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CENTER OF BIOMEDICAL ENGINEERING

Design and Development of Advanced External Fixator for Treatment of Femoral Bone Fracture

A Master's Thesis Submitted in Partial Fulfillment of the Requirements for the Degree of Master of Science in Biomedical Engineering

By

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Addis Ababa, Ethiopia, February, 2017

Declaration

I, the undersigned, declare that this thesis is my original work. It has never been presented for a degree in any institution and that all sources of materials used in it have been duly acknowledged.

Name: ____

Signature: _____________________________________

Date: ____

This MSc. thesis has been submitted for examination with my approval as his internal advisor.

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Certificate of Examination

This is to certify that the thesis prepared by Talaksew Misganaw Agegnehu entitled*: Design and Development of Advanced External Fixator for Treatment of Femoral Bone Fracture* submitted in partial fulfillment of the requirements for the degree of Master of Science in Biomedical Engineering (Biomechanics and Rehabilitation) complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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Associate Director, Postgraduate Program

Abstract

Design and Development of Advanced External Fixator for Femoral Bone Fracture

Talaksew Misganaw

Addis Ababa, 2017

The incidence of accidents causing major injuries globally is increasing every year. Previous studies indicated that more than 90% of the incidences happen in the developing world. In case when the scope of the accident is high, that often creates fractures particularly on strong and heavy bones (femoral and tibia in the lower extremities). In this regard different methods are available to treat fractured bones including tractions, internal and external fixators and their variants.

Traction is one of the oldest treatment methods currently used in many clinics as a temporary treatment of long bone fractures through suspension of weights using ropes over pulleys and attached to the patient bed. Such a procedure does not allow patients movement and could result in many known complications: depression, bed sores, pneumonia and urinary infections to mention a few. The internal fixators like intramedullary nails are the gold standard implants for fixation of long bone fractures. However high cost, lack of adequate professionals and instruments in low resource settings, location of the accident, need for multiple surgeries and cultural and/or physiological patient/family related issues for operation significantly hinder patients from getting the service. External fixation management applies aligning/realigning fractures using pins, wires, clamps, and bars or rings. It has advantages of simplicity, ease of adjustability, and increased access for fracture related wound care and wound monitoring. However, the solid bars often used to make fractured fragments rigid has no flexibility, do not employ a force on the muscles tensioned by the fixators and have no micro movement setup. This creates immediate functionality problem after recovery and reduce fast healing process for the fractured bone because loading has considerable effect on tissue repair and remodeling.

A thorough investigation of literatures on fixators (especially external fixators) carried out in the current study showed that applying continuous load/force on fractured limbs increases the functionality of the muscles during the bone healing process thereby reducing the rehabilitation time after recovery. In this regard, based on Solidwork, an advanced external fixator has been proposed in the current study that makes use of a spring load mechanism to exert a continuous load/force. Detailed 2D and 3D design and simulation of the mechanism has been presented. The proposed external fixator also comes with a traction functionality.

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This thesis could not have been completed without the support and help of my advisors and colleague to whom I am very grateful.

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The generation of the model was supported by my colleague Mr. Biruk Abreham from the Center of Biomedical Engineering based on Solidworks, InVesalius 3.0 and MeshLab Designer softwares.

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Acronyms

2D	Two Dimensions view
3D	Three Dimensions view
AO/OTA	Orthopedics Trauma Association
CT	Computed Tomography
MRI	Magnetic Resonance Imaging
DICOM	Digital Imaging and Communications in Medicine
STL	Stereo lithography
JPG	Joint Photographic
ASTM	American Society for Testing and Materials
ANSI	American National Standards Institute
DIN	Deutsches Institut für Normung (German Institute for Standardization)
ISO	International Organization for Standardization
UN	United Nations Standards

Chapter 1

Introduction

1.1 Background

Fracture of bones occurs in many occasions due to accidents and certain diseases. To make the bone heal and bring it back to normal functions, more than three months of stable fixator is required. In this regard, different kinds and types of fixators are used to fix bone fractures. Three major types of treatments exist: internal fixators, external fixators and conservative management techniques. Due to cost, lack of skilled professionals, and insufficient availability of implants especially in low resource settings, most hospitals in the developing world use external fixators particularly to treat femoral fractures. The method is ordinarily applied in specialized hospitals where orthopedics specialists are available. The most common techniques employ the same principle which is fixing biocompatible pins into the bones and clinching them with screws on rings/curved bars which is to be attached to solid rods.

For long bone fractures, to achieve maximum stability of fractures, more than two pins/wires are inserted into the bone linearly or angularly. Combination of different types of external fixators increases the polytrauma event stabilization. Orthofix and Taylor Spatial Fixator (TSF) are the advanced forms of external fixators with a feature of progressive loading. The fixators are adjusted on a daily basis to lengthen the bone and/or correct for any angular deformity.

In all external fixation systems, the frame structure is fixed to the pins/wires which are inserted to the patient's bone where angulation and space adjustment is possible between the fracture site and the fixator rods. Such a setting of the external fixators, however, comes with major difficulties after their removal or during the healing process. One of the major difficulties is the requirement for long run rehabilitation to bring back the activity of the muscles surrounding the fracture. This calls for the development of a self-powered device that helps the muscles to be in active state during the entire bone healing process. This thesis then investigates the design and development of an external fixator that could effectively apply a continuous micro level force by itself allowing muscles surrounding fractures to be active for the entire duration of the bone healing process there by avoiding the risk of muscle atrophy.

Traction is one of the oldest treatment methods currently used in many clinics as a temporary treatment of long bone fractures through suspension of weights using ropes over pulleys and attached to the patient bed. Such a procedure does not allow patients movement and could result in many known complications: depression, bed sores, pneumonia and urinary infections to mention a few. The internal fixators like intramedullary nails are the gold standard implants for fixation of long bone fractures. However high cost, lack of adequate professionals and instruments in low resource settings, location of the accident, need for multiple surgeries and cultural and/or physiological patient/family related issues for operation significantly hinder patients from getting the service. External fixation management applies aligning/realigning fractures using pins, wires, clamps, and bars or rings. It has advantages of simplicity, ease of adjustability, and increased access for fracture related wound care and wound monitoring. However, the solid bars often used to make fractured fragments rigid has no flexibility, do not employ a force on the muscles tensioned by the fixators and have no micro movement setup. This creates immediate functionality problem after recovery and reduce fast healing process for the fractured bone because loading has considerable effect on tissue repair and remodeling.

A thorough investigation of literatures on fixators (especially external fixators) carried out in the current study showed that applying continuous load/force on fractured limbs increases the functionality of the muscles during the bone healing process thereby reducing the rehabilitation time after recovery. In this regard, based on Solidwork, an advanced external fixator has been proposed in the current study that makes use of a spring load mechanism to exert a continuous load/force. Detailed 2D and 3D design and simulation of the mechanism has been presented. The proposed external fixator also comes with a traction functionality.

1.2 Statement of the Problem

Techniques which are still used by physicians to fix lower extremity fractured bones to align broken legs: 1) do not have a mechanism to exert continuous loading during the bone healing process (except traction systems, which are mostly outdated for use particularly in resource full settings) risking the occurrence of muscle atrophy, 2) have no efficient control mechanisms to adjust forces and spans applied on the fractured leg, and 3) result in complications during bone rehabilitation including muscle weakness, difficulty for movement, deformity, disability, and many other problems in the long run. Traditional traction devices that make use of weights suspended over a pulley system attached to the patient's leg could be used to exert the required span and force during the bone healing process. Such a procedure does not allow patients movement and could result in many known complications: depression, bed sores, pneumonia and urinary infections to mention a few. External fixators do not have such problems but at the same time are not able to generate continuous force by themselves risking muscle atrophy and the resulting complications during the bone rehabilitation process. The right solution is then to develop an appliance that has a traction effect and be used as an efficient external fixator that is able to exert continuous micro level force in a controllable manner based on appropriate fracture philosophy and biomechanics principles.

1.3 Objectives

General Objective:

To survey and design a conceivable and reliable advanced external fixator that can improve the present practice.

Specific Objectives:

- To draft out the mechanism.
- To design the drafted model using softwares.
- To design 3D view of the mechanism.
- To design 2D and 3D view of details.
- To design 3D view of the assembly.
- To perform a simulation study.
- Prototyping and validation of the design.

1.4 Materials and Methods

Revision of different techniques of fracture fixators developed previously in the literature and identifying the merits and demerits of these methods is a major component of the thesis work. Appropriate fracture philosophy and biomechanics principles have been used during the design and development of the proposed external fixator appliance. Solidworks design software has been used to carry out most of the design and simulation tasks in this thesis work. InVesalius 3.0 and MeshLab are the other softwares used to model the femoral bone based on Computed Tomography (CT) DICOM images. For demonstration purpose, prototypes have been fabricated inside a mechanical workshop using a system made of aluminum and steel materials.

1.5 Organization of the Thesis

The whole thesis has been organized into seven chapters. Background medical principles and terminologies, description of femoral musculoskeletal systems, back ground information on fractures, and fracture management systems are all discussed in Chapter 2.

Chapter 3 talks about fixators and traction systems and their types in detail. Already available fixators and traction devices are explained, their communalities and differences in terms of their design principles, components and material usages are described together with explanation on their most applicable areas. Emphasis is given to external fixators.

The softwares used to design and simulate as well as the foreseeable designs are discussed in Chapter 4 including flow chart of the methodology used. Chapter 5 presents the detailed design of the proposed external fixator appliance based on design matrix results generated in Chapter 4. Chapter 6 presents the results and discussions while conclusion and future directions are included in Chapter 7.

Chapter 2

Medical Principles and Terminologies

2.1 Bone Fractures

The number of deaths caused by injuries worldwide is comparable to the combined aggregate number of deaths caused by HIV/AIDS, malaria, and tuberculosis [1, 2, 3]. Out of these, more than 90% occurs in the developing world. Almost 20 to 50 million people get a certain type of injury every year. It is predicted that by 2030 road accident only will become one of the top three injury and death causing factors.

Neglecting treatment causes malunion, shortening and compartment syndrome and such incidences are quite common particularly in developing countries [3]. The problem is severe for the young population between the ages of 14 to 44 years old, which means that such disabilities significantly render the work capacity thereby increasing the unemployment rate. Because disability occurs mostly when there is complex fractures of femoral and tibia which are the strongest and heaviest bones in our body respectively and bones integrated to a motion. In healthy adults, these bones fracture as a result of high-energy trauma and when the complexity of the injury grows, it often forms part of a life threatening injury pattern. Accordingly, severe trauma femoral fractures have become major research areas associated with injuries [4].

2.2 Terminologies used to describe musculoskeletal system

Certain terminologies are used to describe the human body and its movement. These are directional terms to locate the body parts, structures of the human anatomy and the three anatomical planes used to fully define it. The directional terms are used to define the location of one body part or structure relative to the other [5, 6]. Figure 2.1 below shows the direction terms.

Planner or sectional description of the body refers to imaginary planes that pass through the body parts. These are known as sagittal (lateral) plane, transverse (axial) plane, and Coronal (frontal) plane [5, 6].

Frontal Plane (Coronal Plane):- a vertical plane which divides the body into anterior and posterior portions running from side to side.

Sagittal Plane (Lateral Plane):- vertical plane divides the body into right and left side running from front to back.

Transversal Plane (Axial Plane):- horizontal plane divides the body into upper and lower parts.

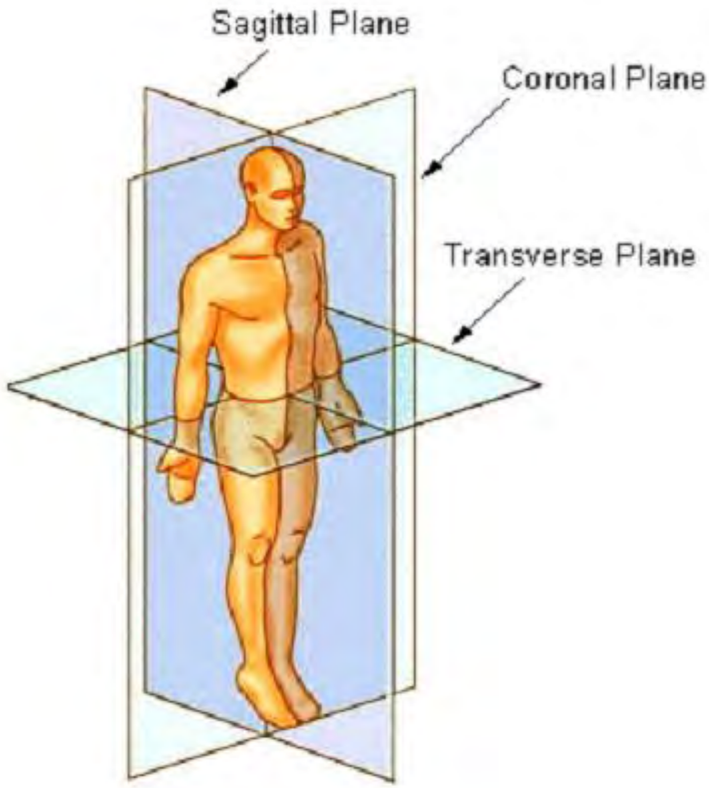


Figure 2.1 Anatomical Body Planes (Courtesy of [6]).

In addition to sectional planes and directional terms, there are also terms used to describe movement of the body.

Flexion / Extension: this is when the body makes an increasing or decreasing angle relative to the frontal plane. Increasing is flexion whereas decreasing is extension.

Abduction / Adduction: The sagittal plane is the reference when the body moves away or towards the plane. Moving away from the sagittal plane is abduction and to the contrary moving towards is adduction.

Protraction / Retraction: along a surface moving forward or backward.

Elevation / Depression: raising or lowering a structure or part of the body.

Medial rotation / Lateral rotation: rotating the structures of the body around an axis of a bone.

Pronation / Supination: backward or forward viewing of the palm parallel to the frontal plane (in anatomical position).

Circumduction: when the body moves all of the above in combination, like rotating to make a cone.

Opposition: fingers and thumb to make an increasing angle relative to the transverse plane or floor.

2.3 Musculoskeletal system

It is the system of muscles and skeleton, which provide posture, meaningful movement, stability, support, and protection for internal organs, regulate internal organs movement and volume, blood cell production, mineral homeostasis, and generate heat for the body [5, 6]. Muscle are divided into three major divisions; cardiac muscle, smooth muscles and skeletal muscles. Skeletal muscles are striated types with bands of muscle fibers made of myosin (thick filaments) and actin (thin filaments) attached to bone, skin, fascia and other muscles. The main movement occurs due to these muscles contraction like a lever system, bones as levers and joints as fulcrum. Cardiac muscles are like skeletal muscles conceiving identical arrangement of actin and myosin fibers and also with same bands, zones, and z discs but they differ at their end where the heart muscles connect to each other. Smooth muscles are found in the skin, around walls of small arteries and veins and also hollow organs like stomach, uterus, and intestine.

The bone is the main tissue in the skeleton system besides tendons, cartridges, and ligaments. Bone has a character of dynamically remodeling (rebuilding the tissues continuously) with complex tissues [5, 6]. The human being is unable to perform its activity without the skeleton. The adult human skeleton consists of 206 bones most of which are pair type. The skeleton is divided in to two major groups: the axial and appendicular.

2.4 The Lower Extremity

The femur, tibia, and fibula, knee cap, phalanges, tarsals and metatarsals in the foot are the lower limb bones which are depicted in Fig. 2.2 below [5, 6]. The femur is the longest, heaviest and strongest bone in our body accounting about a quarter of our height. Its function is to transmit weight from hip bone to the tibia and also it is anchoring point for dozens of different muscles used for movement. Superiorly it rotates on the acetabulum forming ball socket type joint called the hip joint and inferiorly it articulates with the patella and tibia crafting a knee joint. Anatomically the femur is divided into three regions: the proximal femur, shaft, distal femur. The proximal end consists of hemisphere head, fovea capitis (central depression) during child hood where blood for the head of the femur enters through ligamentumteres. Greater and lesser trochanter which are used as some of thigh muscles and tendons attachment area are separated on the front by intertrochanteric line and on the back it is separated by intertrochanteric crest.

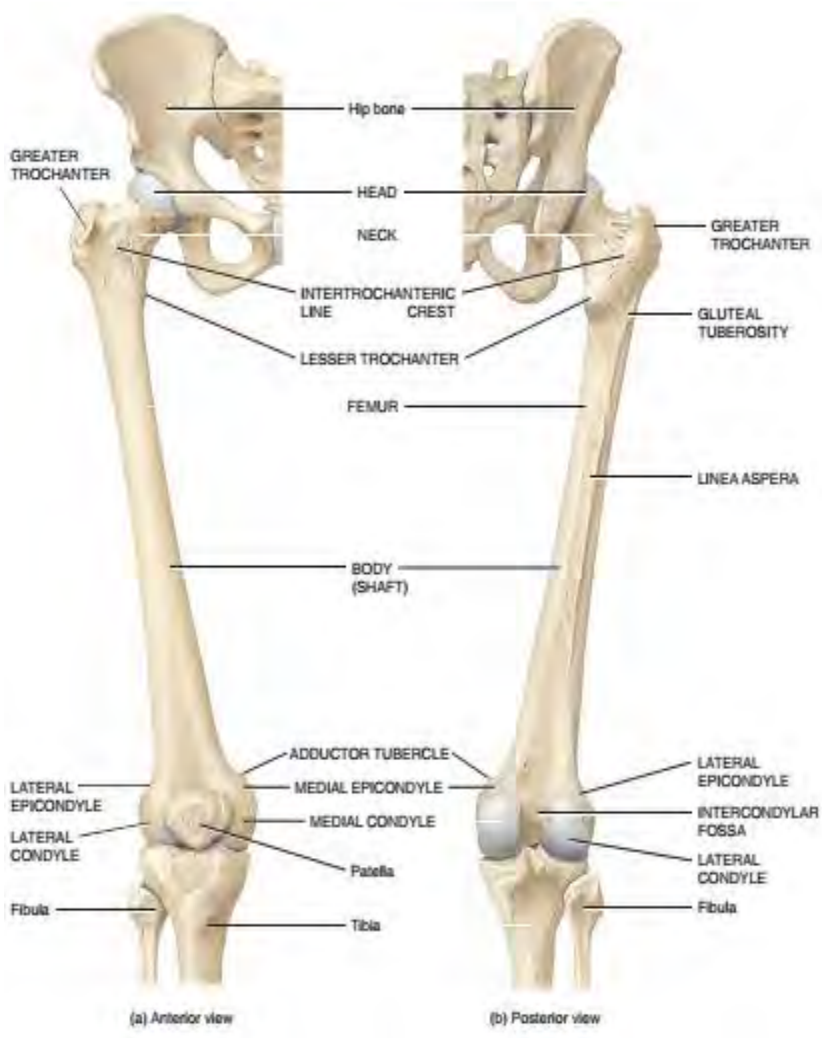


Figure 2.2 Anterior and posterior view of lower limb Femur bone and its joints (Courtesy of [5]).

The quadrate tubercle is found at the tip of the intertrochanteric crest where quadrates femora's muscle attaches. The shaft of the femur is slightly bent to the medial line in order to keep the weight to the center of the body which helps stability in movement. The posterior side of the femur has pectineal line for pectineus muscle attachment and gluteal tuberosity for gluteus muscle and together they form the Linea Aspera where one of the hamstring muscles attach. Linea Aspera distal end has two expanded parts called medial, lateral supracondylar and condylar ridges and in the medial posterior forms popliteal fossa where locking muscle of the knee is attached [5, 6]. The femur has two angles: the angle of inclination created by the intersection of lines passing through the line of the head and line passing through the shaft, and torsion angle. The femoral torsion angle or femoral neck ante-version or angle of declination is formed between the axis passing through the neck of femur and the horizontal line with the normal range of 10-15 degrees when looking at normal to the transverse plane. (See Fig. 2.3 and 2.4 below).

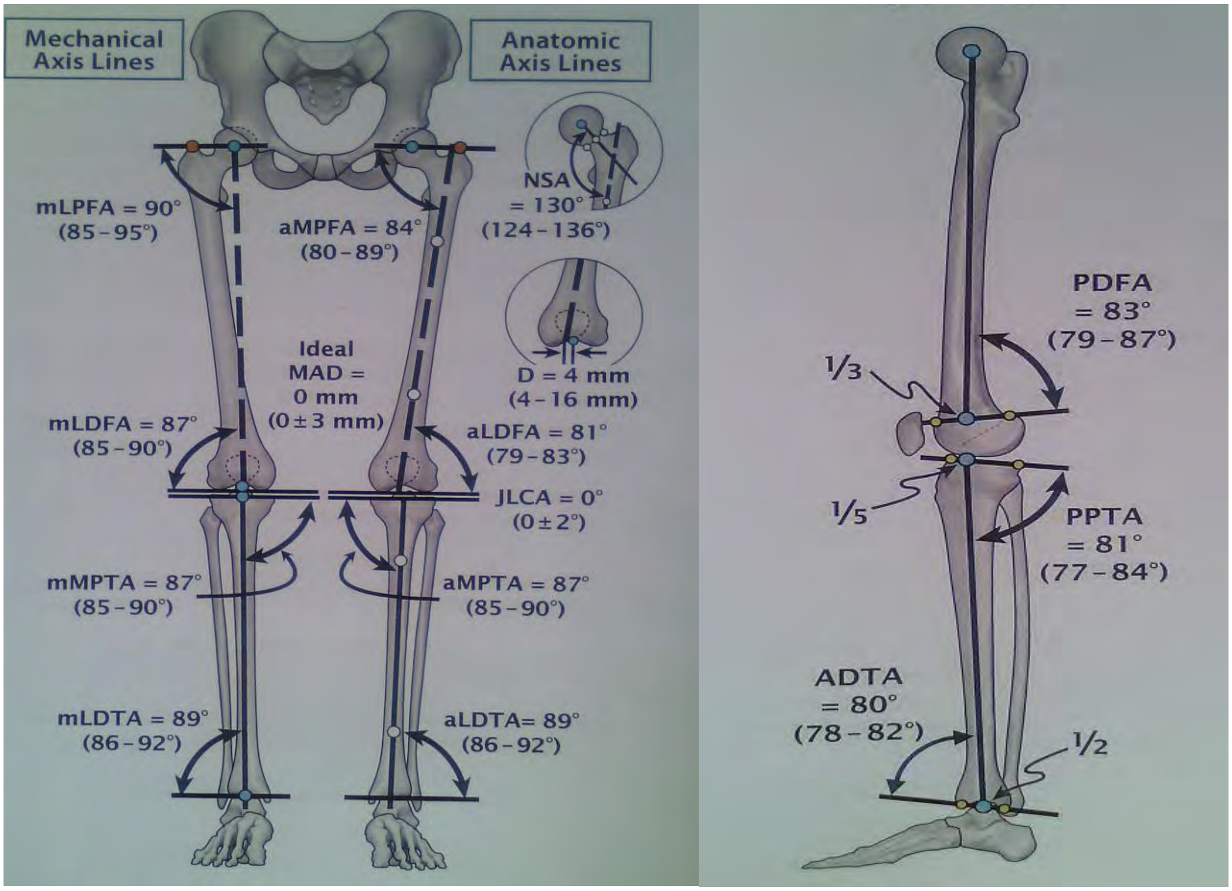


Figure 2.3 Standard Measurement of the lower limb (Courtesy of [6]).

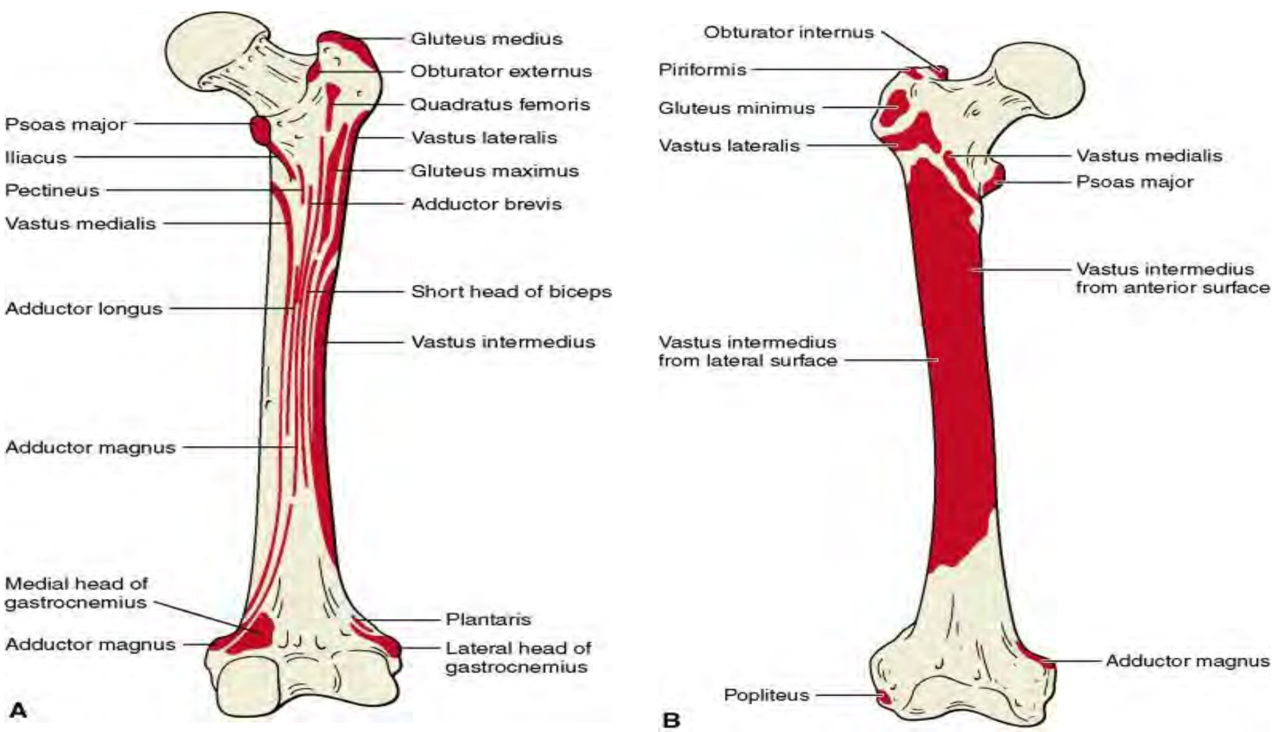


Figure 2.4 Muscles attachment on the thigh bone A) Posterior B) Anterior (Courtesy of [4]).

2.6 Femoral Fracture Classification

Besides the death of more than 1.3 million people in the world specifically due to road accidents, much more become disabled annually [1]. Femoral fracture incidents are at 15.7 to 45.5 per 100,000 people per year for low and middle-income countries respectively which is very high number compared to the figure in the developed nations with similar number per 1.0 to 2.9 million.

