UNIVERSITY OF CAPE TOWN
DIVISION OF BIOMEDICAL ENGINEERING
DEPARTMENT OF HUMAN BIOLOGY
FACULTY OF HEALTH SCIENCES

MASTER'S IN MEDICAL SCIENCES (BIOMEDICAL ENGINEERING)

DESIGN AND DEVELOPMENT OF AN ADAPTIVE EXTERNAL BONE FRACTURE FIXATION SYSTEM

MINOR DISSERTATION

Submitted to

THE UNIVERSITY OF CAPE TOWN

In partial fulfilment of the requirements for the degree

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16 August 2019

Declaration

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Abstract

External fixation is a surgical treatment primarily utilised for long bone fracture stabilisation. External fixation, through either pin or wire insertion, is done by constraining bone fragments and providing support to the injury via external scaffolding built across the fracture., but it can also be used to solve both traumatic and congenital bony deformities. Certain devices, particularly the Ilizarov Ring Fixator, can employ external bone fixation to create a biomechanical environment to gradually correct deformities (comprised of: translation, rotation and angulation). A typical application for deformity correction is the fixation of lower leg fractures, particularly tibial fractures, which have been recognised as the most common incident in long bone fractures. External ring fixators have become more developed; manufactured from sophisticated materials; or designed to incorporate computational support, to achieve accurate correction, however these factors have created limitations regarding their accessibility, complexity and ease in application. In addition, standard systems are not as versatile or correctively exact as required to prove their cost of use, creating reluctance as well as added bias towards the more developed devices. Three-dimensional and multi-planar deformity correction has become major factors for current devices, yet the feasibility to use such expensive and complex devices may not be beneficial for all parties.

External Fixation Systems are considered operationally expensive. Standard systems still utilise expensive and cumbersome setups, while developed devices require computational consultation and extensive training. With such complex procedural actions required to facilitate multi-planar correction, most devices utilise computational support, which in turn minimizes the clinician's control. The current study aims to design a light-weight Adaptive External Bone Fracture Fixation System that can offer definite treatment and full clinical control over the injury. The system is to be able to stabilise and offer correction of planar bony deformities via controlled shape change. The functional verification of the device was limited to (according to the scope) stress testing.

The proposed device consists of hinge systems capable of allowing for full assembly expansion to permit quick installation for various injury structures or states. In addition, the design possesses longitudinal elements that can offer both rapid and finite lengthening (with lock-and-switch) to offer both rapid and gradual system shape change, improving the control over the injury fixation.

The device stress testing had revealed limited capabilities in providing enough scaffolding stability for a certain directional stress condition. To determine the quality of its structural integrity, the device was loaded under direct compressive and tensile load. The strain generated was measured and analysed using a Load-Deformation Curve. The device could support tension close to [3.5 kN], equivalent to standard models, whilst unable to support compression for loads close to [1.2 kN]. The conclusive points that were made had detailed that it was limited by its structural integrity, however the design was evaluated as functionally versatile as and should be further developed.

Future recommendations proposed include the addition of constrained joints; improved locking capabilities; implementation of failure modes for hinges and lastly improved structural integrity by using sophisticated materials to further validate the skeletal structure of the fixation system.

Acknowledgement

I would like to express my utmost gratitude to the following people

My parents, Mr Alan Herbert and Mrs Jenny Herbert, for their sheer support and loyalty throughout my academic career, especially during times of hardship and difficulty. They have truly blessed me with their love and support.

My Supervisor, Associate Professor Sudesh Sivarasu, for the support and dedication to assist me in this dissertation, offering guidance and mentorship throughout this course. You have been able to provide so much more that a Biomedical Engineering Degree and I would like to thank you for everything you have done for me.

My friends and colleagues, Edmund Wessels, Ameen Bardien, Gokul Nair, Giancarlos Beukes, and the rest of the Biomedical Engineering personnel for all their support, generosity and friendship.

I would like to sincerely thank Ms Penny Louw and the rest of the Material Engineering Staff for their support as well as their guidance and efforts in the completion of the experimental study.

Lastly, I would like to thank anyone who has provided me with the motivation to continue and pursue this degree during the times that I was reluctant or doubting myself. I would like to thank all of them.

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1. Introduction

1.1. Background to Study

External Fixation is a surgical treatment, primarily utilised for long bone fracture stabilisation. The treatment is accomplished by stabilising the bone and soft tissue via external scaffolding, creating a fixed setting for bone to heal, and as such, is often used as a temporary treatment for trauma. The external scaffolding providing support is primarily attached across the limb by percutaneously inserting either pins or wires into the bone tissue, providing rigidity across the injury zone. The treatment is currently able to be utilised as a definitive treatment method for both post-traumatic and congenital bony deformities due to devices allowing for small adjustment to gradually correct deformities (Fragomen & Rozbruch, 2007). The External Fracture Fixation Systems, particularly external ring fixators, are often used to correct bony deformities namely bone fractures, creating biomechanical settings to correct deformities comprised of: translation, angulation and rotation. The proficiency to correct planar deformities has made such devices prevalent in the orthopaedic department, due to the reputable principles established with the Ilizarov Ring Fixator. The ring fixator was built to incorporate the definitive principles of limb lengthening as a solution to bony deformities, offering a solution to both traumatic and congenital bony deformities, and thereby making the ring fixator a mainstay within the surgical community (Spiegelberg et al., 2010).

A typical application for temporary or definitive treatment is the fixation of long bone fractures. The fixation of long bone fractures is considered as a frequent medical case, with Tibial Fractures recognised as the most common long bone injury within the developed and developing countries (Court-Brown, Bugler, Clement, Duckworth, & McQueen, 2012). The National Centre of Health Statistics (NCHS) emphasised this fact when they had reported an annual incidence count of 492,000 fractures for Tibia and Fibula per year in the United States (Russell, 1996). Tibial Fractures are often created from the loads within high-energy collisions, or from the accumulation of low-energy stresses from repeated activities, recognised as stress fractures, which accounts for over 10% of all sport injuries and comprising of 30% of specific running sport injuries (Behrens, Deren, Matson, Fadale, & Monchik, 2013). From workplace hazards to body collision sports and activities, these fractures are a common occurrence in countries recognised for their large participation in sports and industry, making the external ring fixator a prominent medical tool in these countries.

The following study will investigate the possibility of a light-weight and cost-effective Adaptive External Ring Fixator for markets within the developing countries, such as South Africa and other African countries. The context of its efficacy is specific to the cultural similarities of South Africa to other countries from the standpoint of its participation in collision sports and industrialised manufacturing. This country has demonstrated its competitiveness within popular sports such as rugby and soccer, while the large industry trade will often require companies to be demanding of workers. The significance of an Adaptive External Ring Fixator would be extensive as the costs for fracture fixation treatments are frequently difficult to meet for a population of low-income communities, that are growing in number across South Africa as well as the African continent.

1.2. Clinical Problem Description

The clinical problem is the lower limb long bone fracture, caused by high energy collisions. These Injury fractures are often a result from impact loads, generating a localised break along the bone. Such injuries are typically prominent in popular contact sports as acute fractures, a common injury that comprises for 5-10% of all sports injuries and accounts as one of the longest return-to-sport post injury (Bathgate, Best, Craig, & Jamieson, 2002)(Price, Hawkins, Hulse, & Hodson, 2004). This injury demands time for treatment and recovery, by which often leads to financial implications for both team and individual (Brukner & Khan, 2012). The lower extremity primarily functions to support the major portion of the body's mass, and since the tibial fracture is a common occurring injury that affects stability and mobility, they often lead to morbidity for athletes. The treatment of long bone injuries is often stabilisation, by using either a splint or fixation to allow the bone to heal without bearing weight. If the severity of the injury demands for more long term care, a more definitive treatment may be needed that allows for gradual correction and long term rectification.

External Fixation is currently a common surgical treatment for long bone fractures, as external ring fixators are substantially proficient in treating bony deformities. The method had first gained popularity in the mid-20th century, during which a device was introduced by Raoul Hoffmann that could stabilise long bone fractures with Steinman pins and bars. Sir John Charnley followed this advancement with a compression device for knee arthrodesis that could increase the fusion rate and decrease the vital consolidation time. However, during the time that the Western World had used external fixators sparingly, Russia had paved the way for these devices, by introducing the Ilizarov Ring Fixator as developed by the physician, Dr G. A. Ilizarov (Fragomen & Rozbruch, 2007).

The Ilizarov System is a ring fixator that was designed to offer both traumatic and congenital bony deformity treatment through external fixation. It primarily gained recognition for its corrective capabilities for planar deformities through its minimalistic system setup, typically comprised of simple and accessible components (Mullins, Davidson, Goodier, & Barry, 2003) (Fragomen & Rozbruch, 2007). The device could stabilise such injuries by constraining bone tissue in suspension and allow for system adjustment to correct the deformity (Spiegelberg et al., 2010). The system popularised the external ring fixator as a proficient device for rapid and rigid fixation as well as introducing deformity correction principles to fracture reduction. This has led to more developed ring fixators such as the Taylor Spatial Frame (Smith & Nephew, Memphis, TN), which integrated the principles into six-axis hexapods, and incorporating it within a computer program (Tan et al., 2014). These hexapod fixators are capable of providing impeccable accuracy however, these and other devices can be expensive and complex, making simpler fixators often favourable.

Ring fixators are comprised of rings and longitudinal elements, that together form scaffolding that stabilises and protects the bone injury. These parts have not changed much since the Ilizarov Ring Fixator's introduction and are made from either steel or aluminium alloy. The setup has remained ergonomically cumbersome, requiring specific frames to be built during surgery, often becoming complex and larger for the severity of the injury. However, a ring fixator built to reduce these very complications may be invaluable, especially within the African market (Dammerer et al., 2011).

1.3. Problem Significance

The study concentrates specifically on the rapid and definite fixation of lower extremity long bone fractures, resulting from medium to high energy collisions. Bone fracture stabilization by using external fixation is often minimally invasive, only requiring the percutaneous insertion of pins or wires. Their placements along the limb as well as the type of frame used is subjective, depending on the clinician's judgement as well as the determined classification from the radiographic image presented. External ring fixators such as the Ilizarov Ring Fixator, Taylor Spatial Frame and TL-Hex Truelok, can correct the planar deformities presented within lower extremity long bone trauma, particularly for those composed of translation, rotation and angulation simultaneously. These deformities increase in complexity as the bone displacement becomes more pronounced, by which the versatility and adjustability of the systems are tested. Solutions to these injuries result from the system's ability to comply with complex shape or profile changes to correct the structure of the injury, as the current external ring fixators are designed to accommodate for these changes.

Even though current devices can accommodate if not calculate solutions for deformities, offering the clinician full control over the injury is still a primary function of the device. Thus, this study is aiming to design and develop a new External Bone Fracture Fixation System that can still provide adequate corrective capabilities for long bone trauma and yet fully ensure that the clinician has complete control of the injury correction process, by offering efficient and accessible mechanisms for structural adjustment. In addition, the device will be designed to reduce the time taken to fully complete the surgical procedures, by reducing the complications of long bone fracture fixation. The results of this study would determine if the structural integrity of an adaptable and versatile system would be applicable for the treatment of the lower-extremity long bone trauma fracture.

The following study focuses on the design and development of a new light-weight external ring fixator that eliminates certain limitations within the surgical treatment procedure, as well as the fracture correction process. Therefore, the results obtained from this study are to demonstrate clear structural comparisons to a market device and thereby relate these results to the standard model, as according their structural integrities. The Ilizarov Ring Fixator can correct trauma lower extremity long bone injuries of singular and multiple planar deformities by using the principles of gradual correction (Spiegelberg et al., 2010). The system was able to clearly demonstrate that the functionality of external ring fixators is valid as a definitive solution to long bone trauma fractures. The Ilizarov Ring Fixator has demonstrated repeatedly in previous studies, that it is capable of correcting lower-extremity bony deformities, however it has fallen short in accuracy to developed devices; and has become ergonomically unsatisfactory during prolonged periods of use; and lastly it is limited by its affordability (Manner et al., 2007) (Tetsworth & Paley, 1994) (Dammerer et al., 2011). The Ilizarov Ring Fixator as well as other similar external ring fixators, possess limitations that have reflected their performances, affordability, and ease in construction and application as well as their ergonomic design. As such there is a research opportunity to determine a new design that is cost effective, adaptable, efficient to install during surgery, effective under operation, and yet be designed ergonomically in order to meet the general concerns of the patients, whilst also meeting the design requirements for acceptable external ring fixators as determined by clinicians.

1.4. Research Approach

The research study is comprised of device design and testing within relevant bench environments. The device design focuses upon the standard practice in applying engineering design principles for medical device development. The functional testing or experimental study focuses upon the research and development as well as the verification of the final design. The Quasi-Static Machine was used as the loaded cell machine to experimentally test the device's structural integrity, under direct loading conditions. This would assist in the verification the device's structural design as well as demonstrate its performance under stress conditions equivalent to long bone fracture fixation.

1.5. Hypothesis

Lower extremity long bone fractures are common forms of injury worldwide. The impact of these fractures has been more severely felt in the more developing countries. The rapid fixation of these injuries to maintain a steady procedure completion rate would effectively accommodate the frequency in incidences for a growing population. In addition, allowing full control over the injury would permit for immediate clinical intervention, reducing implications during correction. Existing external ring fixators possess several design limitations. The solution(s) to these limitations would correspond to the validations of the following hypotheses depicting their corrections:

1. Offering full external ring fixator expansion and closure by employing a hinged ring with rapid or finite element lengthening systems will quicken the fracture fixation process.

2. A light-weight and cost-effective external ring fixator, comprising of a hinged ring and rapid or finite element lengthening systems for rapid installation and fracture fixation, can provide enough assembly stability to support and correct long bone fracture fixation.

1.6. Study Aim

Design and experimentally validate a new Adaptive External Bone Fracture Fixation System that delivers rapid device installation and bone fracture fixation versatility by providing full assembly expansion and controlled multi-directional shape change from longitudinal element lengthening.

1.7. Research Objectives

1. Design and develop the subsystems of the device, to enhance device installation and versatility in bone fracture fixation via assembly expansion and profile shape change.

2. Design and develop the setup of the device, to effectively integrate and incorporate these mechanical subsystems for the purpose of functioning as an external ring fixator.

3. Design and perform an experimental study, to validate the device's usability through an assessment of its structural integrity and comparing the results to a market model.

1.8. Key Study Parameters

The significance of external fixation, particularly for the treatment of lower-extremity long bone injuries, is prominent for South Africa and other developing countries, recognised for sports and industry participation. Focusing device design in efficiency and weight optimisation is essential as the economic climate of South Africa desires medical device that are accessible, affordable and ergonomically appealing. The study integrates these desires as key study parameters for the engineering design process for effective medical device design, which should comprise of design aspects pertaining to: efficacy, practicality and affordability.

The device design parameters are:

1. Design the fixator rings which features:
    I. Light-weight and high strength mechanical properties.
    II. Hinge-and-lock systems to permit smooth rotations for full assembly expansion.

2. Develop the longitudinal support element which include:
    I. Mechanical components (assembly joints and connecting struts) that link-and-lock such that the entire assembly can support the loads across long bone fracture.
    II. Locking Mechanics to stabilise the recorded or measured adjustments as well as to solidify the support structure and prevent tampering from external influence.
    III. Mechanisms to permit controlled lengthening for gradual planar adjustment along the support structures to effectively employ the deformity correction principles.

3. Design the system to comply with existing surgery tools and ring fixator fasteners.
4. Investigate accessible materials to be used in building the Adaptive External Ring Fixator.
5. Produce applicable recommendations that can be integrated into future developments.

The experimental study parameters are:

1. Determine the limits in structural integrity for feasibility in long bone fracture fixation.
2. Evaluate efficacy by comparing the device’s performances to an established ring fixator.

1.9. Scope of the Study

The study was focused upon and is limited to the design of an external ring fixator that can reduce the time taken to fixate lower extremity long bone fractures. The study will be acknowledged as an investigation to determine whether a proof of concept is feasible and a possible marketable product. The scope of this study is to design and experimentally validate if the device design can operate as a functional external ring fixator under equivalent loading conditions, generated by a Quasi-Static machine. Its efficacy in reducing the installation time is assessed through prototyping while the functionality of the device is tested by determining the limits in its structural integrity.

1.10. Dissertation Overview

This document is constructed to systematically describe the design process, device testing, and the methodologies used for this study (as illustrated in Figure 1.1). Chapter 2 (The Literature Review) describes and details the lower extremity long bones as well as existing ring fixators, the clinical problem, existing solutions and the justification for the Adaptive External Ring Fixator. Chapter 3 (Design Methodology) details the approach taken to designing the device that would incorporate the designs produced for each component and subsystem, to function together as an Adaptable External Ring Fixator. Chapter 4 (Design Outcomes) details the design considerations taken to further develop the device's design. Chapter 5 (Experimental Methodology) details the experimental procedure used to validate the device's design and its usability, through mechanical stress testing. Chapter 6 (Experimental Outcomes) further details the experimental procedure by providing and demonstrating the results obtained from testing as well as detailing the analyses conducted to compare the device to the standard model. Chapter 7 (The Discussion) summarises the efficacy of the device for bone fracture fixation based upon the results captured. The chapter concludes by providing evaluations on its feasibility. Finally, Chapter 8 (The Conclusion) concludes the study by evaluating its outcomes and determining if the device is acceptable for development.

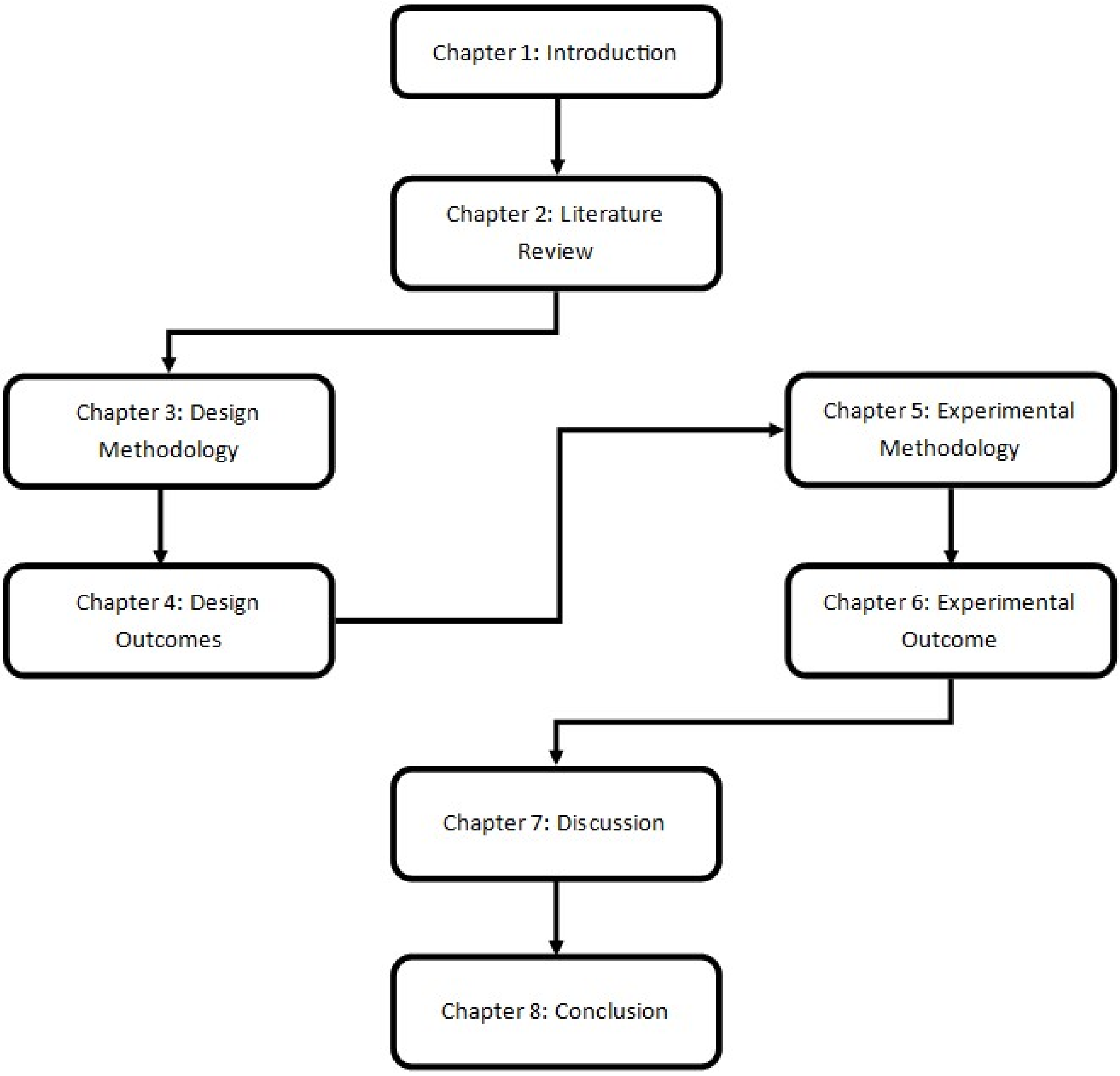


Figure 1.1: A systematic flowchart of the chapters within this thesis, as per acceptable medical device design and validation

2. Literature Review

2.1. Introduction to Lower Extremity – The Lower Leg

The Lower Leg (as illustrated in Figure 2.1) is an extension of the skeletal system between the knee and ankle joints; as well as forming part of the lower extremity with the upper leg. The lower leg functions for weight bearing and body mobility, and as such, a third of all fractures occur here (Court-Brown et al., 2012). The lower leg region is comprised of muscles and tendons structured around two long bones, constituting a major portion of the body's overall mass. Lower leg stability is maintained by the strengths of the surrounding muscles and tendons as well as the anatomical structures of the ankle joints and the Tibia long bones. The Fibula does not form part of the knee joint, meaning the Tibia typically supports the majority of the body's weight along this region. The shape of the Tibia (as illustrated in Figure 2.1) makes it the second longest bone in the body, and by taking loads directly from the ankle joints, it is often susceptible to fracture from high energy collisions, making the tibial shaft fracture a common injury in motor vehicle crashes. In addition, the risk to injury and the level of pain is proportionate to the person's participation in physical activity, particularly from strenuous exercises conducted by athletes and militants (Beck, 1998). These factors in injury susceptibility make the lower leg fracture, particularly the tibial fracture, a frequent incident within bone fracture fixation, and as such, direct loading conditions equivalent to this injury would be able to provide sufficient evidence to fully evaluate the device's usability.

