixator and intramedullary nail used only for distraction, reduces the risk of infection and external fixation time [23,99]. Premature removal of the fixator may lead to fracture, delayed union, pseudarthrosis, loss of length or malalignment [50, 139]. The main concern of combining external fixation with solid nailing is deep infection. The risk ranges between 5 and 15 % [23,75,100].

In recent years, lengthening techniques with intramedullary nail have come to the forefront for the surgical correction of limb lentgh inequality. Despite the developments on these tecniques, complications continue to be the biggest problems for the patients who subjected to these procedures.

In each applied method, lots of complications whether general or method-specific are seen. When the methods like Albizzia, ISKD and FITBONE avaliable and widely used today are examined separately, complications specific to these methods can be clearly observed [80].

With the Albizzia nail, the rotations needed for the extension causes pain and discomfort [39]. Large number of Albizzia implanted patients (22 % - 39 %) referred to the hospital again and needed general or epidural anesthesia in some stages of the extension becouse of the pain at the osteotomy site due to the rotation [39,101]. In the Albizzia nail application, if general anesthesia for the distraction not taken in to consideration, the complication rate after treatment is between 22 % and 29 % [39,101].

The studies about Albizzia nail performed by Guichet JM et. al and Garcia-Cimbrelo et. al. were examined [82,101,102] and the information about complications were given in the tables 6,7 and 8.

Table 6. Guichet JM et al. (1995) study details.

Study Details	Complications	
Guichet JM et al. (1995) **Number of Cases :** 48 (52 femoral)	- Complications that cause pausing extension	31 %
	- Additional surgery	25 %
	- Incomplete extension	8 %
	- Nail breakage	2 %
	- Wear of gear	10 %
	- Fracture of the proximal screw	2 %
Method: Albizzia **Mean follow-up time:** 8.9 months	- Fracture of the distal screw	2 %
	- Blockage of the nail	16 %
	- Fracture after nail breakage	2 %
	- Temporary palsy in peroneal nerve	2 %
	- Dislocation of the knee	2 %
	- Dislocation of the hip	2 %
	- Reactivation of osteitis	4 %
	- Superficial infections	4 %
	- Delayed bone healing	10 %

Table 7. Garcia-Cimbrelo E et al. (2002) study details.

Study Details	Complications	
Garcia-Cimbrelo E et al. (2002) **Number of Cases** : 23 (24 femoral)	- Temporary palsy in peroneal nerve	2 %
	- Infection around the distal locking screws	4 %
	- Postoperative pain at the first 5 days	22 %
Method: Albizzia **Mean follow-up time:** 44.7 months	- Anesthesia need for extension	9 %
	- Tibial valgus deformity	4 %
	- Delayed healing of bone	9 %
	- Bending of the nail	4 %

Table 8. Guichet JM et al. (2003) study details.

Study Details	Complications
Guichet JM et al. (2003) **Number of Cases** : 31 (41 femoral) **Method:** Albizzia **Mean follow-up time:** 50 months	- Hypoesthesia at the ankle dorsal 3 % - Superficial wound infection 6 % - Low pain at last follow 10 % - Fracture of the femur after nail removed 6 % - Abscess requiring drainage 6 % - Device failure 10 % - Nail breakage 3 % - None of the patients are satisfied in terms of functionality.

The intramedullary skeletal kinetic distractor (ISKD) is designed to lengthen gradually as a result of rotational limb movement of 3^o to 9^o between the hip and knee [15]. As the lengthening was so easy to activate, and as there was no "governor" to the lengthening mechanism, the nail is free to lengthen at any rate. Too rapid distraction was a frequent complication. This was referred to as a **"runaway nail"** or "runaway lengthening" [79]. Premature or delayed consolidations reflect difficulties to control the distraction rate and rhythm [18,103,104,105]. Failure to obtain the desired end length occurs in up to 18 % and secondary implant failure (blockage, break) in up to 36 % [30]. Breakages at the site of lengthening were reported for ISKD nails 10 % [86]. Nail blockage also occurred in ISKD series [26]. It is the main underlying cause of premature consolidation, which is about 12 % for ISKD [26, 28, 103]. Runaway nails unintentionally lengthen more than 1,5 mm/day, a problem encountered in around 10 % of ISKDs [18, 26, 27, 30, 106, 107]. Partial or complete bony defects have been reported in up to 22 % for ISKD nails [18, 26].