In the human body, femur bone cannot be easily affected by external factors [7]. However, due to trauma, vitamin A deficiency, low bone density and elderly bone fractures can occur. Bone fracture will tear blood vessels which carry nutrients to the body and cause major complications to our body not to function properly. Especially fracture of the femoral bone in healthy adults occurs with considerable violence, sometimes leading to other life-threatening complications [8]. From its physical properties, fracture of femur requires high energy trauma without pathological problems that weakens the bone. Hence it causes significant pain, deformities, bleeding and varying grades of damages to the lower limb that could be life-threatening.

The femoral shaft fracture is mostly classified depending on: the location of the fracture (distal, middle, or proximal), the pattern of the fracture (the bone can break in different directions, such as cross-wise, length-wise, or in the middle), and whether open or closed fracture (depending on whether the bone come piercing the skin and muscle above the bone or not) [9]. The different types of fracture could be simple, wedge or complex. Beside geometrical and locational classification of fractures, there are two other commonly accepted femoral bone fracture designations considered by physicians: the AO/OTA and the Winquist-Hansen. (See Fig 2.5 and 2.6).

The total assessment of the femoral fracture and proper documentation will help the management of the fracture easily [4, 9]. Because open fractures indicate the severity of the trauma which guides to accomplish another diagnosis farther in order to avoid the complication of the fracture. Also designing methods starting from nursing care and follow-up, priority to emergency and other related setups depends on such kinds of factors.

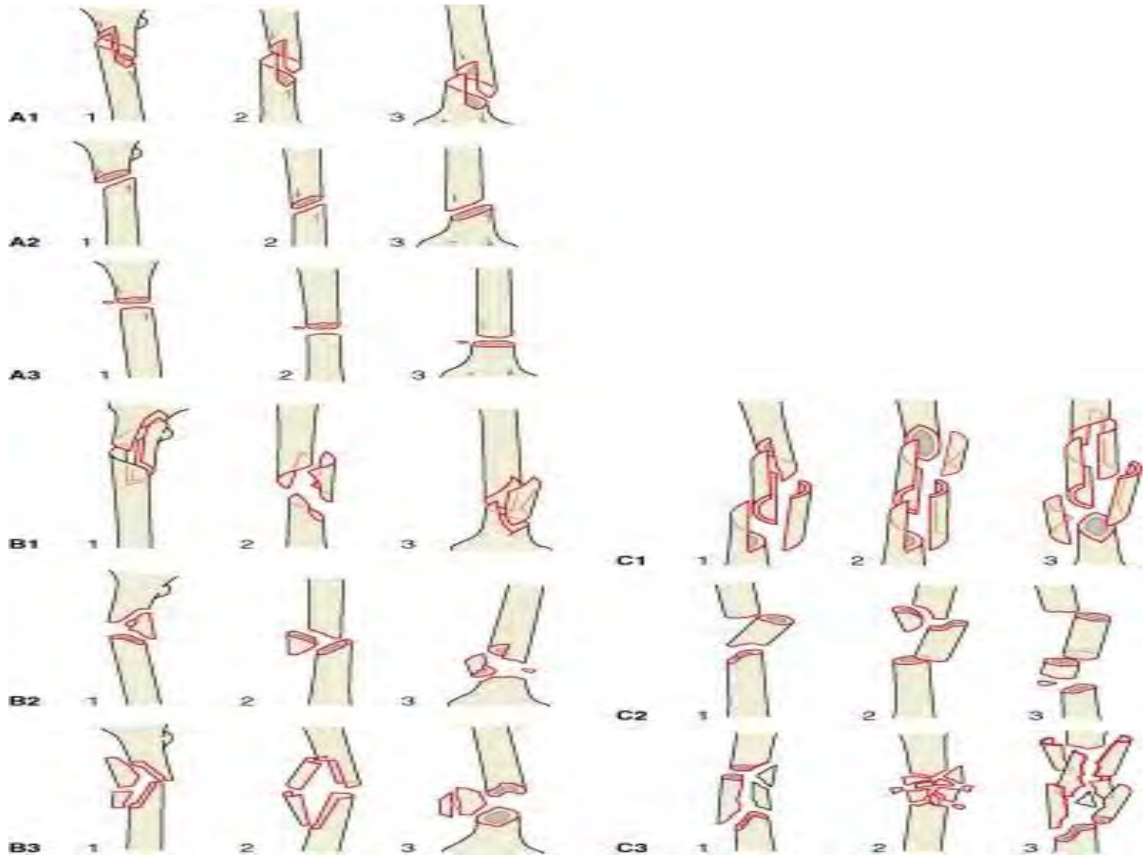


Figure 2.5 AO/OTA classification of femoral shaft fractures (bone 3 shaft 2) (Courtesy of [4]).

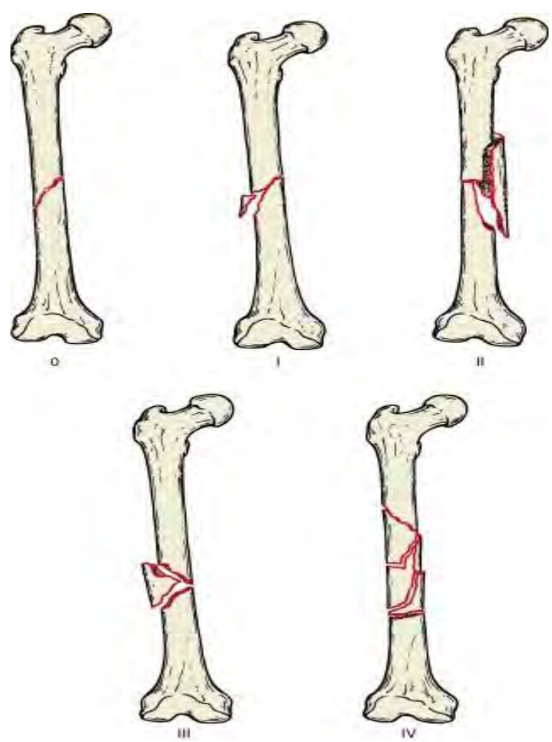


Figure 2.6 Win-Quist-Hansen classification of femoral shaft commination (Courtesy of [4]).

2.7 Fracture management

An essential primary concern is survival of the patient. The harming of the limb and particularly the vascular damage could lead into major hemorrhage [4, 8]. The management of the fracture starts first by checking the doctor's orders. Listing the patient name followed by the extremity to be managed as well as preparing the patient for the treatment are the prior things to take care. Many techniques are available to treat fractured bones. There are three most commonly used methods. Internal fixator method is a closed technique of fixing the fracture like the intramedullary nail which is the gold standard method. External fixators like Ilizarov, Huffmann II, and orthofix are common for open fractured long bone fixations for adults and children [10, 11, 12]. Another method is *Conservative management* which remains the best fixation tool for fractures especially in low-resource settings, because it is low cost and avoids the complications which could arise due to improper setting and fixation [13]. The basic underlying principle of traction is the alignment of a long bone fracture by applying isotonic forces along the longitudinal axis of the soft tissue envelope.

The most frequently applied conservative methods are cast bracing, Perkin's traction and Tomas splint [13]. Manipulating through fluoroscopy guidance helps to align the span of limb accurately. The applied force in the latter two methods differ; the Perkins use gravity based balancing while the Tomas splint use fixed traction. However, gravity cannot correct posterior angulation deformity. Many of the conservative management techniques, however, create complications on the patient including bed sore, mobility problems, deformity, and angular span displacement. The rate of healing for femoral bones requires about 8 weeks, hence, admission of the patient all these days creates complications, cost, and also burden for the caregivers [14]. For example, the tractions currently in use at the Black Lion Referral Hospital and St. Paul Referral Hospital in Addis Ababa, Ethiopia, primarily use as a load a sack filled with sand suspended on a rope attached to the patient's leg. One could simply imagine the inconvenience such a setup could create on the patient as well as the lifelong deformity or disability it could create [15].

External fixators avoid most complications that arise from the use of traction systems [16]. Because they are fixed only on the patient, they allow movement of the patient from place to place leaving his/her bed. Unless correction of angulation or length increment is required, special fixators like TSF or Orthofix are often not used for fixation of fractures [12, 17]. For fixation of fractures, simple rods like carbon fiber are used instead. Details regarding external fixators and their different applications is discussed in the next chapter. This is the basis for the design and development of the new external fixator proposed in this thesis. The chapter also includes quick reviews on traction appliances available in the literature.

Chapter 3

External Fixators

Realignment of fractured long bones by using external fixators started in 1897, by Dr. Clayton Parkhill of Denver, Colorado [10]. The main purpose of the external fixators at the time was trauma care. External fixators were also applied for deformity corrections, arthrodesis and when other methods of skeletal fixation seem risky as well as for temporary fixation before internal fixation implanting were proved to be safer for the soft tissue tenuous condition [17, 18]. External fixators are used with the combination of pins, wires, clamps, and bars or rings. For correction of limb-length, bone loss compensating and mal-alignment ring fixator frames are more acceptable. Ilizarov ring is one of the best external frames, which was developed by G. Abramovich Ilizarov around the 1950's [18]. These days Ilizarov ring is used in many forms to fix fractures and deformities together with other systems.

Particularly for poly-traumatized patients, internal fixation has reservations in giving better results than external fixation in terms of fracture joining, surgical complication rates, and even cost [4, 19]. Especially in developing countries, the level of surgical facilities is at medium standard in health care centers that are not referral hospitals and where well-trained surgeons and health care givers are very scarce. In addition, shortage of appropriate and affordable equipment and implants, and lack of reliably clean surgical environment and the related surgical complications makes the problem even more pronounced.

The major objective of common external fixators is to give an alignment and stability for fractured bones to the optimal level [16, 19]. This method is chosen when there is excessive bone shortening, severe soft tissue injury that precludes nailing or sub-muscular plating, and to reduce surgery related complications. Rigidity is not required for bone healing process, because non-union, delayed union, and stress shielding occur due to rigidity. Instead, optimal form of stability is required that comprises of axially controlled micro-motion inhibiting angular bending, shear, and rotation. Based on fixation configuration planes, external fixators are generally classified as unilateral, bilateral and multi-planner types. Unilateral configuration is less cumbersome in stabilizing and neutralizing bending moment and torsion than bilateral and multi-planner configurations. However, bilateral and multi-planner configurations offer more effective stabilization and neutralization of bending moments and torsions. Figure 3.1 below shows the four basic configurations of external frames.

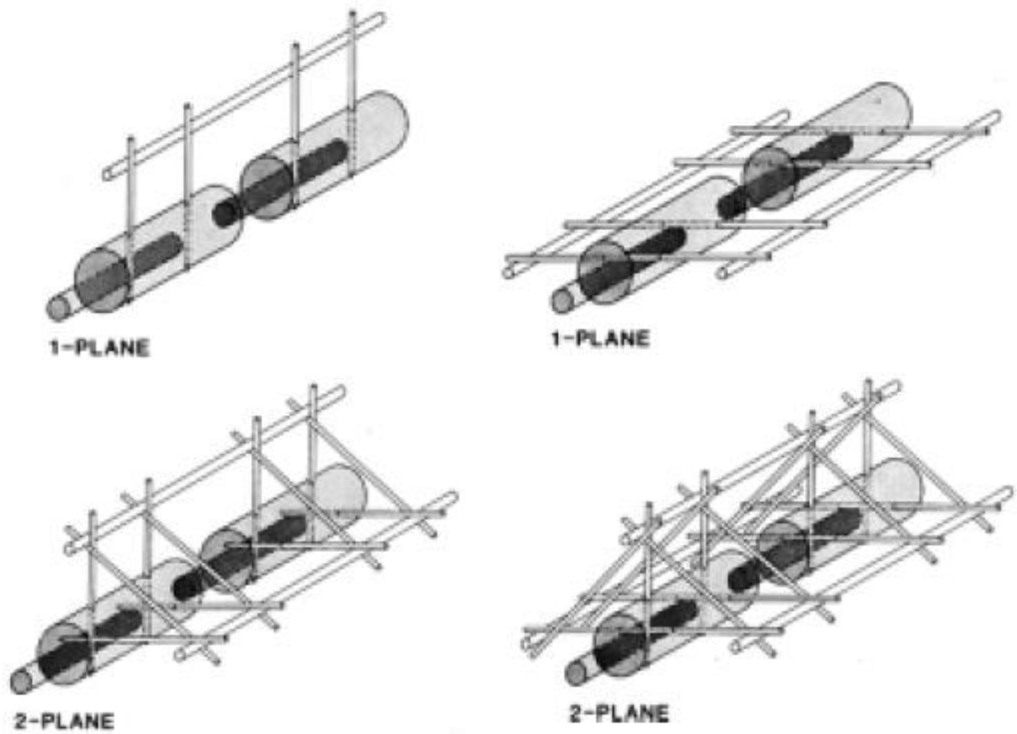


Figure 3.1 1 plane Unilateral (top left), 1-plane Bilateral (top right), 2-plane Unilateral (bottom left), and 2-plane Bilateral (bottom right) fixation external frames (courtesy of [19]).

3.1 Development of External fixators

The first successful use of an external fixator for fracture treatment was introduced in 1897 by Dr. Clayton Parkhill. Five years later, a Belgium surgeon, Dr. Albin Lambotte, developed a unilateral rigid fixation system using better materials in combination of more pins and bars [10]. External fixators were out of favor and called “the nonunion machine” during World War II while used by allied forces. But after so many research on their biomechanical characteristics, they are back in use after 1970s. A modified version of Lambotte’s device which comes with an adjustable pin clamp that allowed manipulation of fractures in all three planes was devised by Anderson and Hoffman, which is considered a precursor for modern external fixators [16]. Since then different companies and surgeons have committed on advancing external fixators. Some of these are Ilizarov, Charles Taylor, Zimmer, Hoffmann II & III, and Orthofix. All available external fixator frames are constructed of pins or wires, clamps, bars or rings, and struts.

Pins and Wires

In 1909, Kirschner (or K- wires) were invented by Martin Kirschner, a surgeon from Heidelberg, Germany. They were fabricated at first in lengths from 7 to 31 cm and in diameters from 0.6 to 3.0 mm [16, 19]. They are critical links between bone and sidebars/clamps used for stability of external fixation. The torsional strength of pins is normally proportional to the fourth power of the core diameter. Which means a 4mm pin has around 5 times less stiffness than a 6mm pin. Pins with larger diameter decrease the stress on the bone and hence using larger diameter pins makes the stability efficient. But the diameter should not exceed 1/3 of the bone diameter to avoid fractures at the pin hole of the shank. When the number of pins increases, the stability also increases. The planner alignment also have great effect on stability. For example, 3 pins aligned in 2 or more planes have more stability than 1 or 2 pins aligned in a single plane. Self-tipping and self-cutting pins are other designations of pins. Also smaller diameter wires are often used in combination with pins. Figure 3.2 demonstrates typical pins and wires often used in different fixation applications.

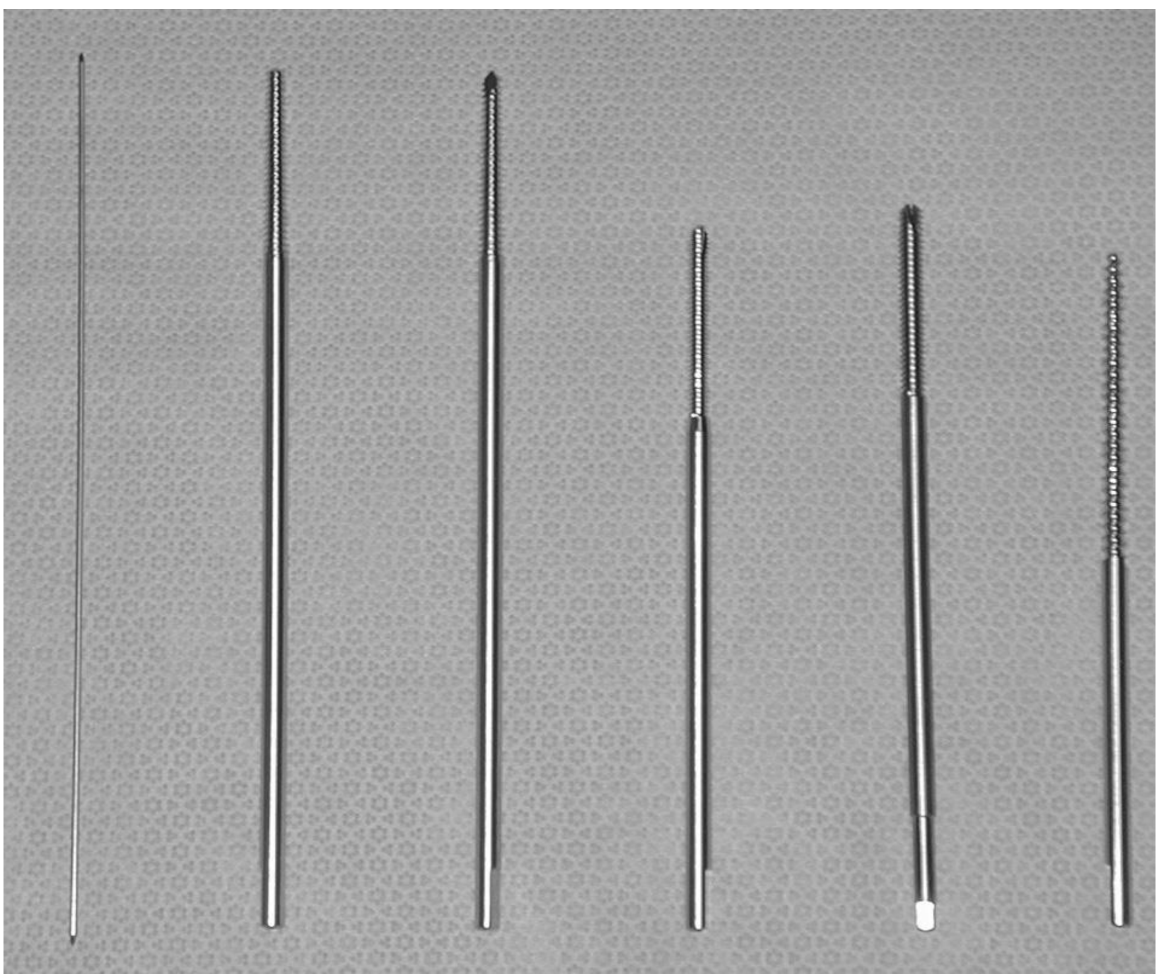


Figure 3.2 A typical wire (left) and difsferent pin types used for External fixators (Courtesy of [16]).

Pin Clamps

A rod or ring is connected to pins/wires with clamps [16, 19]. Different types of clamps are available nowadays to be used for different purposes: simple clamps connect one pin to a rod, whereas modular clamps may connect multiple pins to a rod. Furthermore, there are clamps with varying degrees of freedom intended for various applications. The rigidity as well as the angle flexibility between pins and/or rods are the most important considerations while designing clamps. Three different clamp designs are shown in Fig. 3.3 below.

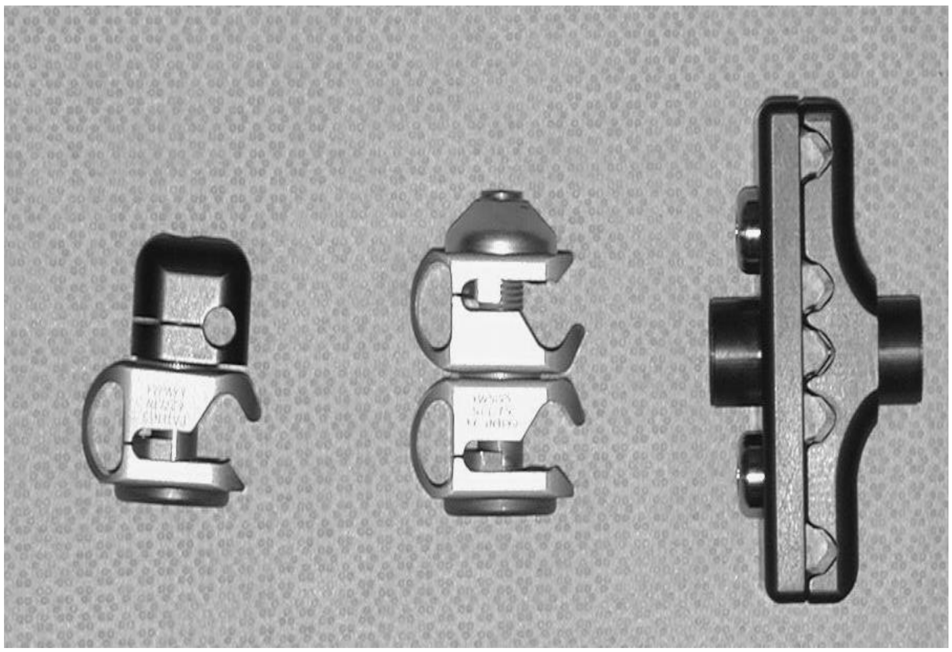


Figure 3.3 Clamps for External fixators (Courtesy of [16]).

Side Bars and Rings

The bridge between pin clamps and rings is constructed using sidebars or connecting rods to unify the bony fragments [16, 19]. Radiolucent (for radiographic assessment), stiff, and lightweight are the features of an ideal sidebar and rings. Traditionally, stainless steel, aluminum alloy, or carbon fiber are materials used to manufacture sidebars and rings. Carbon fibers are most ideal candidates that full fill most characteristics of sidebars and most commonly used nowadays. There are sidebars and rings developed by different companies and individuals for special purposes like corticotomy lengthening and bone transport. For a long time till now, the improvement of external fixator systems is continuing by surgeons. Typical side bars and rings used in clinics are depicted in Fig. 3.4. Some of the most important advancements in the history of external fixators are presented below.

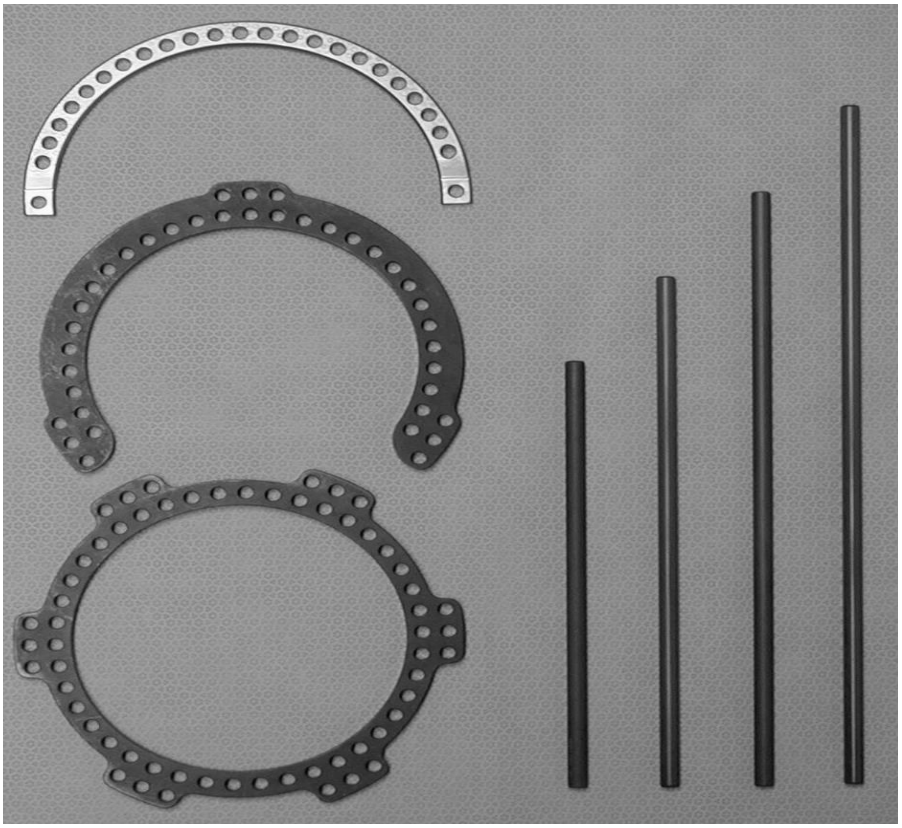


Figure 3.4 Sidebars and Rings for External fixators (Courtesy of [19]).

3.1.1 Gavriil Abramovich Ilizarov

In 1951, Professor Gavriil Abramovich Ilizarov from Kurgan, Russia developed a circular external fixator for the treatment of fractures [18, 20]. Ilizarov discovered the techniques of physeal distraction the so called "tension stress theory". For many decades, he did many researches on clinical applications of bone and soft tissue regeneration. He discovered that other tissues such as blood vessels, nerves, and skin were able to regenerate during gradual distraction and developed his 'Law of tension stress' which explains that under the effect of slow and gradual distraction, bone and soft tissue would regenerate. The versatility of the apparatus and the minimal nature of the surgical intervention needed with an understanding of the mechanical principles create the optimal biologic and mechanical environment for rapid bone consolidation and early functional rehabilitation. Presently, the Ilizarov techniques are applied in all sectors which accomplish procedures like: (1) limb lengthening, (2) treatment of non-unions, bone and soft-tissue defects, and osteomyelitis, (3) correction of bony deformities, joint contracture deformities, and even contour deformities of the limbs, (4) arthrodesis and (5) treatment of fractures and dislocations. The construction of Ilizarov ring with screw frames is shown in Fig. 3.5 below.

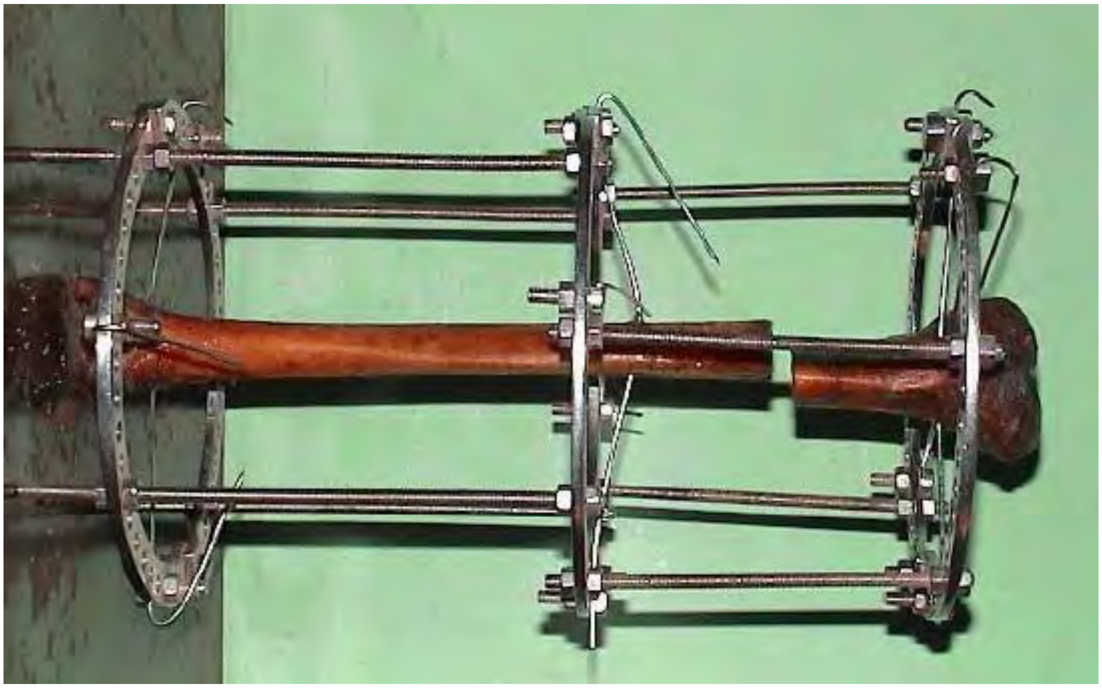


Figure 3.5 Ring construct on a model for Distraction Osteogenesis (Courtesy of [20]).