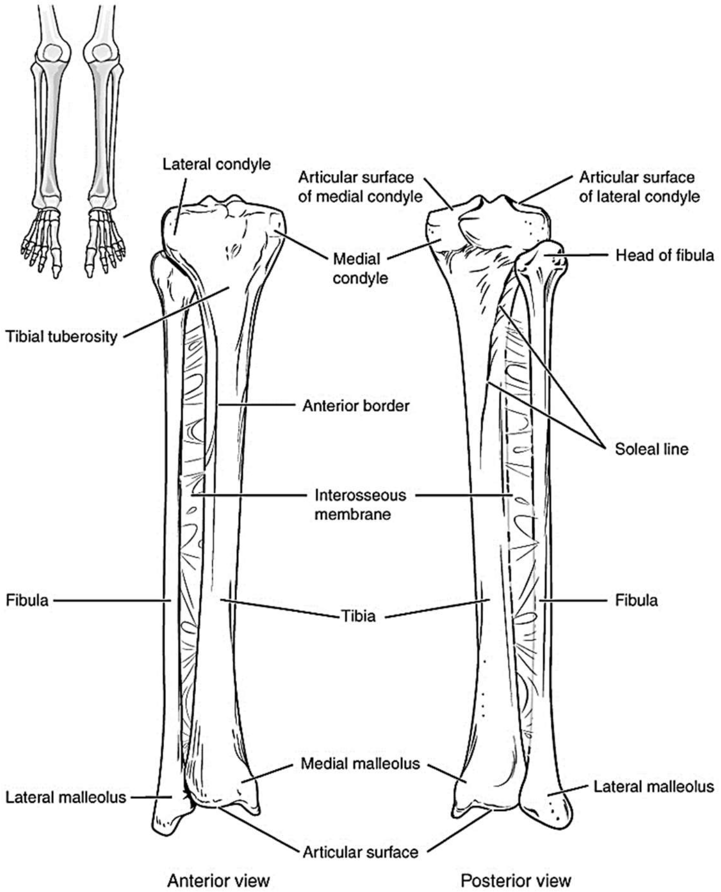


Figure 2.1: Anatomy of the Lower Leg, highlighting Tibia bone's positioning and orientation (image credit:((OpenStax, 2013)*))*

2.2. Clinical Presentation and Evaluation

2.2.1. Injury Description and Causes

The effective functioning of the lower leg results from the strength, structure and stability of the compact bone structures of the Tibia and Fibula as well as the surrounding muscular structures. In addition, bone growth and strength training assists in enduring both static and dynamic loading. A compromised lower leg results from significant damage to bone and soft tissue, weakening the lower leg's structural integrity and reducing its ability to bear weight, thereby its functionality.

Lower extremity injuries are common incidences amongst sport athletes participating in activity with excessive running and collisions (Van Gent et al., 2007)(Murphy, Connolly, & Beynnon, 2003). In addition, studies have shown that the many annual lower extremity injury counts are created from traffic crashes and other related events (Huelke, O'Day, & States, 1982)(Madadi et al., 2010). These many causes in injury has also made the tibial fracture, the most common type of long bone fracture in developing countries, a detail that has been demonstrated across Africa. Kilimanjaro Christian Medical Centre had revealed in 2014 that open lower-limb fractures were the second leading cause of death in the orthopaedic departments (Clelland, Chauhan, & Mandari, 2016). With the frequency in injury due to high energy collisions, the tibial shaft fracture is often the resulting factor to recorded compromised lower legs. However, the more significant factor is that the fracture type is a common problem within the developed countries as the number of vehicles increase, leading to a higher injury rate, by which rapid stabilisation would become a requirement in current fracture fixation procedures. (Court-Brown et al., 2012)(Court-brown & Caesar, 2006).

2.2.2. Symptoms and Classification

A lower leg fracture, typically the tibial shaft fracture, would occur along the shaft of the bone in various positions, depending on the nature of the collision. The resultant outcome of the fracture is instability along the lower leg. With the bone's structure compromised, the severity of the injury may scale regarding the continued harm to bone tissue and the surrounding muscular structures.

A long bone fracture would result in immediate and severe pain. Depending on the severity of the fracture, the patient would most likely be incapable of walking or bearing weight on the leg. With higher levels of severity due to high energy collisions, bone may be exposed through the skin with fractured bone protruding through skin and muscle tissue. In all occasions, blood loss and soft tissue damage is present, and the patient would potentially experience loss of feeling in the leg.

The classification of the type of fracture is a key phase of the fracture fixation process. The most common utilised fracture classification system is based off the OTA/AO Classification, by which the classification depends on the affected region, energy and mechanism of injury. Open Fracture Classification usually follows the verified Gustilo-Anderson classification, but as a basic approach, due to the general consensus that the difficulty in clinical prognoses may always scale with injury severity for infections, non-unions, and other complications. Altogether, Classification allows for an understanding of the structure and nature, making it easier to differentiate between patterns.

2.2.3. Treatment Methods

The treatment methods available for long bone fractures, depend on the severity of the injury, particularly the classified type of bone fracture, by which the method can be short or long term. The common treatment method is recognised as stabilisation, constraining the current state of the injury, whereby the treatment method creates a healthy environment for bone tissue to heal. A minor injury experienced along the bone would most likely have the patient wear a brace or splint for some time, to hold firm the injury until swelling reduces and limb functionality returns. As the severity of the injury rises, surgery may be required, and the fixation of the fractured bone is the recommended stabilising method, comprising of either internal or external fixation. Internal fixation employs device implantation along or through the bone often requiring open surgeries, whilst external fixation is minimally invasive, achieving sufficient stabilisation via an exoskeleton. In recent literature, potential treatment methods for non-union fractures have been tested and evaluated such as tissue engineering, by which employs stem cells as the building blocks for bone implants to replace bone grafts; and shock wave treatment that can induce planar micro motions.

2.2.4. African Relevance

The need for an accessible and adaptable external ring fixator within the South African region extends further towards the rest of Africa as the participation in football and other popular sports increases with popularity and commercialisation. The injury rates within sports increase with the increasing populations across Africa and in addition the rates in road traffic injuries. Globally, road traffic injuries has now been reported as the leading cause of death among people aged 5-29 years (Geneva: World Health Organisation, 2018), whilst within Africa, the recorded rates from a selection of regions amounted to 26.6 per 100,000 people, the highest rate globally, with a large portion of the recorded mortalities as pedestrians and cyclists. South Africa's increasingly large participation in industry and manual labour has also led to the rise in industry across the continent and thereby a rise in work related injuries, as accidents become are a common occurrence within workplaces with minimal safety protocols. Within South Africa, younger workers were recorded to be most prone to long bone injuries, particularly fractures resulting from falls and machine threats with the injury costs proportionate with a worker's age and health (Eppenberger, 2009). To keep a healthy workforce, often workers demand for the easiest and quickest medical solution.

In accordance to daily lifestyles of workers and athletes, Africans commonly participate in cardio and strenuous activities that over time increase the risk of long bone injuries. Stress fractures are another cause for complete fractures, resulted from regulated stresses applied to long bones due to activities with large amounts of running such as athletics, rugby and soccer. With the high degree in participation in such strenuous sports, work or hobby related activities, active people are often prone to bone trauma, which is further supported by the high rate in road traffic injuries. Producing a light-weight, accessible ring fixator that can adapt to the usual complications of long bone fracture fixation would be beneficial to both the patient's financial and physical wellbeing. In addition, the external ring fixator should be able to significantly shorten the surgical process to minimize surgery time and cost, whilst still enable complete control over the fixed frame. These design factors if implemented correctly would ensure that the device can excel within the African orthopaedic department and the current market, and as such, should be the aim of this study.

2.3. Tibia Long Bone

2.3.1. Function

The long bone is a hard, dense skeletal component that provides strength, structure and mobility. A typical healthy long bone allows for a large amount of load before breaking. The second longest bone, Tibia, functions by supporting the body's weight through both the knee and ankle joints, by which the weight allowance is dependent on age, gender and prior training (Neumann DA, 2010). The long bones of the lower limb support the upper body and endure the added weight created by mobility and body collisions, resulting in injuries specific to higher loading of the lower limb (Milner, Davis, & Hamill, 2006). Once the long bone has been compromised, supporting weight becomes difficult, requiring effective stabilisation to preserve the strength, structure and stability. The aim of the external ring fixator stress testing would be to provide the investigator with detail evidence of the device's structural integrity and thus its feasibility for long bone fracture fixation. The aim is accomplished by employing direct loading to generate applicable stress conditions.

2.3.2. Biomechanics of the Tibia Bone

The biomechanical characteristics of a bone can be analysed through the relation of bone tissue to any general material placed under different loading conditions (as illustrated in Figure 2.2). The bone can be regarded as an anisotropic and viscoelastic material, meaning it behaves differently depending on the direction and speed of the load. The behaviour of any material to a load can be determined by its strength and stiffness, categorised by its structural integrity. When an external load is applied, there is an internal reaction i.e. a level of resultant deformation. By relating the bone tissue to a loaded material, one would be able to determine the limits in material elasticity.

A typical Tibia bone, and other long bones, can support large loads, depending on the age, gender and prior strength training conducted by the person (Neumann DA, 2010). Such factors determine the limits of the bone's functionality, however for the accomplishment of this study's experiment, the subjected long bone will be equated to the average person, meaning the stress generated by the loading should be limited to stress conditions equivalent to an average person, particularly a healthy male, for experiment repeatability and reproducibility. The typical male, as per the 95th percentile male, can accumulate body weight for up to [102 kgs], and according to a conducted study, the mobility of an elderly male through activities such as walking can create peak loads of over [400 kgs] along the Tibia (Voinescu et al., 2011). However, this study will be limited to the average axial loading demonstrated as 3.5 times the body weight, approximating to [3.5 kN]. Thus, the study's experiment would be employing external loading by means of a loaded cell machine and apply loading upon the extremities of the external ring fixators, generating functional failures.

The relations of the applied load (external force) to the resultant deformation (internal reaction), can be portrayed using the Load-Deformation curves (as illustrated in Figure 2.2), depicting the material's behaviour under direct loading (Holtrop, 1975). This method has often been used to determine the structural integrity of certain devices in the form of device testing, and therefore this experiment will be conducted similarly, testing the device by loading it until functional failure.

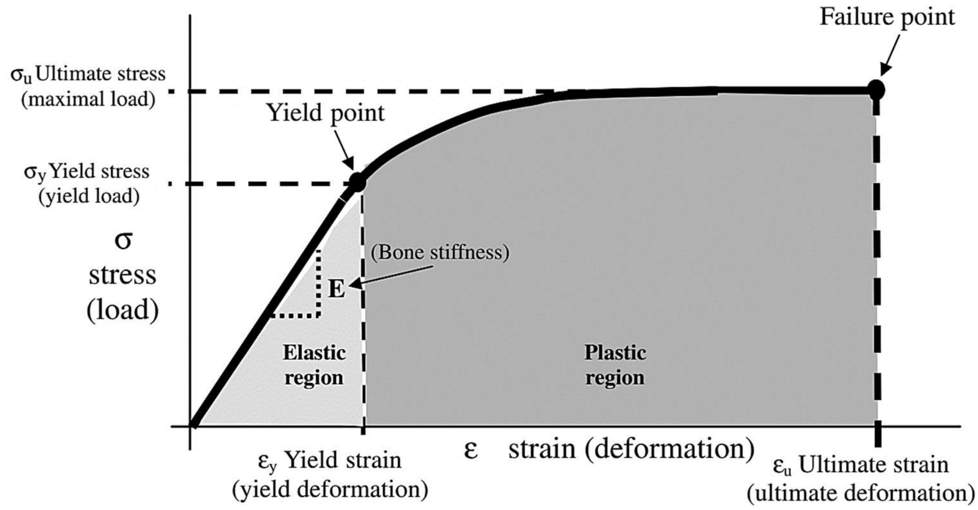


Figure 2.2: A linear graph for a Load-deformation (Stress-Strain) curve obtained by loading a experimental sample of compact bone in tension. E - is the stiffness (Young's modulus for isotropic materials) (image credit: (Sharir, Barak, & Shahar, 2008)*)*

By incorporating the average male body weight and the resultant axial load created through body mobility, the experimental study will focus on loading the built devices to a peak load of [3.5 kN]. The experiment would be using Load-Deformation Curves (as shown in Figure 2.2) as the graphical representations for the performances (stiffness) under load conditions, as well as analytical tools for comparisons. Furthermore, the experiment is to be limited to direct axial loading generated within the loaded cell, applying load directly to the fixed fixator ring. The Load-Deformation curves produced would represent the relation of the applied load and the resultant linear deformation. Since long bone injuries commonly result when the bone material is compromised, the presence of bone material may not be required for the tests as failure would be determined if the device is unable to bear the weight. Thus, the experimental study would pertain to loading only the device.

2.4. External Fixation

2.4.1. Overview

External fixation (as shown in Figure 2.3) can be simplified as a surgical treatment method used to stabilise bone and soft tissue to allow for the fractured bone to heal. The treatment comprises of either interosseous pin or tensioned wire fixation, by which support along the limb is provided by external scaffolding. The treatment is frequently utilised in trauma management, by offering temporary modalities for the rapid stabilisation of long bone and periarticular injuries in civilian and military environments (Monni, Birkholtz, de Lange, & Snyckers, 2013). The conversion from temporary external fixation to a more definitive treatment method is still a common choice within trauma, however available external fixators can offer both congenital and traumatic deformity correction with the benefits of minimal invasiveness and biomechanical influence (Fragomen & Rozbruch, 2007). The available external fixators currently have been divided into three categories: simple, clamp and ring (Watson, Mathias, & Maffulli, 2000), with simple and clamp grouped as pin fixators by the community. The external fixators can be identified by the fixation type such as pin fixators (as illustrated in Figure 2.3). Pin fixators differ in principle to the ring fixator by which, the ring fixator is often built as an exoskeleton, whilst allowing gradual structural adjustment, to progressively correct the planar deformities that had produced the fracture (Watson et al., 2000).

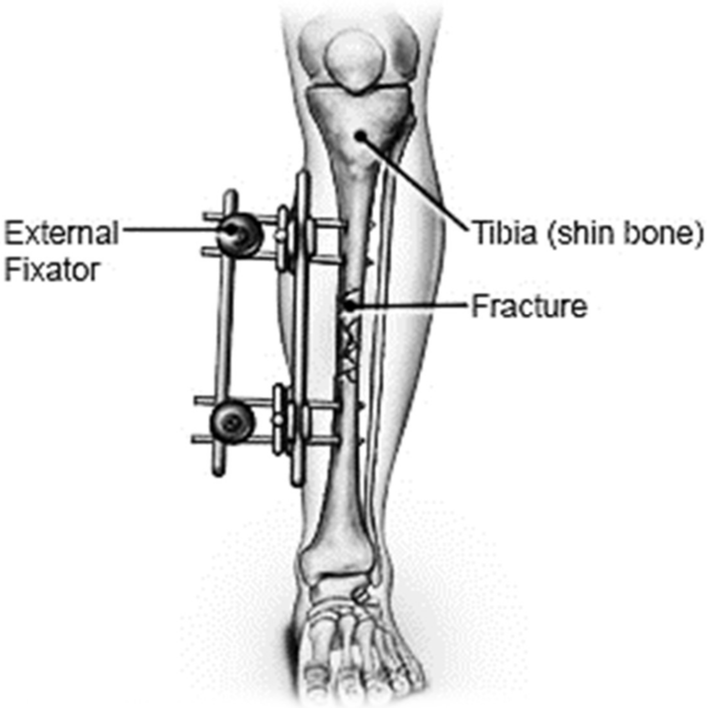


Figure 2.3: Anatomy of External Pin Fixation applied upon a Tibia Long Bone Fracture (*image credit: (Drugs.com, 2018)).*

The surgical treatment when using ring fixators can require some time to complete, accumulating from planning and construction during theatre. Ring Fixators are designed to allow the clinician to adjust the system to correct deformities as a result of: translation, rotation, and angulation (Manner et al., 2007). The Ilizarov Ring Fixator is capable of correcting such deformities by using multiple components (Ilizarov, 1992) and building frames appropriate for certain complex injuries. Subsequently the numerous parts can elevate the learning curve of the treatment often requiring extensive training and time to build the appropriate frames. The aim of the study's experiment is to determine whether the newly designed ring fixator created to be efficiently installed as well as fully adaptable to an injury's status, would be able to function as an adequate external ring fixator. In addition, assess the final design's functionality regarding its overall structural integrity to load.

2.4.2. External Circular Bone Fracture Fixation –Ring Fixators

Ring Fixators provide stability via scaffolding comprised of ring blocks separated by longitudinal elements, suspending the bone fragments within frames (Watson et al., 2000). Frequently, ring fixators provide stability by utilising tensioned wires to constrain the motions of bone fragments (Ferreira, 2012). The degree of constrain depends upon the number wires and their relative alignments to one another (Ferreira, 2012). Ring fixators bear lower axial stiffness to mono-lateral fixators, and the tensioned wires operate to yield a higher axial stiffness for higher loads, and as such ring fixators mimic ligaments and tendons by their non-linear, load-dependent axial stiffness (Ferreira, 2012). Understanding the effect of the ring fixator's biomechanical attribute in the management of complex trauma fractures, offers a resource to define a more proficient design (Ferreira, 2012). The biomechanical influence correlates with the system's mechanical properties and Table 2 summarises the effects of each component variable to the mechanical properties.

Table 2.1 Summary of the effects of each component variable to the mechanical properties of a circular external bone fracture fixator (table credit: (Watson et al., 2000))

Component	*Variable/type*	*Primary effects/comments*
Rings	Diameter	Decrease in diameter, increases stiffness
	Material: Steel Aluminium Carbon comp	Steel is stiffer at low loads. Carbon composite does not deform plastically at loads greater than 1450 N (maintaining wire tension)
	Segment Size	Open ends may reduce the stiffness properties
	Position relative to each other	Should be placed as far apart as possible on each bone augment with small bridge across fracture site
Connectors	Slotted bolts Cannulated bolts	Prevents wire slippage (maintaining wire tension) Slotted bolts withstand highest loads
Longitudinal Elements	Complex distraction assemblies	Best type as yet undetermined. However, complex assemblies often enable multi-planar adjustment

2.5. Fracture Fixation

2.5.1. Introduction to Fracture Fixation

The fracture fixation treatment is the stabilization of loose bone fragments, enabling healing along the injured extremity and returning it to full functionality (Benjamin, Sheppard, & Hunter, 2003). The stabilisation of bone fractures results by constraining bone fragment mobility, whereby the injury is fixed from manipulation. General anaesthesia and open surgery are common when treating long bone trauma. There are available devices that can offer definite fracture treatment however, external fixators have often been used as provisional solutions. Definite treatment can be accomplished by using the biomechanical influences of the ring fixators i.e. stabilising the bone to allow healing as well as loading it to regain its original strength and thus its functionality. Bone restoration is achieved by returning it to full functionality (mobility and weight bearing), which is further supplemented by allowing for micromotions along the limb for effective bone restoration (Watson et al., 2000). This has made external fixation an effective treatment, as it often ensures that the bone reaches early weight bearing quickly, without concerns of stress shielding, common in internal fixation, resulting in weakened bone structures (Uhthoff, Poitras, & Backman, 2006).