Due to the uncontrolled lengthening rate and rhythm the ISKD had a very high complication rate. The nail would often lengthen at a rate that exceeded the ability for distraction osteogenesis of bone and histogenesis of soft tissues leading to many complications. Restriction of activities and bracing were required to try and prevent and control too rapid lengthening. Failure of bone formation required separate bone grafting procedure for deficient regenerate [19,28,79,107,108]. It was recently removed from the market and is no longer available [79]. Some studies about ISKD are shown in the Table 9.

Table 9. Studies about ISKD.

Studies	Number of limbs ISKD implanted	Complications	
Kenaway et al. (2011)	57	- Superficial wound infection - premature consolidation - insufficient bone regenerate - runaway nails - nondistracting nails	1 4 11 9 3
Simpson et al. (2009)	33	- Difficulty in achieving length - uncontrolled lengthening - refracture - implant failure	8 7 1 2
Kubiak et al. (2007)	11	- Additional surgery	7
Hankemeier et al. (2004)	4	- Not reported	
Cole et al. (2001)	20	- hardware failures	2

Currently, FITBONE is the most popular and widely used intramedullary nailing system but several complications can be seen like device failure, nail breakage, discomfort of the antenna and locking bolts, blockage of the lengthening system and need for anesthesia because of pains at the high levels that occurs during the lengthening period [19].

By the end of 2003, worldwide, 297 Fitbone implantations (24 patients, 178 femurs, 119 tibias) had been performed. In three cases (2%), the intramedullary nail broke, in eight cases (5%) the achieved length of distraction was partially lost, in nine cases (6%) technical difficulties were reported. Altogether the implant had to be changed in only five cases (3%) [109].

The details of the a study carried out by Fitbone application were given in Table 10. In 25% of cases there were need for a second operation and 8% of them temporary hypoesthesia in the anterior proximal tibia has occured. Besides, 8% motor failure and 8% broken wire were encountered [56].

Table 10. Baumgart R. (1997) study details.

Study Details	Complications
Baumgart R. (1997) **Number of Cases**: 12 femoral	- Additional surgery 25 % - Bone graft 8 % - Soft tissue irritation around locking screw 8 % - Temporary hypoesthesia in anterior the proximal tibia 8 % - Wire breakage 8 % - Motor failure 8 %
Method: Fitbone **Mean follow-up time:** min. 2 years	

The Precice is the second FDAcleared implantable lengthening nail device (July 2011) and the first one to have bidirectional control (lengthening and shortening) [79]. Although the initial experience with this device in the United States and several countries around the world has been declared as excellent there were many complications encountered that Paley et al. described in their retrospective stduy (Table 9). Data were obtained retrospectively from a consecutive series of 48 patients who underwent placement of 65 Precice implants.

Complications like nail breakage, mechanism failure, premature consolidation, operator error and pain when using Precice system were listed in the Table 11 [79].

Table 11. Paley e al. (2014) study details.

Study Details	Complications	
Paley e al. (2014) **Number of Cases**: 48 patients, 65 implants	Implant breakage	
	- Nail breakage/fatigue failure	3
	Mechanism failed to lengthen	
	- Premature consolidation	1
	- Operator error	2
	- Nail failed to distract	0
	- Dense regenerate/high resistance	4
	- Screw cutout/prominent hardware	2
	- Periprosthetic fracture	1
	- Deep infection/implant removal	2
	- Failed regenerate/bone grafting	3
Method: Precice Nail **Mean follow-up time:** 9.6 months	- Hematoma evacuation	1
	- Soft-tissue contracture release	3
	- Compartment syndrome	0
	- Superficial infection	1
	- Deep vein thrombosis	1
	- Patient request to stop early	7
	- Joint subluxation	2
	- Pain/tightness preventing final goal	12
	- Final length less than preoperative goal	22

The new system needs only 300N (it depends on the patient but average amount is 300N) loading for mechanical lengthening. The deformation value of whole system at 300N is 0.224mm. This is very small amount with respect to the gap between two bone parts (in average 7mm). This is an elastic deformation in which the deformation is not stationary. During the bone lengthening process, due to the varying hardness of the bone untill it is fully healed, the load distribution between implant and bone at each stage is different. At normal conditions, the maximum load acting on one leg is three times of the body weight. When 800N is considered as average human weight, the implant must withstand minumum 2400N load. Considering the safety conditions, we applied 4000N load on the new system. At 4000N, the whole system shows only 1.465 mm deformation which is less than the gap between the two bone parts. Also, when the system is implanted inside the bone, the loads are distributed proportionally between the bone and the implant. So, except for extraordinary conditions, the newly developed system is highly rigid and safe.