3.1.2 Charles Taylor

With a software program conjunction, the Taylor Spatial Fixator (TSF) can correct any deformity (from simplest to complex), malunions, and nonunions [17]. TSF consists of six telescopic struts and two full or half rings of Ilizarov connected with the struts through special joints called universal joints that can rotate and translate. Adjusting only the struts, the length of one side can be altered relative to the other, enabling correction of any deformities in six axes. The telescoping struts has three standard lengths: short (90mm-125mm), medium (116mm-178mm), and long (170mm-280mm) sizes.

Figure 3.6 Taylor Spatial Frame fixator with different rings (Courtesy of [17]).

3.1.3 Orthofix

Depending upon mechanical stabilization, bone healing proceeds by direct (primary), indirect (secondary) or a combination of the two procedures [12]. Direct/primary healing is when the fractured fragments are fixed with internal fixators or external fixators to make movement non-existent. The bone heals by crossing the fracture site where the fragments are in direct contact, which is extremely slow. Indirect/secondary healing is when there is some degree of freedom between the fragments reducing the gap between them. In this circumstance, external callus forms in the attempt to bridge the gap.

Rigid fixator normally works against the stimuli of nature. Pioneered by Orthofix surgeons, the concept of dynamization was introduced to circumvent the limitations of rigid fixators. The two types of dynamization are cyclic movement and progressive loading. Cyclic movement is opening and closing of fracture gaps in specified periods. Progressive loading is applying a controlled load at the fractured site with schedule. Many experiments have shown the important contribution of dynamization on callus formation for bone healing. The first Orthofix dynamic fixators were designed by De Bastiani which transfer progressive load at appropriate time on the fracture site. A modern Orthfix apparatus is depicted on Fig. 3.7.

Figure 3.7 Orthofix apparatus (Courtesy of [12]).

3.1.4 Hoffmann II

A surgeon from Geneva, Switzerland called Raoul Hoffmann, in 1938 designed an innovative External Fixation System. The basic features of this system were its modular design to make post-operative corrections to the alignment of fragments in three planes with the frame in situ and the ability to reduce fractures. The Hoffmann II system is designated for complete and temporary fracture fixations particularly for: open fractures or severe soft-tissue injuries, peri-articular fractures, intra-articular fractures where a joint bridging frame can be used, temporary fracture stabilization leading to definitive treatment, poly-trauma patients, and other indications including osteotomies and arthrodesis.

Surgeons are able to treat variety of indication using Hoffmann II systems because they are highly versatile to construct unlimited number of frame configurations. Some of these are ankle joint frames, pelvic frames, unilateral and bilateral tibia/femur frames (see Fig. 3.8).

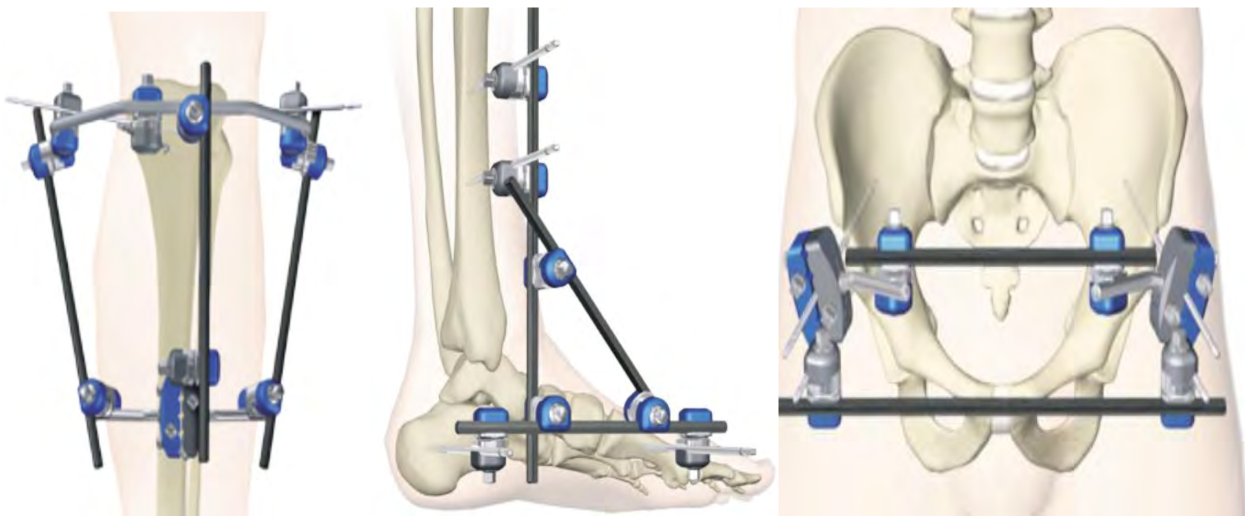


Figure 3.8 Hoffmann II Construction: bilateral tibia, ankle joint, and pelvic frames (Courtesy of [11]).

3.2 Principle Commonalities and Differences between External Fixators

The basic principles used by the External Fixation systems is to set the fractured limb in its natural position without distraction until the fracture is healed [10, 11, 12, 19]. All external fixators apply fixing half pin/wires into the bone fragments and clamping it on frames which are used to join sidebars to give stability. External fixators like Orthofix and TSF have axial progressive loading mechanism which helps for bone transport and deformity correction as opposed to the solid bars used in conventional fixators as a rigid fixation mechanism. Other external fixators like Hoffmann II and Zimmer have clamps that can be adjusted in every angle and also for different anatomical locations. Depending on the type of fracture, physicians decide the general set-up of the fixation system, the type of frames, pins and sidebars and the type of materials to be used during their procedures.

3.3 Biomechanics and Clinical Applications of External Fixators

There are basic biomechanical principles applied in designing external fixators for use in stabilization and alignment of fractured bone fragments [16, 19]. Failure to maintain stability and alignment causes catastrophic problems to the fracture. Most commonly, there are two types of conventional construction of external fixators: Unilateral where less than 90^0 of the limb sector is encompassed by the fixators, and Bilateral when more than 90^0 of the limb sector is encompassed by the fixators. Ilizarov rings, for example, often apply bilateral fixations. Both of these configurations (Unilateral, Bilateral) can be made in one plane or two plane setups as shown previously in Fig. 3.1. Increasing the number of pins/wires together with frames increases the stiffness of the fixator while decreasing access to the wound areas and ability to create micro-movements, which are required for bone healing and tissue atrophy reduction. This biomechanical principle is also applicable for circular frames.

There is a wide range of applications of external fixators [16, 20]. The major clinical utilizations of external fixators are compression, distraction, and/or neutralization of forces on the bone under consideration. Compressive forces can be used to fix transverse pelvic fractures, long bone fractures, joint arthrodesis, and congenital pseudoarthrosis. Distractive external fixation is used to treat ligamentotaxis, distal radius fractures, pilon fractures (demonstrated in Fig. 3.9), span comminuted long bone fractures and also bone lengthening. Thigh muscles are the largest and longest muscles which cause significant deformities on the leg unless an equal and opposite directional force is acted during the whole healing process [4, 21]. The biomechanics lays its foundation on continuously applying an equal magnitude force in reverse direction of the muscles' action (see Fig. 3. 10).

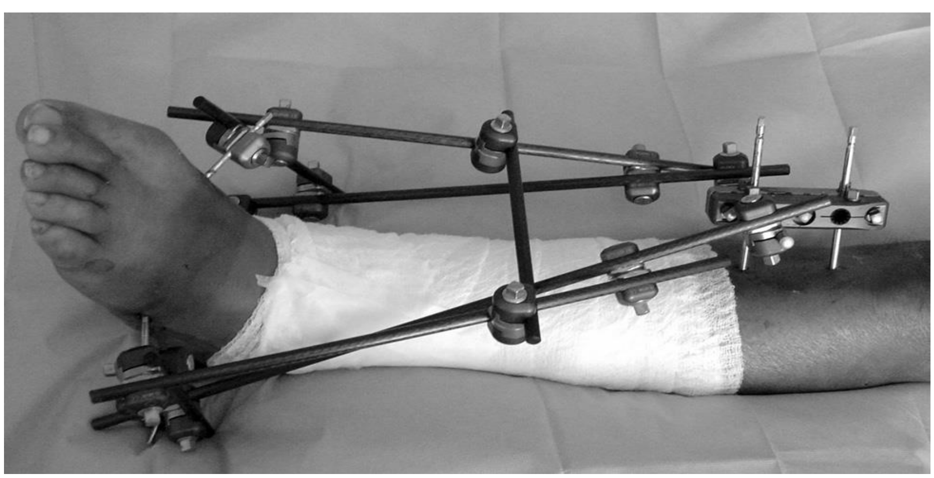


Figure 3.9 Treatment of pilon fracture using delta construction (courtesy of [16]).

Deformities of rotation are when the broken side rotates about its femoral axis from its normal position [5, 16]. In the state of no-fracture or resting, the pulling action of all the muscles is balanced and the femur remains in its natural position [7]. During proximal shaft fracture, Gluteal muscle together with Iliopsoas muscle pull out the small proximal fragments to the lateral side whereas Adductor Minimus and Longus muscles together with Adductor Magnus tract the longer distal portion to the lateral side. The compensation muscles of the adductors and extensors reduce the deformity deviation of mid-shaft fracture of the femur. Most of the distal fractures of the femur have lesser deformity relative to proximal fractures because most attachments of muscles are at the proximal fragment. While supracondylar fractures will have a greater chance for even more pronounced deviation because of hypertension which happens as a result of the pull of the gastrocnemius muscles [4] (see also Fig. 3.10).

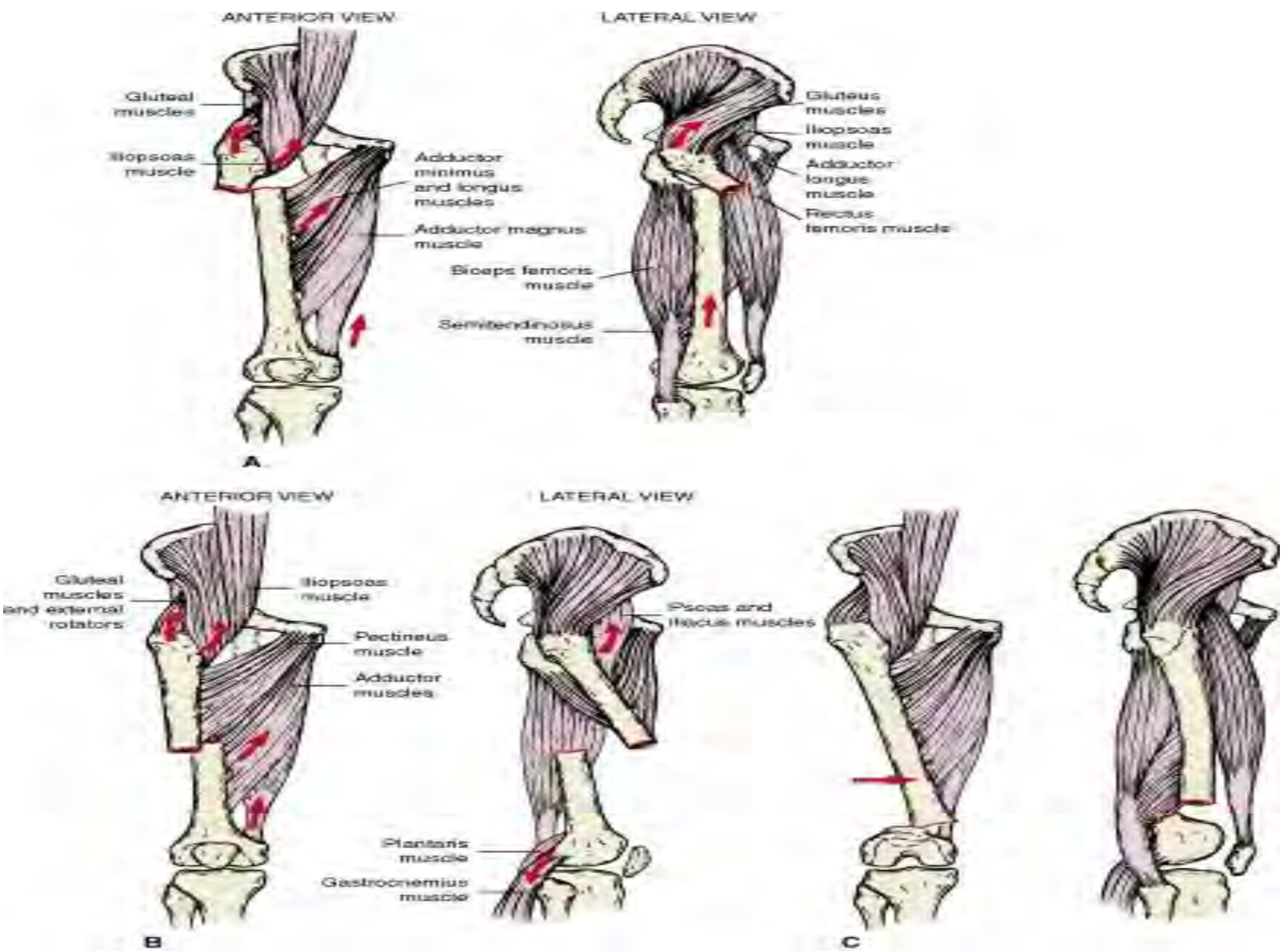


Figure 3.10 Femoral fracture deforming directions (proximal [A], mid shaft [B], and distal [C], due to unbalanced muscle forces (Courtesy of [16])).

3.5 Internal Fixators

Internal fixation is the gold standard method of stabilizing fractures absolutely [15, 19]. At present time, more surgeons prefer using internal fixation methods to fix a fracture of long bones. Internal fixation was started in 1858 by Julius Nicolaysen using nails for stabilization of femoral neck fractures, then Smith-Peterson developed four flanged and three flanged intramedullary nails for femoral fracture fixation [3]. Plates and screws are other internal fixation techniques commonly used (which are shown in Fig 3.11 below). There are different forms and applications of plates and screws. The common problem of internal fixators is the requirement of a second surgery. During cold weather conditions, internal fixators create pains; also there is sharing of the compressional force of the healing bones with the fixators which results in loss of full natural strength of the bones. Hence internal fixators are categorized as rigid types as movement in any direction is not possible, which in turn affects the bone healing process as well as functionality of the surrounding muscles.

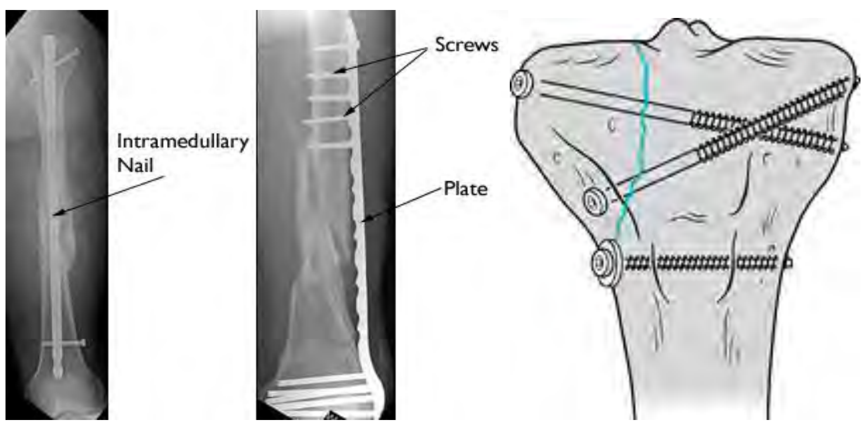


Figure 3.11 Internal fixation of femur using a nail, a plate and screws respectively (Courtesy of [19]).

3.6 Traction systems

Traction is a type of conservative treatment which is the act of pulling and drawing against a counter action of force to reduce pain and muscle spasm, to immobilize fractures, to prevent and correct deformities, to maintain good alignment and reduce possibility of further fractures [21, 22]. Three major types of tractions exist: manual, skin and skeletal. When using manual tractions, we directly pull off the fracture by hand; skin tractions apply straps around the body and the straps are pulled with cords or ropes; and skeletal schemes use a pin or wire inserted into the bone and the wire is pulled underweight attached with a cord.

The idea of isotonic traction, i.e. suspending a weight attached to the leg by a cord over a pulley attached on a bed frame, for the treatment of fractures of the femur is believed to begun in 1519 G.C by Guy de Chauliac [21]. For over 500 years, the method had only limited use due to practical considerations. In the nineteenth century, the technique was implemented widely for treating femur fractures without changing the system setup.

For both traction systems (skeletal and skin), the counterweight, which is mostly the patient's body, is a leading factor which is built for each patient considering their weight. Before setting up the system, the necessary tools and equipment must be prepared. The common materials used for both skin and skeletal traction systems are orthopedic bed, cords, sack of loads, slings/straps, and frames. Different additional materials and tools are used depending on the system type. Figure 3.12 below demonstrates a typical traction setup still in use for pateints admitted at the Black Lion Hospital, Addis Ababa, Ethiopia.

Figure 3.12 Traction setup at Black Lion Hospital, Addis Ababa, Ethiopia (date picture acquired: 3/23/2016).

Chapter 4

Proposed Advanced External Fixator System

For designing the mechanism for the new external fixator appliance, a thorough review of long bone fracture fixation devices which have been in use by orthopedic surgeons in recent years has been carried out in the current study [10, 12, 16]. External fixator is one of the common methods still practiced by most hospitals of the developing countries. Improving the construction setup of such systems could have vital importance so that they work more effectively and efficiently. Orthofix, Hoffmann II and Taylor Spatial Frame Fixator (TSF) are the other External fixation systems used as a reference for drafting the new traction appliance in this thesis project.

The core concept of all traction systems is to apply a continuous load of weight in a different direction to bring the resultant force course parallel along the bone axis [14, 23]. The continuous force application gives the muscle tensional load reserving it from myo-atrophy during the healing process which may take long time [23]. Sleeping only on one side for a long period of time comes with various complications including: restricted patient mobility which could cause social and physiological depression, bed sore, muscle atrophy and stiffness on the joint of the limb (which could pose challenges on the patient's leg functionality after recovery), need for strict follow-up of patient's movement (for example, position shift could result in nonunion or malunion and loosening of the pin fixation) which does not guarantee the fractured limb not to have deformities after healing [24]. Other issues include excess weight loading which might result in further fractures, pneumonia and bronchopneumonia and urinary system infections. In order to overcome these issues, a way should be devised so that the device is attachable only to the patient with accurately measurable applied load and displacement. Figure 4.1 shows fracture healing as a function of time during cyclic micro movement and progressive loading.

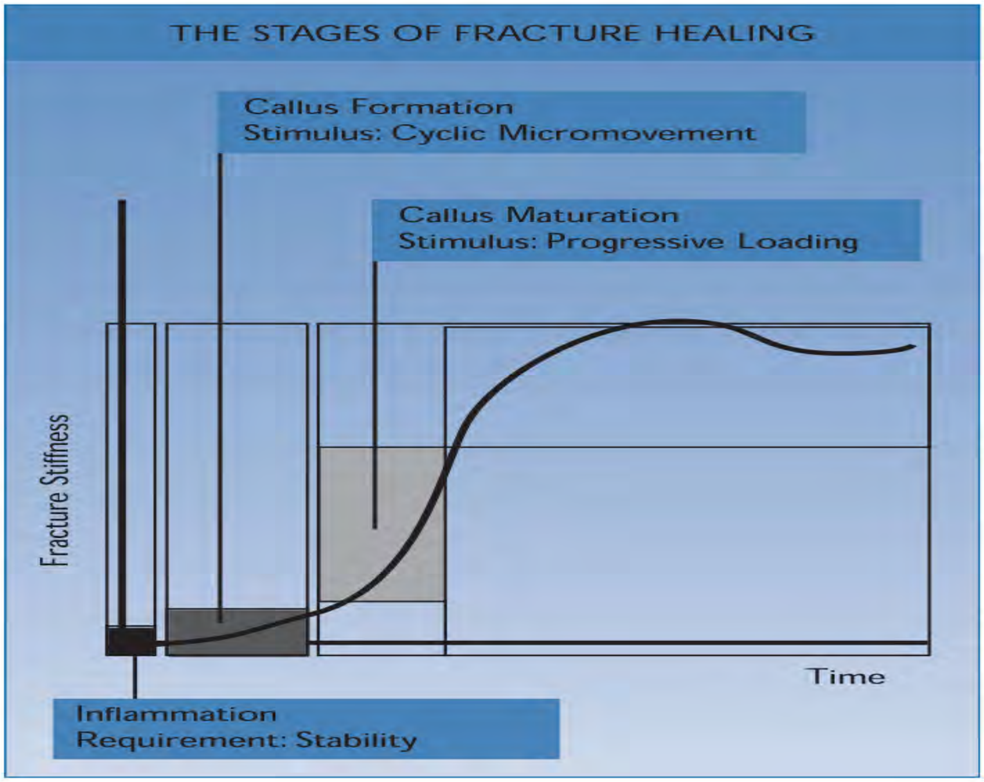


Figure 4.1 Fracture healing during cyclic micro movement and progressive loading (Courtesy of [12]).

The major problem of all external fixators, however, is that there is no continuous load application which results in their inability to facilitating bone healing process, avoid myoatrophy and stiffness (in case of fixation on joints) [16, 18, 19]. The micro-movement and progressive load application presumably fasten the healing process plummeting the time for the patient to stay together with the fixators thereby reducing complications and contribute to the patient's comfort.

Hybridization of the good features of external fixators and traction load can improve the system to better function. Continuous load is possible with the traction device and the external fixator allows the device to be attached only to the patient's leg with clamps and pins. In this regard, modifying the bars used to join opposite side of the fracture to give optimal stability is one issue. As described above, almost all the conventional external fixators use solid bars made of different materials that can give light weight, strength, and radiolucent to X-ray. The proposed system will have advantage of both the external fixator and traction system.

4.1 Designing the Proposed Appliance

The following flow chart shown in Fig. 4.2 presents the steps used to design the traction device proposed in this thesis.

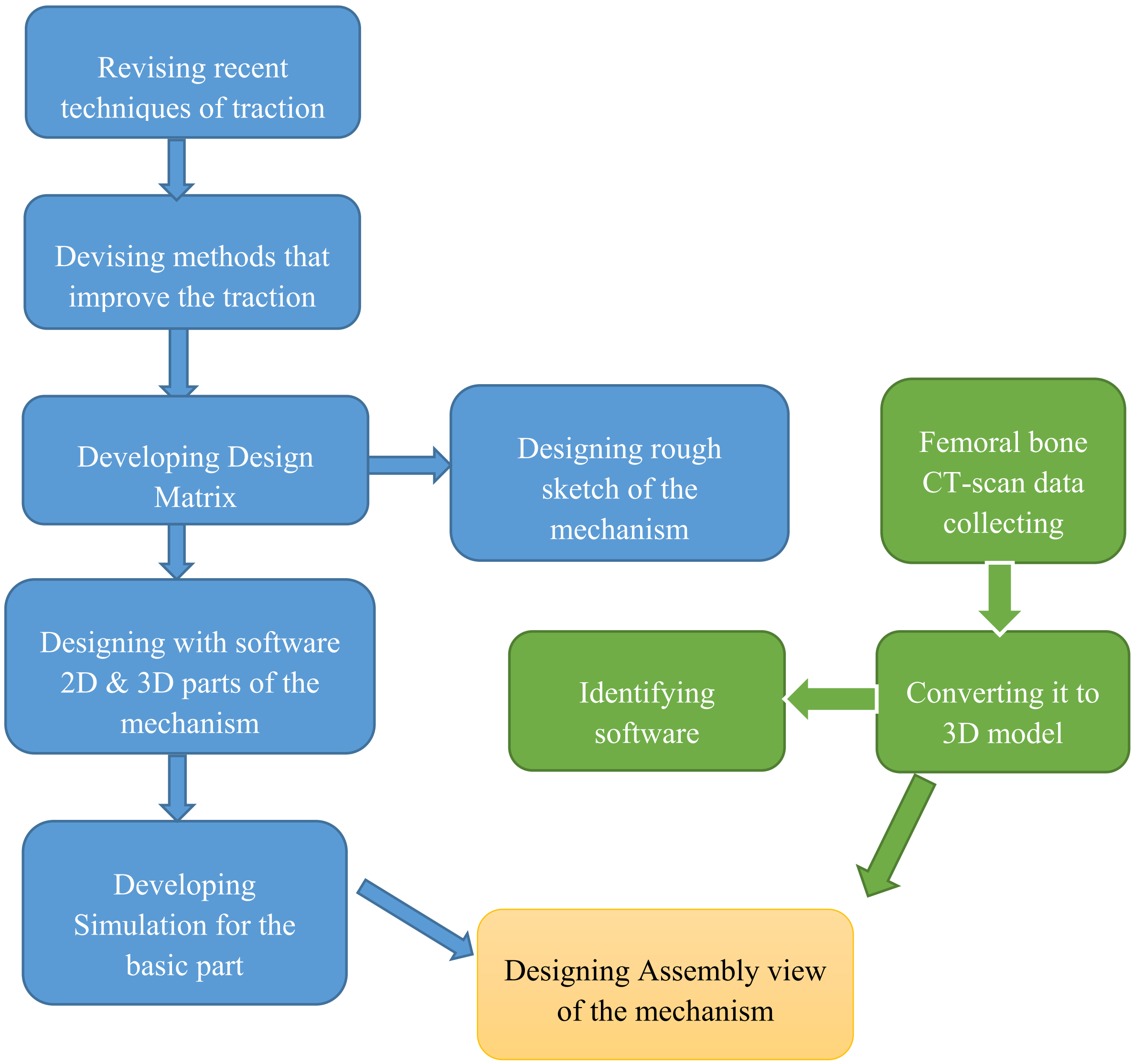


Figure 4.2 Flow chart showing the traction device design process.

The first step is to get familiar with the chosen design software "Solidworks". Solidworks was used to design 2D and 3D components of the new traction system. The simulation of the basic components of the mechanism part is also done by this software. The target is to have dimensioned parts which could be fabricated with little modification. The final step is to show the assembled view of the mechanism with the femur bone using this software.