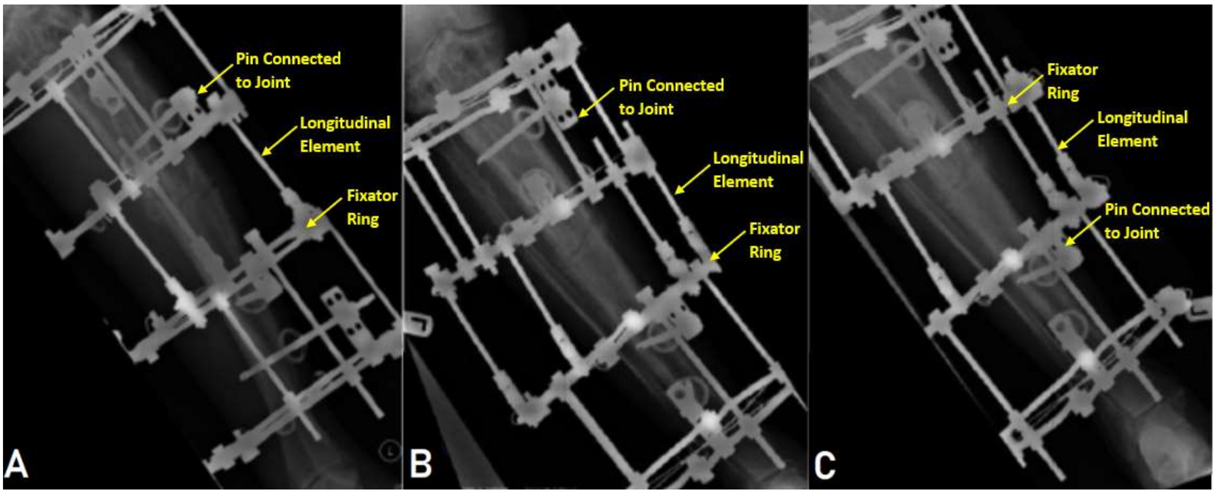


Figure 2.4: Images showing the application of external ring fixators to treat tibial shaft fractures (image credit: (Pillai, 2015)).

2.5.2. Methods for Fracture Fixation

The stabilisation of bone and soft tissue for trauma injuries is accomplished by constraining the injury from mobility and manipulation. The fractured bone should be fully secured, allowing bone to heal until it can begin to bear load and body weight. The choice of method for fracture fixation depends on the severity and classification of the present injury. This pertains to its structure and state, regarding the damage to the bone and the amount swelling to soft and muscle tissues. In addition, the choice is further supplemented by the current state of the long bone injury, specific to the time of creation, by which the type of modality would need to be determined for injury stabilisation. Thus, the chosen fracture fixation method would depend on these specific factors.

The application of fracture fixation can be accomplished using either internal or external fixation i.e. both methods create healthy settings along the fractured limb for bone to mend and heal. The degree of restrain affects the setting created, whereby the rate of healing is evaluated according to the small allowance in bone mobility i.e. axial micro motions. Such micromotions promote bone regeneration and soft tissue formation, which popularised external fixation (Watson et al., 2000). Internal fixation on the other hand is promoted for injury security and support for trauma, due the complete stabilisation of fragmented bone, resulting from intramedullary nailing and plating. Although internal fixation is a more stable method, manipulating the implanted system is difficult often requiring open surgery, thus external fixation is often employed initially, such as the conversion of external fixation to the more stable intramedullary nailing. Each of the fixation types can be adequate for the nature of the injury, however the aim for this study is to design and develop a new device that is optimized for adaptability and maintaining control over the injury.

2.5.3. Existing Devices

Due to the biomechanical influence at which frame adjustment can manage fracture correction, ring fixators were developed (Watson et al., 2000). The biomechanical environment created by these frames assist in influencing the pattern and rate of healing (Ferreira, 2012). In addition, they assist in the realignment, growth and early weight bearing of fractured long bone. Several devices exist that can apply circular external fixation i.e. standard and hexapod fixators. Standard devices utilise semi-permeable frames built across the fracture zone, allowing linear adjustment, whereas hexapod fixators can offer multiplanar gradual adjustment, by employing computational support.

The Ilizarov External Ring Fixator can be considered as the fundamental setup, primarily made up of metallic rings and threaded rods, connected create a cylindircal frame to act as an exoskeleton. The device functions by allowing linear modification to correct fractures (Spiegelberg et al., 2010). The Taylor Spatial Frame (Smith & Nephew, Memphis, TN, USA) is the modern development of the external ring fixator, incorporating the gradual correction principles and a six-axis platform to produce shape change, governed by a computer program (Feldman, Shin, Madan, & Koval, 2003). Hexapod fixators uses platforms with six-degrees-of-freedom as bases for deformity correction, using six telescopic struts aligned to offer access to many angles and translations within a three dimensional space, achieving accurate realignment and lengthening (Taylor, 2002). By employing the multi-directional platform, lengthening of the telescopic struts becomes essential, as stability is generated from the frame’s strut arrangement, thus often governed by the computer program.

Ilizarov External Ring Fixator

The Ilizarov Ring Fixator (as illustrated in Figure 2.5) was developed by Dr Ilizarov in the aftermath of World War II to establish a less invasive and percutaneous approach to osteogenesis (Fragomen & Rozbruch, 2007). The device provides stable fracture fixation by using tensioned wire insertion through bone and soft tissue, supported within a semi-permeable cylindrical frame. The fixation of a typical long bone fracture is accomplished by establishing wire fixation with adequate relative wire angulation to generate sufficient frame stiffness (Tejwani, Polonet, & Wolinsky, 2015). The placement of the wires and the relative angulation determines the degree, at which loading can be applied to the wires from the frame. This loading is generated by the adjustment of the frame's structure, as per the correction principles of the Ilizarov Ring Fixator (Spiegelberg et al., 2010). The device is often built as an exoskeleton, using the smallest possible rings for sufficient stability, and coupled into a stable frame, with a few well-placed threaded rods to maintain good stiffness. During the fixation reduction process, the clinician could apply gradual lengthening across the bone fracture by adjusting the positioning of the threaded nuts, applying loading along the wires. The device will produce loading in accordance to the amount distancing applied between the threaded nuts, typically varying within a millimetre. By using this deformity correction principle, the system has been used to correct fractures resulting from: translation, rotation and angulation.

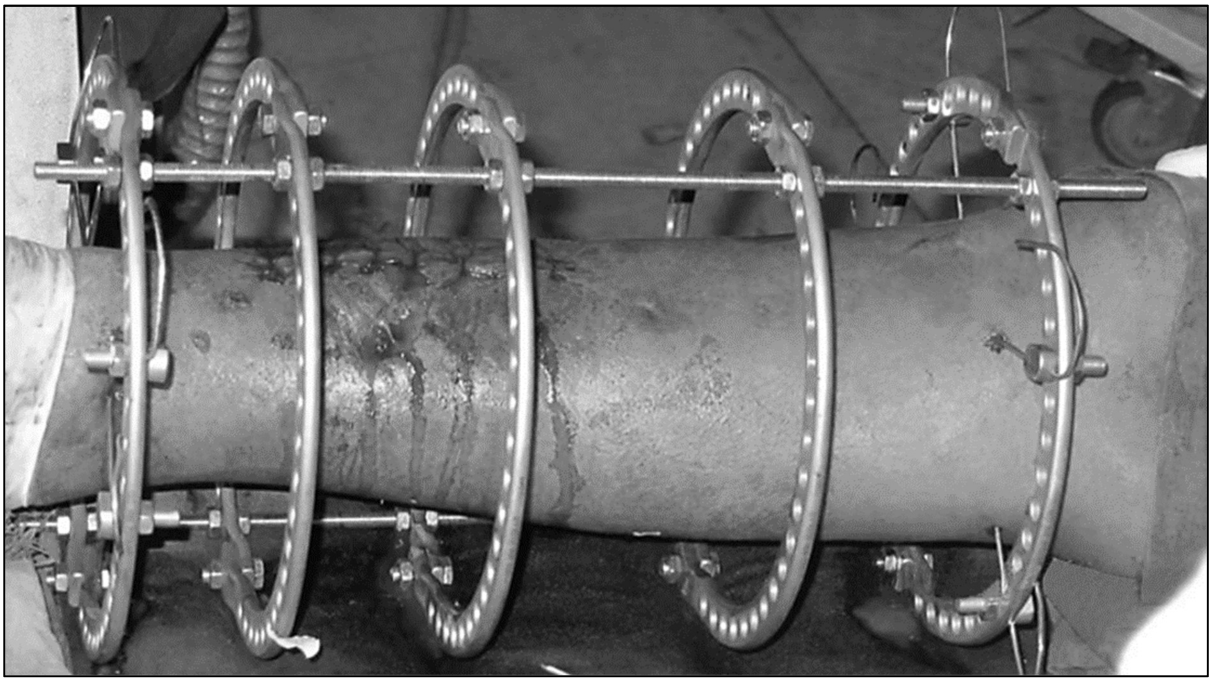


Figure 2.5: An interoperative photograph of external fixation using the Ilizarov Fixator (image credit: (Chaudhuri et al., 2015))

Taylor Spatial Frame

The Taylor Spatial Frame (Smith & Nephew, Memphis, TN, USA) was developed by an orthopaedic surgeon and an engineer, to determine a multi-planar approach to complex deformity correction by correlating the gradual correction principles and six axis deformity analysis incorporated in a computer program (Eidelman, 2017). The device can be applied by using either two methods to begin fracture reduction, mainly "rings first" and "modified first ring" (as illustrated Figure 2.6a). The initial method requires the orthogonal placement of the two rings independently, whilst the lengths are recorded, determining the reference and moving rings (as illustrated in Figure 2.6b).

The final method allows the orthogonal placement of both rings and the six telescopic struts left unlocked, by which the rings are distracted until they become parallel and the struts locked for recording. Both methods allow the clinician to use the residual program post application, whereby the strut lengths are used as benchmarks from which the gradual adjustment can begin. The acute application of the device in trauma is common, particularly tibial fractures, whereby it can be used to treat closed and open fractures with accurate corrective results (Al-Sayyad, 2008). The device's attractiveness in fracture reduction particularly comes from its ease in injury application as well as the accuracy generated by the computer program. Furthermore, authors have demonstrated that with the available resources, the learning curve for the device can be pleasantly low when applying the device and can be as simple as building the device and then overseeing the gradual adjustments as per the calculations of the program (Feldman et al., 2003) (Manner et al., 2007). However, this may weaken the control over the fracture correction process as error in correction can result from poor strut management between sessions, due to poor computational experience.

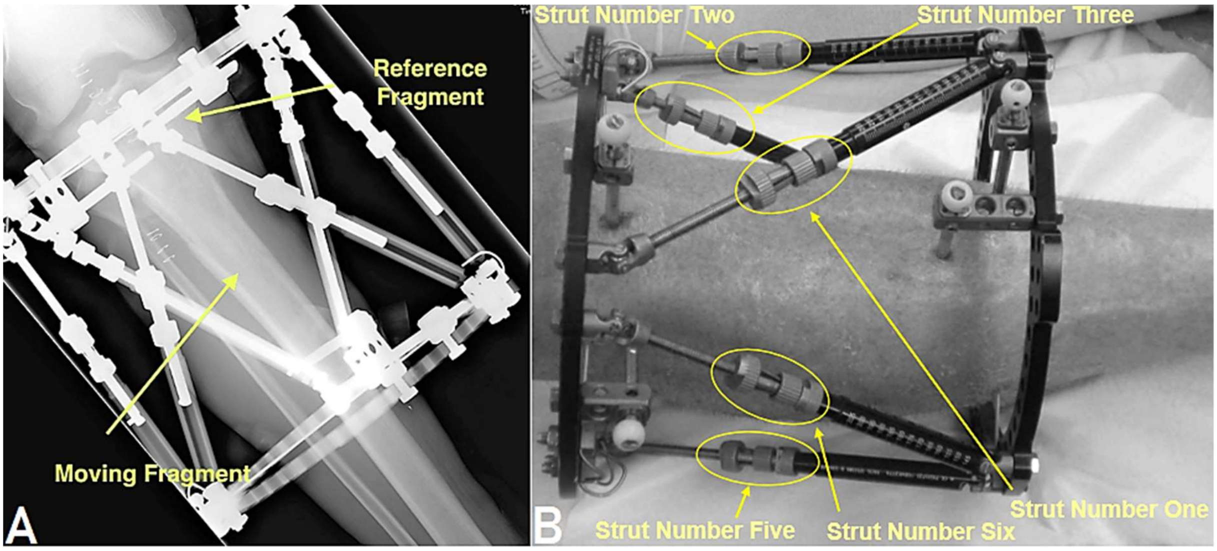


Figure 2.6: A) An intra-operative photograph of the Taylor Spatial Frame applied to the Tibial bone, with strut lengths fixed B) Image indicating the reference and moving bone fragments as per the fixator rings (image credit: (The Bone School, 2009)).

2.5.4. Limitations

Introduction to Limitation

External ring fixators have been frequently tested in previous studies to evaluate their corrective capabilities, when compared with one another, particularly for lower extremity long bone trauma (Manner et al., 2007) (Dammerer et al., 2011) (Tan et al., 2014) (Menakaya, Rigby, Hadland, Barron, & Sharma, 2014). Although these devices have improved the clinician's control over the deformity correction process, they do possess certain limitations. These limitations highlight the functionality and application of the external ring fixators for their use in bone fracture fixation. In addition, the following listed factors were highlighted by the identified design limitations.

- Performance and Adjustability
- Ease of application and Functioning
- User ergonomics and Affordability

Performance and Adjustability

As previously mentioned, studies have been made to evaluate the performances of the available devices, particularly the Ilizarov Ring Fixator and Taylor Spatial Frame. In addition, they have also been compared with conclusions made upon the differences in their functionality and application.

Research suggests that the Ilizarov Ring Fixator produces relatively satisfactory corrective results, however this depends on both knowledge and experience of the clinician, by which extend to the steep learning curves of deformity correction (Ferreira, 2012) (Farmanullah, Khan, & Awais, 2007). The gradual correction of angular deformities and lengthening is proposed as possible, however it is complex and prone to error, leading to revaluation (Dammerer et al., 2011) Due the device's limited capability to correct multiple bony deformities, authors had become reluctant in using it for more severe injuries, leaving it to be used for simpler bony deformities and pure lengthening. In addition, this reluctance was due the attractiveness of the Taylor Spatial Frame, a fixator that demonstrated better accuracy without the complexity of deformity analysis, making applying and fracture reduction easier, assisted by a computer program (Dammerer et al., 2011). It is therefore evident that the Taylor Spatial Frame is regarded as more reliable than the Ilizarov Ring Fixator. Existing research indicates that the Taylor Spatial Frame performs better, when operating with the computer program (Manner et al., 2007) (Dammerer et al., 2011) (Tan et al., 2014). On the other hand, it was indicated that experienced surgeons were reluctant to use the modern fixator, signifying large learning curves when using the system with the program (Fadel & Hosny, 2005). Therefore, the effectiveness of the Taylor Spatial Frame extends to the correlation of the device with the computer program, as well as the competency of the clinician to utilise all design factors.

Ease of Application and Functioning

Effective functioning of External Ring Fixators depends on the level of knowledge and experience of the clinician when employing the deformity correction principles. This aspect has thus made the Taylor Spatial Frame a more attractive device, as it functions by reduces the reliance upon the clinician's expertise (Dammerer et al., 2011). The Ilizarov Ring Fixator utilises the process of linear adjustment to apply loading the wires, directly correlating the principles (Spiegelberg et al., 2010), however this is limited the device's inability to access the multiple angles and translations, making correction of angular deformities difficult, often requiring the clinician to more complex frames. The Ilizarov Ring Fixator utilises multiple components to build these suitable frames for complex deformities (Ilizarov, 1992) however, the inclusion of such components makes the learning curve much steeper and strenuous, by increasing the time and cost to fully fixate the long bone fracture. The device is capable, but such deformities still make the process difficult (Manner et al., 2007).

Both Ilizarov Ring Fixator and Taylor Spatial Frame utilise full and half rings in fracture reduction. The application of each device requires the clinician to circumvent possible exposed bone and damaged soft tissue when building frames to suit the fracture fixation. The devices are utilised for both closed and open fractures, meaning they must adjust to most injury structures. Therefore, the difficulty in applying the device becomes more complex regarding the severity of the injury, affecting the component placement and the operation of mechanisms. These devices can be built into rigid or versatile frames however, building the fixators can still be difficult for certain injuries.

User Ergonomics and Affordability

The aspects identified pertaining to user ergonomics corresponded to assembly mass, diversity in lengthening, and the materials selected for the components in the external ring fixator assembly. These aspects had also generated design considerations pertaining to concerns such as soft tissue impingement; mechanism inaccessibly; and heightened susceptibility to damage and tampering. Furthermore, the identified limitations had focused more on the Ilizarov Ring Fixators. In the case of lower extremity long bone fracture fixation, patients are required to accommodate the device for the prolonged periods of injury rehabilitation and physiotherapy (as illustrated in Figure 2.7). As such, the mass and size of the device may greatly affect the lifestyle of the patient, during this time. Thus, optimizing assembly mass is essential as well as utilizing materials that are affordable. The device is often exposed, semi-permeable, and built from simple components such as threaded rods. These components can be manipulated if not tightened adequately, but more importantly, this provides the design consideration of integrating locking mechanism to the assembly is secure and protected from external influence. Lastly, a major factor to be considered is the affordability of the device as many authors have expressed concerns over the high costs associated with the use of the Ilizarov Ring Fixator and the Taylor Spatial Frame, which were even higher due to the telescopic struts employed (Dammerer et al., 2011) (Menakaya et al., 2014). As such, the adaptive external ring fixator should be designed and developed from components that form an assembly that can be considered as cost effective by minimizing the expenditure regarding its manufacture.

Figure 2.7: Images illustrating the controlled and monitored lower-extremity limb exercises during the rehabilitation period, demonstrating how they are conducted with the Ilizarov Ring Fixators (image credit: (Sheffield Limb Reconstruction, 2017))

2.6. Materials and Manufacturing

2.6.1. Material Considerations

This study is limited to the design and development of the External Ring Fixator. The design of the device is to comprise of components and subsystems built with the aim of stabilising long bone fractures via external scaffolding built along an injured limb, and therefore this study will consider appropriate, yet accessible materials available locally (Cape Town, South Africa). These materials will be used to manufacture each component and subsystem to form the scaffolding that will be built from the half-pins and their joints fixed along the injured limb, using available manufacturing tools provided by the University of Cape Town's Health Faculty. These materials were selected for evaluation and then judged through a material analysis process (as illustrated in the Appendix C).

The following materials were selected for the manufacture of the components and parts of the external scaffolding for their high strength-for-weight qualities and their machinability such that the manufacture can accurately achieve the intricate designs, the desired structural integrity and practicality of the mechanisms. The aspects that will contribute towards the device's usability.

Mild Steel – is a very affordable and rigid metal, offering a good balance of toughness, strength and ductility, suitable for scaffolding requiring stability and some tolerance for micromotions. The low carbon steel possesses a high resistance to breakage and as opposed to higher carbon steels, mild steel is quite malleable, possessing much higher tensile and impact strengths. Higher carbon steels usually shatter or crack under stress, while mild steel bends or deforms, reducing the brittleness of assemblies and components. Mild steel is specifically desirable for construction due to its weldability and machinability, making it easier to form the designed shapes and frames for the external scaffolding (Metal Supermarkets - The Convenience Stores For Metal, 2016).