The working principle of the new system is based on two independent mechanisms that are mechanic and electronic. Both ways of operation can be used for lengthening together or apart within the same nail system at any time depending on the clinical conditions. This is the most novelty of our system. This also provides an advantage that if any of the powering mechanisms (mechanic or electronic) fails, the lengthening process can continue with the other. And this provides falut tolerance. There is no system defined in the literature which has this specialty.

Bliskunov Nail [15, 79], Albizzia Nail [81, 82] and ISKD [79, 85, 86] have mechanical working principles and in these systems, lengthening process is obtained by rotational movement of the extremity. This rotational movement causes complications like pain, dislocation and uncontrolled lengthening [15, 19, 39,77, 78, 82, 101]. In our newly developed system, when using mechanical operation method, during the extension process, there is no rotational motion. Only axial stimulation is needed for the activation of the mechanism. This is one of the advantages of our system.

Fitbone [55, 57, 79], has motorised working principle and an antenna comes out of one end of the nail. This antenna and a receiver combination are implanted subcutaneously apart from the nail. The nail is powered and controlled by radiofrequency which is given by the external control unit outside of the body. Antenna wire breakage and receiver failure are the most common complications. The Precice Nail has also external magnetic control unit and lengthening is achieved by this external control unit. In our system, the power unit and the control unit are all inside of the system and there is no any external parts. This is the other important advantage of our system.

Further more, the patient will be able to carry out extension process alone and there will be no longer need for medical assistance and an additional surgical intervention.

Both the mechanical unit and the electronical units are designed to be extended 0.1 mm at each activation. This means that the optimal amount of distraction (1mm/day) can be achieved in a controlled way. In other systems, the distraction amount can not be fully controlled and complications seen on other systems [18, 26, 27, 30, 106, 107], like distruption of callus due to the excessive distraction and nonunion of the bone can be encountered. This is also the most important advantage of our system.

6. CONCLUSION

In this study, in order to minimize the existing and possible complications of current lengthening systems, a different, easy applicable and effective intramedullary lengthening nail system has been tried to be designed and developed.

The success of the system at practice will be examined with *in-vivo* animal experiments and according to the results, it will be ready for use on human by performing necessary restorations.

There is hope that continued research will produce better, easier to handle interlocking nails. Also, the design and improved material will improve with possible impregnation with biologically active biomaterials to promote bone healing. And also, it might be possible in future to have biodegradable intramedullary polymers. These could also be impregnated with slow release antibiotics to eliminate infections especially in open fractures.

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8. SUPPLEMENTS

Ethical Committee Report

DOKUZ EYLÜL ÜNİVERSİTESİ
GİRİŞİMSEL OLMAYAN ARAŞTIRMALAR ETİK KURULU

Konu: Karar hk.- 532

03.10.2011

Prof.Dr.Hasan HAVITÇIOĞLU
Bora UZUN

Kurulumuz tarafından 29.09.2011 tarih ve 335-GOA protokol numaralı 2011/32-06 karar numarası ile görüşülen **"Ortopedik Cerrahide Kullanılan Boy Uzatma Mekanizmalarının Geliştirilmesi"** konulu araştırmanıza ilişkin Kurulumuz kararı ekte sunulmuştur

Bilgilerinizi ve gereğini rica ederim.

Prof.Dr.Banu ÖNVURAL
Başkan

Dokuz Eylül Üniversitesi Sağlık Yerleşkesi İnciraltı 35340 İZMİR-TÜRKİYE
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Ethical Committee Report