4.2 Softwares used to Design and Simulate

Developed by Dassault system, Solidworks is often used for seamlessly designing different parts for manufacturing purposes. It can do models from part design, assembly, simulation, and product data management. The sketching starts in new windows for each part and saved as a 3D model in any file place. 2D sketch and assembling parts have their windows to select. After finishing the modeling process in parts window, one can open 2D or assembly window to model it in 2D or insert it into assembly. For the purpose of validating a certain design, the simulation tool built in Solidworks could be used. Cost estimation, rendering, animation and product data management are other benefits of Solidworks. Solidworks is hence a basic tool used in design, validation, collaboration, and building [25].

InVesalius3.0 is a software used for medical image 3D reconstruction by importing DICOM 2D image slices acquired with CT or MRI. The software was developed by Tatiana Al-Chueyr, et.al. and it can store to different file formats like STL, JPG or for rapid prototyping [26]. The CT-scan data of the whole body was downloaded from a free source (*http://www.osirix-viewer.com/resources/dicom-image-library/)* and imported into InVesalius 3.0 by reducing the number of slices as the number of 2D slices was too much for our purpose, and a 3D image was then reconstructed [27].

To convert the 3D image reconstructed by InVesalius 3.0 into mesh structures for editing purpose, a software called MeshLab was used. MeshLab was developed by Visual Computing Lab-ISTI-CNR and enables us to change scan points to mesh structures or point cloud formats.

4.3 The Design and Decision Matrices

A design matrix is a tabular form used for comparing different design ideas generated by creating decisive criterions as design specifications. The requirements for a design matrix are at least three feasible design alternatives with short, self-explanatory titles, and 6-10 categories are sufficient to compare [28]. For each design alternative, a 1-5 score is assigned where 1 is the lowest and 5 is the highest score. The rating (1-5) is then multiplied by the weight and cumulatively divided by the total score. The total weight must add up to 100. The design criteria weight is listed beside the respective criteria list in descending order of importance. The design matrix in this thesis was generated based on comparison done on three alternative designs. The basis for these three designs was the type of load exerting method used at the connecting bar: pneumatic, manual or hydraulic.

The decision matrix is the arrangement of the design attributes in ranking order to achieve the design solution. ‘Cost’ and ‘Safety’ are two regular criterions for developing design matrices while the others should be focusing on medical device design customary. One of them is ‘Patient Comfort’, which is the major component of the design matrix in our case. This is so as the traction device remains with the patient for a long time (at least for 3 months). A good such design avoids the pain on the joints due to pulling force of gravity while the patient walks or sits. Appropriate size and shape of the device also contribute to patients’ comfort.

‘Manufacturability’ is the other criteria for selecting from alternative designs. After the complete design of the device, the parts should be fabricated with the available materials. ‘Ease of Use’ refers to the easiness of the system for operation. Physicians should be able to operate and use the device with little effort. ‘Durability’ is the strength of the device to be used again and again for different patients. ‘Adjustability’ of the device is critical criteria because the device may not necessarily be adjusted only by physicians or professionals. Instead, most of the time the patient/family or other local staffs do the adjustment when necessary. Table 4-1 presents the decision matrix created to design the traction system proposed in the current study with all entries.

Table 4-1 Decision Matrix

	Patient comfort	**Adjustability**	**Durability**	**Ease of use**	**Manufacturability**	**Safety**	**Cost**	**Total sum**
Patient comfort		0	0	0	0	0	0	
Adjustability	1		0	1	1	1	0	
Durability	1	1		1	1	1	0	
Ease of Use	1	0	0		1	1	0	
Manufacturability	1	0	0	0		1	1	
Safety	1	0	0	0	0		0	
Cost	1	1	1	1	0	1		
Total	6	2	1	3	3	5	1	21
Percentile	**30**	**10**	**5**	**15**	**15**	**20**	**5**	**100**

From the table, we see that ‘Patient comfort’ scored highest compared to the others with percentage value 30. The rest criterions scored in descending order as follows: safety = 20; Ease of use = 15; Manufacturability = 15; Adjustability = 10; Durability = 5 and Cost = 5.

Once the decision matrix is computed, the next step is creation of the design matrix to make a tabular comparison between the pneumatic, manual and hydraulic alternative systems with respect to the criterions used to derive the decision matrix. A rank of 1-5 was assumed where 1 means poor, 2 fair, 3 good, 4 very good and 5 excellent. These values are given depending on practical situation of the mechanisms observed on other devices. Accordingly, patient comfort is more suitable in case of manual systems rather than pneumatic and hydraulic ones. This is mainly because the weight of pneumatic and hydraulic systems is more than manual systems due to the pump required to push the air and the hydraulic fluid. Also, the sound they create during operation (each time the device is extended) could be discomfortable to patients. Use of pneumatic and hydraulic systems for a long time could result in leakages which could be a safety risk. This could indirectly reduce the load needed for traction. It is also clear that assembly and setup of the mechanism for hydraulic and pneumatic systems is much more difficult than manual systems which are often easy to use and adjust. Manufacturing the hydraulic and pneumatic parts particularly in low resource setting is presumably more difficult than the manual counter-parts. Also, the number of parts that need to be assembled in constructing pneumatic and hydraulic systems is more than that of manual systems. Not only that, the cost of the parts is also high for hydraulic and pneumatic systems due to costly manufacturing and materials required for fabrication. Durability increases for hydraulic and pneumatic systems because of the quality materials they are made of and quality fabrication. Typical sketches of pneumatic, hydraulic and manual systems are shown in Fig 4.3 below.

Table 4-2 Design Matrix

Criteria's	**Weight**	**Alternatives**		
		Pneumatic system	Hydraulic system	Manual Spring system
Patient Comfort	30	3*30=90	2*30=60	4*30=120
Safety	20	2*20=40	1*20=20	4*20=80
Ease of Use	15	4*15=60	2*15=30	5*15=75
Manufacturability	15	3*15=45	3*15=45	4*15=60
Adjustability	10	4*10=40	4*10=40	5*10=50
Durability	5	4*5=20	4*5=20	3*5=15
Cost	5	3*5=15	2*5=10	4*5=20
Total	100	310	225	**420**

(a) (b) (c)

Figure 4.3 Pneumatic system (a), Hydraulic system (b), Manual system (c) (Designed with Solidworks)

Results derived from the design matrix presented in Table 4.2 above showed that a manual system is a preferred choice than a pneumatic or a hydraulic system. Accordingly, a detailed design process of a manual traction appliance proposed in this thesis is presented in the next chapter.

Chapter 5

Designing the New Appliance

This chapter mainly deals with the mathematical foundations and design calculations as well as the 3D modeling representations of the newly proposed appliance. Mathematical computations consider manufacturability, ease of operation and durability of the system. Materials used for fabrication could be changed depending on their availability as well as other designer's criterions. In the current thesis work, aluminum alloy of 1060 for the screws and compressing tubes due to their light weight and ease of fabrication were selected. Compressional spring is the major part of the system. An Ilizarov ring and Hoffman II pin clamping and/or Orthofix clamping devices were used to connect the new appliance with the bone.

5.1 Design Parameters

The load applied on the fracture site is the parameter for designing the screws and the spring. Skin traction loads typically range from 2-16kg while for skeletal tractions 11-18kg loads are commonly applied [24]. The mechanism proposed in the current study could be used for both skin and skeletal loads. As the skeletal load is higher than the skin load, the former style is used for designing purposes assuming the same design could be used for both systems. The device weight, sustainability during fine-tuning and post adjustment and cosmetic are other proceeding factors to be considered respectively after justification of the prototype.

5.2 Extending Screw Design

The strength determination for a thread is very complicated because the male threads pull the female threads, or vice versa and the threads fail in shear, not in tension [29]. Therefore, the stripping strength of an assembly depends on the shear strength of the nut and bolt materials.

5.2.1 Thread Terminologies

A form of a helix ridges on either internal or external surface of a cylinder in a uniform section is a screw thread; bolts, studs, or screws are examples of external threads and tapped holes are examples of internal threads [30]. The deep part of the thread is the Crest and the bottom part is the Root while the line joining the two is the Flank.

5.2.2 Thread strength formula

When designing threads, two fundamental rules should be considered [29, 30].

- **i.** To make sure that the threaded fasteners are recognized under standards such as ASTM, ANSI, DIN, ISO or other standards.
- **ii.** The design should promote prior to stripping the male/female threads breaking off bolts under tension. Because broken bolt is an obvious failure rather than stripping threads which are unpredictable after installation.

Multiplying the ultimate tensile strength by its tensile stress area simply will give the amount of force required to break the bolt. But determining the strength of the thread is more complicated. Internal thread strength formula is given by:

$$F = Su * Ats \tag{1}$$

Where, Su is the shear strength of the nut or tapped material and Ats is the cross sectional area through which the shear occurs.

$$Ats = \pi n Ledmin\left[\frac{1}{2n} + 0.57735(dmin - dpmax)\right] \tag{2}$$

Where, n is thread per inch or 2.54cm; $dmin$ is the minimum major diameter of external threads; $dpmax$ is the maximum pitch diameter of internal threads; Le is the length of thread engagement.

The profiles of a thread are mostly classified using standards while, the ISO or UN are commonly used once. The basic thread profiles (UN or Metric class) have a flat surface at the root with approximate dimensions of a quarter of the pitch. In the case of ISO rounded fillet at the root is the profile [31, 29].

Radial relationships between the major and minor diameter from the above figure metric thread with flat profile can be driven as:

$$dr = d - 1.299038p \tag{3}$$

$$dp = d - 0.649519p \tag{4}$$

In the current study, aluminum was selected due to its light weight and ease of fabrication, while other metals or plastic rods could be used instead for the same purpose.

Using the 1060 alloy aluminum we have:

Shear modulus, $Su = 275321.7\ Kgf/Cm^2 = 2.7*10^6 N/cm^2$

Applied force, $F = 180N$, because 18kg is the maximum weight suspended for skeletal traction. Therefore , $Ats = \frac{F}{Su}$, from Eqn. (1):

$$Ats = \frac{180}{2.7} = 66.67*10^{-6}cm^2 = 66.67*10^{-4}mm^2 = 0.006667mm^2$$

Which means threads having this cross sectional area could be used to support the load. Comparing this *Ats* result with the values in appendix A, with respect to both the nut and bolt tensile stress area and minor-diameter area, it is almost negligible. Even the smallest diameter used in Appendix A, i.e. 1.6mm and pitch 0.35 mm have 1.27 mm^2 tensile area, which is 1.26mm^2 more than the tensile area computed. This indicates that we can select any standard pitch diameter (starting from the minimum shown in Appendix A) to design our screw to be used for the proposed traction system in thesis.

The other basic parameter considered to decide the diameter of the threaded shaft is buckling/bending due to the applied load because a wire can be robustly strong under tension but gets distorted easily under a small compressive load [29].

Many previous studies have shown that it is difficult to give body proportions for all human beings [32]. For the Pygmies of Africa, for example, the minimum height is 144.9cm for men and 136.1cm for women whereas for Dutch of Europe it is 184cm for men and 170.4cm for women respectively. The length of the femoral bone for adults is roughly computed as a function of height as:

Femoral bone length= (Height – 65.53)/2.32 for male and (Height – 54.13)/2.47 for females [32]. Estimating the average height to be 175cm for male and 165cm for female, the femoral bone length would be around 47cm and 45cm respectively. Accordingly, the proposed traction device could assume an assembly length of maximum 40cm leaving 7or 5cm for clearance. From the 40cm length, the screw to be designed will segment more than 10cm length. Using Euler equation, the diameter of the rod subjected to compressive load should be determined in order to avoid buckling because the segment of the rod will have more than 10cm length.

Using the Euler column formula, $Pcr = \frac{C\pi^2 EI}{l^2}$ (5)

Where, *Pcr*= critical load, *E*=Young's modulus, *I*= moment of inertia *C*= end-conditions, and *l* is the length. The recommended value for the constant C for ends fixed at both sides is 1.2. Assuming the rod is a round aluminum 1060 alloy, the diameter could be computed from the equations, $A=\pi d^2/4$ and $k = \sqrt{\frac{I}{A}}$ $= [(\pi d^4/64)/(\pi d^2/4)]^{1/2} = d/4$. Then using the expression for *Pcr* derived in Eqn. (5) above the diameter can be computed as: $d = \sqrt[4]{\left(\frac{64Pcrl^2}{\pi^3 CE}\right)}$

But $Pcr=180N, l=100mm, C=1.2, E=7.034*10^4 N/mm^2$

Therefore, $d = \sqrt[4]{\frac{64*180*100^2}{\pi^3*1.2*7.034*10^4}} = (44.0165)^{1/4} = 2.58mm$

That means a rod with minimum diameter of 2.58mm with a length a minimum length of 100mm can withstand a maximum load of 180N with any pitch of thread greater than or equal to 0.35mm.

Manufacturability and comfort are other parameters that need to be considered during the screw design. This could be attained if accurate advancement could be guaranteed during adjustment. Based on results presented in Appendix A, selecting 10mm nominal major diameter and fine-pitch of 1.25mm screw with 1060 aluminum alloy material is sufficient to do the purpose.

5.3 The Loading Spring Design

Spring is a mechanical object that deforms when acted upon by external force and returns to its original shape when the external force is removed [29, 33]. There are different forms and types of springs while each kind has its own functions. The major functions of the spring are absorbing energy and mitigating shock, applying a definite force or torque, isolating vibrations, indicating or controlling loads or torque, as well as providing an elastic pivot or guide. This is of course the part that made the proposed traction device quite novel. As energy stored is the multiplication of force and deflection length, high tensile strength materials which contain 0.8 to 0.9 percent carbon (fabricated by cold drawing known as A227) are selected from Appendix A for designing the spring used for this thesis project. Another principle applied during spring design is spring rate (a change of load or force per unit deflection) which is a basic goal for our design because micro-movements and progressive loadings have significant effect on physiology and bone healing process.

5.3.1 Helical Round Wire Compression Springs

In machine design, different types of springs are implemented for a variety of applications. For our system compressional helical round wire springs are preferred because they are efficient, cheap to manufacture particularly in bulk, and need compact space [29, 33].

5.3.2 Design Elements of Compressional Spring

Major design elements of a compressional spring are the winding direction left hand or right hand (particularly when the spring is used over threads) and spring ends (generally compressional spring ends are divided into four: plain ends, closed or squared plain ends, ground ends, and square-ground ends). For better transfer of force or load, square-ground ends are preferable [29, 33]. The four compressional spring ends are depicted in Fig 5.2 below.

Dimensions of the spring are the other important factors for designing it. In our scenario, the outer and inner dimensions conclusive for developing the cylinder dimensions, the spring index (which is the ratio of the mean diameter to the wire diameter of the spring) as well as the free length and solid height, were considered during designing [29, 31, 33] (see Fig. 5.3 below).

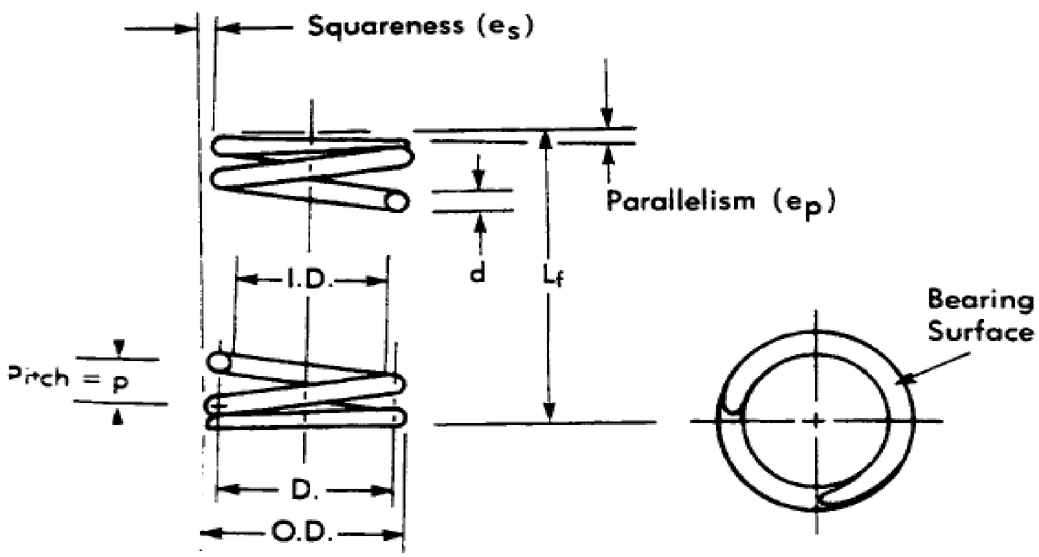


Figure 5.1 Helical Compression Springs Dimensional Terminology (courtesy of [32]).

5.3.3 Design Calculation

For good operation and manufacturability, a spring index (C) of 8 to 10 and active coil numbers values $3<Na<15$ to maintain linearity are recommended [29, 33]. Our traction load applied axially ought to generate a weight in the range 11-18kg which is equivalent to 110-180N. Following our screw design, we have a major diameter of 10mm screw which would be the inner diameter of the spring.

The recommended design constraints for a spring operating in free area are:

$4 \leq C \leq 12; 3 \leq Na \leq 15;\ \xi \geq 0.15;\ ns \geq 1.2$

$L_f < \pi D/\alpha\ [2(E - G)/2G + E]^{1/2}$, which means for HD A227, $L_f < 4.116D$

The data we have are a maximum force of 180N and we assume a deflection length of 5cm (the maximum possible traction length), and we have also the inner diameter to be > 10mm or ID = 10mm + clearance.

The minimum diametric clearance between the spring and cavity or rod is:

0.05D - when D_r is greater than 13 mm (0.512 inch)

0.10D - when D_r is less than 13 mm (0.512 inch)

Where D_r is the diameter of the rod or cavity.

$ID = D - d$, therefore, $D - d = 10mm + clearance$

$D - d = 10mm + 0.1D$

$$0.9D = 10mm + d \tag{6}$$

Prior decisions have to be made regarding the type of material to be used and estimated diameters of the wire. Here we chose to use hard drawn wire A227 due to its low cost and availability, the spring to be square and ground, and robust linearity $\xi = 0.15$.

We will start by selecting our wire diameter to be 1mm. Thus from Eqn. (6) we have

$D = \frac{10+1}{0.9} = \frac{11}{0.9} = 12.22mm$

From Appendix A, for hard drawn wire *m=0.190, A= 1783 Mpa. mm^m, hence d=1mm*

The ultimate tensile strength is $S_{ut} = \frac{A}{d^m} = \frac{1783}{1^{0.190}} = 1783\text{Mpa}$

The torsional yield strength for hard drawn wires is assumed to be:

$S_{sy} = 0.45 S_{ut} = 0.45 * 1783 = 802.35\text{Mpa}$

The spring index is $C = \frac{D}{d} = \frac{12.22}{1} = 12.22$

The curvature effect $K_B = \frac{4C+2}{4C-3} = \frac{4*12.22+2}{4*12.22-3} = 1.109$

Allowable shear stress, $\tau_s = \frac{K_B 8(1+\xi)FmaxD}{\pi d^3} = \frac{1.109*8*(1+0.15)*180*12.22}{\pi*1^3} = 7143.536$N/mm^2

Factor of safety at closure $n_s = \frac{S_{sy}}{\tau_s} = \frac{802.35}{7143.536} = 0.112$

Outer diameter $(O.D) = D + d = 12.22 + 1 = 13.22$mm

Number of active coils is: $N_a = \frac{Gd^4 y_{max}}{8D^3 F_{max}}$. But from appendix A, $G = 80.0GPa = 80{,}000Mpa$ and hence

$N_a = \frac{80{,}000*1^4*50}{8*12.22^3*180} = 1.522$

Again from Appendix A, we have Total number of coils $N_t = N_a + 2 = 1.522 + 2 = 3.522$

Solid length of the spring $l_s = dN_t = 1 * 3.522 = 3.522$mm

Free length of the spring $l_f = y_{max} + l_s = 50 + 3.522 = 53.22$mm

Repeating the above procedure for different wire diameters and analyzing which one fits to the recommended condition allows us to find the final dimensions of the spring.

The Matlab code shown in Appendix B generates results for the constraints and compare it against the recommended design conditions. Wire diameter of 1.5mm is the ideal value for the spring. Evaluating the result of the Matlab code with the spring design constraints, a spring with minimum wire diameter d ≥ 1.5mm, and minimum number of active coils Na ≥ 7 is efficient to exert maximum force of 180N. From the above formulas the spring outer diameter (O.D) =12.78mm**.**

5.4 Designing Compressing Cylinders

The design of compressing tubes or cylinders is driven by the screw and the spring dimensions. The cylinders are used to guide and support the spring. In addition they are used to fix load sensor and length label indicators. The dimensions of the cylinders are derived from the screw rod and spring magnitude results. Figure 5.4 shows the internal and external cylinders designed using Solidworks.

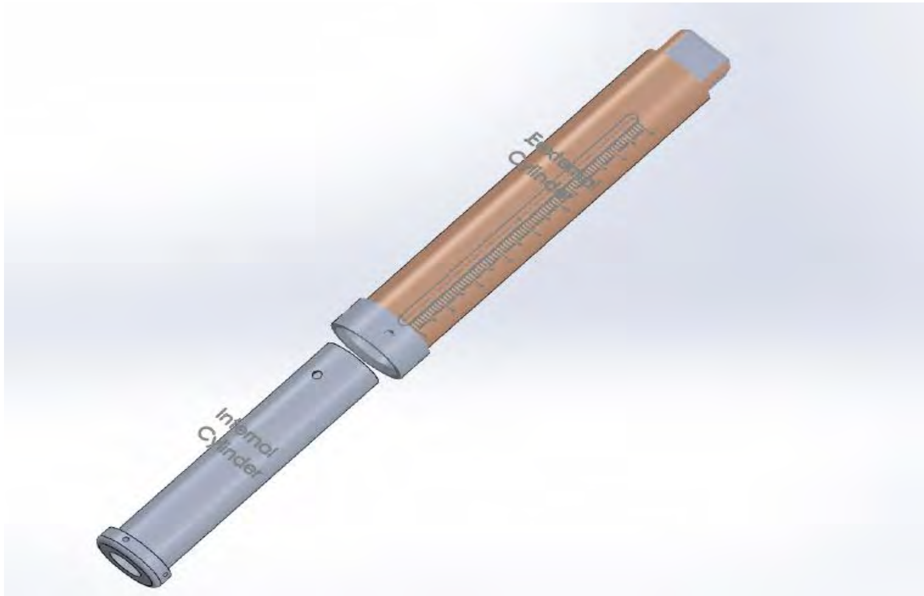


Figure 5.2 External and Internal Cylinder (designed with Solidworks).

5.5 Measurement Setup

Two types of measurement systems are included in the new appliance [30]. The first is length measurement. Traditionally physicians use measurement tapes to manually adjust the length of the fixation device as needed. On the proposed system, the slot on the external cylinder is inscribed by millimeter measurements to let the physician easily adjust the length of the fixator. The second measurement tool embedded on the proposed device is comprised of digital compression load cells used to measure the load applied during tightening the screws. These cells are available on the market and can measure loads at any precision and required load range. The cells are fixed on the external cylinder and compressing cylinder to read the applied force when the spring is compressed. Sample load cells with different designs are shown on Fig. 5.8 below.

Figure 5.3 Load cells of different model and display system (from SENSY's and EILERSEN).

Chapter 6

Results and Discussion

This chapter discusses the design and simulation results of the proposed traction model and points out some of its limitations. The detailed 3D view of the model is included in appendix D with 2D view including their dimensions. The final design of the proposed appliance has passed several developmental processes

6.1 Designed Parts

The main finding of this thesis is a mechanism that is foolproof while torqueing and which have benefits for both soft tissue and bone healing process. The 3D view as well as assembly view of the mechanism is shown in this chapter.

Figure 6.1 below shows the assembly parts of the new appliance which are designed using Solidworks software. The transparency and exploded views of the assembly are depicted in Fig. 6.2 and 6.3 respectively. Also, the setup when used together with different frames is shown. The detailed design steps are listed under Appendix B. The bilateral as well as the unilateral views of the complete fixation device are shown in Fig. 6.4 and 6.5 respectively. The proposed fixation system coupled with Ilizarov ring system is shown in Fig. 6.6.

Figure 6.1 Assembly view of the new device (designed using Solidworks).

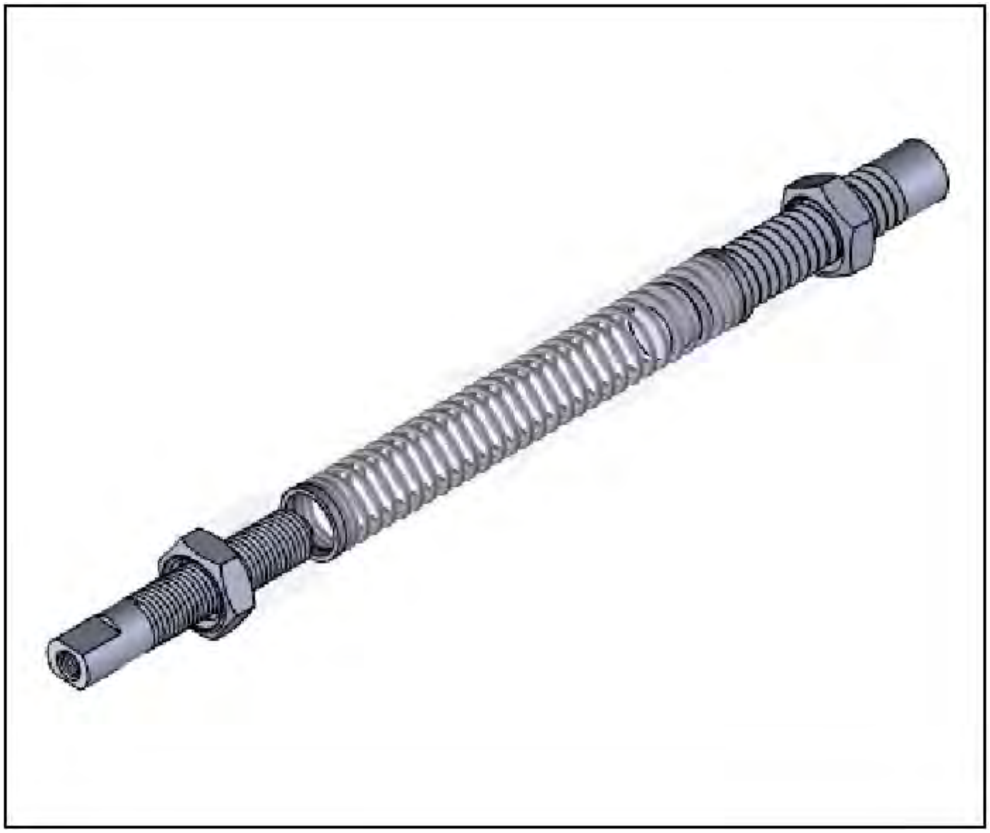


Figure 6.2 Transparency view of the assembly (designed using Solidworks).