Aluminium - is a non-ferrous metal with high strength, rigid with exceptional light weight qualities. Although the metal has weaker elastic resistance, the strength-to-weight ratio is far superior to the majority of low-high carbon metals, whilst still possessing good machinability and low thermal conductivity, gaining higher strength for lower temperature conditions. The metal also provides minimal magnetic properties and high corrosion resistance and is suitable for the manufacture of light electronic devices and high precision aircraft body parts. (Non Ferrous Metals Works, 2018a)

Brass CDA385 – is a cost effective non-ferrous metal with a high tensile and compressive strength and a high impact resistance. The material has a favourable wear resistance and higher rigidity when compared to aluminium alloy. The material offers exception machine qualities that sets the bar for other metals, suitable for manufacturing small components with very good accuracy and surface texture. Its elastic resistance is very good for the mechanical benefits, the material is able to provide to the construction of assembly components. Due to the material's basic structure and lead concentration, it has great engineering properties for low cost machining and producing such parts as bushes and plumbing tubes, whereby accuracy and surface appearance is favourable and often desired (Non Ferrous Metals Works, 2018b).

2.6.2. Manufacturing Considerations

This study will make use of the equipment and services provided by the University of Cape Town. The parts and components that will be implemented into the device's design will be manufactured and shaped from tool machining within the faculty's workshop, conducted by the trained artisans. The manufacture of the parts and components will be a successful collaboration of the engineer, who will be using Solidworks 2018, the latest version of the computer-assisted design software, to design and generate the engineering drawings, and the trained artisans who will be making use of the drawings and the available machinery to create the physical models of the design concepts. This collaboration will also be attributed by the correct production of the design concepts, as the successful creation of these concepts will depend upon the available manufacturing methods, as employed by the artisans within the faculty's shop floor, thus the identification of these methods, accessible to the artisans in regard to the existing manufacturing tools, will need to be considered.

The machinery that will be used by the workshop staff, will incorporate standard manufacturing methods to generate the conceptual designs. These specific methods comprise of: drilling, turning and milling. All tool machinery will be used according to the chosen manufacturing method, since the choice of method will contribute towards the mechanical properties of the built components. The manufacturing methods that will be used for this study will be as close to common as possible, as to minimize complication and cost in manufacture. A common method may be categorised as part of the methods employed by large scale manufactures within major product production lines.

Furthermore, manufacturing methods of a higher-level of accuracy (computerised) will only be considered when the certain methods are considered inaccessible to the artisans or the level of accuracy in unattainable when using existing manufacturing tools within the faculty's shop floor, particularly methods that may employ the use of laser cutting and computer-aided machining. These methods may be arguably expensive and infeasible to the study's scope thus the necessity for the manufacture of certain components using such methods will need to be validated through sufficient research and calculative material. Lastly, a number of three-dimensional printed models from polymer filament materials will be generated to create smaller scaled models of the design concept, to allow for product previews and initial evaluations over the final structures and shapes. These generated three-dimensional models will not provide data in regard to the functionality of the product but will be able to provide the behaviour of part and components within the mesh.

2.7. Summary

Lower Extremity Long Bone Fractures of the Tibia and Fibula bones due to high energy collisions with the workplace and sports are widespread and frequent with the African countries. These injuries are often treated by stabilising the fractured bone (temporarily or definitively) by using the treatment method known as external fixation. Fixation is achieved by restraining the fractured bone within a solid frame, stabilising the bone and soft tissue. In addition, the correction of bony deformities can be accomplished by inducing loading along the wires by adjusting the built frame. As such this study will be aim to benchmark test a new adaptive external ring fixator, designed to optimize: adjustment versatility; assembly affordability and mass; and lastly clinician ergonomics. The final design should function as an acceptable medical device for long bone fracture fixation.

3. Design Methodology

3.1. Introduction

This chapter details an investigation upon a design for the Adaptive External Ring Fixator with the aim of introducing adaptive capabilities into the fracture fixation process. The main function of the device is to offer complete stabilisation for either temporary or definite bone fracture fixation, creating a healthy setting for damaged bone to mend and heal. The device should possess a simple and comprehensive mechanical setup that can be built and shaped according to the injury status, as well as allow for some adjustment to transfer loading upon the percutaneously inserted wiring.

Certain external ring fixators are incapable of providing multi-directional shape change without complications affecting the frame construction, fracture management and control over the injury. In addition, some are also limited to only allow adjustment along a degree-of-freedom i.e. axially. This device design considers the limitations of existing devices with the intention of addressing their significance by focusing on patient ergonomics, system versatility and adjustment diversity. These factors would make the device nuance. The design would also aim to offer either rapid or finite multi-directional adjustment to ensure that system shapes are reproducible and repeatable. Figure 3.1 illustrates the potential application of the device for long bone fractures fixation, by indicating the use of the hinged ring and longitudinal elements for installation and adjustments.

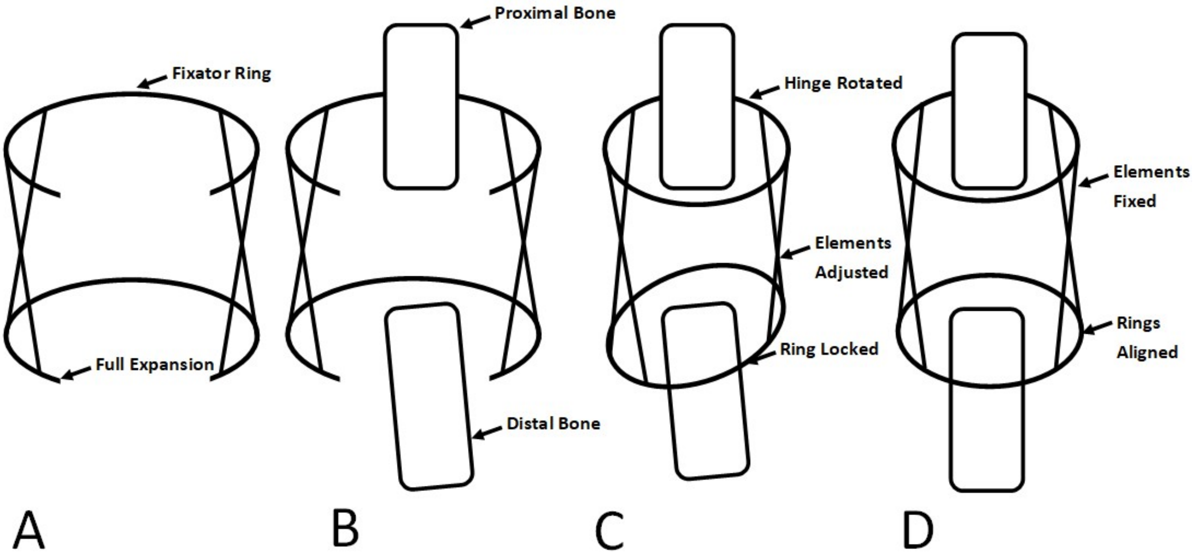


Figure 3.1: Schematics demonstrating the progression of correction when using the external ring fixator for fracture fixation. A) Expansion of the fully assembled device prior to surgical procedure B) Enclosure of the device over injury zone or fracture C) Adjustment of the device to meet the structure or state of the injury (comprising of: translation, angulation and rotation) (D) The continued alignment and correction of the long bone fracture within the frame, as according to adjustments made.

The following chapter will be divided into three separate major sections for design consideration I) Fixator Rings II) Longitudinal Elements and III) System Integration. Figure 3.2 details the design methodology followed to generate the conceptual designs for the Adaptive External Ring Fixator.

3.2. Design Methodology Flow Chart

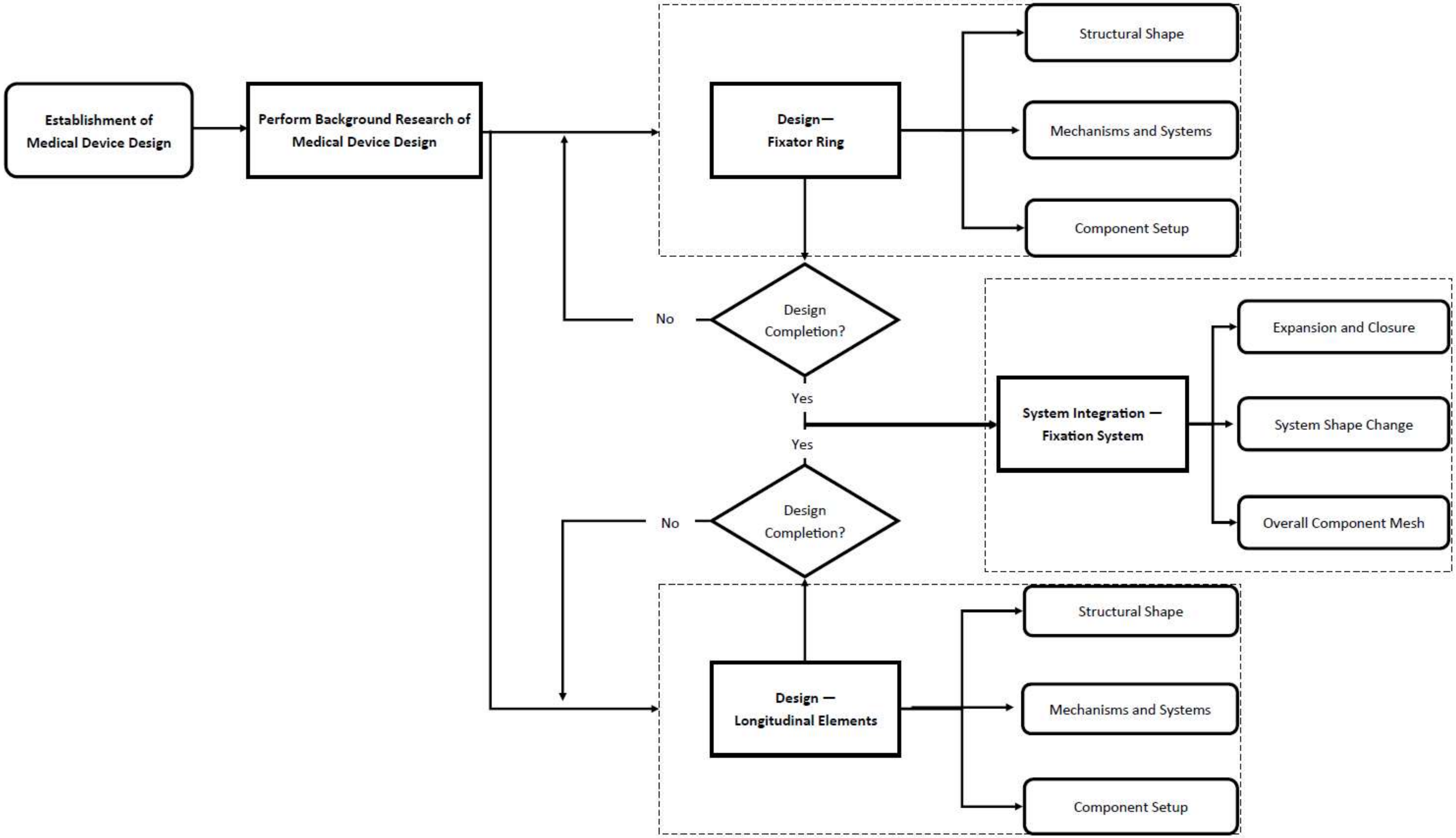


Figure 3.2: Flow Chart depicting the Design Methodology for the study's Design Process

3.3. Design Considerations

The basis for the Adaptive External Ring Fixator is to induce innovative design to key features and supplement the External Fracture Fixation System's functionality for long bone fracture fixation. It is also noted that the integration of designs void of both functional and structural considerations would produce potential problems that would weaken the device's feasibility for fracture fixation. Thus, designs for the subsystems would be produced by integrating certain design considerations. The aim of this study is to develop an Adaptive External Ring Fixator that would be compliant with the practices of external fixation but enhance the process by integrating the research objectives – Section 1.7 with a major emphasis upon efficient fracture fixation and system shape change.

In addition, certain design specifications were listed to assist in defining the design considerations in accordance to the device's structural integrity and functionality. The design specifications were further detailed by the research gathered pertaining to user requirements, clinical input, material selection, patient ergonomics and the competitive mechanical properties of existing ring fixators.

I. Fixator Rings
    i. Fixated segment ring system requirements/specifications
        a. Capable of maintaining stability for human body weight [3.5 kN]
        b. Assembled ring mass of less than 200 grams
        c. Capable of disassembly for maintenance and emergency
    ii. Mechanical ring pivot system requirements/specifications
        a. Capable of pivoting for an angulation of [45-60°]

II. Longitudinal elements
    i. Mechanical element locking system requirements/specifications
        a. Support loading distributed from the human body weight [1.2 kN]
        b. Capable of element length locking (should be semi-permeable)
        c. Capable of maintaining support for the defined angulation [45-60°]
    ii. Mechanical element lengthening system requirements/specifications
        a. Capable of lengthening for distances of 100 – 150 mm
        b. Allow for lengthening as small as 0.5 mm or large as 5 mm
        c. Capable of disassembly for maintenance and emergency

III. System Integration
    i. The designs should mesh with one another without complication in shape change

The Adaptive External Bone Fracture Fixation System is the assembly of two major subsystems. This would mean that the operation of the device would be the effective incorporation of these specific subsystems as well as their individual mechanisms and intricate systems. The conditions for building the desired shapes or frames and ensuring that they enclose over the injury correctly, depend on the efficacy and proficiency of these two subsystems. By focusing and treating these two subsystems individually would ensure that the designs are intricate and detailed. Thus, each of the two subsystems will be demonstrated and detailed, including their assembly integration.

3.4. Fixator Rings

3.4.1. Introduction and Specifications

The fixator ring will be regarded as a basis for the built frame that is to be installed during surgery, by which the frame construction will start with one ring and end with the longitudinal elements. The mechanical structure of the rings will be simplified to just the core structure of the ring, which means that the ring's functionality would depend on its material properties and structural profile. Thus, these factors will be attributed by material selection, structural shape, hinge system design and the ring's integration with the longitudinal elements. The identified design considerations for the mechanical structure will be integrated into the design to meet defined design requirements.

3.4.2. Design Considerations and Conceptual Design Generation

Design Considerations for the Mechanical Structure

Two conceptual designs were consecutively generated for the mechanical structure of the fixator ring. These concepts were influenced by the defined design considerations either specific to or in conjunction with the study as illustrated in Table 3.1. The design considerations have included the aspects that are custom to medical device design and patient ergonomics as well as those explicit to the success of the following study. Each of the two design concepts were created to preserve the defined conditions of limited accessibility to resources and manufacturing facilities, as well as focusing upon the considerations for weight and wear, predominantly for core material selection. The study specific considerations will focus upon the movement of rings regarding their expansion as well as their integration with the longitudinal elements to determine a more adaptable design. The progression from one design concept to another was attributed by several evaluations made in accordance to design challenges discovered, aiming to determine a new design that would be more balanced in aspects pertaining to patient ergonomics and device functionality. The design concepts were evaluated further by scoring the complexity and reproducibility of manufacture as well as other lower-level design considerations that benefit the modification of the ring's design. As a conclusion to the evaluation process, the design concepts were also evaluated according the aesthetic appeal and maintenance requirements, to choose a design that is ergonomically better. This process was conducted in the form of concept screening with reference to these factors.

Table 3.1: Design considerations for the mechanical structure of the fixator ring

Design Considerations	*Type of Consideration*
Movements of Rings	Specific
Expansion and Locking of Rings	Specific
Longitudinal Element Integration	Specific
Wear	Material Selection
Weight	Material Selection
Manufacturability	Conjunction
Feasibility	Conjunction
Structural Integrity	Conjunction

Concept 1: Mechanical Structure for the L-jointed Ring

The first design concept for the ring's mechanical structure was the L-jointed ring mechanism. This concept was inspired by the hinge joints that would attached flush to door and drawer arches. The segmented rings were shaped as angled sections, to offer support for transversal and sagittal loading as well as to allow for either strict axial or angulated longitudinal element integration. The hinge was kept dimensionally static during the concept generation, as a market hinge was chosen. The Mechanical Structure for the L-jointed Ring is illustrated in Figure 3.3.

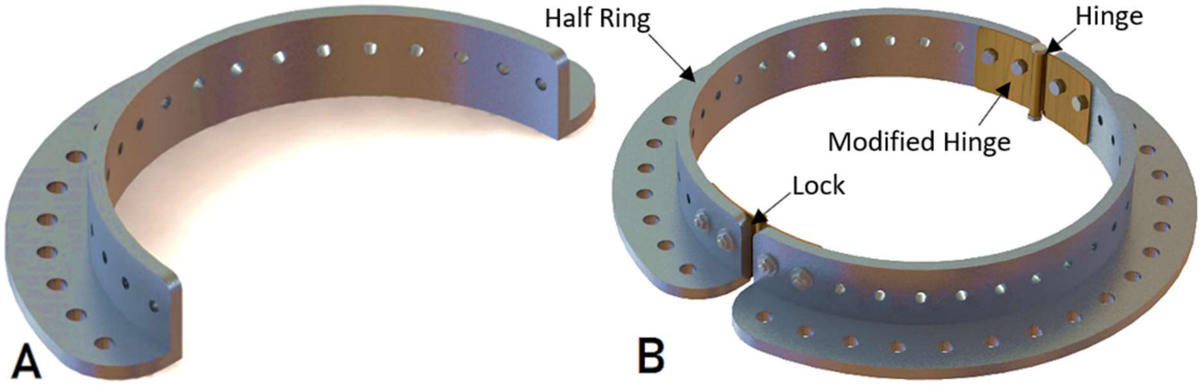


Figure 3.3: Concept 1 – (A) The segmented half ring of the L-jointed fixator ring assembly (B) A full completed assembly of the L-jointed ring with opposing and mirrored hinges, that assembled together would form the ring's mechanical structure.

The image illustrates the mechanical structure for the L-jointed ring in the ideation phase of the study. The images show that the fixator rings are lockable, as both bolted-nut hinges can be mechanically fastened tightly by utilizing standard fasteners. When the ring is unlocked, the ring can be expanded for a mouth range of 60 ° to partially enclose the device over the injury. The longitudinal elements (strictly axial) would be attached via the 6 mm (face) holes (42 in total) drilled into the face, equally-spaced around the ring, while the sagittal (side) holes would allow for angulated longitudinal element attachment for multi-directional support and system shape change. (B) illustrates the complete assembly of the ring when locked. The L-ring allows for quick installation via full assembly expansion during the surgery since the mechanical structure can stabilise the chosen shape when expanding the ring. Lastly, modifications to an existing hinge was done to make it attach flush to the surfaces.

The mechanical structure for the L-jointed ring was designed to act as the basis for the built frame, by which the segmented rings, connected by the hinges, would provide the foundational support. When full assembled and the shape fixed, the segmented rings via the rotation of the bolted-nut hinge system would expand the fixator ring's mouth and enclose the entire device over the injury. This particular feature would therefore quicken the installation process as well as circumvent the various structures resulting from damaged bone and soft tissue. The ring stability is dependent upon the structural integrity of the segmented ring, which are shaped as angled sections to apply good structural strength. Thus, the material selection would vital for minimal weight gain as well as ensuring enough structural stability. The identified design challenges were listed as follows:

1. *Maintain low-weight and high-strength properties for the segmented rings and the manufactured hinge systems regarding mechanical structure and material selection*

2. *The fixator ring will be required to provide support of direct tension and compression, but in addition support torsional loading where it may be applied*

Concept 2: Mechanical Structure for the C-jointed Ring

The second design concept for the ring's mechanical structure was the C-jointed ring mechanism. This concept is a development of the first concept by considering the identified design challenges and exploring patient ergonomics as well as system-scale optimisation. Implementing to a more optimized structure would result in a more lightweight and portable structure. The hinge system was designed as a simple bolted-nut, to specifically meet the fixator ring's curvatures and shapes. The Mechanical Structure for the C-jointed Ring is illustrated in Figure 3.4.