DOKUZ EYLÜL ÜNİVERSİTESİ
GİRİŞİMSEL OLMAYAN ARAŞTIRMALAR ETİK KURUL KARARI

ETİK KOMİSYONUN ADI	DOKUZ EYLÜL ÜNİVERSİTESİ GİRİŞİMSEL OLMAYAN ARAŞTIRMALAR ETİK KURULU
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BAŞVURU BİLGİLERİ	DOSYA NO:	335-GOA	
	ARAŞTIRMA	UZMANLIK TEZİ ☐	AKADEMİK AMAÇLI ☐
	ARAŞTIRMANIN AÇIK ADI	Ortopedik Cerrahide Kullanılan Boy Uzatma Mekanizmalarının Geliştirilmesi	
	ARAŞTIRMA PROTOKOL KODU	-	
	SORUMLU ARAŞTIRMACI ÜNVANI/ADI/SOYADI ve UZMANLIK ALANI	Prof.Dr.Hasan HAVITÇIOĞLU Doktora Öğr.Bora UZUN Biyomekanik B.D	
	DESTEKLEYİCİ VE AÇIK ADRESİ	-	
	DESTEKLEYİCİNİN YASAL TEMSİLCİSİ VE ADRESİ	-	
	ARAŞTIRMAYA KATILAN MERKEZLER	TEK MERKEZ ☒	ÇOK MERKEZLİ ☐

	Belge Adı	Tarihi	Versiyon Numarası	Dili
DEĞERLENDİRİLEN BELGELER	ARAŞTIRMA PROTOKOLÜ	Mevcut		Türkçe ☒ İngilizce ☐ Diğer ☐
	ARAŞTIRMA İLE İLGİLİ LİTERATÜR	Mevcut		Türkçe ☐ İngilizce ☒ Diğer ☐
	BİLGİLENDİRİLMİŞ GÖNÜLLÜ OLUR FORMU	Mevcut		Türkçe ☒ İngilizce ☐ Diğer ☐
	OLGU RAPOR FORMU	Mevcut		Türkçe ☒ İngilizce ☐ Diğer ☐

Dokuz Eylül Üniversitesi Girişimsel Olmayan Araştırmalar Etik Kurulu Karar Formu

Ethical Committee Report

KARAR BİLGİLERİ	**Karar No:2011/32-06** — **Tarih: 29.09.2011** Prof.Dr.Hasan HAVITÇIOĞLU 'nun sorumlusu Bora UZUN'ın yürütücüsü olduğu "**Ortopedik Cerrahide Kullanılan Boy Uzatma Mekanizmalarının Geliştirilmesi** " isimli klinik araştırmaya ait başvuru dosyası ve ilgili belgeler araştırmanın gerekçe, amaç, yaklaşım ve yöntemleri dikkate alınarak incelenmiş, etik açıdan çalışmanın gerçekleştirilmesinin uygun olduğuna oy birliği ile karar verilmiştir.

ETİK KURUL BİLGİLERİ

ÇALIŞMA ESASI	Dokuz Eylül Üniversitesi Girişimsel Olmayan Araştırmalar Etik Kurulu İşleyiş Yönergesi İyi Klinik Uygulamaları Kılavuzu