Figure 6.3 Exploded view of the assembly (designed using Solidworks).

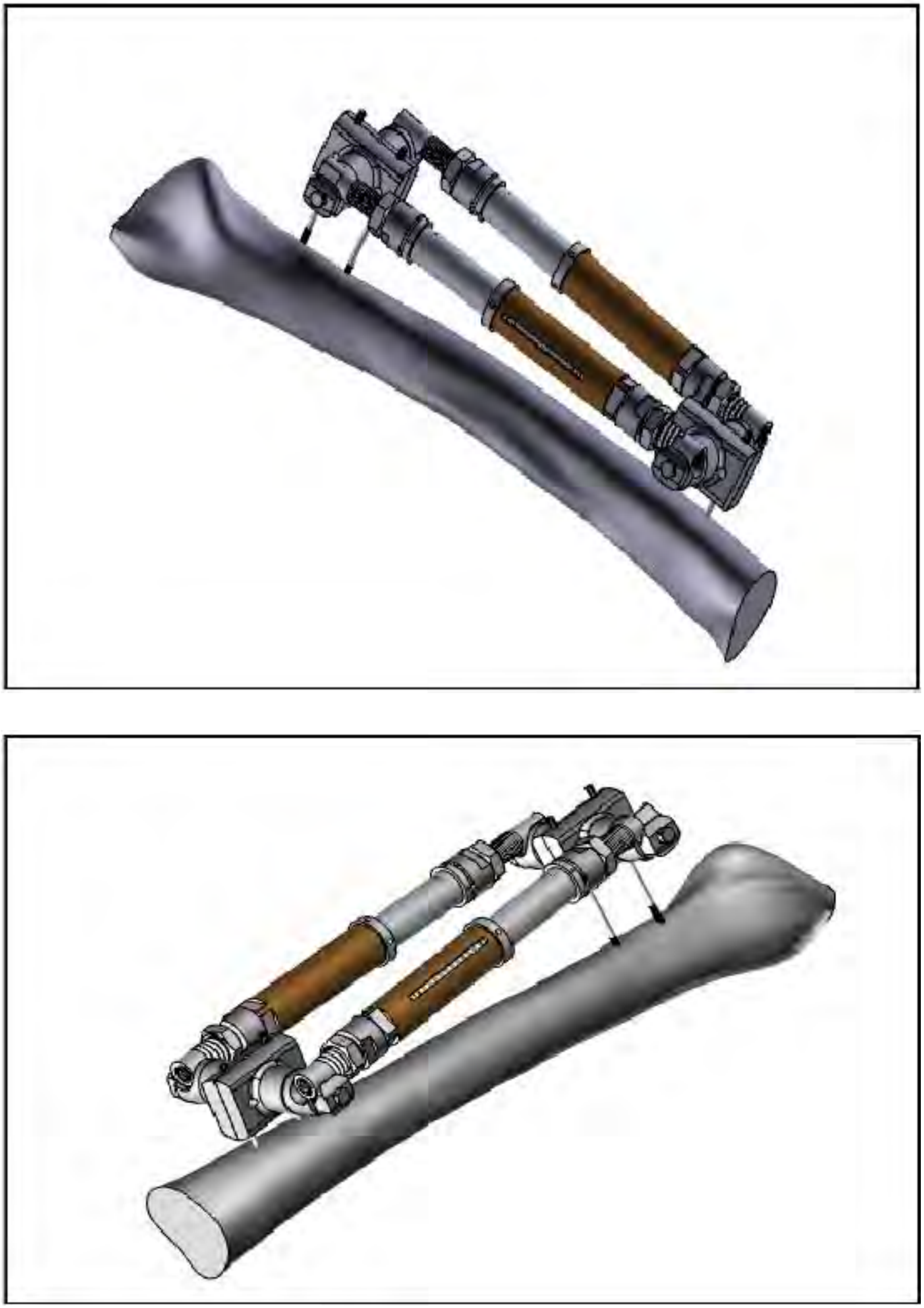


Figure 6.4 Bilateral fixation design (designed using Solidworks).

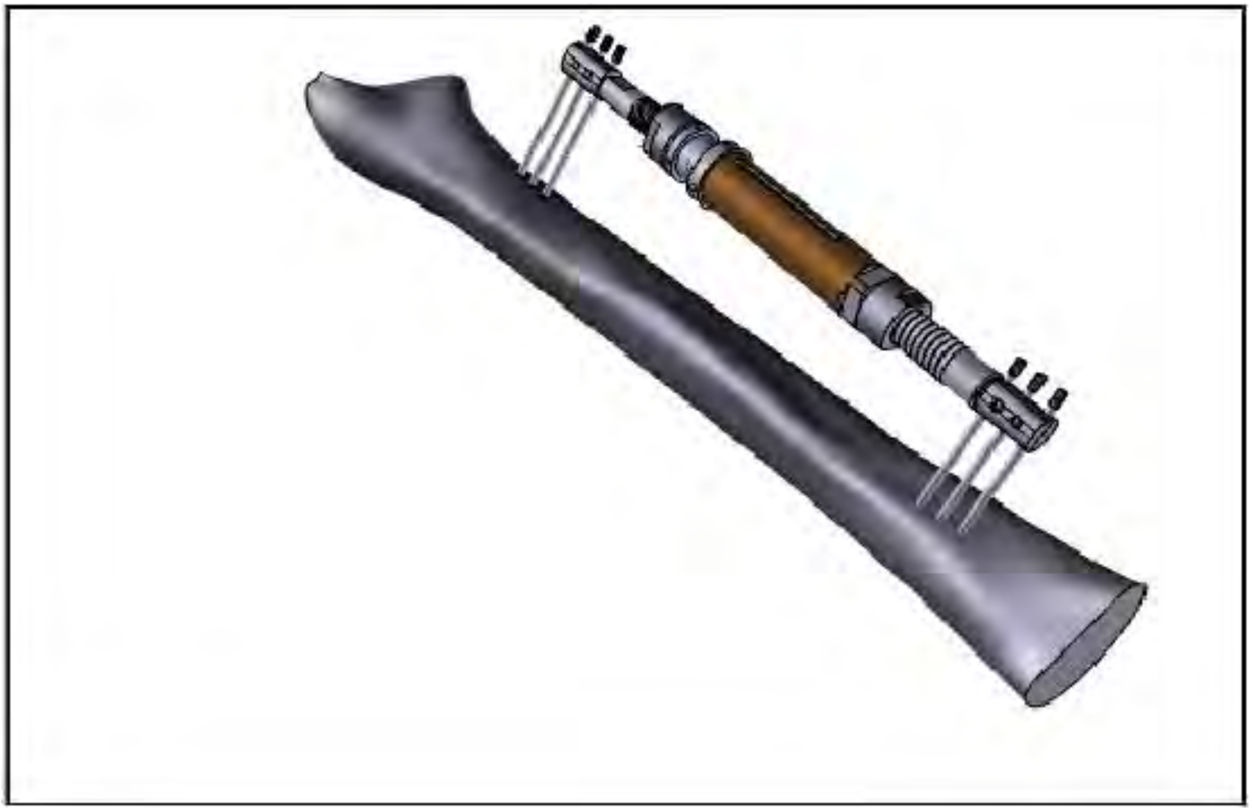


Figure 6.5 Unilateral fixation system (designed using Solidworks)

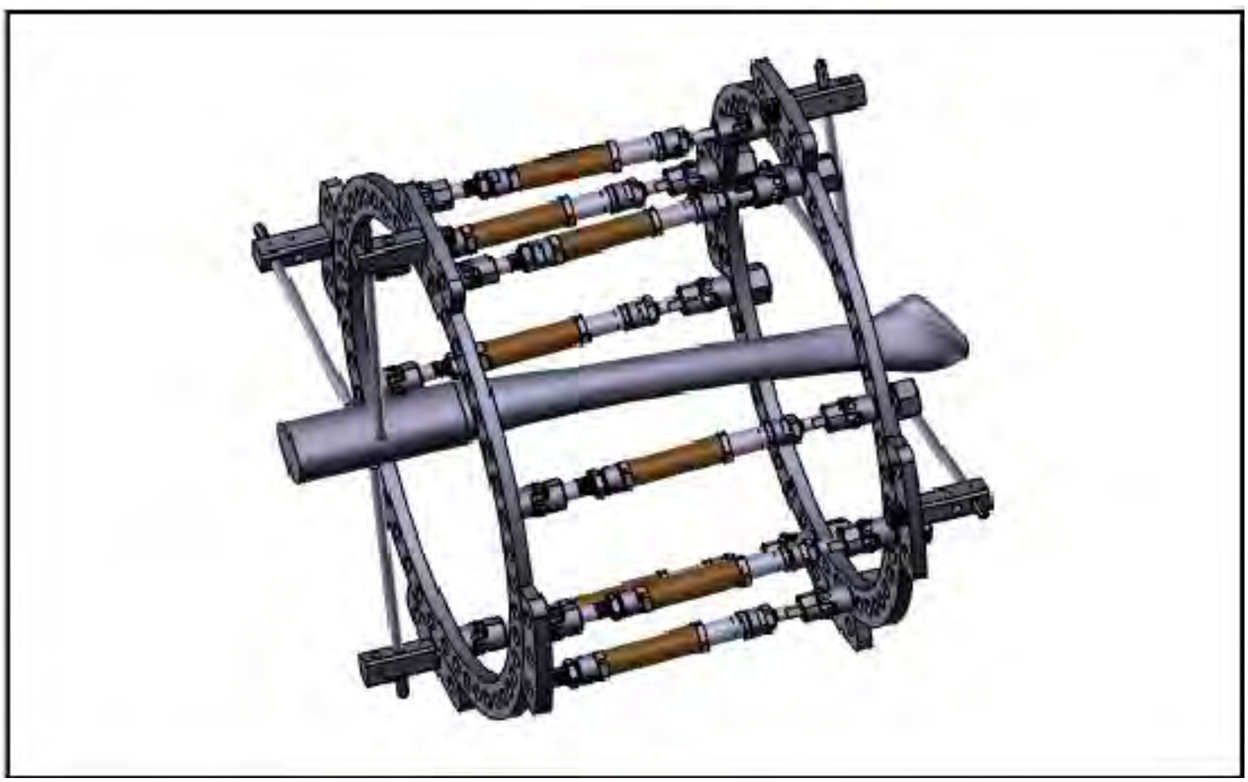


Figure 6.6 Ilizarov ring coupled with the proposed fixation device (designed using Solidworks).

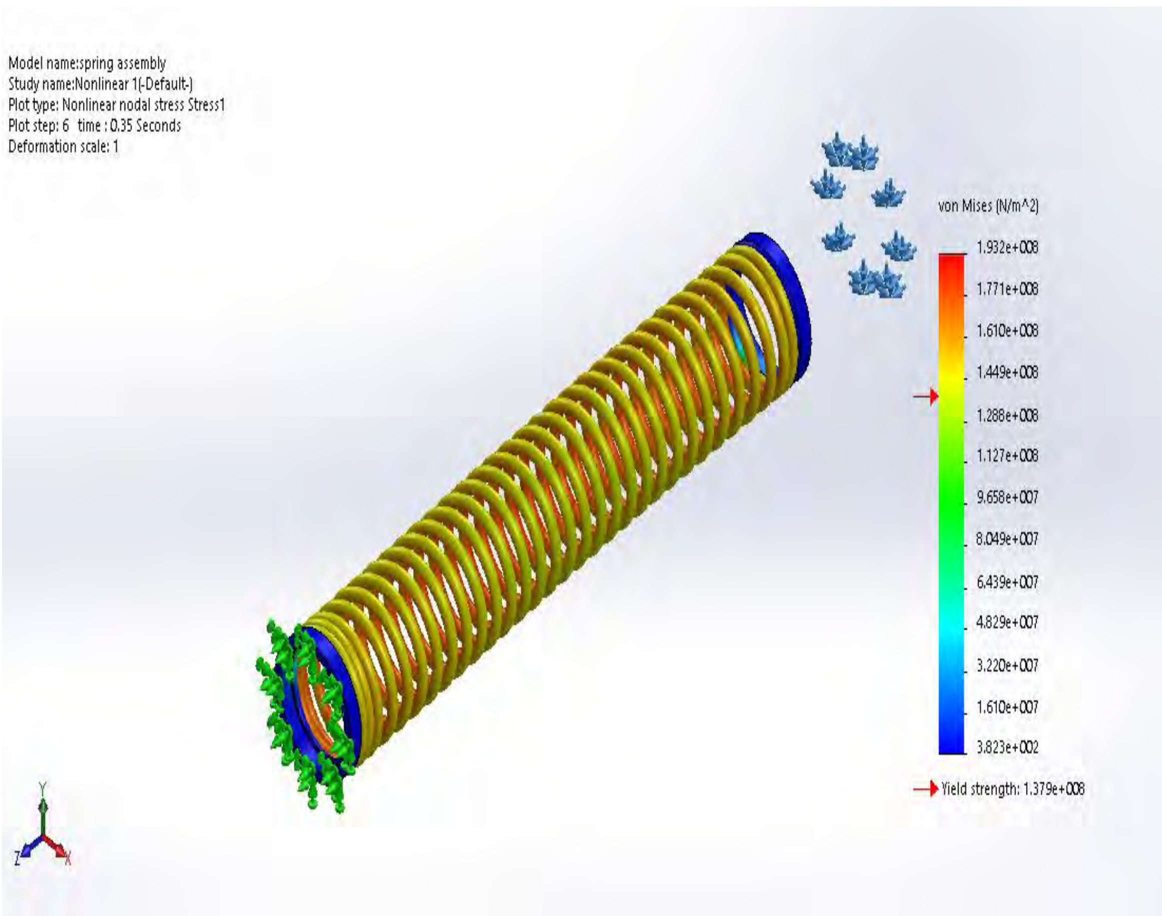
6.2 Simulation result of the spring

The simulation study is a nonlinear-static study of the spring which is found inside the mechanism. As seen in Appendix C, 10mm nominal major diameter and fine-pitch of 1.25mm making use of screw made of 1060 aluminum alloy material is 100 times more than the optimum requirement. The ideal values of the spring parameters from the iteration results are 1.5mm wire diameter and outer diameter of 12.78mm. The simulation results indicate also that based on the spring stress strain curve output, a wire diameter of 1.5mm and outer spring diameter of 12.78 offer the best minimal values for a stress of $1.4x10^8 N/m^2$ up to $2.8x10^8 N/m^2$, for a maximum deflection 17mm. The deflection is more at the close end of load application area of the spring and decreases evenly towards the fixed end of the spring. Hence, the strain is uniform throughout the spring length. The nonlinear study is assumed because the spring deflects in larger deformation.

One interesting feature of the spring is that depending on the anatomical ranges of patients, it triggers different internal force effects to be exerted. Using springs to generate continuous load/force and coupling it with external fixators reduce complications, advance the external fixator system and considerably increases patients comfort. The implications due to the existence of such external fixator devices particularly in low resource settings could be tremendous. Three simulation results are presented on Fig. 6.7 showing outputs for stress-stress, strain-strain as well as displacement values generated by the Solidworks software.

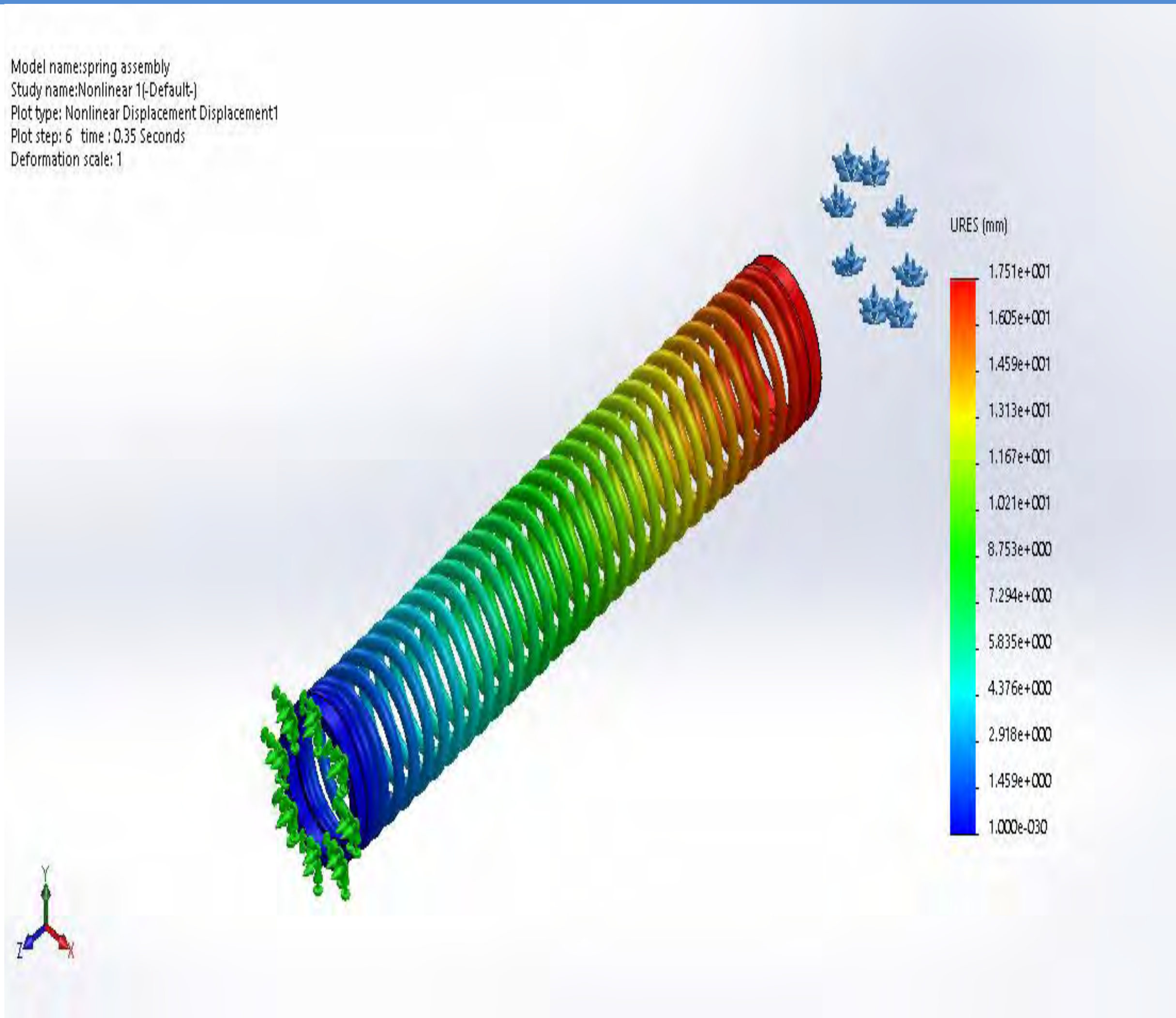
Stress-strain curve is depicted on Fig. 6.8. It is clear to see that the stress or the load per unit area is proportional to the strain. The spring deflects constantly trough the force applied. It does not reach to the yield point until it deflects fully so that for the selected range of loads, the physical properties of the material is good enough to be used. This indicates how smoothly the progressive load/force is transferred to the fracture site.

Name	Type	Min	Max
Stress1	VON: von Mises Stress at Step No: 6(0.35 Seconds)	382.334 N/m^2 Node: 268471	1.93169e+008 N/m^2 Node: 1719



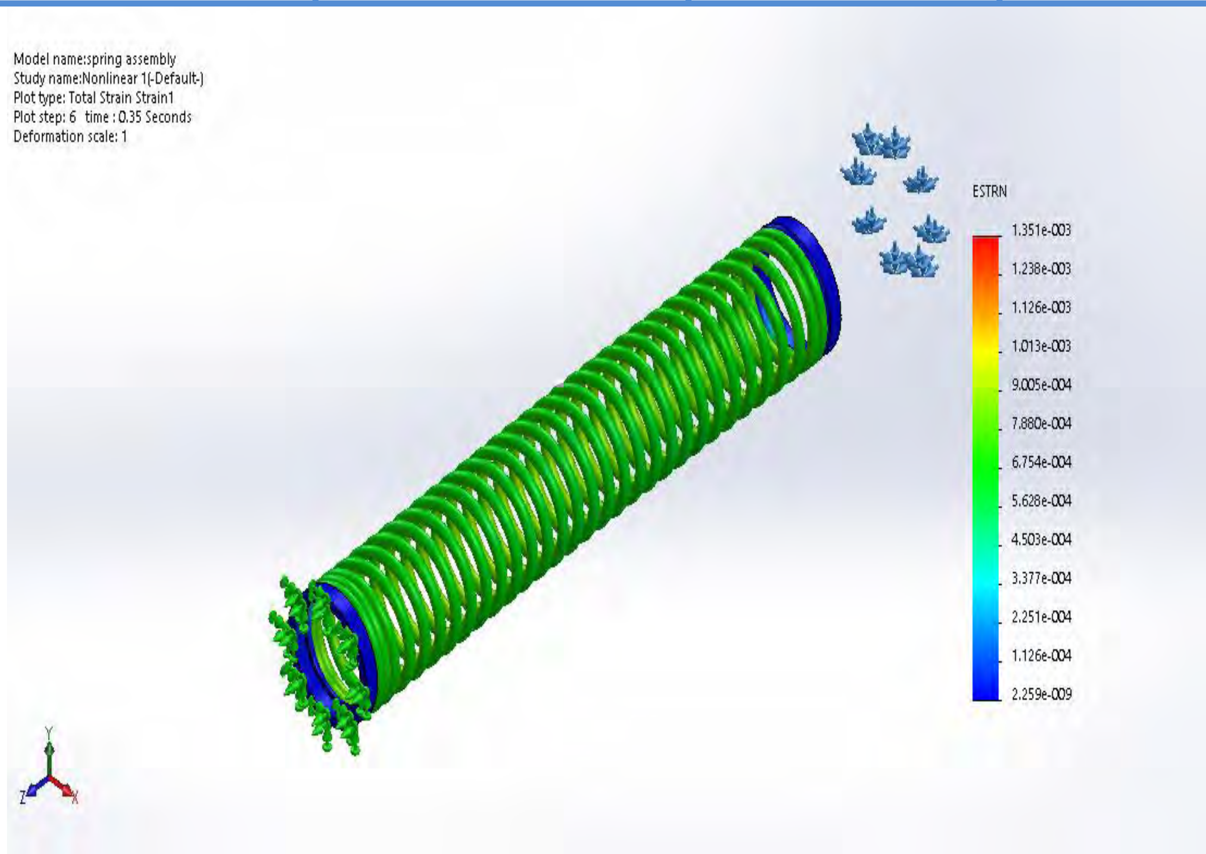
spring assembly-Nonlinear 1-Stress-Stress1

Name	Type	Min	Max
Displacement1	URES: Resultant Displacement at Step No: 6(0.35 Seconds)	0 mm Node: 1	17.5059 mm Node: 105237



spring assembly-Nonlinear 1-Displacement-Displacement1

Name	Type	Min	Max
Strain1	ESTRN: Equivalent Strain at Step No: 6(0.35 Seconds)	2.25881e-009 Element: 162724	0.00135081 Element: 23495



spring assembly-Nonlinear 1-Strain-Strain1

Figure 6.7 Spring assembly-Nonlinear -Stress, Displacement and Strain simulation (Simulated with Solidworks).

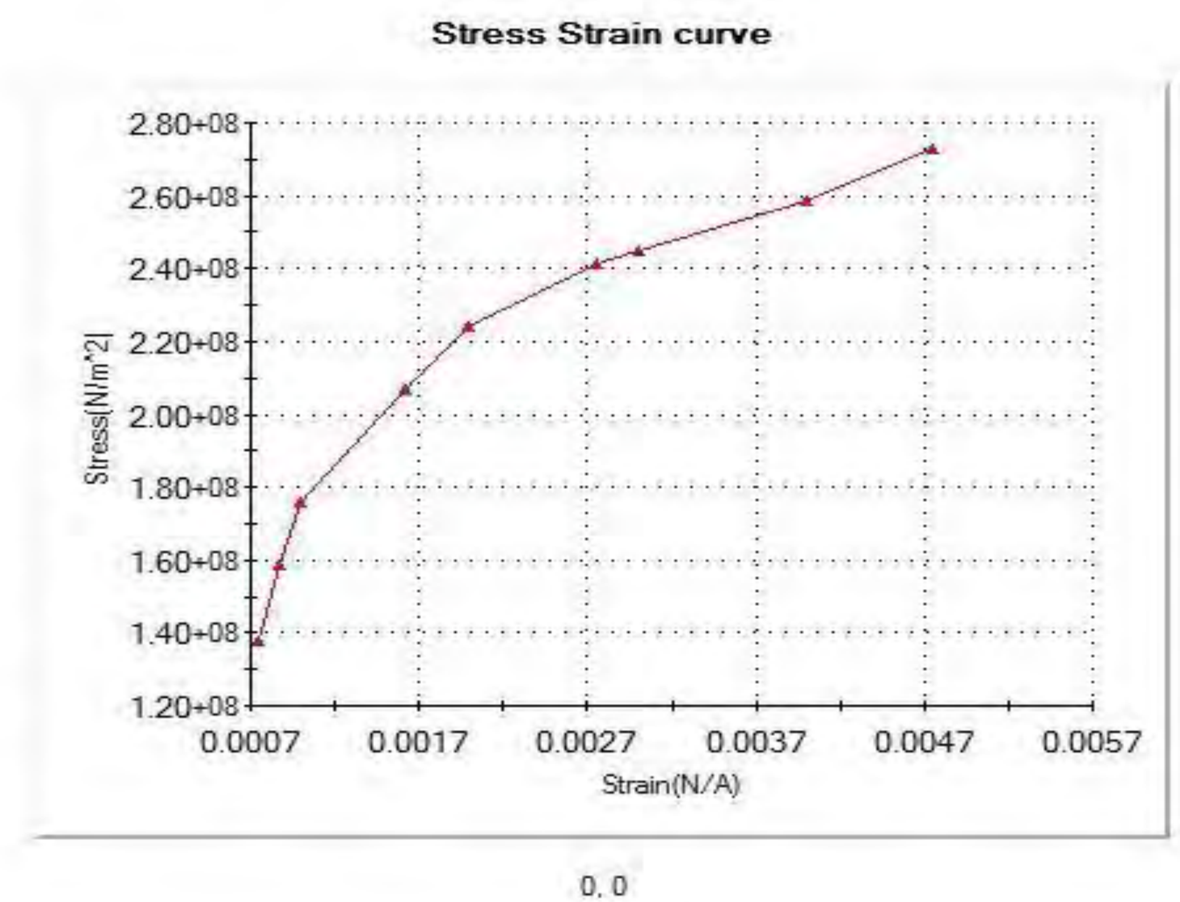


Figure 6.8 Stress Strain Curve (Plotted with Solidworks).