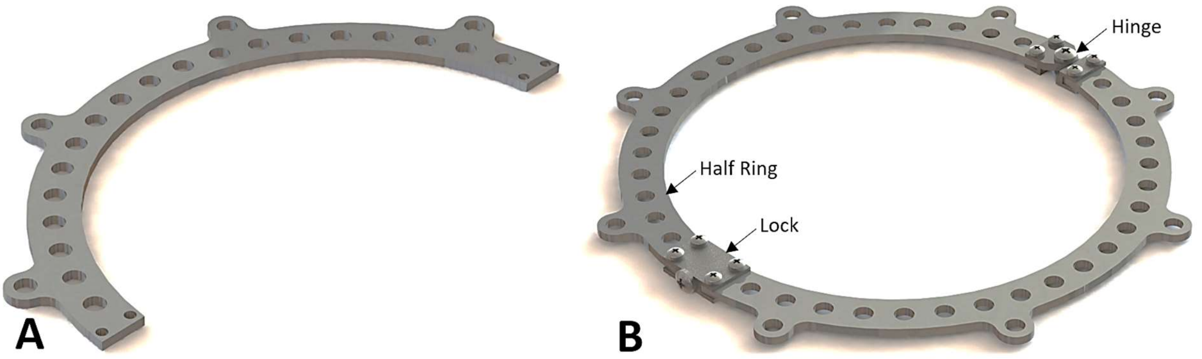


Figure 3.4: Concept 2 –A) The segmented half ring of the C-joint ring assembly (B) A full completed assembly of the C-jointed ring with the bolted hinge-and-lock system, that when assembled together would form the fixator ring's mechanical structure.

The image illustrates the mechanical structure for the C-jointed ring in the ideation phase of the study. The images show that the fixator rings are lockable, as the locking system is a simple bolted-nut joint, mirrored by the hinge system. When unlocked, the ring would expanded for a mouth range of 120 ° to fully enclose the device over the injury. Image (B) shows the completed assembly, which can allow for both strictly axial and angulated longitudinal elements attachment via the equally spaced 6 mm holes (of 42) along the faces of the ring. Longitudinal element attachments will be inducing direct loading through the faces of the segmented fixator rings. This design concept would also allow for quick device installation from either component assembly or full device assembly as the mechanical structure is designed to ensure that the system can be disassembled easily as well as maintain a fixed shape during device expansion. Finally, the components are made standardized for maintenance.

This design concept investigates the advantages of optimising mass by employing materials with high strength and density to produce a simpler design, to address the identified design challenges. Certain design considerations were also highlighted for factors pertaining to practicality, patient ergonomics and structural integrity. The ring design possesses a mechanical structure that can be considered thin and compact, maximizing the mass-strength properties of the core material, as well as ensuring the ring has a shape that unimposing. The hinge-and-locks were simplified and designed to conform to the shapes of the rings to reduce the blockage to possible injury swelling. In conclusion, the design concept was developed to preserve simplicity as a key factor for the final design, however certain consequent design challenges for this concept were identified as follows:

1. *Ensure that the mechanical properties of high strength and high density regarding the core material for both the fixator rings and hinge systems can effectively support the loading.*

2. *The fixator ring will be required to provide support of direct tension and compression, thus the loading applied to the joints between the segmented rings would need to be supported.*

Concept Screening – Mechanical Structure for the Fixator Ring

The conceptual designs for the fixator ring's mechanical structure were evaluated against each other through concept selection process, established as a table. The created table shown below utilizes chosen aspects of the generated designs for the external fixator from a hierarchical basis as a means to determine the most applicable design in accordance to the production and eventual use of the device. These aspects were categorised to singular definitions, taking into account the identified design considerations, with significance to the study's aim. The standard practices of engineering device design were incorporated and thus a constructed concept screening process was conducted to efficiently conclude the concept evaluation. The framework is to determine the most appropriate concept for further product development and prototyping. As illustrated within Table 3.2, each conceptual were ranked/marked according to the hierarchy of the specific aspect.

Table 3.2: Fixator ring mechanical structure concept selection

Selection Criterion (weight)/ Concepts	*Connection Diversity (1)*	*Structural Integrity (3)*	*Manufacturability (3)*	*Weight (2)*	*Practicality (2)*	*Assembly Volume (1)*	*Total*
1	3	3	3	1	1	1	26
2	2	2	2	3	3	3	29

Sample calculation: The total score for Concept 1 was calculated as follows:

$$\text{Total} = \sum(\text{Criterion weight x rating})$$

$$= (1 \times 3) + (3 \times 3) + (3 \times 3) + (2 \times 1) + (2 \times 1) + (1 \times 1)$$

$$= 26$$

The aspects chosen for the table above, categorises the specific qualities of the product for that specific subsystem by its functionality and appearance, such qualities that accumulate to a well-rounded product for potential product development.

Connection Diversity – reflects not only the number of connections that can be made to link opposing fixator rings together but in addition, the variety and diversity of the subsystem connections for longitudinal elements – concept one succeeds as the design offers strut connections through the faces and along the circumference, allowing for axial and transverse support. *Structural Integrity* – reflects the stability and strength of the ring with regards to a visual inspection of its support structure for withstanding the applied weight and loading transferred through the system, an aspect regarded highly as per the device's functionality – concept one excels in this aspect as the design solely aims to offer support in several directions. *Manufacturability* – reflects the intricate aspects that govern the production of the product from the access to materials to the specific designs for certain components – concept one manages to excel in this regard as the parts are simpler to build. *Weight* – reflects the concepts contribution to the total mass of the system – concept two excels due to mass optimization. *Practicality* – reflects the workability of the device in regards to the overall mesh and coordination of subsystems – concept two succeeds as one's ring structure limits the angulation of struts (particularly when aligning struts across the ring's face). *Assembly volume* - reflects the size, shape and available space of the ring with respect to its use (space for swelling and leg room) - concept two succeeds in this regard as the assembly bears a reduced subsystem volume with thinner components.

As such the table above shows an accumulated final score and thus the resultant concept that would be chosen for product development, as the result of the table will dictate the concept that would best suit the final design of the external fixator.

Based on the above results, as detailed in Table 3.2, the second generated concept was ranked higher as the results show that the distribution of ratings had leaned towards the functionality of the ring's assembly design. This result takes into consideration that the second concept offers clearer adaptive features due to its much sleeker design, but it may need to overcome certain concerns pertaining to the structural integrity of the ring's structure. The design considerations do show that the concept has potential, however this would depend upon achieving the structural integrity required for bone fracture fixation. In conclusion to this evaluation, the ring's structure would not need any further modification, but would need to be built from an acceptable material.

Hinge and Lock Systems for the Fixator Ring

The integration of the bolted-nut systems into the fixator ring design has offered the choice of full assembly installation via the simple process of rotating segmented rings about a designated axis. The basis of the hinge is often based upon the separation of two individual parts, by rotating them about a common axis, particularly for the purposes of opening devices to perform maintenance. However, the aim of these concept designs was to develop the hinges to be used as mechanisms for device expansion and allow for rapid installation by enclosing the entire device over the injury.

To fully install an external ring fixator, the clinician may need to navigate certain parts to avoid exposed bone and damaged soft tissues, regarding the severity of the long bone injury. Thus, the shape and structure of the fixator ring was to be designed to accommodate for such conditions. The conceptual designs that were generated in this section ensured that the entire device can be installed across the injury without complication and to avoid this problem, the ring's structural shape was made semi-permeable or unlockable. With the integration of hinge systems and the intricate designs pertaining to the longitudinal elements and the full assembly, one may be able to determine a device design that would be able to eliminate these complications in fracture fixation and make it an attractive choice for the stabilisation of traumatic long bone fractures. In conclusion, the hinge systems are included into the design of the Adaptive External Ring Fixator as one of the key design features that would make it feasible for fracture fixation however, this would need be further validated by the efficacy and functionality of the proceeding components.

3.5. Longitudinal Elements

3.5.1. Introduction and Specifications

The mechanical aspects of the longitudinal elements will determine whether the chosen assembly design will be able to support the distributed load that will pass through the entire fixation system. The longitudinal elements provide the body of the device and thus its overall structural stability, by offering stability to certain points within the three-dimensional space that the system occupies. In addition, the study aims to the integrate measured lengthening of the longitudinal elements as the definitive mechanic for induced shape change and thus achieve the desired adjustments. The biomechanical aspect of the external ring fixator will be dependent upon these longitudinal elements and their correlation with the rings, thus its relevance to the ring designs is essential. This section will detail the generation and screening of concepts that will consist of these aspects.

3.5.2. Design Consideration and Conceptual Design Generation

Design Considerations for the Mechanical System

Two design concepts were consecutively generated for the mechanical system of the longitudinal elements, aimed at offering adequate stability and efficient yet accessible lengthening mechanics. These concepts were influenced by the defined design considerations for the study and further updated in response to the evaluations made upon the ring concepts, as illustrated in Table 3.3. The updated design considerations include the lengthening mechanisms (angulation), expansion rate capabilities and fixator ring integration (structurally dependent) as well as the considerations resulting from clinical and patient input. Furthermore, the progression from one design concept to another was utilized once more, and attributed by specific evaluations, referencing the design challenges identified, aiming to create a mechanical system with a clearer competitive advantage. The functionality of the longitudinal elements is a major focus for this study, as the adaptive capabilities will be evaluated according to this key component. The efficient shape changes in frame building through the application of either gradual or rapid lengthening will be its key design feature. Assembly expansion and rapid installation are other key attributes that are to be kept in mind as the concepts develop into more appropriate designs. As a conclusion to the element design process, the design concepts will be evaluated according the design considerations of this section. This process was again be concluded in a concept screening, using these key factors.

Table 3.3: Design considerations for the mechanical system of the longitudinal element

Design Considerations	*Type of Consideration*
Lengthening and Locking	Specific
Fixator ring Integration	Specific
Wear	Material Selection
Weight	Material Selection
Manufacturability and Affordability	Conjunction
Structural Integrity	Conjunction

Concept 1: Mechanical System for Finite (Gradual) Lengthening

The first conceptual designs for the mechanical system were the finite lengthening mechanisms. This concept was inspired by the structures of radial bearings and their movement independency. The rotations of the elements can be done gradually with minimal effect to the ring's orientation. This system also utilises pivot joints to further angulate the attachments of the ring and element, such that the constructed assembly can provide support to the more angulated loads and stresses. The Mechanical System for Finite (Gradual) Lengthening is illustrated in Figure 3.5.

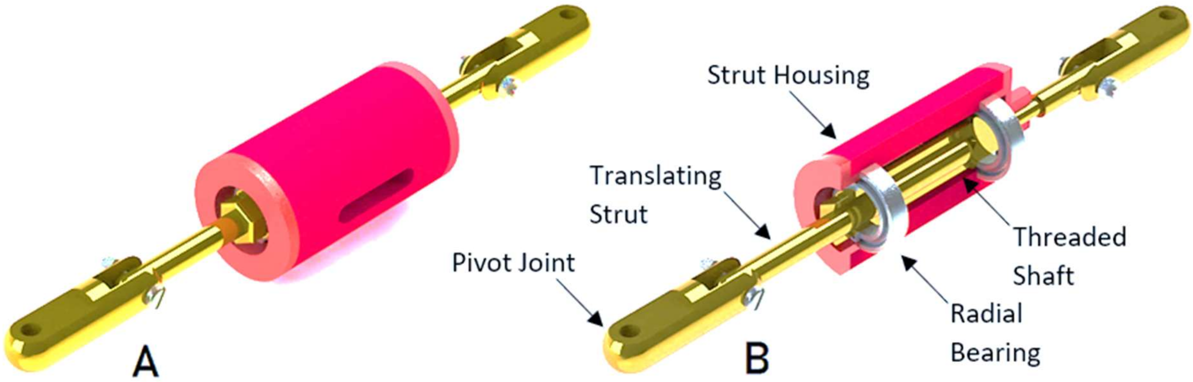


Figure 3.5: Concept 1 – (A) The Longitudinal Element Mechanical System developed for Finite Lengthening (B) A half section of the completed assembly, detailing the integration of radial bearings to the rotation and translation of the element shaft.

The images illustrate that the finite lengthening longitudinal element's mechanical system in the ideation phase of this study. Image (B) shows a sectioned element at a sample length with the pivot joints tightened and angulated along the axis. The mechanical system mimics telescopic struts by offering gradual lengthening though rotation over threading, whilst using pivot joints for angulation to correct fractures, that would comprise of deformities such as: translation, angulation and rotation. The adjustment to the system by the longitudinal element is dependent upon its alignment and lengthening, offering control over the fracture fixation process. Image (A) shows that the open slot that can be used to measure the lengthening via housing rotation (full rotation creating 1+- mm). The direction of lengthening is dependent upon the element's orientation across the injury. The angulation, lengthening and attachment all influence the change in shape of the system, from measured rotations.

The mechanical system for the longitudinal element that incorporates finite (gradual) lengthening was designed to ensure that any shape can be met progressively and more importantly accurately. When fully assembled and a length chosen, the longitudinal element can be manipulated slowly, by rotating the element and translating the strut within the assembly by distancing the pivot-joints until a desired length has been reached. This feature ensures accurate element lengthening by reducing human error. However, the lengthening through a translating strut is not nuance and thus the element was designed to be independent by incorporating the radial bearings as the foundation for the element. This means that the element's orientation and angulation to the rings will have little effect upon lengthening of the element. Compared to standard telescopic strut, these longitudinal elements can be adjusted without disassembly. The design challenges that may need to still be considered include safety features such as locking to prevent tampering. As such the consequent design challenges for this concept were identified as follows:

1. *The dependency of the structural integrity to the pivot joints attached at extremes*

2. *The addition of more locking capabilities for safety and security considerations.*

Concept 2: Mechanical System for Rapid-Finite Lengthening

The second concept design for the mechanical system was a finite-rapid lengthening mechanism. This concept was the development of the first concept and several iterations of similar attempts, by exploring and implementing diverse actions resulting from longitudinal element manipulation. The system incorporates both two lengthening rates independently, to offer the clinician variety in adjustment and shape change, and thus enabling full control over the injury or fracture fixation. The Mechanical System for the Rapid-Finite Lengthening is illustrated in Figure 3.6.

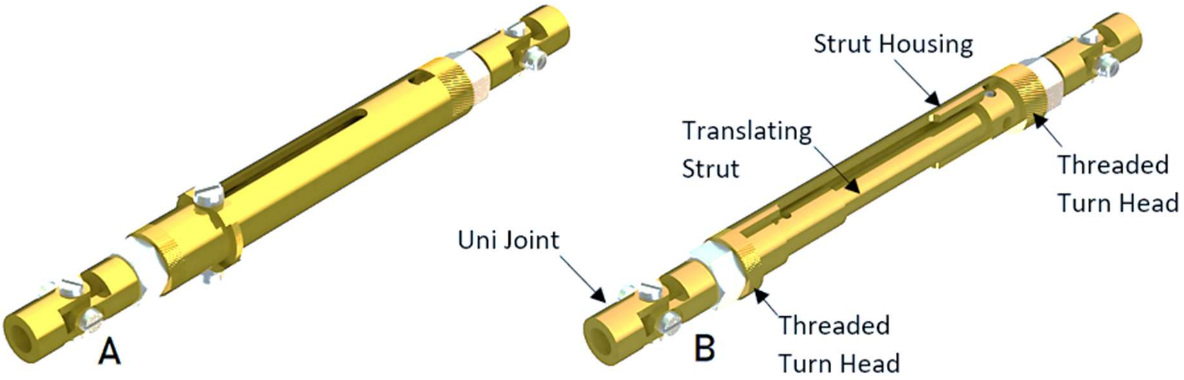


Figure 3.6: Concept 2 – (A) The Longitudinal Element Mechanical System developed for Rapid-Finite Lengthening (B) a half section of the assembly, detailing the incorporation of slide translation and rotation over thread for varied lengthening rates.

Images illustrate the rapid-finite lengthening longitudinal element's mechanical system in the ideation phase of this study. Image (B) shows a sectioned element with the uni-joints tightened, orientated and angulated along the element's axis. The mechanical system utilises modified threaded nuts (turn heads) to translate the central strut and produce gradual lengthening while rapid lengthening is achieved by sliding the translating strut along the cylindrical chamber. The acquisition of both types of lengthening rates ensures that certain shapes can be met quickly or progressively regarding stabilising and correcting traumatic long bone fractures. The significance of the longitudinal elements will depend upon its alignment and orientation within the fixator assembly, as the injury control will be affected by the direction of adjustment as according to the way the element is integrated. The mechanical system allows for measured lengthening via the bolted-nut joint and the exposed slot, but the lengthening Is further measured by the element's angulation relative to the attached ring thus uni-joints were included to permit complete ring angulation. The angulation, length and attachment all influence the change in shape of the system

The conceptual design investigates the advantages for possessing rapid and gradual lengthening simultaneously within a longitudinal element, with the aim of accomplishing adjustment diversity. This particular feature was designed in response to the identified design consideration pertaining to user ergonomics. The concept possesses mechanical systems that are manually manipulated to achieve a desired length quickly or if required accurately depending on the circumstances of the injury. This is would be useful for rapid device installation and stabilisation of trauma injuries whilst accurate injury correction can be conducted through gradual lengthening. More complex shapes would be achieved by employing rapid lengthening to reach a certain profile shape and then utilize gradual lengthening to reach the desired shape with the applicable loading applied. Lastly the mechanical system was designed to enable locking to fix a chosen length, however there were still design challenges that would need to be considered before finalising the design:

1. *Improvements upon the structural integrity and mechanism within the locking mechanics.*

2. *The longitudinal element will need to be manufactured accurately for smooth rotations.*

Concept Screening: Mechanical System for the Longitudinal Elements

The conceptual designs for the mechanical system for the longitudinal elements were evaluated against each other through concept selection process. The created table shown below utilizes chosen aspects of the generated designs for the external fixator from a hierarchical basis as a means to determine the most applicable design in accordance to the production and eventual use of the device. These aspects were categorised to singular definitions, taking into account the identified design considerations, with significance to the study's aim. The standard practices of engineering device design were incorporated and thus a constructed concept screening process was conducted to efficiently conclude the concept evaluation. The framework is to determine the most appropriate concept for further product development and prototyping. As illustrated within Table 3.4, each conceptual were ranked/marked according to the hierarchy of the specific aspect.

Table 3.4: Mechanical System for the Longitudinal Elements concept selection

Selection Criterion (weight)/ Concepts	*Length Accuracy (1)*	*Structural Integrity (3)*	*Manufacturability (3)*	*Weight (2)*	*Practicality (2)*	*Assembly Volume (1)*	*Total*
1	3	3	2	1	2	1	25
2	2	2	2	3	3	3	29

Sample calculation: The total score for Concept 1 was calculated as follows:

$$\text{Total} = \sum (\text{Criterion weight x rating})$$

$$= (1 \times 3) + (3 \times 3) + (3 \times 2) + (2 \times 1) + (2 \times 2) + (1 \times 1)$$

$$= 25$$

The aspects chosen for the table above, categorises the specific qualities of the product for that specific subsystem by its functionality and appearance, such qualities that accumulate to a well-rounded product for potential product development.

Length accuracy – reflects accurate fracture correcting and ensuring good bone growth through gradual adjustment, which stems from small changes to the longitudinal element – concept one excels by allowing rotational movements to induce lengthening with minimal effort as the rotations and translations are independent to one another, preventing human error.
Structural Integrity – reflects the stability and strength of the longitudinal elements with regards to a visual inspection of its support structure to withstand applied weight and loading transferred through the system, particularly through the centre of the elements – concept one excels in this aspect as it was designed to be very stable along its lengths, with minimal play.
Manufacturability – reflects the intricate aspects that govern the production of the product from the access to materials to the specific designs for certain parts – both concepts have an average rank as they require a considerable amount of accuracy.
Weight – reflect not only the mass of the system – concept two excels due to the mass optimized components and systems.
Practicality – reflects the workability of the device in regards to the mesh and coordination of subsystems – concept two succeeds as it can offer both rapid and gradual lengthening, providing more opportunities to fracture fixation and correction.
Assembly *Volume*– reflects the overall size and shape of the assembly design for the longitudinal elements with regards to its operations (space for swelling) – concept two excels in this aspect with a reduced assembly design (sleeker and smaller).

As such the table above shows an accumulated final score and thus the resultant concept that would be chosen for product development, as the result of the table will dictate the concept that would best suit the final design of the external fixator.

Based on the above results, as detailed in Table 3.4, the second generated concept was ranked higher as the results show that the distribution of ratings had leaned towards the importance of ergonomics for the surgeon. This result takes into consideration that the second concept offers a variety of lengthening forms for more intricate operations, but it may need to overcome certain concerns pertaining to the resistance of stress applied angularly. This would be dependent upon the intricate designs of the components and their contributions to the overall assembly stability as well as the development an adaptable system. In conclusion to this evaluation, the longitudinal element would be used, but its functionality would need to be further defined through iterations.

Storage and Transportation Consideration

One consideration that was taken into account when designing the Adaptive External Ring Fixator was the means of transportation of the device between locations such as surgical theatres. Since it would be inefficient to deliver the system fully constructed and assembled, an acceptable means of delivery was determined with reference standard practices for delivering ring fixators. The standard practice predominantly includes the storage of the individual components in cases specialised to fasten and hold each component or part included within the external ring fixator.