ETİK KURUL ÜYELERİ

Unvanı/Adı/Soyadı	Uzmanlık Alanı	Kurumu	Cinsiyet	Araştırma ile İlişkili mi?		İmza
Prof.Dr.Banu ÖNVURAL (Başkan)	Tıbbi Biyokimya	DEU Tıp Fakültesi Tıbbi Biyokimya Anabilim Dalı	Kadın	E ☐	H ☒	
Prof.Ph.D.Besti ÜSTÜN (Başkan Yardımcısı)	Ph.D.Yüksek Hemşire	DEU Hemşirelik Yüksekokulu	Kadın	E ☐	H ☒	
Prof.Dr.Osman AÇIKGÖZ	Fizyoloji	DEU Tıp Fakültesi Fizyoloji Anabilim Dalı	Erkek	E ☐	H ☒	
Prof.Dr.Mehtap MALKOÇ	Ph.D.Fizik Tedavi ve Rehabilitasyon	DEU Fizik Tedavi ve Rehabilitasyon Yüksekokulu	Kadın	E ☐	H ☒	Katılamadı
Prof.Ph.D.Zuhal BAHAR	Ph.D. Yüksek Hemşire, Halk Sağlığında doktora	DEU Hemşirelik Fakültesi	Kadın	E ☐	H ☒	Katılamadı
Prof.Dr.Nejat SARIOSMANOĞLU	Kalp Damar Cerrahisi	DEU Tıp Fakültesi Kalp Damar Cerrahisi Anabilim Dalı	Erkek	E ☐	H ☒	
Prof.Dr.Adnan MENDERES	Plastik Cerrahi	DEU Tıp Fakültesi Plastik Cerrahi Anabilim Dalı	Erkek	E ☐	H ☒	
Prof.Dr.Ece BÖBER	Pediatrik Endokrinoloji	DEU Tıp Fakültesi Çocuk Sağlığı ve Hastalıkları Anabilim Dalı	Kadın	E ☐	H ☒	Katılamadı
Prof.Dr.Hüseyin BASKIN	Mikrobiyoloji	DEU Tıp Fakültesi Mikrobiyoloji Anabilim Dalı	Erkek	E ☐	H ☒	
Prof.Dr.Servet AKAR	İç Hastalıkları (Romatoloji)	DEU Tıp Fakültesi İç Hastalıkları Anabilim Dalı	Kadın	E ☐	H ☒	
Doç.Dr.Mukaddes GÜNELİ	Tıbbi Farmakoloji	DEU Tıp Fakültesi Tıbbi Farmakoloji Anabilim Dalı	Kadın	E ☐	H ☒	
Doç.Dr.Ayşe Aydan ÖZKÜTÜK	Mikrobiyoloji	DEU Tıp Fakültesi Mikrobiyoloji Anabilim Dalı	Kadın	E ☐	H ☒	
Doç.Dr.Işıl TEKMEN	Histoloji ve Embriyoloji	DEU Tıp Fakültesi Histoloji ve Embriyoloji Anabilim Dalı	Kadın	E ☐	H ☒	
Prof.PhD.Meltem Kutlu GÜRSEL	Hukuk	D.E.Ü Hukuk Fakültesi İdare Hukuku Anabilim Dalı	Kadın	E ☐	H ☒	Katılamadı
İhsan ÇELİKDEMİR	Sağlık mensubu olmayan üye	75. Yıl Özel İlköğretim Okulu Müdür Yrd.	Erkek	E ☐	H ☒	

Dokuz Eylül Üniversitesi Girişimsel Olmayan Araştırmalar Etik Kurulu Karar Formu

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Educatıon

Degree	Department/Program	Unıversıty	Year
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B.S.	Mining Engineer	Dokuz Eylul Universiy	2003

Work Experıence

Unıversıty	Country	Cıty	Department	Tıtle	Perıod
Dokuz Eylul University	Turkey	Izmir	Biomechanics	Research Assistant	08.2006-present

Areas of Interest

Biomechanics, orthopedic implants design and development, orthosis and prosthesis, limb *lengthening.*

Projects

1) Research project: Development of self-guided, multiple cannulated intramedullary fixation nail used in treatment of long bones.

Title: Researcher.

Funding Agency: The Scientific And Technological Research Council Of Turkey

University/Institute: Dokuz Eylul University / Institute of Health Sciences.

City/Country/Period: Izmir / Turkey /November 2011 – May 2013

2) Research project: The Protective Effect Of Adipocyte-Derived Adult Stem Cells On Radiotherapy Applied Skin For Healing Of Incision Scar

Title: Researcher.

Funding Agency: Dokuz Eylul University.

University/Institute: Dokuz Eylul University / Institute of Health Sciences.

City/Country/Period: Izmir / Turkey / June 2010 – December 2010

3) Research project: The use of hyaluronic acid obtained from alternative sources on human

Title: Researcher.

Funding Agency: State Planning Organization

University/Institute: Dokuz Eylul University / Institute of Health Sciences.

City/Country/Period: Izmir / Turkey / Jan 2006- Jan 2007

4) Research project: Development of expandable prosthesis and intramedullary nails used in reconstruction of bone tumor and limb lengthening

Title: Researcher.

Funding Agency: State Planning Organization

University/Institute: Dokuz Eylul University / Institute of Health Sciences.