6.3 Discussion

The aim of this dissertation was to design and develop an appliance that exerts a continuous load on the traction site throughout the healing process. As discussed in the early chapters, all fracture fixators, including the modern ones, have advancing screws to apply a load progressively for bone transport purposes. Even the bone transport mechanism is not a foolproof, which is dependent on the person torqueing the nuts to increase the length. If excess effort is applied, different complication like damages on nerves, blood vessels as well as soft tissues could occur.

Early traction devices and external fixators which are fixed on patients heavily require assistance from skilled personnel to correct and modify traction setups including required orientations and loads. Even though the proposed appliance in this thesis greatly reduces requirement of highly skilled and experienced physicians to manage it, the need is still there to estimate the load required for individual patients which requires deflection of the spring. In this sense, the proposed appliance is not fully automated (only semi-automatic) and requires human intervention. Despite the fact, the proposed external fixator, which also has a traction functionality, is presumed to significantly reduce the amount of time required to adjust traction setups in the clinics. This could have tremendous implications in practical situations in terms of assistance cost, patient comfort, and ease of use among other things.

Understanding the concept of loading in fracture treatment accelerates healing of the bone, fibrous tissues, and skeletal muscles. The proposed fixation mechanism in this thesis is devised in such a way that even if the personnel using it is not experienced, it will adjust the load applied to be smooth enough. It balances the force exerted by whoever managing it and whatever torque is applied, it won't be directly transmitted to the fracture site. Instead it will be transmitted to the fracture site through the spring deflection after balancing the load capability of soft tissues. It has multiple purposes compared to the conventional external fixators as well as the modern ones. One of the major benefits is that it avoids the requirement by the surgeon or the health professional working on it to check the load applied frequently. Micro-movement is possible with little effort from the patient.

In addition, the continuous load exerted by the spring always activates the muscles thereby protecting them from atrophy, which enables patients to quickly recover and comeback to their normal activities at the earliest thereby reducing the rehabilitation time. Also, recent studies showed that callus formation is fast if there is a micro-movement around the fracture site [20, 34]. The spring, which is inside the mechanism will have micro-movements in every little motion accomplished by the patient. This could reduce the patient- physician interaction considerably.

Increasing the wire diameter increases the deflection force required per centimeters. This allows the traction system to accommodate different force effects which are patient specific depending on their anatomic ranges. Using springs to create and apply the required forces and adopting the setup to external fixators should reduce complications there by advancing the traction system and making it comfortable for patients.

Chapter 7

Conclusion and Recommendation

7.1 Conclusion

Thorough literature review has been carried out before designing the proposed appliance in this thesis. Pros and cons of available external fixators have been investigated, their principles, mechanisms and related subjects have been researched giving a solid foundation for designing the proposed appliance.

This thesis has developed a traction bar to be used together with available external fixator clamp systems which could be attachable only to the patient. The new traction bar made use of principles derived from existing modern traction systems and external fixators to achieve better results during fractured bone healing process. Except the newly proposed TSF fixator, almost all currently available external fixators use solid bars to connect one side of the ring or clamp pins to the other to stabilize the fracture. The basic difference between such fixators and the now 'old fashioned' isometric fracture treatment methods is that the recent ones allow open space for the skin to ventilate and direct fixation of the pins on the bone which in turn could reduce the risk of malunion as well as deformity. But still those new techniques suffer from problems related to complications on the muscles, bone healing, and fast recovery. The TSF fixator has similar problems but to a lesser extent due to the progressive loading it applies.

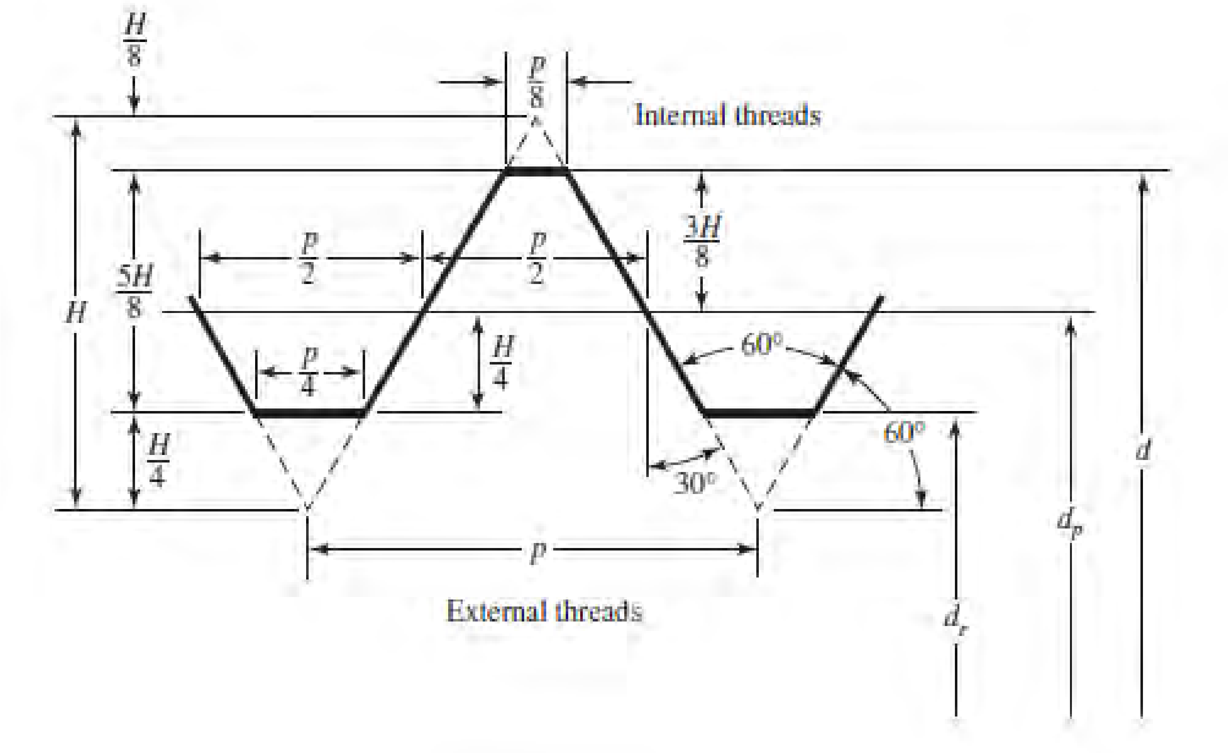
The traction bar system proposed in this thesis mainly tried to address the above mentioned problem, like muscle atrophy, and fast recovery/rehabilitation. Implementing the proposed traction bar avoids the complication risks which could arise due to lack of force on muscles. The new traction bar is proposed as a substitute to the solid bar connector with spring loaded mechanism used in previous models with interesting features embedded on it including labeled length displacement indicator as well as digital load sensors. The spring is simply compressed with the tubes sliding over it and digital load sensors are attached on it. Continuous smooth load application is possible because spring compression forces are continuous. As load required for traction purposes varies from patient to patient, the continuous load generated by the spring system embedded in the proposed appliance could relive physicians from manual weight estimations. It only requires making use of the screws until the essential measure of adjustment is reached.

7.2 Recommendations

Manufacturing a prototype of the appliance and testing and validation are required as a proof of concept that the newly proposed appliance does its purpose. Its performance should be compared with existing appliances particularly those that use Ilizarov rings, clamps, and circular rods Huffman II.

In order to achieve more precision fixation of fractured bones, the device should be upgraded from manual system to fully computerized system to automatically regulate the load required per individual patient. This could be achieved by installing electric motors on the appliance with micro-level sensors embedded on it to feed information to the computer program. With the current setup of the new appliance, making it computerized is assumed to be not too difficult. Even intelligent fixator is possible. The type and magnitude of forces exerted by each individual muscle surrounding the femur could be computed, categorized and used as an input for machine learning. This procedure permits development of a traction system which is well advanced, precise, with minimal human intervention. Investigation of such and other issues awaits further research.

Appendix A



Basic profile of metric thread: d =major diameter, dr =minor diameter, dp =pitch diameter, p=pitch, H=thread depth, H =√(3/2) p (Courtesy [29])

Dimensional formulas for compressional spring (Courtesy [29])

	Type of Spring Ends			
Term	**Plain**	**Plain and Ground**	**Squared or Closed**	**Squared and Ground**
End coils, N_e	0	1	2	2
Total coils, N_t	N_a	$N_a + 1$	$N_a + 2$	$N_a + 2$
Free length, L_0	$pN_a + d$	$p(N_a + 1)$	$pN_a + 3d$	$pN_a + 2d$
Solid length, L_s	$d(N_t + 1)$	dN_t	$d(N_t + 1)$	dN_t
Pitch, p	$(L_0 - d)/N_a$	$L_0/(N_a + 1)$	$(L_0 - 3d)/N_a$	$(L_0 - 2d)/N_a$

Diameters and Areas of Coarse-Pitch and Fine-Pitch Metric threads. (Courtesy [29])

Nominal Major Diameter d mm	Coarse-Pitch Series			Fine-Pitch Series		
	Pitch p mm	Tensile-Stress Area A_t mm²	Minor-Diameter Area A_r mm²	Pitch p mm	Tensile-Stress Area A_t mm²	Minor-Diameter Area A_r mm²
1.6	0.35	1.27	1.07			
2	0.40	2.07	1.79			
2.5	0.45	3.39	2.98			
3	0.5	5.03	4.47			
3.5	0.6	6.78	6.00			
4	0.7	8.78	7.75			
5	0.8	14.2	12.7			
6	1	20.1	17.9			
8	1.25	36.6	32.8	1	39.2	36.0
10	1.5	58.0	52.3	1.25	61.2	56.3
12	1.75	84.3	76.3	1.25	92.1	86.0
14	2	115	104	1.5	125	116
16	2	157	144	1.5	167	157
20	2.5	245	225	1.5	272	259
24	3	353	324	2	384	365
30	3.5	561	519	2	621	596
36	4	817	759	2	915	884
42	4.5	1120	1050	2	1260	1230
48	5	1470	1380	2	1670	1630
56	5.5	2030	1910	2	2300	2250
64	6	2680	2520	2	3030	2980
72	6	3460	3280	2	3860	3800
80	6	4340	4140	1.5	4850	4800
90	6	5590	5360	2	6100	6020
100	6	6990	6740	2	7560	7470
110				2	9180	9080

*The equations and data used to develop this table have been obtained from ANSI B1.1-1974 and B18.3.1-1978. The minor diameter was found from the equation $d_r = d - 1.226\,869p$, and the pitch diameter from $d_p = d - 0.649\,519p$. The mean of the pitch diameter and the minor diameter was used to compute the tensile-stress area.

Helical coil compression spring design flowchart for static loading (Courtesy [29])

STATIC SPRING DESIGN

Choose d

Over-a-rod

As-wound or set

$$D = d_{rod} + d + \text{allow}$$

Free

As-wound

$$S_{sy} = \text{const}(A)/d^{m\dagger}$$

$$C = \frac{2\alpha - \beta}{4\beta} + \sqrt{\left(\frac{2\alpha - \beta}{4\beta}\right)^2 - \frac{3\alpha}{4\beta}}$$

$$\alpha = \frac{S_{sy}}{n_s} \qquad \beta = \frac{8(1+\xi)F_{max}}{\pi d^2}$$

$$D = Cd$$

Set removed

$$S_{sy} = 0.65A/d^m$$

$$D = \frac{S_{sy}\pi d^3}{8n_s(1+\xi)F_{max}}$$

In-a-hole

As-wound or set

$$D = d_{hole} - d - \text{allow}$$

$$C = D/d$$

$$K_B = (4C+2)/(4C-3)$$

$$\tau_s = K_B 8(1+\xi)F_{max}D/(\pi d^3)$$

$$n_s = S_{sy}/\tau_s$$

$$\text{OD} = D + d$$

$$\text{ID} = D - d$$

$$N_a = Gd^4 y_{max}/(8D^3 F_{max})$$

N_t: Table 10–1

L_s: Table 10–1

L_O: Table 10–1

$$(L_O)_{cr} = 2.63D/\alpha$$

$$\text{fom} = -(\text{rel. cost})\,\gamma\pi^2 d^2 N_t D/4$$

Print or display: d, D, C, OD, ID, N_a, N_t, L_s, L_O, $(L_O)_{cr}$, n_s, fom

Build a table, conduct design assessment by inspection

Eliminate infeasible designs by showing active constraints

Choose among satisfactory designs using the figure of merit

Constants A and m of Sut=A/d^(m) for estimating Minimum Tensile Strength of common spring wires (Courtesy [29])

Material	ASTM No.	Exponent m	Diameter, in	A, kpsi · in^m	Diameter, mm	A, MPa · mm^m	Relative Cost of wire
Music wire*	A228	0.145	0.004–0.256	201	0.10–6.5	2211	2.6
OQ&T wire†	A229	0.187	0.020–0.500	147	0.5–12.7	1855	1.3
Hard-drawn wire‡	A227	0.190	0.028–0.500	140	0.7–12.7	1783	1.0
Chrome-vanadium wire§	A232	0.168	0.032–0.437	169	0.8–11.1	2005	3.1
Chrome-silicon wire‖	A401	0.108	0.063–0.375	202	1.6–9.5	1974	4.0
302 Stainless wire#	A313	0.146	0.013–0.10	169	0.3–2.5	1867	7.6–11
		0.263	0.10–0.20	128	2.5–5	2065	
		0.478	0.20–0.40	90	5–10	2911	
Phosphor-bronze wire**	B159	0	0.004–0.022	145	0.1–0.6	1000	8.0
		0.028	0.022–0.075	121	0.6–2	913	
		0.064	0.075–0.30	110	2–7.5	932	

*Surface is smooth, free of defects, and has a bright, lustrous finish.
†Has a slight heat-treating scale which must be removed before plating.
‡Surface is smooth and bright with no visible marks.
§Aircraft-quality tempered wire, can also be obtained annealed.
‖Tempered to Rockwell C49, but may be obtained untempered.
#Type 302 stainless steel.
**Temper CA510.

Mechanical Properties of Some Spring Wires (Courtesy [29])

Material	Elastic Limit, Percent of S_{ut} Tension	Torsion	Diameter d, in	E Mpsi	GPa	G Mpsi	GPa
Music wire A228	65–75	45–60	<0.032	29.5	203.4	12.0	82.7
			0.033–0.063	29.0	200	11.85	81.7
			0.064–0.125	28.5	196.5	11.75	81.0
			>0.125	28.0	193	11.6	80.0
HD spring A227	60–70	45–55	<0.032	28.8	198.6	11.7	80.7
			0.033–0.063	28.7	197.9	11.6	80.0
			0.064–0.125	28.6	197.2	11.5	79.3
			>0.125	28.5	196.5	11.4	78.6
Oil tempered A239	85–90	45–50		28.5	196.5	11.2	77.2
Valve spring A230	85–90	50–60		29.5	203.4	11.2	77.2
Chrome-vanadium A231	88–93	65–75		29.5	203.4	11.2	77.2
A232	88–93			29.5	203.4	11.2	77.2
Chrome-silicon A401	85–93	65–75		29.5	203.4	11.2	77.2
Stainless steel							
A313*	65–75	45–55		28	193	10	69.0
17-7PH	75–80	55–60		29.5	208.4	11	75.8
414	65–70	42–55		29	200	11.2	77.2
420	65–75	45–55		29	200	11.2	77.2
431	72–76	50–55		30	206	11.5	79.3
Phosphor-bronze B159	75–80	45–50		15	103.4	6	41.4
Beryllium-copper B197	70	50		17	117.2	6.5	44.8
	75	50–55		19	131	7.3	50.3
Inconel alloy X-750	65–70	40–45		31	213.7	11.2	77.2

*Also includes 302, 304, and 316.

Appendix B

```
% To calculate the values for wire diameter here is a simple formula
% we have given Constanat values Fmax,robust linearity e and hard drawn wire A227
% d is wire diameter with values 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5
d= (1:0.5:6)
D = (10+d)/0.9  % D is the nominal diameter
% for hard drawn wire of A227
m = 0.190;
A = 1783;
Sut= A./(d.^m); % Sut the ultimate tensile strength
Ssy = 0.45* Sut; % Ssy the torsional yield strength
C = D./d  % spring index
OD= D+d % ourter diameter of the spring
KB = (4*C+2)/(4*C-3); % the curvature effect
e = 0.15;  % linearity
Fmax = 180; % maximum load at defelction of 5cm
SMS = (KB*8*(1+e)*Fmax*D)./(pi*d.^3); % allowable shear stress
ns = Ssy./SMS  % factory of closure safety
G = 80000; % rigidity constant
Ymax = 50; % maximum deflection for
Na = (G*(d.^4)*Ymax)./(8*(D.^3)*Fmax) % number of active coils
Nt = Na+2  % total number of coils
ls = d.*Nt  % solid length
lf = ls+Ymax % free length
lfcr = 5.26.*D  % critical free length
```

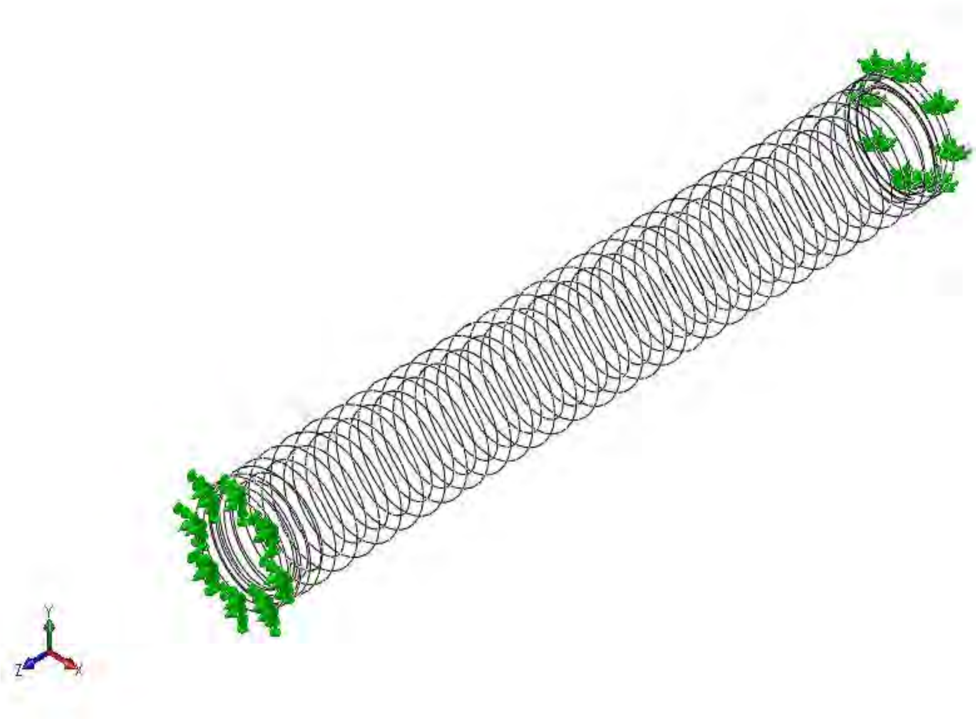
```
d =

  Columns 1 through 7

    1.0000    1.5000    2.0000    2.5000    3.0000    3.5000    4.0000

  Columns 8 through 11

    4.5000    5.0000    5.5000    6.0000


D =

  Columns 1 through 7

   12.2222   12.7778   13.3333   13.8889   14.4444   15.0000   15.5556

  Columns 8 through 11

   16.1111   16.6667   17.2222   17.7778


C =

  Columns 1 through 7
```

```
   12.2222    8.5185    6.6667    5.5556    4.8148    4.2857    3.8889

  Columns 8 through 11

    3.5802    3.3333    3.1313    2.9630


OD =

  Columns 1 through 7

   13.2222   14.2778   15.3333   16.3889   17.4444   18.5000   19.5556

  Columns 8 through 11

   20.6111   21.6667   22.7222   23.7778


ns =

  Columns 1 through 7

    0.1036    0.3097    0.6662    1.1972    1.9215    2.8535    4.0044

  Columns 8 through 11

    5.3832    6.9968    8.8505   10.9488


Na =

  Columns 1 through 7

    1.5214    6.7406   18.7500   40.5000   74.6586  123.5082  188.9213

  Columns 8 through 11

  272.3774  375.0000  497.6004  640.7227


Nt =

  Columns 1 through 7

    3.5214    8.7406   20.7500   42.5000   76.6586  125.5082  190.9213

  Columns 8 through 11

  274.3774  377.0000  499.6004  642.7227




ls =
```

```
   1.0e+03 *

  Columns 1 through 7

    0.0035    0.0131    0.0415    0.1063    0.2300    0.4393    0.7637

  Columns 8 through 11

    1.2347    1.8850    2.7478    3.8563


lf =

   1.0e+03 *

  Columns 1 through 7

    0.0535    0.0631    0.0915    0.1563    0.2800    0.4893    0.8137

  Columns 8 through 11

    1.2847    1.9350    2.7978    3.9063


lfcr =

  Columns 1 through 7

   64.2889   67.2111   70.1333   73.0556   75.9778   78.9000   81.8222

  Columns 8 through 11

   84.7444   87.6667   90.5889   93.5111
```

Published with MATLAB® R2013a

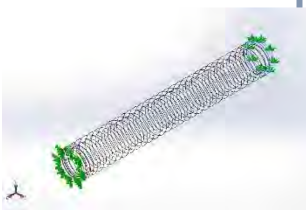
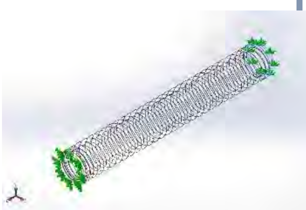
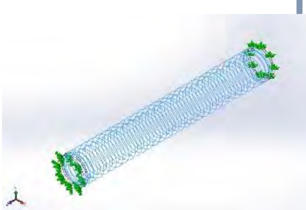
Appendix C



Model name: spring assembly

Current Configuration: Default

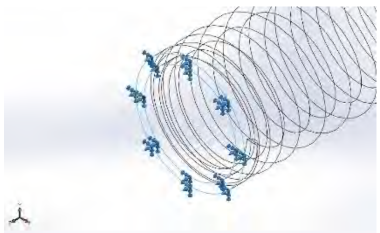
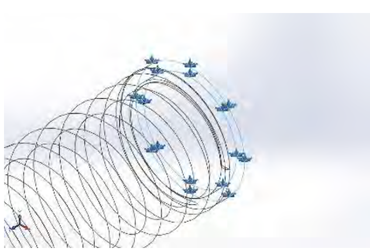
Solid Bodies			
Document Name and Reference	Treated As	Volumetric Properties	Document Path/Date Modified

Cut-Extrude1 	Solid Body	Mass:0.000770476 kg Volume:9.63094e-008 m^3 Density:8000 kg/m^3 Weight:0.00755066 N	C:\Users\Toshiba\Desktop\talak\New folder (2)\final design\spring ends.SLDPRT Nov 25 15:45:24 2016
	Solid Body	Mass:0.000770476 kg Volume:9.63094e-008 m^3 Density:8000 kg/m^3 Weight:0.00755066 N	C:\Users\Toshiba\Desktop\talak\New folder (2)\final design\spring ends.SLDPRT Nov 25 15:45:24 2016
Cut-Extrude1 	Solid Body	Mass:0.0188521 kg Volume:2.35651e-006 m^3 Density:8000 kg/m^3 Weight:0.18475 N	C:\Users\Toshiba\Desktop\talak\New folder (2)\final design\spring.SLDPRT Nov 27 11:34:37 2016

Study name	Nonlinear 1
Analysis type	Nonlinear - Static
Mesh type	Solid Mesh

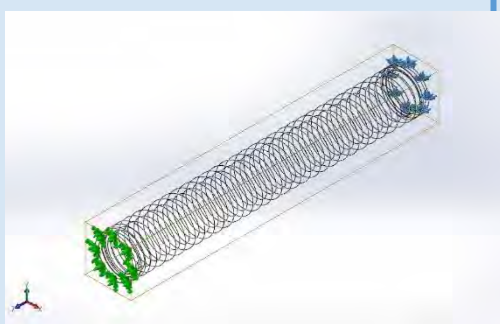
Start time	0 Seconds
End time	1 Seconds
Time increment	Auto stepping
Large displacement formulation:	On
Update load direction with deflection:	Off
Large strain formulation:	Off
Save data for restarting the analysis	Off
Thermal Effect:	On
Thermal option	Include temperature loads
Zero strain temperature	298 Kelvin
Solver type	FFEPlus
Incompatible bonding options	Simplified
Control technique:	Force
Iterative technique:	NR(Newton-Raphson)
Integration Method	Newmark

Result folder	SOLIDWORKS document (C:\Users\Toshiba\Desktop\talak\New folder (2)\final design)

Fixture name	Fixture Image	Fixture Details			
Fixed-1		**Entities:** 1 face(s) **Type:** Fixed Geometry			
Resultant Forces					
Components	**X**	**Y**	**Z**	**Resultant**	
Reaction force(N)	**0.000396922**	**-0.000727495**	**-0.296035**	**0.296036**	
Reaction Moment(N.m)	**0**	**0**	**0**	**0**	
On Flat Faces-1		**Entities:** 1 face(s) **Type:** On Flat Faces **Translation:** 0, 0, 50 **Units:** mm			
Resultant Forces					

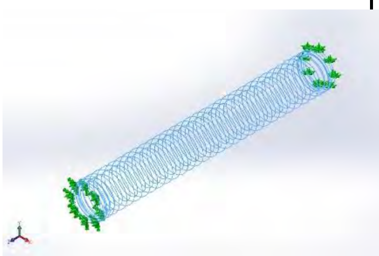
Fixture name	Fixture Image	Fixture Details

Components	X	Y	Z	Resultant
Reaction force(N)	-0.000396958	0.000727547	0.296035	0.296036
Reaction Moment(N.m)	0	0	0	0

Contact	Contact Image	Contact Properties
Global Contact		**Type:** Bonded **Components:** 1 component(s) **Options:** Incompatible mesh

Unit system:	SI (MKS)
Length/Displacement	mm
Temperature	Kelvin
Angular velocity	Rad/sec
Pressure/Stress	N/m^2

Model Reference	Properties	Components

	Name: **AISI 316 Annealed Stainless Steel Bar (SS)** Model type: **Plasticity - von Mises** Default failure criterion: **Unknown** Yield strength: **1.37895e+008 N/m^2** Hardening factor (0.0-1.0; 0.0=isotropic; 1.0=kinematic): **0.85** Elastic modulus: **1.93e+011 N/m^2** Poisson's ratio: **0.3** Mass density: **8000 kg/m^3** Thermal expansion coefficient: **1.6e-005 /Kelvin**	**SolidBody 1 (Cut Extrude1) (spring ends-1),** **SolidBody 1(Cut-Extrude1) (spring ends-2),** **SolidBody 1(Cut Extrude1) (spring-1),**

Mesh type	Solid Mesh
Mesher Used:	Curvature-based mesh
Jacobian points	4 Points
Maximum element size	0.144812 cm
Minimum element size	0.0482701 cm