The Adaptive External Ring Fixator would be transported in a similar manner, using a specialised case. The rings are to be stored in segments as they can be undone by disassembling each of the bolted-nuts joints. For the longitudinal elements, each universal joint will remain assembled but separate from the full assembly, as the process would more efficient and safer when storing them individually. The body of the longitudinal elements on the other hand would be stored locked (fully assembled) to prevent loss of smaller key components, during which the housing will be fastened inside the case. The system and all its components are to be transported in these cases.

3.6. System Integration

3.6.1. Introduction and Specifications

The Adaptive External Ring Fixator will be the integration of the conceptual designs for the fixator rings and longitudinal elements to create a bilateral frame that can stabilise long bone fractures. The primary function of the External Ring Fixator will be to utilize the two subsystems to generate a biomechanical setting for bone to heal i.e. achieve injury stabilisation and deformity correction. In essence, the designs for both the fixator rings and the longitudinal elements should correlate with one another to replicate and ultimately function as an acceptable external ring fixator thus, the concepts were generated in the attempt to produce a functional medical device for this study. The designs generated from the subsystem concept generation will be detailed in this section

3.6.2. Conceptual Design Integration and Evaluation

The following concepts were generated to integrate the subsystem designs and construct designs for the Adaptive External Bone Fracture Fixation System. The aim of the concepts is to detail the full assembly construction as well as its expansion from the complete rotation of the fixator rings. In addition, the concepts are detail to demonstrate the points of attachment between the fixator rings and the longitudinal elements that will be applying the changes to the shape of the device.

Concept 1: Multi-Connective Ring Fixator with Finite Lengthening

The first concept design was created as the Multi-Connective Ring Fixator with Finite Lengthening. The concept was a mesh of the L-jointed Rings and the Finite Lengthening Longitudinal elements, by which the aim of the assembly would be to achieve accurate shape acquisition with minimal complication and error from the manipulation of the elements and other connected components. The system would be developed to meet certain shapes, by orientating the end pivot joints of the elements. The Multi-Connective Ring Fixator with Finite Lengthening is illustrated in Figure 3.7.

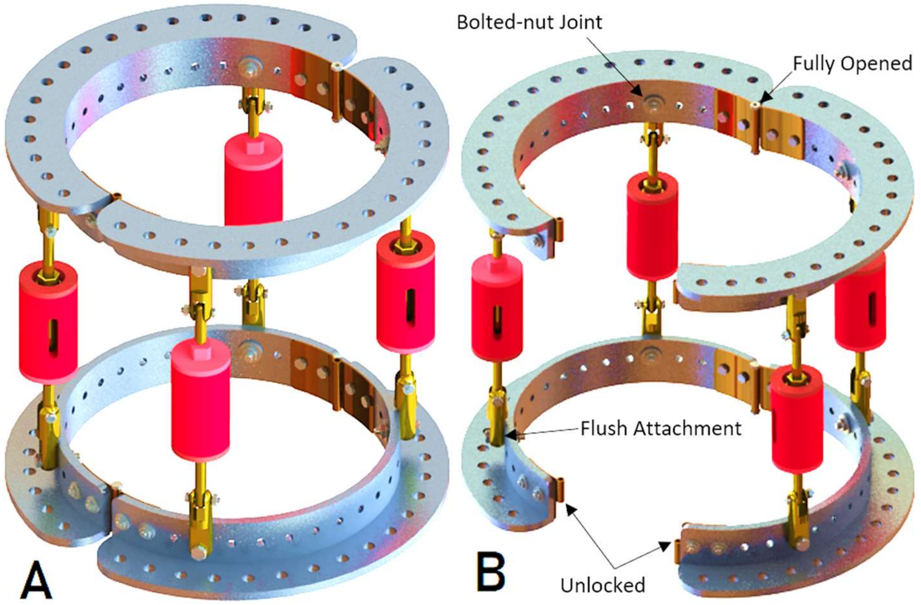


Figure 3.7: Concept 1 – (A) The full completed assembly of the Finite Lengthening External Ring Fixator (locked) (B) The system when unlocked and the fixator rings rotated about the hinge system, widens the mouth to expand to 60° fully opened.

Concept 2: Light-Weight Ring Fixator with Rapid-Finite Lengthening

The second conceptual design was the Light-Weight Ring Fixator with Rapid-Finite Lengthening. This concept would be developed to optimize mass, patient ergonomics, and complex adjustment, by correlating the intricate designs from the C-jointed rings and rapid-finite lengthening elements. The system investigates the advantages of a sleek and compact design in the attempt to minimize assembly bulk as well as to optimize a possibility for rapid installation and gradual shape change. The Light-Weight Ring Fixator with Rapid-Finite Lengthening is illustrated in Figure 3.8.

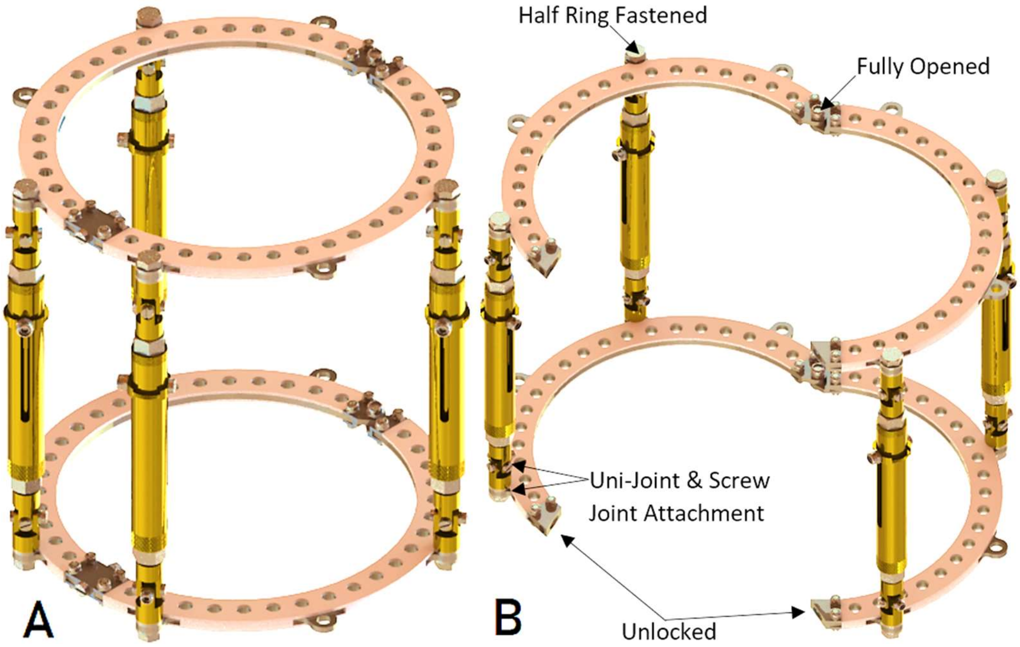


Figure 3.8: Concept 2 – (A) The full completed assembly of the Rapid-Finite Lengthening External Ring Fixator (locked) (B) The system when unlocked and the fixator rings rotated about the hinge, widens the mouth to expand to 120° *fully opened.*

Concept Evaluation for further Development

As previously mentioned, a sample concept screening process for each subsystem was conducted to evaluate the functionality and significance of each of the individual conceptual designs. The screening process had incorporated the identified design considerations specific to device design however, there is an opportunity to fully evaluate them from the basis of the full fixator assembly.

The first concept design was developed to be primarily focus upon the accuracy of adjustments. This aspect makes changes in shape slow and constrained to achieve good lengthening precision, however this in turn can limit the control over injuries, especially during the times of error and damage when major adjustments are required. Furthermore, the focus on the device's structural integrity and gradual lengthening may not differentiate the device from other known fixators.

The second concept design was developed to incorporate almost all mechanical aspects of the external ring fixators by offering both rapid and finite lengthening into a smaller versatile frame. The design was created to provide the clinician with the complete freedom to decide the course action for the fracture correction process by offering adjustment diversity. Lastly, this concept differs from the previous by employing a more light-weight structure that was shaped to optimise material strength for structural strength, making full use of the material's mechanical properties.

4. Design Outcomes

4.1. Introduction

In the previous chapter, the process that was undertaken to determine the most appropriate designs for both the fixator rings and the longitudinal elements was detailed and demonstrated. The concept screening process had produced the second concepts as the optimal choices for each of the designs. They had demonstrated structures and systems that had further expanded upon the ideas of the initial concepts as well as integrating additional and innovative design features, that would be key to further enhancing the device's functionality. The aim of each of the concepts was design a ring fixator to provide multi-directional shape change efficiently, allow for assembly expansion, minimize impingement to swelling, and lastly effectively reduce any hindrances to the construction of the ring fixator over long bone traumatic injuries of varying structures and states.

The second concept, *Light Weight with Rapid-Finite Lengthening*, had demonstrated these factors and thus would be able to meet as well as enhance the defined design requirements. As such, the factors that focused on smooth adjustability, affordability, ease of application, system versatility and patient ergonomics, had produced a final design that could successfully complete this study. Although this concept was selected, it had undergone further development through numerous iterations until a more appropriate design was developed, by employing the following aspects:

- Accommodate the device for several assembly configurations (element positioning).
- Integrate bolted-nut joints along the translating shaft to further lock chosen lengths.
- Shape system to meet chosen ring size (smallest), thus 150 mm inner ring diameters.
- Further develop the compact shape of the ring fixator, to better its aesthetic appeal.

4.2. Concept Development for the Fixator Ring

Determining a more structurally stable fixator ring design was a basis for the many changes to the second concept. The aim was to preserve the ring's thin, light-weight structure with a levelled and sleek shape, minimizing its obstruction to swelling and healing of damaged bone and soft tissue. This had also made the device more aesthetically appealing, ensuring that clinicians and patients would be forthgoing use to it. The structure was supplemented by a detailed material analysis (as demonstrated in Appendix C). In consequence, the final designs had: reduced the components' contributions to the overall assembly mass; ensured that the rings were cost effective; made the rings easier to grip and operate; and lastly made the assembly simpler to construct and install. This design was established using Solidworks (3D computer-aided engineering software), by which the scale and dimensioning was determined and measured. The actions of the mechanisms were also analysed and smoothened to better the rotations of the segmented rings. The rings were manufactured from Mild Steel Sheets, accessible from suppliers within Cape Town. The material was chosen for its good mechanical properties, accessibility and affordability (as compared to other materials in Appendix C). The rings had integrated the bolted-nut joints as the mechanisms for rotation, manufactured from key steel. All parts were shaped from tool machining by artisans.

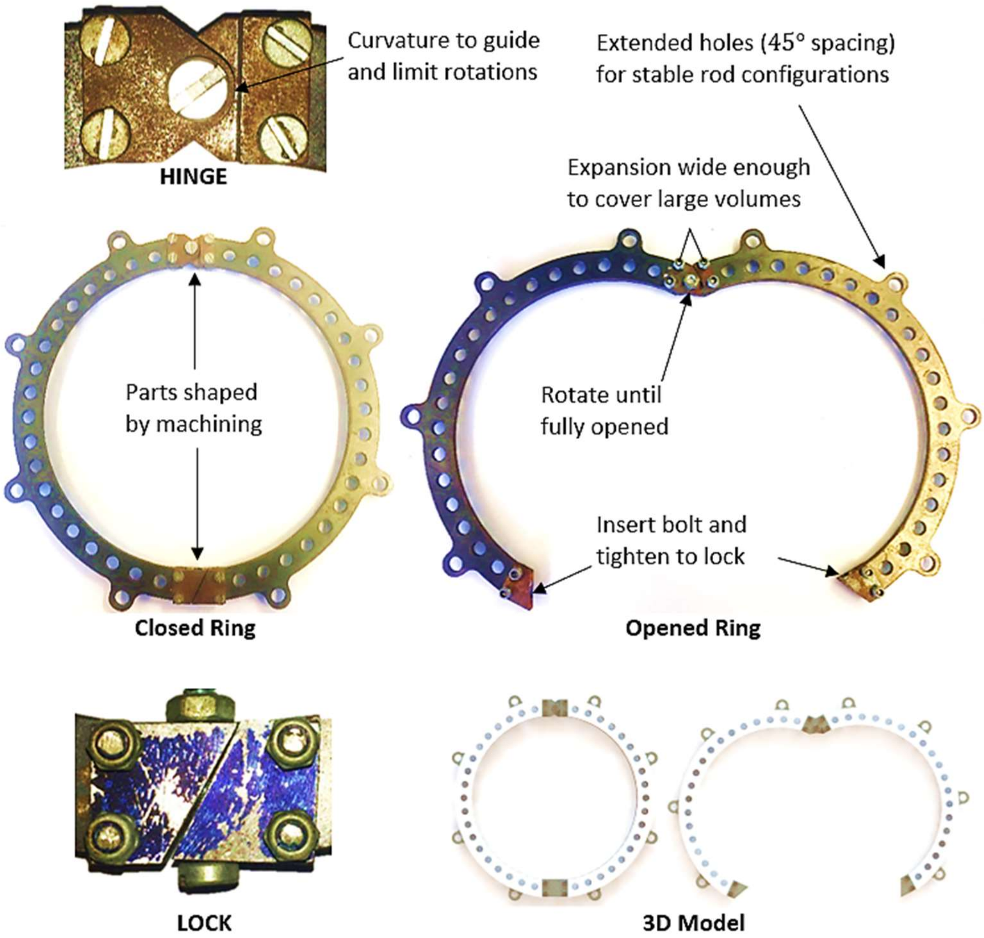
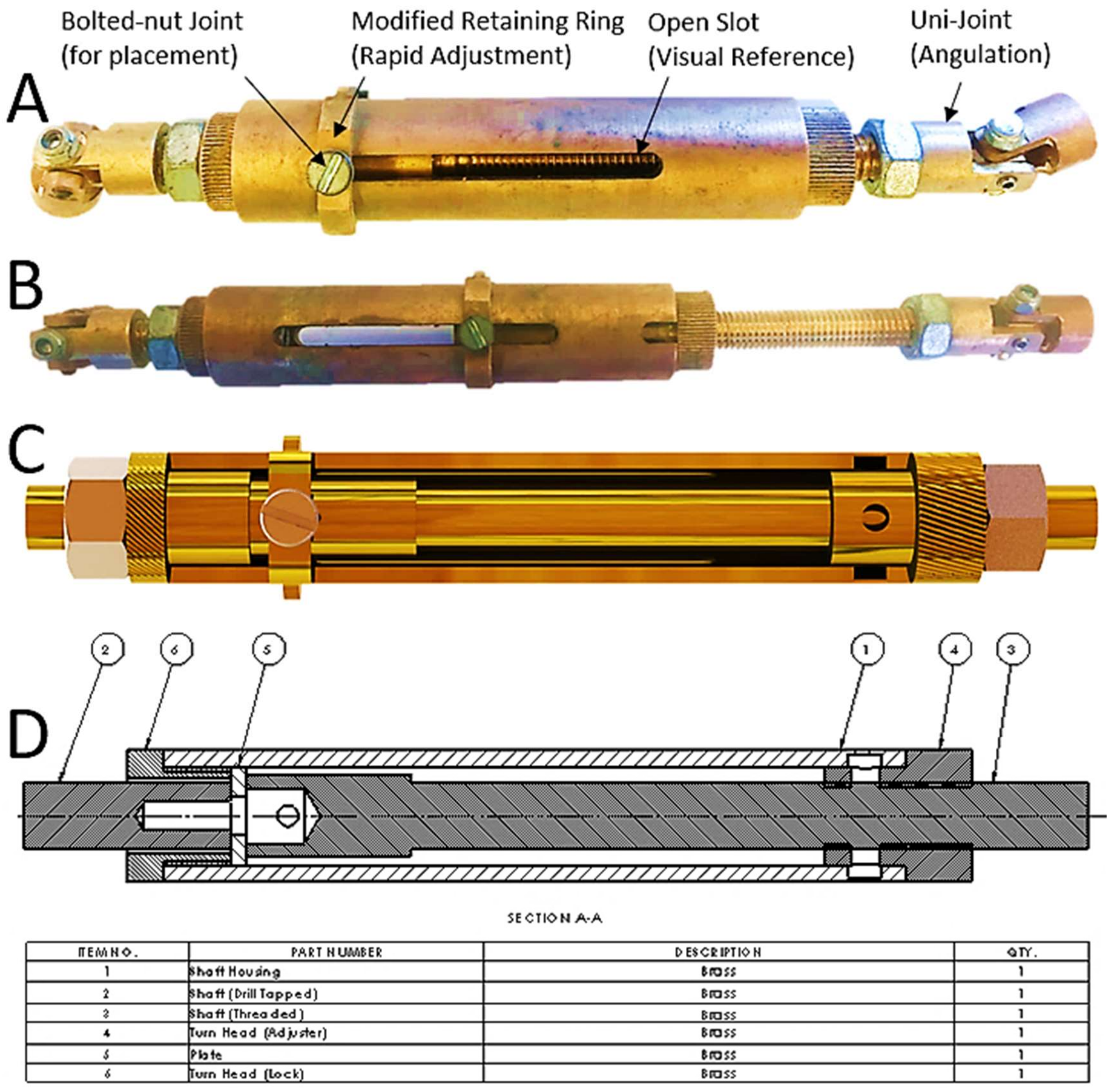


Figure 4.1: Images demonstrating the physical outcomes of the components and parts for the C-jointed fixator ring assembly. The images are labelled to detail and demonstrate the operations of certain systems as well as the applications of key design features integrated into the design of the fixator ring as part of the final assembly for the Adaptive External Ring Fixator.

4.3. Concept Development for the Longitudinal Elements

The longitudinal elements went through several iterations, that spanned across numerous designs pertaining to the designs of the internal mechanisms, and how they should operate between rapid and gradual movements. The functionality of the longitudinal elements was to primarily support body weight, and then generate translational movement to produce the desired shape changes. The application of diverse lengthening rates was the key design feature to differentiate this device from other models. Each rate has a particular significance desired by clinician and patient. Gradual lengthening offers progressive adjustment to correct planar deformities, whilst rapid lengthening can be used generate profiles quickly to stabilise injuries. Thus, these mechanisms were treated in full detail to incorporate both the rapid and finite lengthening rates, and thereby generate a competitive advantage. The longitudinal elements were thus developed to integrate the lock-and-switch mechanism to preserve the independency between lengthening and enhance its structural integrity; had included a modified retaining ring for quick length acquisition, integrated additional bolted-joints to further solidify the linear structure, and lastly modified standard universal joints to operate effectively within the assembled system. Consequently, this design had also made the device versatile, providing the freedom to determine the amount of shape manipulation needed, and as such, the device can be used for long bone trauma injuries of varying structures and states.

The designs for the longitudinal elements had undergone material analysis with a large focus on the parts pertaining to the support structure and lengthening (as demonstrated in Appendix C). This was further detailed using Solidworks, as it was used to employ its internal finite elements analyses upon both the fixator ring and longitudinal element. The final designs for the longitudinal elements (as illustrated in Figure 4.2) uses translation to produce rapid and gradual adjustment, depending on which internal component manipulated. For a length to be achieved, the clinician would use the customised retaining ring to pin point and lock a desired length, and then translate the shaft through rotations for better accuracy. The longitudinal elements would be designed to be as accurate and smooth as possible, thus Brass was chosen as the most appropriate due to its accessibility, machinability, good mechanical properties and its corrosion resistance. This was also supplemented by a material analysis that had shown the material as a balance between providing good material strength and quality part manufacture. Lastly, the modified joints were made from the same materials and were all manufactured to shape from tool machining by UCT's artisans.



ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	Shaft Housing	Brass	1
2	Shaft (Drill Tapped)	Brass	1
3	Shaft (Threaded)	Brass	1
4	Turn Head (Adjuster)	Brass	1
5	Plate	Brass	1
6	Turn Head (Lock)	Brass	1

Figure 4.2: (A) Physical outcome of the Rapid-Finite Longitudinal Elements, indicating specific and intricate parts (B) A sample length of the longitudinal element, demonstrating the positioning of the translating shaft relative to the element's length (C) Sectioned 3D graphic of the longitudinal element detailing the parts within the final assembly (D) A full labelled schematic of the longitudinal element demonstrating the component makeup of the assembly as part of the Adaptive External Ring Fixator.