City/Country/Period: Izmir / Turkey / Jan 2006- Jan 2008

Publıcatıons

A. Artıcles Publıshed ın Internatıonal Refereed Journals

A1. Mehmet Aykut TÜRKEN, Mehmet AKDEMIR, Bora UZUN, Mustafa ÖZKAN,"Biomechanical evaluation of different internal fixation methods for humerus shaft fractures with medial butterfly fragment", Acta Orthopaedica et Traumatologica Turcica, 47(3):173-178, 2013

A2. Muratlı SK, Karatosun VA, Uzun B, Celik S,"Subtrochanteric Shortening in Total Hip Arthroplasty: Biomechanical Comparison of Four Techniques.", J Arthroplasty, S0883-5403(13)00648-7, 2013

A3. Ünal A, Baran Ö, Uzun B, Turan A,"Comparison of screw-fixation stabilities of first metatarsal shaft osteotomies: A biomechanical study", Acta Orthopaedica et traumatologica Turcica, 44(1):70-75 2010, 2010

A4. Turan A, Uzun B, Ünal A, Uyulgan B, Ünver B, Günal İ," Investigation of radioulnocarpal joint load distribution effects of radial shortening osteotomy for the treatment of Kienböck disease: a biomechanical study", J Dis Relat Surg, 21/2/98-103/2010, 2010

A5. Kazımoglu C., Akdogan Y., Şener M., Kurtulmuş A., Karapınar H., Uzun B.,"Which is the Best Fixation Method for Lateral Cortex Disruption in the Medial Open Wedge High Tibial Osteotomy? A Biomechanical Study.", THE KNEE, D-08-00026R3,2008

B. **Proceedıngs Presented ın International Conferences**

B1. Havıtçıoğlu H, Uzun B, Baran Ö, Türken M, Oflaz H, Turan A,"The Effects Of Patients Extremity Position On Tensile Forces During Distraction. A biomechanic study.", 5th Meeting Of The A.S.A.M.I. International, Russia, May 2008.

C. Proceedıngs Presented ın natıonal Conferences

C1. Dinçer C, Karakaşlı A, Uzun B, Ertem F, Taylan O, Havıtçıoğlu H," Development of Multi-jointed Controlled Hip Prosthesis Design and Biomechanical Properties ",VII. Internationally Participated National Congress of Biomechanics, ISPARTA, October 2014

C2. Muratlı SK, Karatosun VA, Uzun B, Çelik S," Subtrochanteric Shortening in Total Hip Arthroplasty: Biomechanical Comparison of Four Techniques.",23. National Congress of Orthopaedics and Traumatology, ANTALYA, October 2013

C3. Düzel S, Ertem F, Taylan O, Uzun B, Havıtçıoğlu H," Development of Self-Guided Multichannel Intramedullary Fixation Nail in the Treatment of Long Bones .", Innovation and R & D in Orthopedics and traumatology Biomechanics Research, BALÇOVA, June 2013

C4. S. Kıvanç MRATLI, Bora UZUN, Salih ÇELİK," Biomechanical Comparison of Percutaneous Pin Methods Used in Distal Radius Fractures ",VI. Internationally Participated National Congress of Biomechanics, SAKARYA, September 2012

C5. Urgu K, Karaca C, Yılmaz M, Demirdöver C, Vayvada H, Menderes A, Atabey N, Kunter İ, Çetingöz R, Arıcan Alıcıkuş Z, Karagüler Z, Ergür BU, Cilaker Mıcılı S, Uzun B," Effect of adipose derived adult stem cells in the radiotherapy applied skin on primary wound healing ", Turkish Society of Plastic and Reconstructive Surgery, 33. National Assembly, ÇEŞME, September 2011

C6. Uzun B, Taylan O, Gültekin B, Havıtçıoğlu H,"Dynamic Measurements of Musculus Tibialis Anterior Ligaments With Different Angle", Internationally Participated National Congress of Biomechanics, ÇEŞME, September 2010

C7.Çelik S, Yurt A, Uzun B, Havıtçıoğlu Ç, Karakaşlı A.,"Comparison Of The Radioactivity And Biomechanical Properties Of Strontium, Magnesium, Chitosan And Chitin","Journal Of Biomechanics, V. Internationally Participated National Congress of Biomechanics, ÇEŞME, September 2010

C8. Erduran M., Uzun B., Cecen B., Gursan O., Erdemli D., Havitcioglu H. The biomechanical effects of adductor hallusis tendon on hallux valgus deformity. 5th International Participation National Congress of Biomechanics, at Izmir, Turkey, September 23-25, 2010, 26 pp.(The abstract of this proceeding was also published in Journal of Biomechanics 2011, 44, 2 pp).