Mesh Quality	High
Re-mesh failed parts with incompatible mesh	On
Total Nodes	314399
Total Elements	185973
Maximum Aspect Ratio	13.542
% of elements with Aspect Ratio < 3	99.6
% of elements with Aspect Ratio > 10	0.00161
% of distorted elements(Jacobian)	0
Time to complete mesh(hh; mm;ss):	00:00:13
Computer name:	Toshiba S55-C

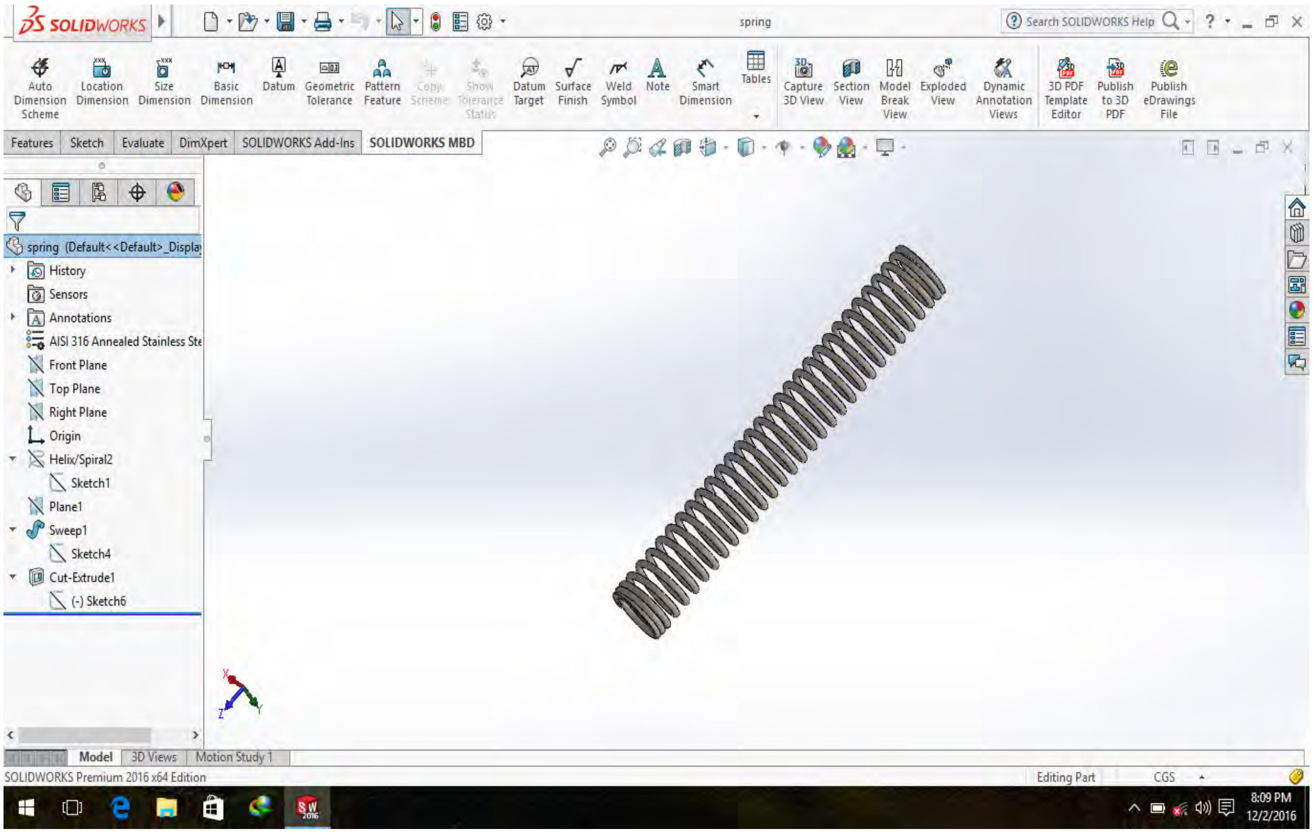
Reaction force

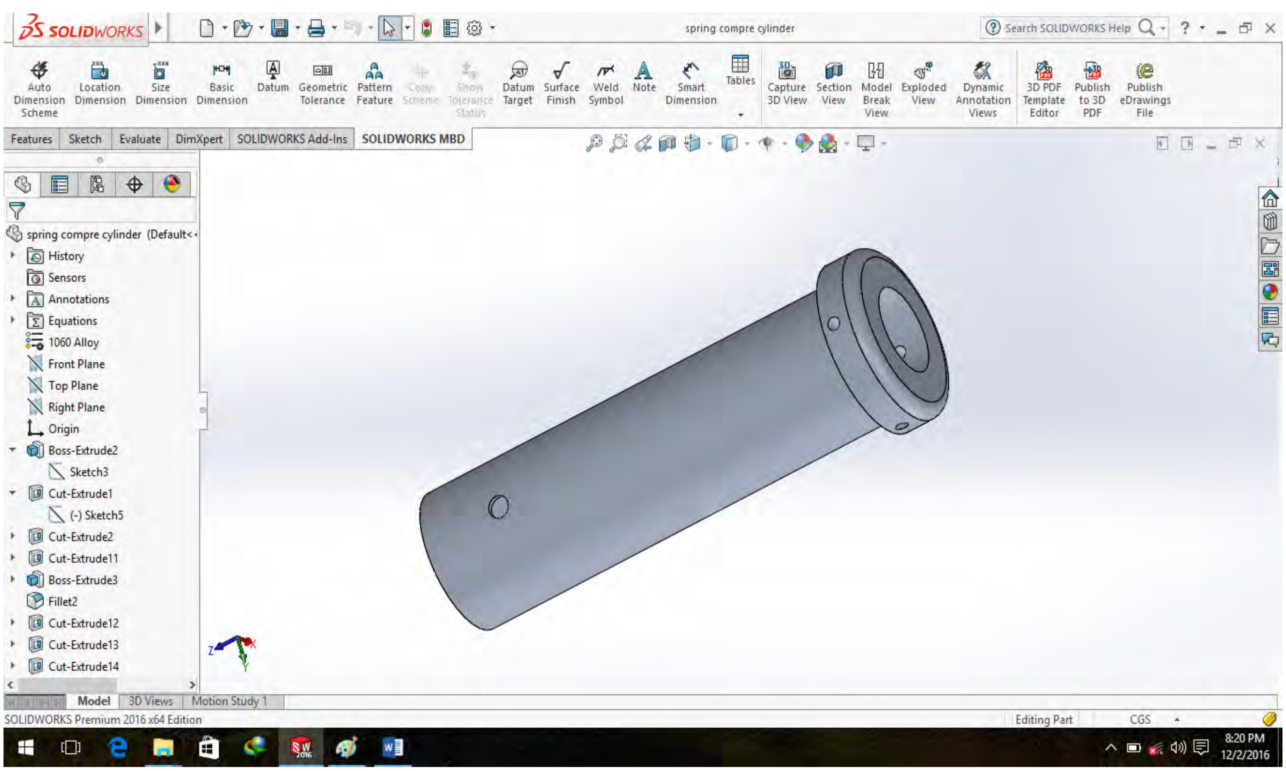
Selection set	Units	Sum X	Sum Y	Sum Z	Resultant
Entire Model	N	-2.12913e-008	1.26274e-008	-1.45925e-007	1.4801e-007

Reaction Moments

Selection set	Units	Sum X	Sum Y	Sum Z	Resultant
Entire Model	N.m	0	0	0	0

Appendix D


spring
spring (Default<<Default>_Displa
History
Sensors
Annotations
AISI 316 Annealed Stainless Ste
Front Plane
Top Plane
Right Plane
Origin
Helix/Spiral2
Sketch1
Plane1
Sweep1
Sketch4
Cut-Extrude1
(-) Sketch6
SOLIDWORKS Premium 2016 x64 Edition
Editing Part
8:09 PM
12/2/2016


spring compre cylinder
spring compre cylinder (Default<
History
Sensors
Annotations
Equations
1060 Alloy
Front Plane
Top Plane
Right Plane
Origin
Boss-Extrude2
Sketch3
Cut-Extrude1
(-) Sketch5
Cut-Extrude2
Cut-Extrude11
Boss-Extrude3
Fillet2
Cut-Extrude12
Cut-Extrude13
Cut-Extrude14
SOLIDWORKS Premium 2016 x64 Edition
Editing Part
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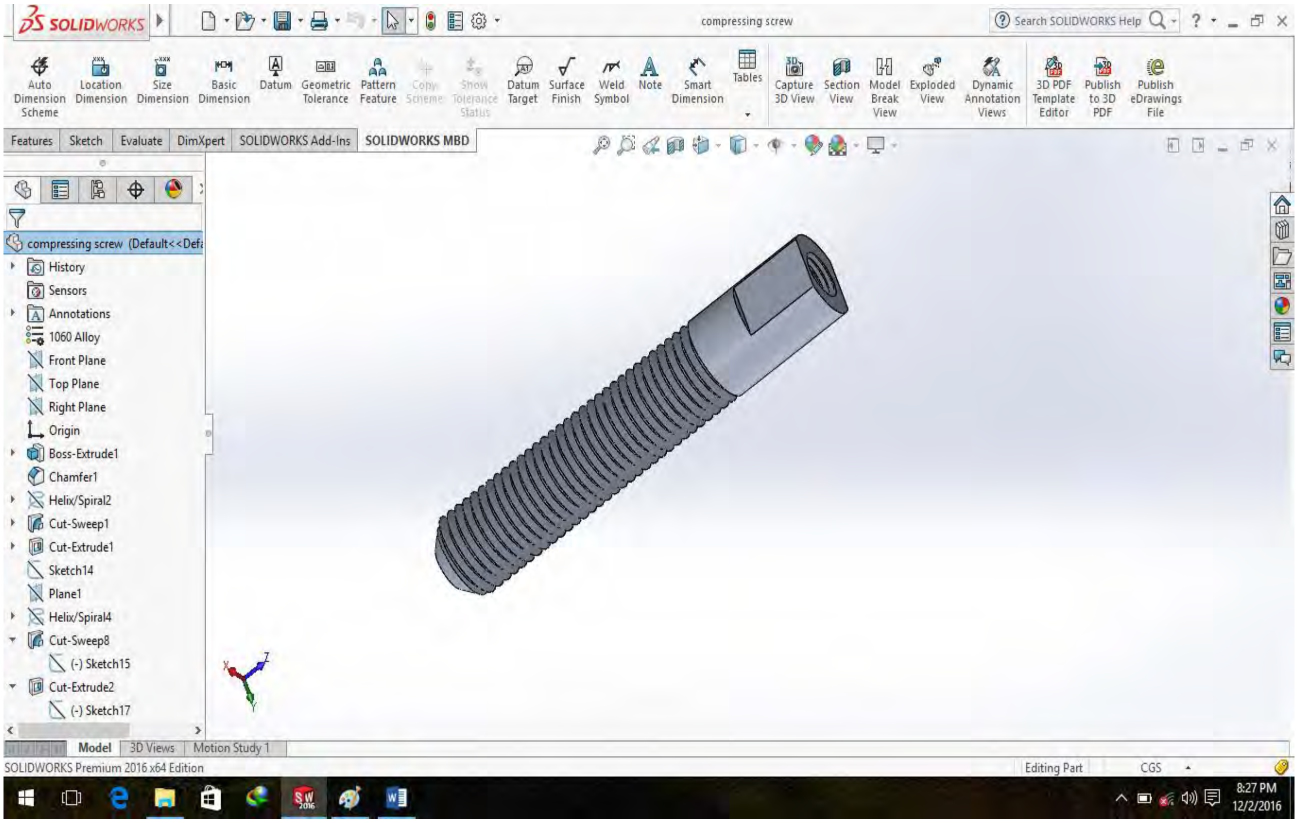
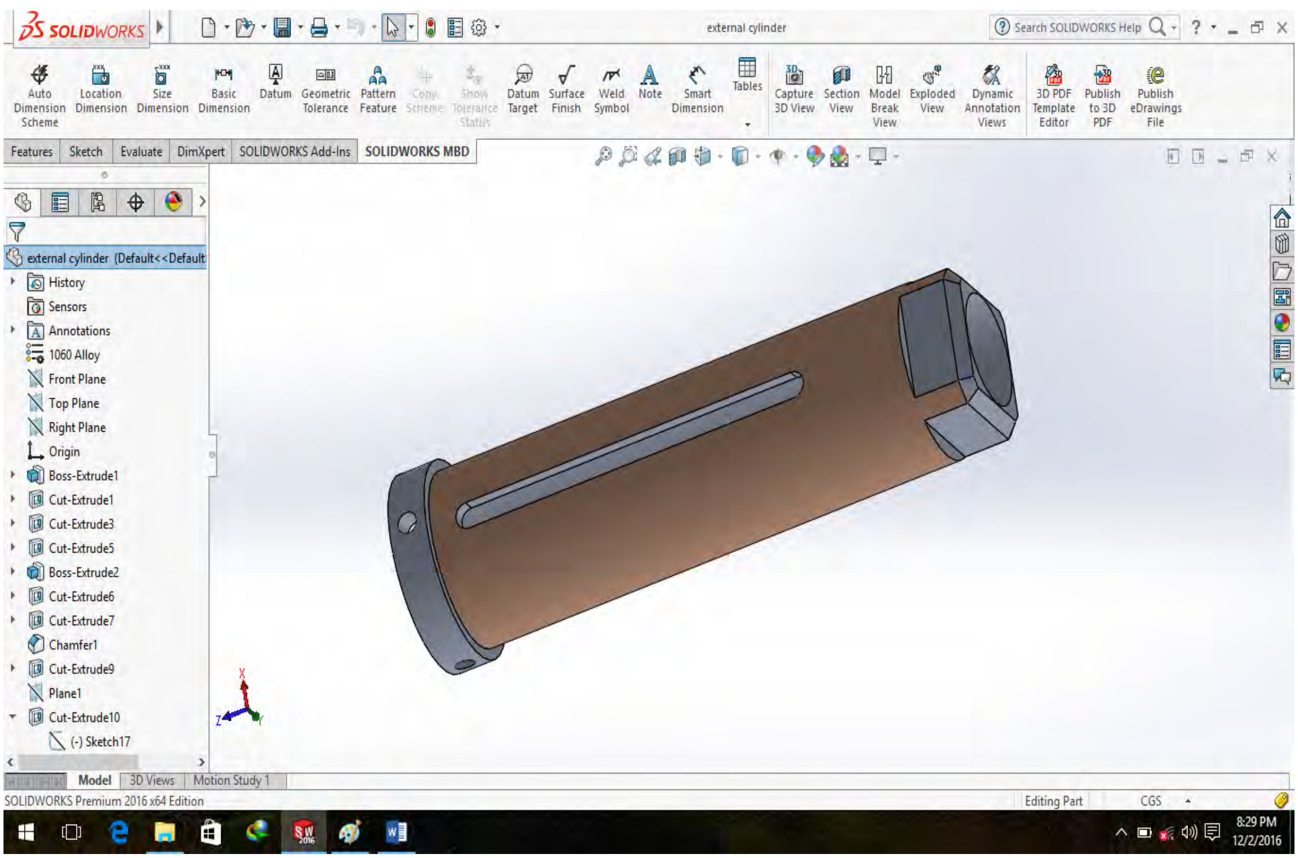
12/2/2016


SOLIDWORKS
compressing screw
Search SOLIDWORKS Help
Auto Dimension Scheme
Location Dimension
Size Dimension
Basic Dimension
Datum
Geometric Tolerance
Pattern Feature
Copy Scheme
Show Tolerance Status
Datum Target
Surface Finish
Weld Symbol
Note
Smart Dimension
Tables
Capture 3D View
Section View
Model Break View
Exploded View
Dynamic Annotation Views
3D PDF Template Editor
Publish to 3D PDF
Publish eDrawings File
Features
Sketch
Evaluate
DimXpert
SOLIDWORKS Add-Ins
SOLIDWORKS MBD
compressing screw (Default<<Def
History
Sensors
Annotations
1060 Alloy
Front Plane
Top Plane
Right Plane
Origin
Boss-Extrude1
Chamfer1
Helix/Spiral2
Cut-Sweep1
Cut-Extrude1
Sketch14
Plane1
Helix/Spiral4
Cut-Sweep8
(-) Sketch15
Cut-Extrude2
(-) Sketch17
Model
3D Views
Motion Study 1
SOLIDWORKS Premium 2016 x64 Edition
Editing Part
CGS
8:27 PM
12/2/2016


SOLIDWORKS
external cylinder
Search SOLIDWORKS Help
Auto Dimension Scheme
Location Dimension
Size Dimension
Basic Dimension
Datum
Geometric Tolerance
Pattern Feature
Copy Scheme
Show Tolerance Status
Datum Target
Surface Finish
Weld Symbol
Note
Smart Dimension
Tables
Capture 3D View
Section View
Model Break View
Exploded View
Dynamic Annotation Views
3D PDF Template Editor
Publish to 3D PDF
Publish eDrawings File
Features
Sketch
Evaluate
DimXpert
SOLIDWORKS Add-Ins
SOLIDWORKS MBD
external cylinder (Default<<Default
History
Sensors
Annotations
1060 Alloy
Front Plane
Top Plane
Right Plane
Origin
Boss-Extrude1
Cut-Extrude1
Cut-Extrude3
Cut-Extrude5
Boss-Extrude2
Cut-Extrude6
Cut-Extrude7
Chamfer1
Cut-Extrude9
Plane1
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3D Views
Motion Study 1
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CGS
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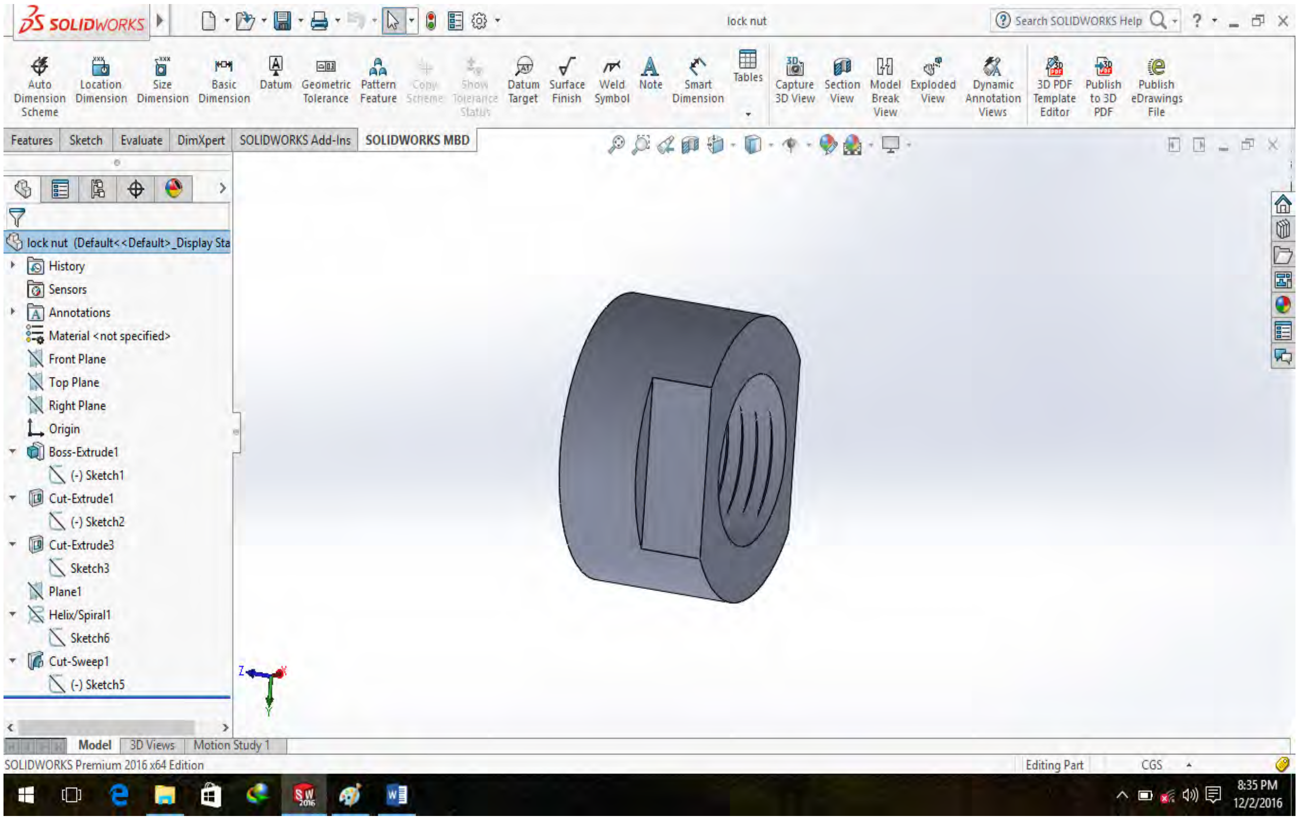
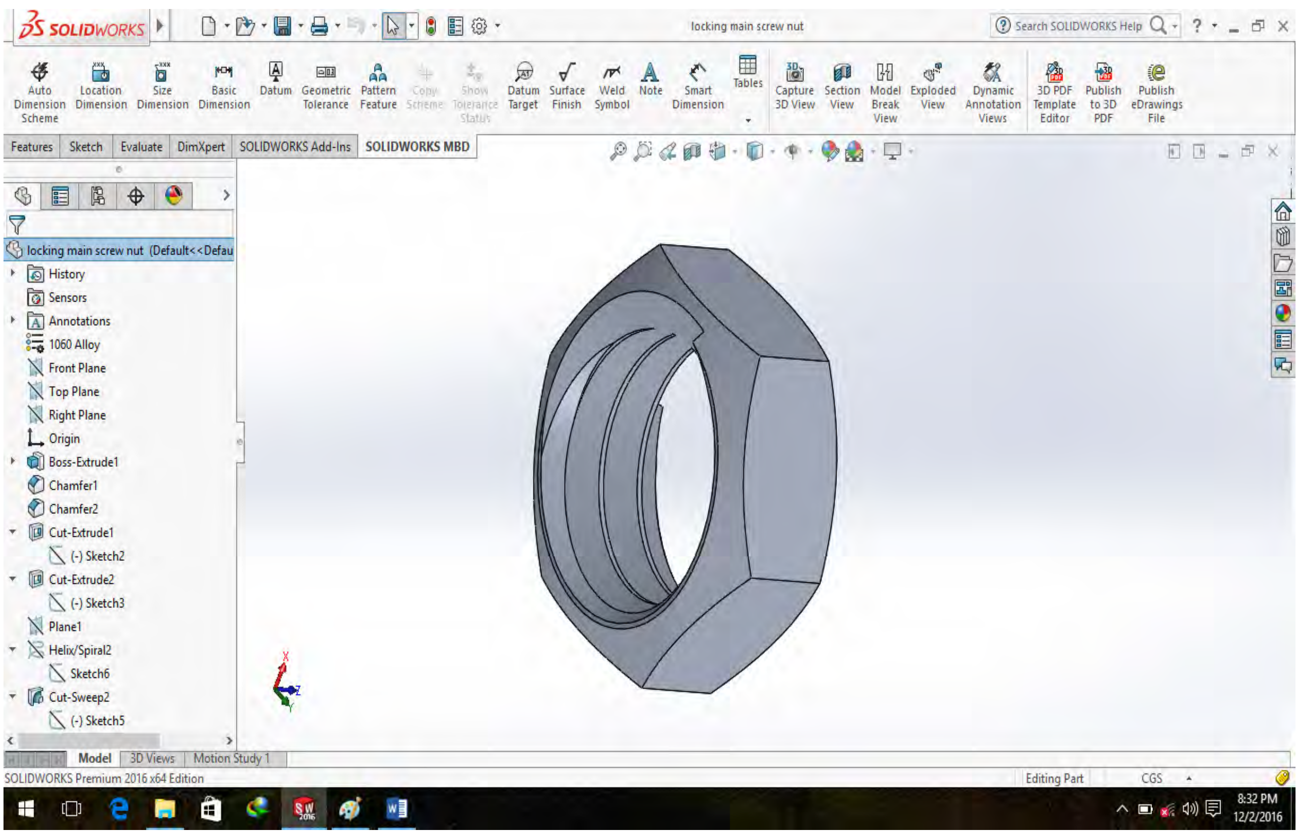
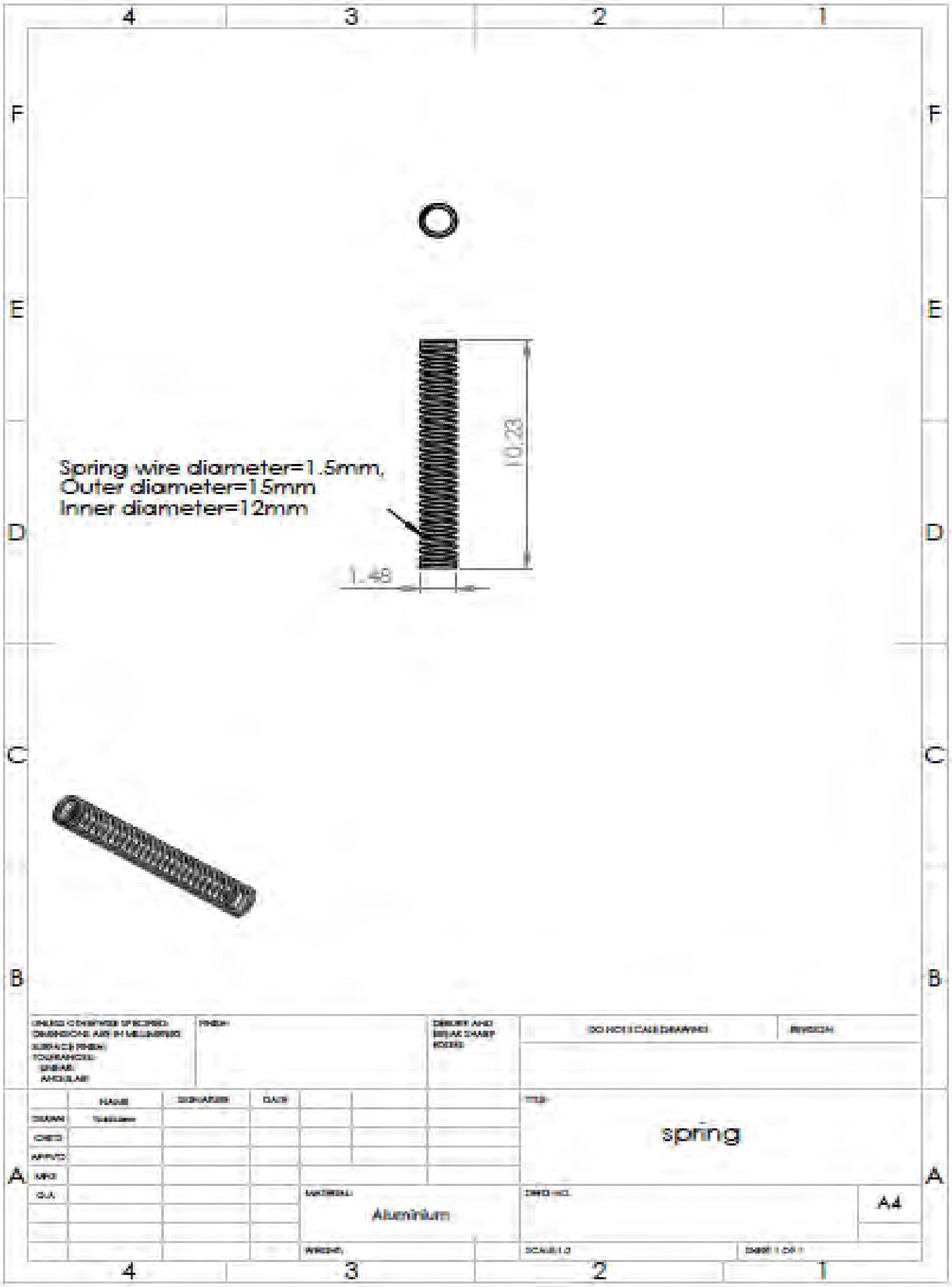
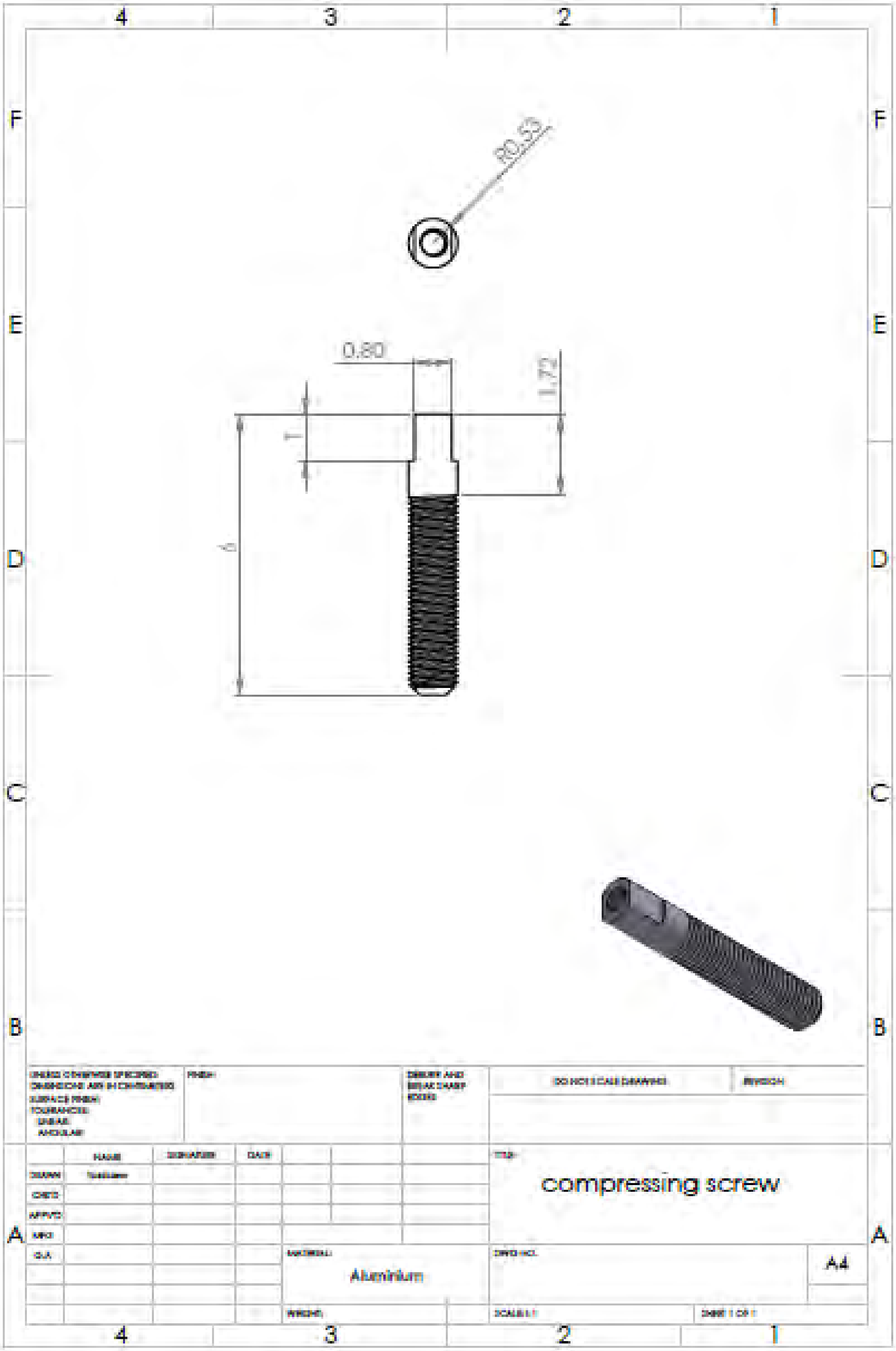
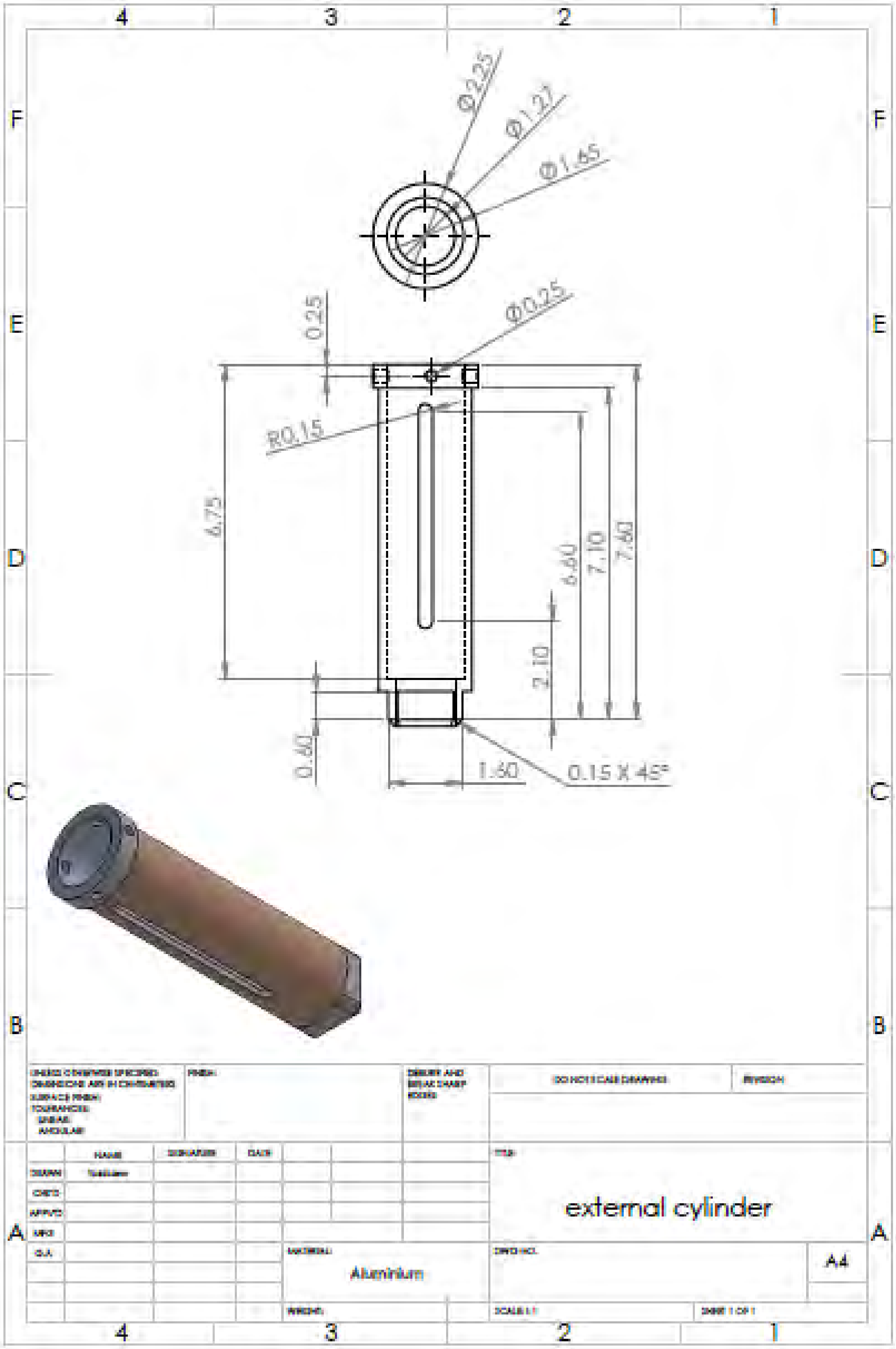
12/2/2016