To understand how the built longitudinal elements for this device operate, it should be noted the distinction between subsystem components that generate: lengthening from sharp translations and lengthening from gradual rotations. These specific components mesh with another to achieve the definitive lengthening forms such as: the *retaining ring* (connected by a bolted joint) can be shifted to sharply slide the sliding shaft through the centre of the system, steadying it at a specific location at a margin of error of less than 5 mm, and *adjustor heads* that can be turned to gradually alter the positioning of the *sliding shaft* via the internal threading within the system, accurately stabilizing it at a specific longitudinal length at margin of error of less than 1 mm. The *grub screws* provide lock capabilities, preventing sliding and enabling only gradual movements for corrections.

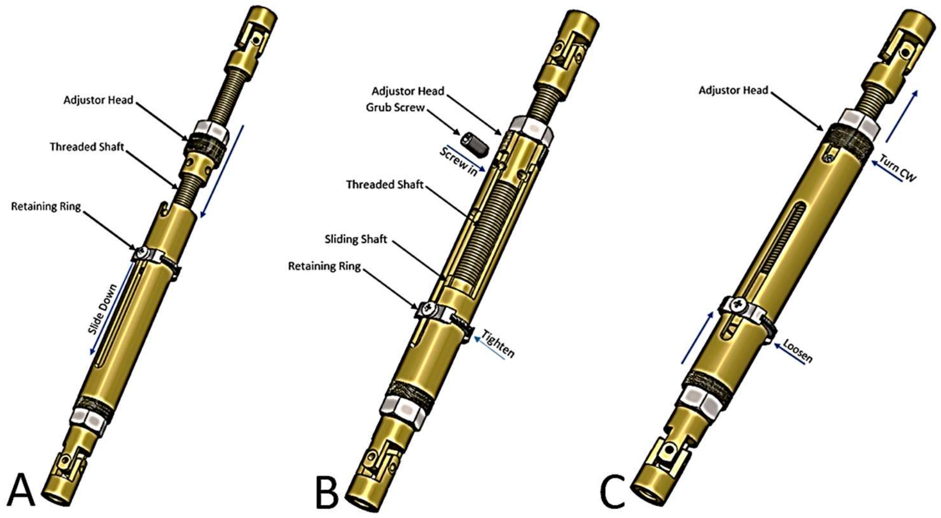


Figure 3: Images depicting process to determining a desired length with the longitudinal element and gradually adjusting it. A) Reach a certain length via sliding, B) Fix via retaining ring and grub screw and lastly C) Gradually length via adjustor head.

The designed longitudinal elements accommodate explicit linear movements, common with most current systems, however these elements can offer the two mains in combination, and if operated correctly, could be produced independently i.e. mutually exclusive to one another. Taylor Spatial Frame possesses two specific struts that are often used: the standard strut and the fast-effect struts. Both offer gradual lengthening, by turning the system over internal threading, and the fast-effect strut allows the user to adjust the strut's total length quickly however, this particular strut's structure does not ensure that the sliding shaft is jammed in place between movements, meaning switching between rapid and gradual is often instantaneous and thus it is recommended regularly that the strut should be locked at all times. Gradual lengthening is still offered when the strut is locked but attempting to switch can be difficult and dangerous. This device's longitudinal element offers both movements mutually and in combination. Another device the Orthofix Truelok, offers this function however, the adaptive longitudinal elements are designed to ensure that connecting points between rings are mutually exclusive from each other when struts are extended over the fracture, meaning their alignments are unaffected, and the loading would pass over the systems. In essence, the applied loading across the strut's length does not pass through the shaft, reducing the chance of slippage when switching lengthening forms. The retaining rings and grub screws are utilized to ensure that the switch is smooth and safe, locking rapid lengthening, and only allowing gradual lengthening to remain. Unloading the grub screws would remove this limitation, offering quick release on the system for its removal or to radically change to the assembly's current shape.

4.4. Finite Element Analysis

Finite Element Analyses were conducted upon the components designed and developed for the final assembly, by employing the load scenarios as detailed in the material analysis (Appendix C). One of the particularly difficult components was the fixator rings as there were visual evidence of structural instability, specifically for the hinged half ring exclusively. The analysis was completed by using the standard approach of inducing a static structural load upon the part. By this method, one would be able to determine the structural behaviour (deflection and strain), during scenarios of static weight bearing, by applying a point load through the face. The conditions specified also included the concept of uniform distribution of the loading created by the body weight of a 95th percentile male. The analysis of the component was conducted in iterations and had shown that achieving good structural integrity from the ring would be difficult and would need be supported through further component development i.e. adjustments to the core structures. In addition, the iterations had suggested that the inclusion of sophisticated materials would be able to offer better structural strength, however the accessibility of resources and manufacturing tools had dissuaded this design consideration. As such, the fixator ring and other components were put forward for manufacture, using the mild steel and brass as the core materials, with the dimensioning adjusted accordingly by taking into account the predicted strain outcomes from the influence of the loads. Figure 4.4 illustrates a static structural analysis iteration for the fixator ring, due to a point load.

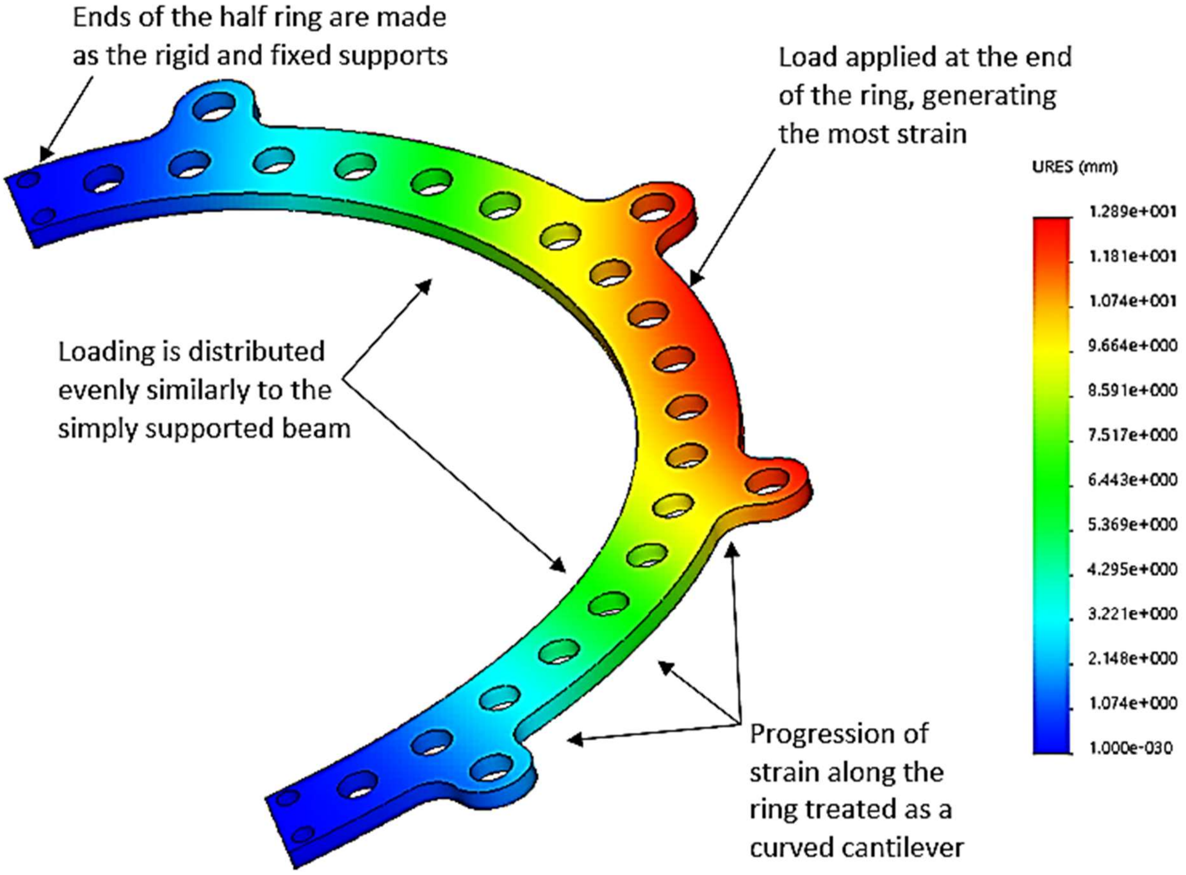


Figure 4.4: Image demonstrating a sample Finite Element Analysis problem for the Fixator Ring, indicating the extent of the generated deflection for a load applied at the furthest hole (load from longitudinal element). Image demonstrates that the loading would be distributed uniformly along the circumference of the ring illustrating a simply supported curved cantilever.

4.5. Concept Development of the Complete Assembly

The development of the final assembly was conducted in regard to the manufacture of each part. This focused on the accuracy of the parts and how they connect with one another. Most of the changes were conducted upon the ring as to determine the manufacturing technique that would be used to produce the best physical outcome. The identified concern was the positioning of the holes along the face of the ring. The standard Taylor Spatial and Ilizarov External Fixator Rings, [150 mm] inner diameter, use 42 holes, spaced equally about their centres. This was an essential detail, as this was a design parameter specific to the experimental study for validating the device. It is required that the external ring fixator meets the dimensioning of the test rigs that would be used to effectively deliver the loading upon the device, thus the device had to be adjusted to meet the structure of the test rig. The condition that determines adequate device installation inside the test rig is the number and positioning of the 42 holes thus, the accuracy of the technique was key to success, leaning towards CNC and laser cutting as the more likely methods, however the rings were actually tool machined by the faculty's workshop personnel with whom had also employed machining to shape the rings according to the holes allocated for stable assembly configurations.

4.6. Physical Outcome of the Complete Assembly

The components were produced accurately with very smooth surface textures. The longitudinal elements could be assembled quickly with minimal clipping, which in turn made assembly very efficient, taking around [125 secs] to reach a static profile (similar to Figure 4.5). The only concern was the orientation, size and positioning of the holes for grub screw insertion, as the holes were key to maintaining stability. There was enough stability to hold the shape and yet possess clearance to allow for some micromotions to assist in the bone reconstruction. The rings were successfully manufactured, as they were quite rigid in shape. The hinges-and-lock joints were manufactured accurately, however locking was considered as awkward, particularly when bolting.

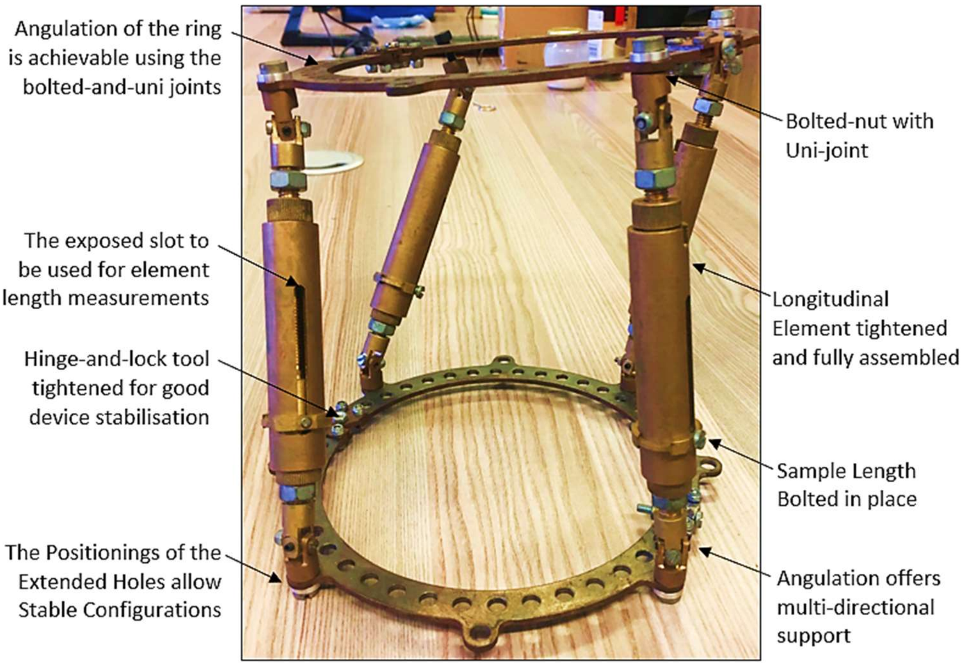


Figure 4.5: Image illustrating the physically assembled form of the Adaptive Bone Fracture Fixation System, as well as detailing the key design features that can be fully utilized when applying the Adaptive External Ring Fixator for bone fracture fixation.

5. Experimental Methodology

5.1. Introduction

This chapter centres upon the detailing of the experimental procedure(s) for the validation of the device's structural integrity and functionality to determine if it meets operational approval. The chapter details the research hypothesis, the experimental scope and setup, the experimentation, the process of data capture and collection, the data analysis process, future recommendations, and ethics approval. The measure of validation as according to the device's structural integrity will be determined graphically through the depiction of test results as clear linear graphs. Other factors will also be detailed specifying measurement and procedural testing considerations, and lastly the ethical conduct of the participant regarding to the experiment study and the use of the apparatus as provided by the University of Cape Town's Mechanical Engineering Department.

The experimental study can be detailed in consecutive stages as according to the associative goals produced from the aim and objectives. The progression of the experimental study is governed by the thorough completion of each of these stages defined for the study's successful completion.

a. Perform the defined Experimental Procedures for device validation

b. Extract experimental data and perform a comparative study

c. Provide adequate experimental considerations for future endeavours

The experimental study for validating the built adaptive device follows the experimental practice of externally loading a device under controlled stress conditions pertaining to direct loading. The method is often employed with the aim of determining the limits in loading that can applied to a device is determine operational approval or to produce evidence of functional failure (yielding). This experimental method will be able to assist the investigator in making evaluations of the device's functionality by detailing its performance through the application of graphical depictions, usually represented by linear graphs. These evaluations would be manufactured from the analysis of the generated data, particularly strain, to detail the structural stability of the device under the applied loading. The experimental study would be utilising the available apparatus known as the Quasi-Static Machine to induce the direct loading onto the device, while the generated strain data will be recorded by the machine and suitable gauges accessible from the engineering department.

The completion of the experimental study can be summarized by a flow chart (as illustrated in Figure 5.1). The flow chart details the proposed scope of the experimental study as actions are either completed or disregarded as per factors determined from completing stages in the study

5.2. Experimental Methodology

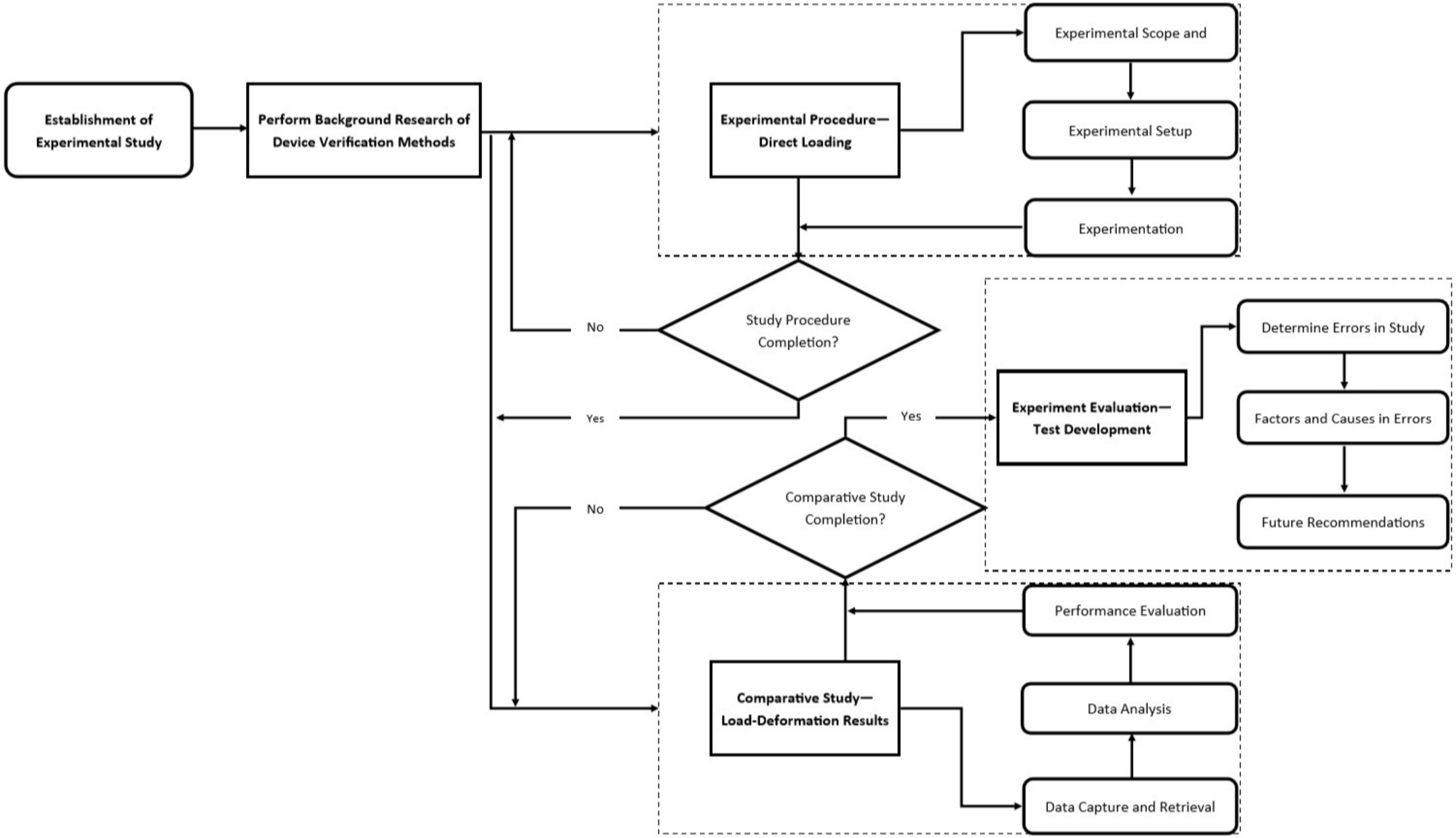


Figure 5.1: Experimental Methodology Flow Chart

5.3. Experimental Hypothesis

The research hypotheses for the experimental study is detailed as follows:

1. An Adaptive External Bone Fracture Fixation System, comprising of hinged ring and rapid-finite element lengthening systems for rapid installation and shape change, will maintain assembly stabilisation and support to the applied directional load for up to 3500 Newtons

2. The longitudinal elements designed and developed will maintain assembly stabilisation and support the distributed directional loads without functionally failing i.e. collapse.

5.4. Experimental Procedure

5.4.1. Experimental Scope and Work

The experimental procedure to be conducted upon the Adaptive and Comparative Ring Fixators would pertain to the application of a loaded cell machine to produce the desired stress conditions. The procedure would be completed in the University of Cape Town's Mechanical Engineering Department, where engineering tools and machinery for stress testing are made available. The experimental study would be designed to validate the device's structural integrity by generating the stress conditions equivalent to weight bearing and body mobility i.e. direct axial loading. The procedural testing would be completed in divisions of compression and tension for each fixator. Data would be generated from the resultant strain caused by a loading acting through the fixator. The quantitative outcome of the study would only be the generated data for the resultant strain, across the lengths of both fixators and their longitudinal elements (external and internal strain). The data would be extrapolated and translated into visual depictions, and as such, linear graphs (Load-Deformation), categorised by loading type and assembly configuration, would be produced. Figure 5.2 illustrates two assembly configurations that can be used, this study would be using the stable configuration, by which future tests may expand this by using the unstable choices.

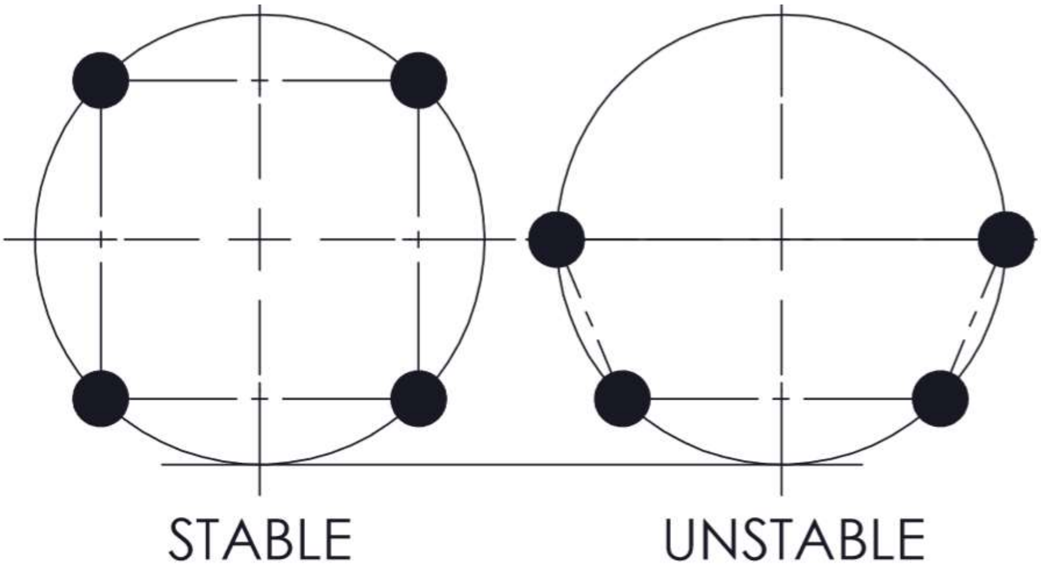


Figure 5.2: Images demonstrating differences in the assembly configurations as according to the positioning of the attached longitudinal element or threaded rod. Stable configuration was chosen and would employ a square profile across the ring.