C9.Çecen B., Uzun B., Karakasli A., Baran O., Havitcioglu H. The effects of the ankle joint prosthesis over the load distribution on the foot with different angles. 5th International Participation National Congress of Biomechanics, at Izmir, Turkey, September 23-25, 2010, 37 pp.(The abstract of this proceeding was also published in Journal of Biomechanics 2011, 44, 3-4 pp).

C10. Ercan U.K., Cecen B., Uzun B., Mutlu I., Baran O., Havitcioglu H. The biomechanical properties of peripheral nerve tissue. 20th Turkish National Congress of Orthopaedics and Traumatology, at Ankara, Turkey, October 23-28, 2007, Poster. (The abstract of this proceeding was published in Acta Orthopedica Traumatologica Turcica, Supplementum-III 2007, 41, 138 pp).

C11. Havitcioglu H., Baran O., Coskun B., Uzun B., Dogruoz I., Cecen B. Evaluation of biomechanics and clinical characteristics of inequalities extremity at different reconstructions after resection of the tumor. 20th Turkish National Congress of Orthopaedics and Traumatology, at Ankara, Turkey, October 23-28, 2007, Poster. (The abstract of this proceeding was published in Acta Orthopedica Traumatologica Turcica, Supplementum-III, 2007, 41, 258 pp).

C12. Türken M., Özkan M., Uzun B., Bacakoğlu A., Ekin A.," Biomechanical evaluation of different internal fixation methods for humerus shaft fractures with medial butterfly fragment ", Acta Orthopaedica et Traumatologıca Turcıca, 43/suppl1/50/2009",XXI. Turkish National Congress of Orthopaedics and Traumatology, ÇEŞME, November 2009

C13. Meriç ÜNAL, Baran Ö, Uzun B, Turan A," Comparison of screw-fixation stabilities of first metatarsal shaft osteotomies: A biomechanical study", XXI. Turkish National Congress of Orthopaedics and Traumatology, ÇEŞME, November 2009

C14. Bora Uzun, Önder Baran, Hasan Havıtçıoğlu," Expendable intramedullary nail by mechanically load ",14. BIYOMUT , IZMIR, May 2009,

C15. Uzun B, Havıtçıoğlu H, Baran Ö, Oflaz H, Türken M, Turan A," effect of patient's limb position on tensile forces during distraction: biomechanical study ", IV: Internationally Participated National Congress of Biomechanics, ERZURUM, October 2008

C16. Binbaş Ö, Uzun B, Oflaz H, Baran Ö, Havıtçıoğlu H," Biomechanical Comparison of new designed micro motion plate and rigid plates",IV. Internationally Participated National Congress of Biomechanics, ERZURUM, October 2008

C17. Hakan OFLAZ, Bora UZUN, İşve H. DOĞRUÖZ, Önder BARAN, Hasan HAVITÇIOĞLU," Micro motion biological palte ",XX. Turkish National Congress of Orthopaedics and Traumatology, ANKARA, October 2007

C18. Bora UZUN, Hakan OFLAZ, Önder BARAN, Hasan HAVITÇIOĞLU," Effects of different femoral stem diameters of the modular tumor prosthesis on femoral cortex ", XX. Turkish National Congress of Orthopaedics and Traumatology, ANKARA, October 2007

C19. Hakan OFLAZ, Bora UZUN, İşve H. Doğruöz, Mehmet SARIKANAT, Hasan HAVITÇIOĞLU," Finite Element Analysis of Dynamic Hip Plate ", XX. Turkish National Congress of Orthopaedics and Traumatology, ANKARA, October 2007

C20. Hasan HAVITÇIOĞLU, Önder BARAN, Başak COŞKUN, Bora UZUN, İşve H. DOĞRUÖZ, Berivan ÇEÇEN," Biomechanical and clinical evaluation of the features of different reconstruction of extremity inequality following tumor resection" XX. Turkish National Congress of Orthopaedics and Traumatology, ANKARA, October 2007

D. PATENTS:

D1. Intramedullary fixation pin, European Patent Office (EPO), 2007

E. AWARDS:

E1. "Best Project Award ", Dokuz Eylul University " Innovation and R & D in Orthopedics and traumatology Biomechanics Research " Sempozyumu, First Award, 2013

E2. "2011 Expert Research Competition ", Turkish Society of Plastic Reconstructive and Aesthetic Surgery, Research Award, 2011

E3. "Patent Incentive Award ", Dokuz Eylul University / Institute of Health Sciences, Incentive Award, 2008