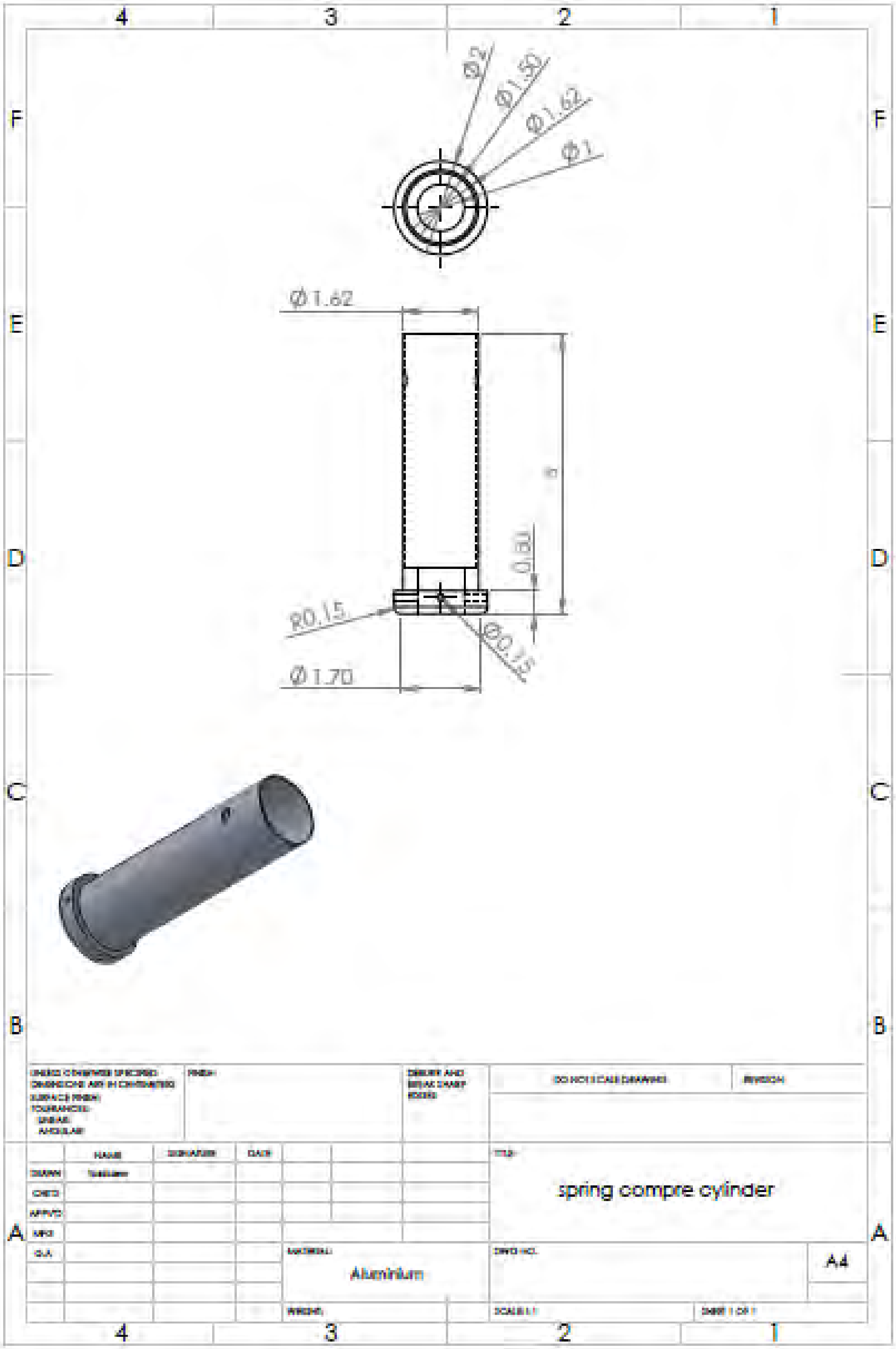


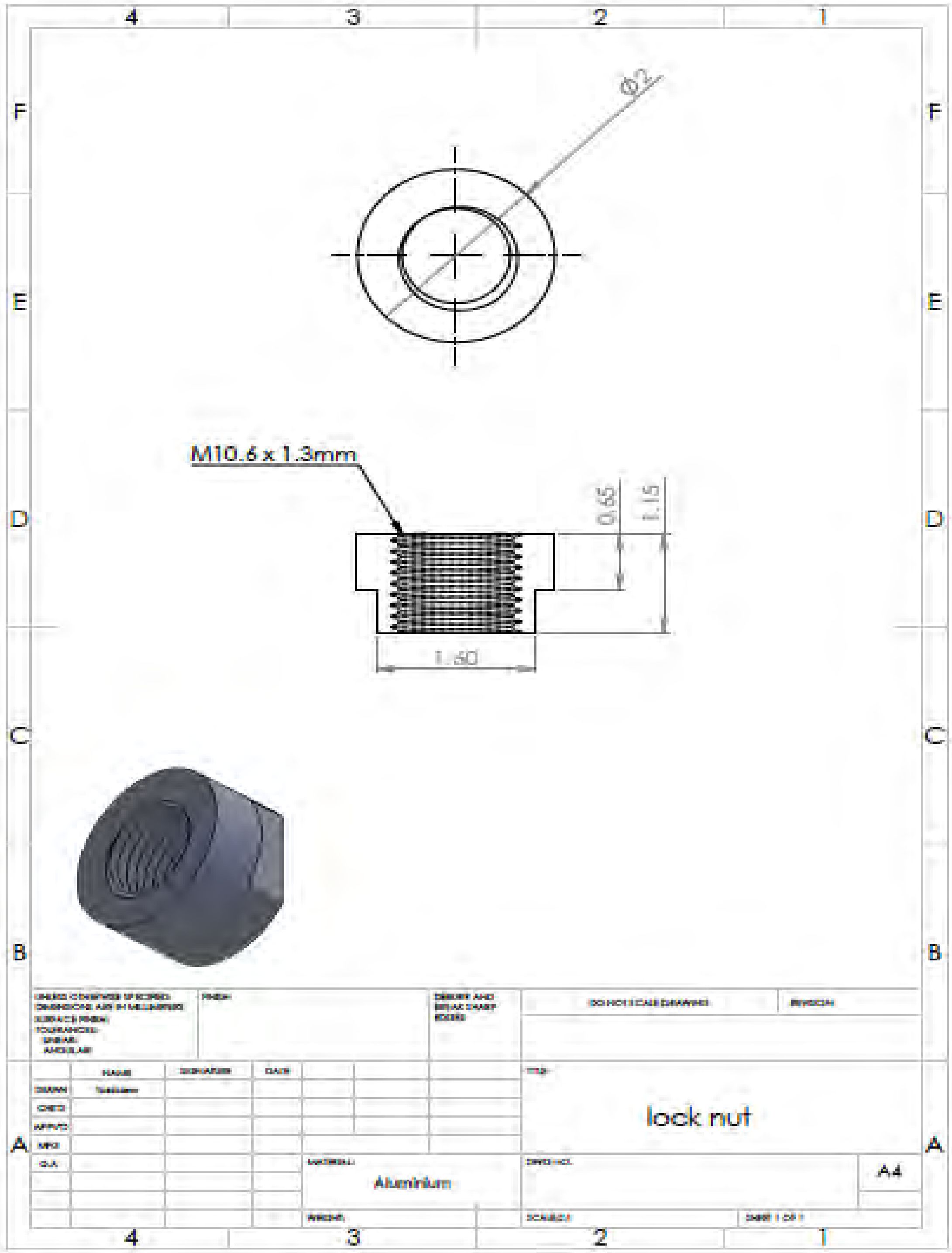



Spring wire diameter=1.5mm,
Outer diameter=15mm
Inner diameter=12mm
10.23
1.48
DO NOT SCALE DRAWING
REVISION
NAME
SIGNATURE
DATE
DRAWN
CHK'D
APPV'D
MFG
Q.A
MATERIAL:
Aluminium
DWG NO.
A4
TITLE:
spring
WEIGHT:

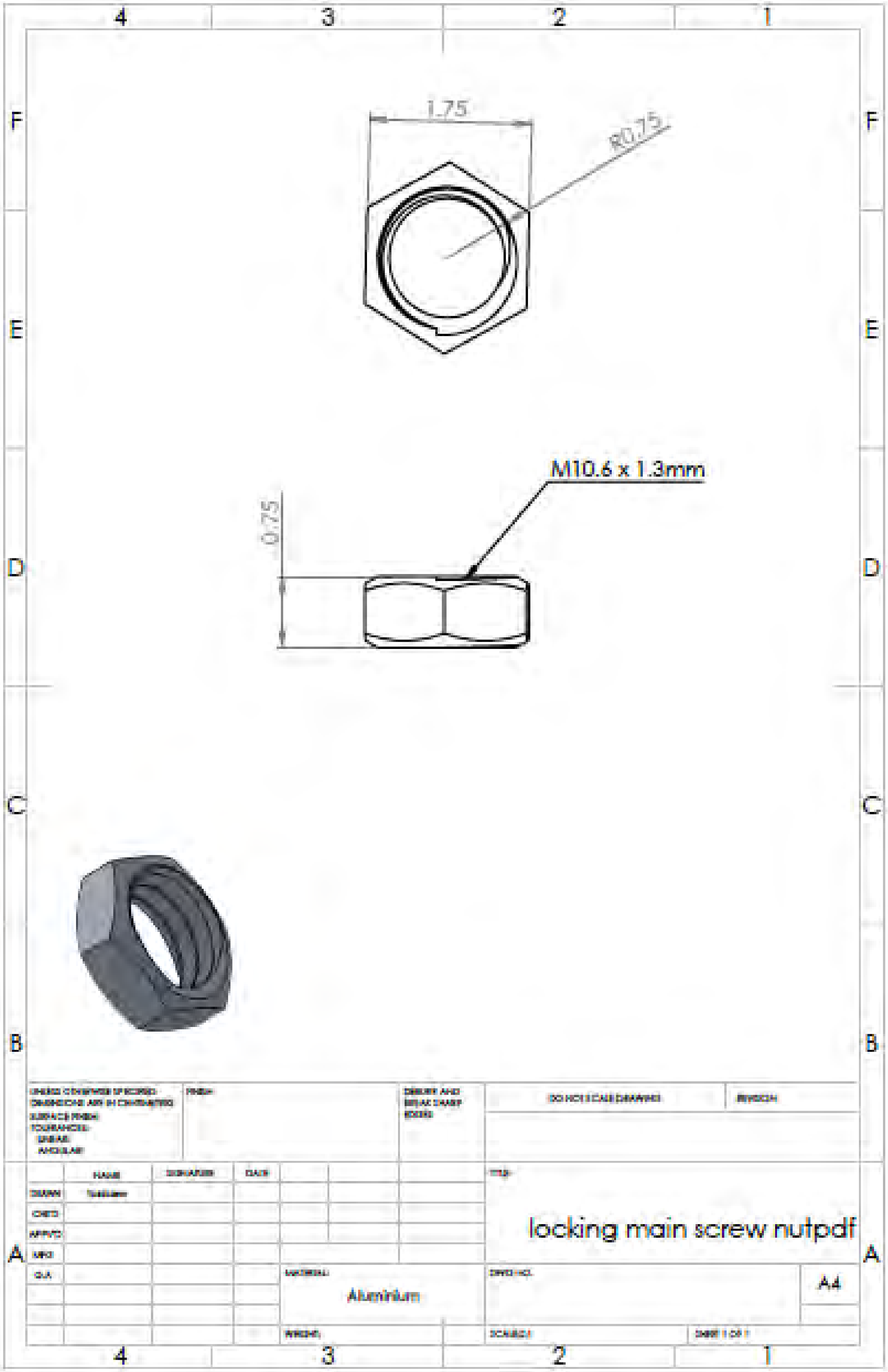

R0.53
0.80
1.72
1
6
compressing screw
Aluminium
A4


Ø2.25
Ø1.27
Ø1.65
Ø0.25
0.25
R0.15
4.75
6.60
7.10
7.60
2.10
0.60
1.60
0.15 X 45°
external cylinder
Aluminium
A4


Ø2
Ø1.50
Ø1.62
Ø1
Ø1.62
8
0.30
R0.15
Ø0.15
Ø1.70
DO NOT SCALE DRAWING
REVISION
NAME
SIGNATURE
DATE
DRAWN
CHK'D
APPV'D
MFG
Q.A
TITLE:
spring compre cylinder
MATERIAL:
Aluminium
DWG NO.
A4
WEIGHT:
SCALE:1:1
SHEET 1 OF 1



Ø2
M10.6 x 1.3mm
0.65
1.15
1.60
lock nut
Aluminium
A4


1.75
R0.75
M10.6 x 1.3mm
0.75
locking main screw nutpdf
Aluminium
A4

References

[1] A. J. kiran and et.al, "Estimating the Global Incidence of Femoral Fracture," *The Journal of Bone and Surgery,* Vols. 97-A, no. 31, pp. 1-9, 2015.

[2] L. G. Zirkie, "Injuries in Developing Countries - How Can We Help?," *Springer,* vol. 466, pp. 2443-2450, 2008.

[3] Patrick Sekimpi and et.al, "Femoral Fracture Fixation in Developing Countries: An Evaluation of the Surgical Implant Generation Network (SIGN) Intramedullary Nail," *THE JOURNAL OF BONE AND JOINT SURGERY,* vol. 93, pp. 1811-8, 2011.

[4] J. Browner and et.al, "Skeletal Trauma in Children, Medicine, Treatment of Injuries," 8 November 2015. [Online]. Available: http://Zombie.host.sk. [Accessed 16 November 2015].

[5] G. J. Tortora and B. H. Derrickson, Principles of Anatomy and Physiology, 13th ed., John Wily & Sons, Inc, 2012, pp. 182-288.

[6] K. S. Saladin and C. M. Porth, Anatomy and Physiology: The Unit of Form and Function, McGraw-Hill, 1998, pp. 284-287.

[7] F. M. John and S. L. David, "Femoral Shaft Fractures," in *Fracture's in Adults* , Wolters Kluwer Health , 2015, pp. 987-1023.

[8] P. Allison and et.al, "Open Fractures of the Femur in Children: Analysis of various Treatment Methods," *Spring,* vol. 5, pp. 101-108, 2011.

[9] U. E. Anyaehie and et.al, "Pattern of femoral fractures and associated injuries in a Nigerian tertiary trauma centre," *Nigerian Journal of Clinical Practice,* vol. 18, no. 4, pp. 462-466, 2015.

[10] Zimmer, *External Fixation System Large & Small: Surgical Technique,* USA: Zimmer.Inc, 2014.

[11] A. Gernote and et.al, *Hoffmann II External Fixation System,* Selzach: Stryker, 2005.

[12] G. Anthony and S. John, Orthofix External Fixation: Basic Considerations, Verona: Orthopeadic International , 2010.

[13] R. A. Buxton, "The Use of Perkins' Traction in the Treatment of Femoral Shaft Fracture," *The Journal of Bone and Joint Surgery,* pp. 362-366, 1981.

[14] T. Byrne, A Complet Reference Guide to the Basics of Traction, Zimmer Inc., 2005 & 2009.

[15] E. Ahmed, "Outcome of SIGN Nail Initiative in Treatment of Long Bone Fracture in Addis Ababa Ethiopia," *East and Centeral African Journal of Surgery ,* vol. 2, pp. 87-96, 2011.

[16] M. P. David and T. C. Nirmal, *Biomechanics of External Fixation,* New York: Bulletin of the NYU Hospital for Jont Diseases, 2007.

[17] T. J. Charles, "Correction Of General Deformity with The Taylor Spatial Frame Fixator," Memphis, Tennessee, 2002.

[18] P. Dror and et. al, "Ilizarov Technology," *Advances in Operative Orthopeadics,* vol. 1, pp. 243-284, 1993.

[19] C. W. Micheal , " Principles of Internal and External Fixation," in *Chapman's Orthopedic Surgery*, Lippincott Williams & Wilinks, 2001, pp. 24-60.

[20] A. M. Abdel-Aal, "Ilizarov Bone Transport for Massive Tibial Bone Defects," Orhtopedics, 2006. [Online]. Available: http://www.orthosupersite.com/view.aspx?. [Accessed 23 November 2016].

[21] L. F.Peltieis, "A Brief History of Traction," *The Jorunal of Bone and Joint Surgery,* vol. 50, no. 8, pp. 1603-1616, 1968.

[22] D. L. Richard Gosselin, "Perkins traction for adult femoral shaft fractures: a report on 53 patients in Sierra Leone.," *Springer,* vol. 31, pp. 697-702, 2006.

[23] H. M. G. Lowry, "The Physics of Rusell Traction," *The Journal of Bone and Join Sugery,* vol. XVII, no. 1, pp. 174-178, 1935.

[24] R. Prissana and et.al, "Students' Understanding Physics Concept of Traction Therapy," *Science Direct,* vol. 197, pp. 135-139, 2015.

[25] D. S. S. Corporation, *Introducing Solidworks,* Waltham, 1995-2013.

[26] Tatiana, Al-Chueyr and et.al, *InVesalius 3.0,* InVesalius3.0 Beta 1, 2007-2010.

[27] C. Paolo and et.al, *MeshLab,* Visual Computing Lab, 2005-2013.

[28] W. T. D. Manual, *Design Matrix Procedures,* 2016.

[29] N. Bundynas , Shigley's Mechanical Engineering Design, Eight ed., USA: McGraw-Hill Companies Inc., 2006, pp. 396-400,501-550.

[30] *Screw Thread Design.* [Performance]. Fastenal Engineering & Design Support, 2009.

[31] K. Seyyed, Eingineering Design Process, Saylor,org, 2005.

[32] B. Barry and V.-s. I. Maria, "Leg Length, Body Proportion, and Health: A Review with a Note on Beauty," *International Journal of Environmental Research and Public Health,* vol. 7, pp. 1047-1075, 2010.

[33] A. M. Wahl, Mechanical Srings, First ed., Ohio: Penton Publishing Company, 1944, pp. 25-193.

[34] B. A. Joseph and G. J. Alan, "Loading of Healing Bone, Fibrous Tissue, and Muscle: Implications for Orthopaedic Practice," *The American Academy of Orthopaedic Surgeons,* vol. 7, no. 5, pp. 291-299, 1999.