5.4.2. Experimental Setup

The Experimental procedure is to be successfully accomplished by applying load onto each fixator. The application of a loaded cell would be applicable, and as such, the Quasi-Static Machine was chosen as the source for the Compressive and Tensile Loads to generate the stress conditions. The machine, (as illustrated in Figure 5.3a), is located in the Materials Engineering Department and is used to stress test engineering materials until yielding or beyond, making it a good choice for the experimental study, taking into mind the ethical considerations when using the apparatus. The machine can only generate direct axial loading (compressive and tensile), and thus a portable test rig was created to assist in the procedures pertaining to the loading of external ring fixators.

The test rig, (as illustrated in Figure 5.3b) was designed and developed to allow the user to control and generated the stress conditions required for this experimental procedure. It was built to lock external ring fixators inside the Quasi-Static Machine and allow load to pass through the system. The test rig is able to lock the external ring fixator by interlinking the parts for both machine and fixator into a loaded system. The test rig employs the simple concept of a simply supported beam to deliver the load across the face of the loaded ring fixator, as well as allow the user to adjust the positioning of both load and device. The test rig was built to produce different failure scenarios that can generate distinctive strain readings, however for the scope of the following study, its functionality would be limited to only applying direct axial loading of compression and tension. Figure 5.3 illustrates the Quasi-Static machine and test rig that will form the experimental setup.

Figure 5.3: (A) The image demonstrating the Quasi-Static Machine located in the Material's Engineering Department and (B) indicates how the constructed test rig was fitted and installed inside the Quasi-Static Machine for the procedural test

The experimental procedure would provide generated strain data as the quantitative outcomes from the experimental study, so as to be translated into visual depictions for the analysis process. The generated strain data results from the applied loading of the Quasi-Static Machine generated upon the fixators, and as such, the resultant strain readings would be extrapolated as the external strain while the internal strain would pertain to the strain data generated by two strain gauges. The Quasi-Static Machine would be used to record the strain across the entire systems as distance covered by the machine and translating the strain data into its own experimental testing program. Internal strain would be extrapolated from the strain iteratively generated by the strain gauges attached along the longitudinal element, (as illustrated in Figure 5.4a). The sacrificial longitudinal element would be utilised for all tests to maintain reproducibility and repeatablilty as well as to preserve the conditions between test iterations. The external and internal strain data would be extracted separately by consulting the apparatus used to record the type of generated strain data.

The procedural tests pertain to generating the comparable stress and strain measurement results. Therefore, each procedural test would be setup to possess similar test parameters and conditions. The Quasi-Static Machine records the resultant strain across the system for the applied load, and as such, tests are initiated once the load and distance covered by the machine is reduced to zero. The two linear strain gauges attached along the longitudinal element (as illustrated in Figure 5.4a) are to be used throughout the experimental study as to continue the same experimental format. In order to maintain experimental reproducibility, measurements of the experimental format was to be conducted, preserving the test conditions as according to the chosen assembly configuration (as illustrated in Figure 5.4b). The experimentation commences once conditions are acceptable.

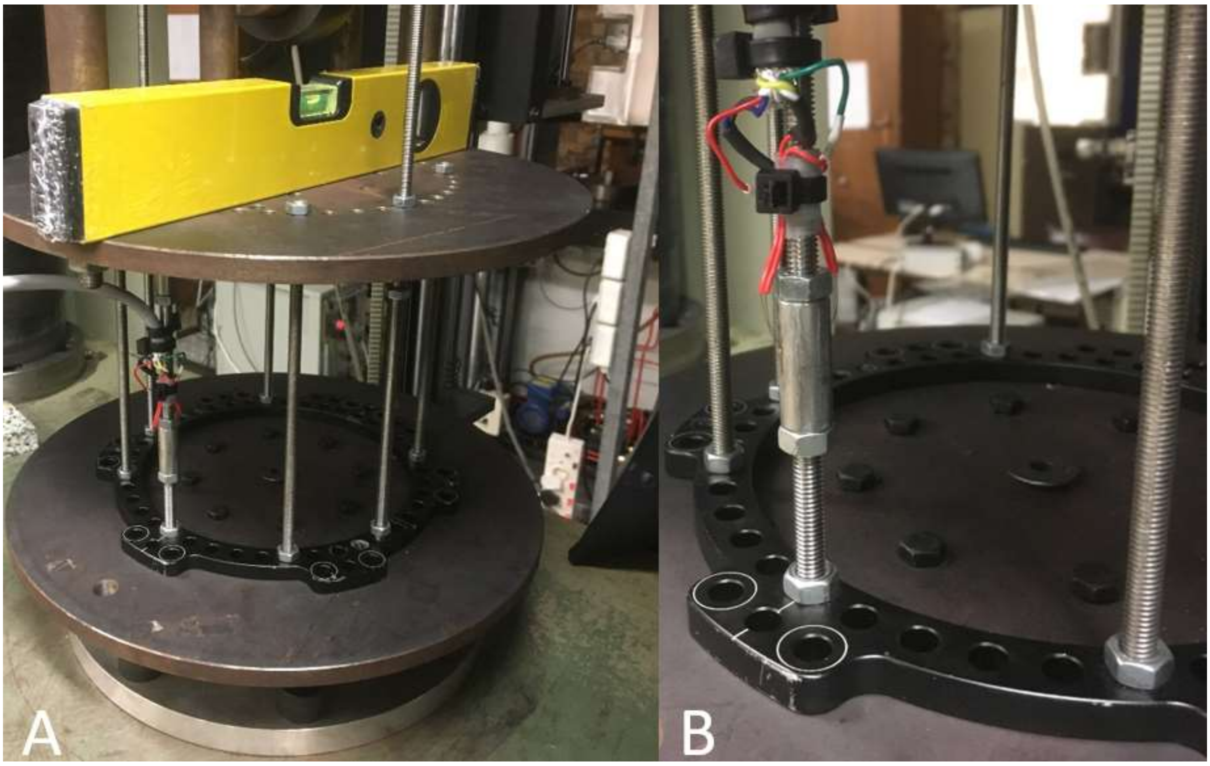


Figure 5.4: Images (A) demonstrating the experimental setup and measurements done before each iteration of the procedural tests while (B) is illustrating the Strain Gauges attached parallel and opposing along the threaded rod, or longitudinal element

5.4.3. Experimentation

The Experimental Procedure is scoped to be completed after the fixator has been successfully loaded to either a maximum load value or has reached the point of potential or definite yielding. The applied load from the machine is to be allowed to increase from zero load, by which the chosen load type would deliver the force upon the test ring. Aligned through the centre, the load is to increase according to the chosen rate (distance covered for time of experiment - 0.5 mm/s). The load magnitude is to be allowed to reach a peak maximum of 3500 Newtons, otherwise cease all loading whether the system is collapsing or yielding. Tests are to end by unloading all excess loading and the strain data captured onto accessible files catergorised by fixator and loading type. Each iteration is to be completed with a collection of data specific to machine and strain gauges.

5.5. Comparative Study

5.5.1. Data Capture

The direct axial load and resultant strain are to be detailed as an analogous Stress-Strain Curves, as illustrated by Load-Deformation curves, to visually demonstrate each fixator’s performances. The Quasi-Static machine captures and records the performances simultaneously as Load-Deformation curves, projected by its own computation testing program. The progression of the test could also be evaluated by using the same program. Similar Load-Deformation curves were produced for the resultant strain generated by the strain gauges, using another testing program. The strain data from both strain gauges and machine were extrapolated into excel spreadsheets.

5.5.2. Data Analysis

The Load-Deformation curves, recorded by the Quasi-Static Machine and translated from the data generated by strain gauges, were to be produced within excel spreadsheets. The iterative strain data would be recorded as time-based readings, making the performances easier to calibrate. These readings were to be categorised by configuration and loading type for each loaded fixator. The data was projected and refined as linear graphs depicting the progression of strain resulting from the applied load. The linear graphs were loaded with both adaptive and comparative fixator, providing visual details and clear differences of their performances, to provide enough evidence to make evaluations of the device’s usability. The analysis would be concluded by describing their behaviours visually and physically, comparing details from the graph to the physical performance.

5.5.3. Performance Evaluation

The procedural testing would be conducted in variations by employing two directional loadings, (compression and tension), by which would demonstrate the structural integrity of each fixator. The similar stress conditions allow for clear evaluations of their performances by monitoring the progression of strain caused by the applied load and determine any potential flaws in the designs. The chosen configuration would be used for the experimental study to fully evaluate the fixator’s most stable construct and to generate adequate test results for effective comparisons. However, without much diversity within the experimental study, testing is still limited to certain factors that would often be made variable in fracture fixation, and thus adaptability can be further evaluated.

5.6. Future Recommendations

The scope of the experimental study was constructed to validate the fixator's structural integrity as per the loading of the device under compression and tension, equivalent to fracture fixation. The validation was dependent upon the device's strength under certain loading conditions with factors specific to the configuration and loading type. The procedural tests were designed to apply strict directional loading that could be: monitored, controlled and altered as the test progressed. However, the validation of the device's structural integrity can be further investigated through the application of more diverse loading types such as bending and torsion. It may be also be beneficial to diversify the conditions by controlling certain variables, particularly load positioning.

If the aim may be to develop towards *in vivo* verification, the tests may require more extensive validation by using stress conditions that may be more strenuous than long bone fracture fixation. The application of *in vivo* verification trials in conjunction with the verification of the device's structural integrity may also successfully validate the functionality and usability of the device, as per the conditions of rapid and finite lengthening. Stabilisation of bone for various structures is one of the many factors to achieve device approval and thus *in vivo* verification would need to be included within the development of the device. The application of a sample number of cadavers, preferably with intact lower limbs, as an applicable surgery setup can be used to expertly validate the usability of the device and successfully determine its significance for bone fracture fixation.

5.7. Ethical Considerations

The study was conducted within the boundaries of the Material's Engineering Department of the UCT's Mechanical Engineering with the primary component of the experimental study belonging to the department, and as such, the appropriate ethical considerations were identified and followed, specifically for the use of the Quasi-Static Machine. The scope of the experimental study was completed primarily without human and non-human experimentation with minimal risk. However, an ethics application was filed to the Human Ethics Committee (HREC), code: 314/2017. Ethical approval was required for device testing to begin as there was a potential to continue the study towards *in vivo* verification trials and thus the application of cadavers for the device testing, was to be validated through an acceptable ethics application. The constructed protocol for the ethics application was reviewed and approved (as illustrated in Appendix A) by two academic staff members with insurance that the study would be successfully completed with adequate ethical consideration for all parties and personnel. It was required that the cadavers were to be treated with the outmost respect and handled with care for the duration of the experimental study. Although the ethics application was approved, and the letter of approval sent, the scope of this study could not allow for the application of cadavers within the following experimental study.

6. Experimental Outcomes

6.1. Introduction

This chapter will detail the quantitative outcomes from the experimental study, that pertained to the direct loading of both Adaptive and Ilizarov External Ring Fixators, (as illustrated in Figure 6.1). The procedure that was conducted, utilised the loading generated by the Quasi-Static Machine to produce the stress conditions required to validate the structural integrity of each ring fixator. The validation procedure was limited to the application of compression and tension, by which the ring fixators were arranged into a stable configuration and loaded to produce test results, depicted as Load-Deformation Curves. The readings for both the applied loading and generated strain were recorded by the measurement gear, comprising of the Quasi-Static machine and strain gauges. The procedure was concluded by recording the time-based readings and linear graphs within excel spreadsheets, generated after each test iterations, spanning from compressive to tensile tests.

This chapter will also detail the evaluations and conclusions made of the tested device's structural integrity and its performance, by analysing and comparing the resultant behaviours to the loading. A statistical analysis of the quantitative data produced by the Quasi-Machine and strain gauges, was not possible as the sample size was insufficient (as summarised in Appendix B). The loadings of both Adaptive and Ilizarov External Ring Fixators were conducted individually, and as such, the quantitative data were recorded separately and compared. The graphs generated for comparison were listed according to the type of loading and generated strain, for the chosen configuration. Lastly, the details for the device's limitations and differences in functional performance will be provided, by which adequate future recommendations will be produced for further development.

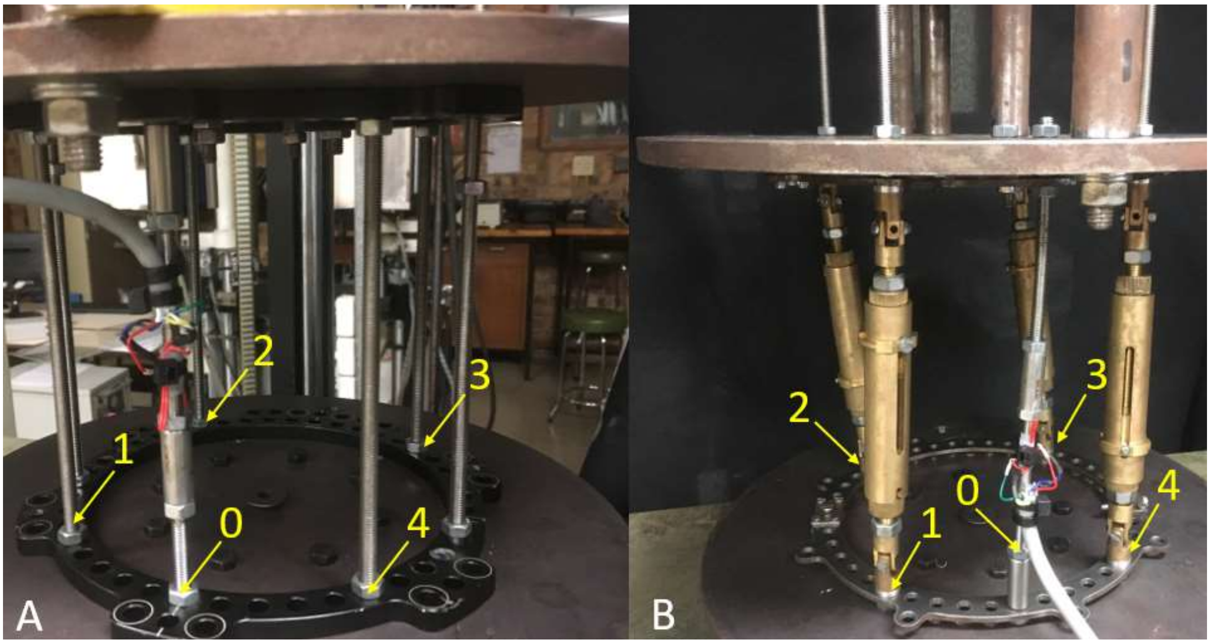


Figure 6.1: A) Image illustrating the Ilizarov Ring Fixator installed inside the load cell, whilst utilising the stable configuration (B) Image illustrating the Adaptive Ring Fixator installed inside the load cell, whilst utilising the stable configuration

6.2. Compressive Loading Test

The test results from the direct axial compression are detailed in the following section. The data pertaining to the loading and generated strain was translating into the following linear graphs. The compression tests were completed once the load had reached a maximum or device yielding. The stress and strain measurements recorded by both the machine and strain gauges are shown.

6.2.1. External Strain Results

Figure 6.2 illustrates the results obtained from the Quasi-Static machine for the compression of the two ring fixators (stable configuration). The figure shows the extent of each fixator's structural integrity, when placed under direct axial compression i.e. maintaining assembly stability. The test was completed by using a loading speed of [0.5 mm/s] with applied loading beginning from [0 N].

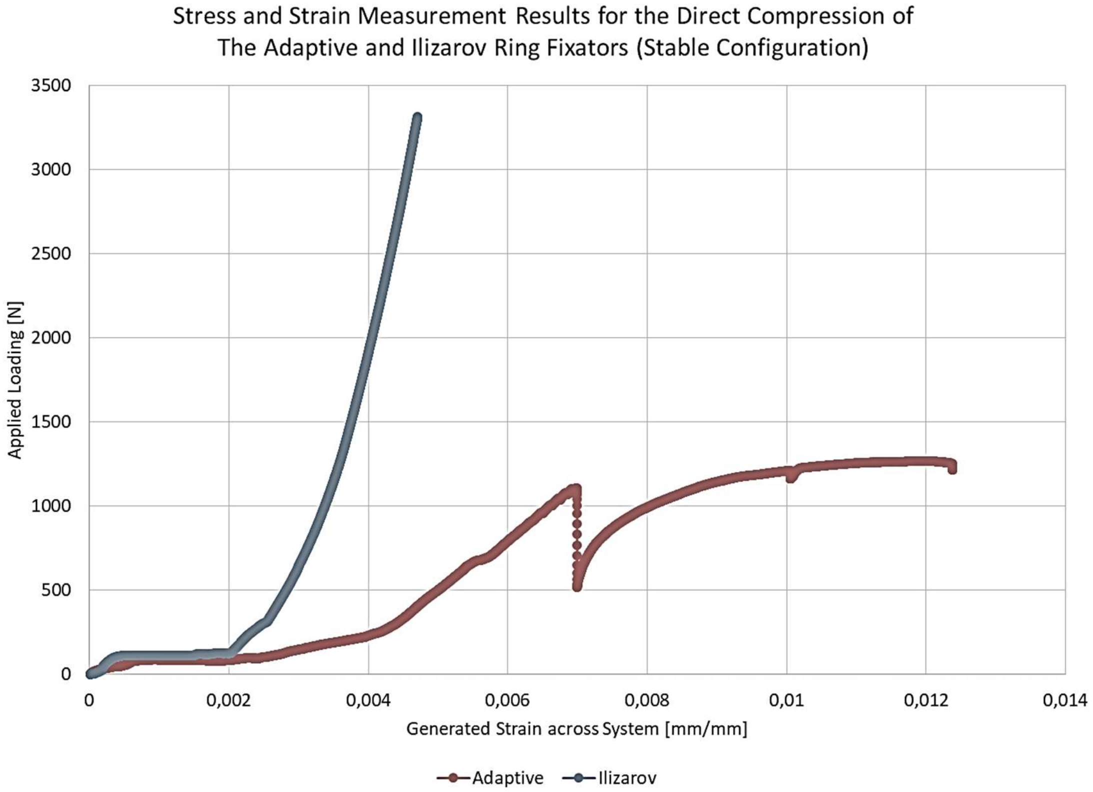


Figure 6.2: Stress and Strain Measurement Results for the compressive loading across the Ring Fixators

The image illustrates the Stress and Strain measurement results for the compression of the Adaptive and Ilizarov Ring Fixators. The results indicate that the Adaptive Ring Fixator had begun to destabilise towards [1.2 kN], indicating structural yielding

The Ring Fixators were successfully loaded to either a maximum load [3.5 kN] or until there was evidence of structural yielding present during the procedural test (visually and physically). The Quasi-Static machine had captured the strain data, as the applied loading for distance covered, by which had demonstrated the progression of strain as the loading is increased to meet a chosen rate. The visual evidence of peaking and drop in load suggests collapse, detailing yielding. As such, the Adaptive Ring Fixator was unable to maintain stability comparable to the Ilizarov Ring Fixator, as the increasing compression had demonstrated structural instability for loads ranging [1-1.3 kN]. The conclusion from this test had suggested that the device had maintained stability, until loading had generated instability; leading to peaking and thus yielding; demonstrating assembly collapse.

6.2.2. Internal Strain Results

Figure 6.3 illustrates the results obtained from the strain gauges for the compression within the Adaptive Ring Fixator (stable configuration) i.e. the stress and strain measurement results across the opposing faces of a single longitudinal element. Figure 6.3 illustrates the structural behaviour of this element whilst the increasing compression is induced and distributed through the system.

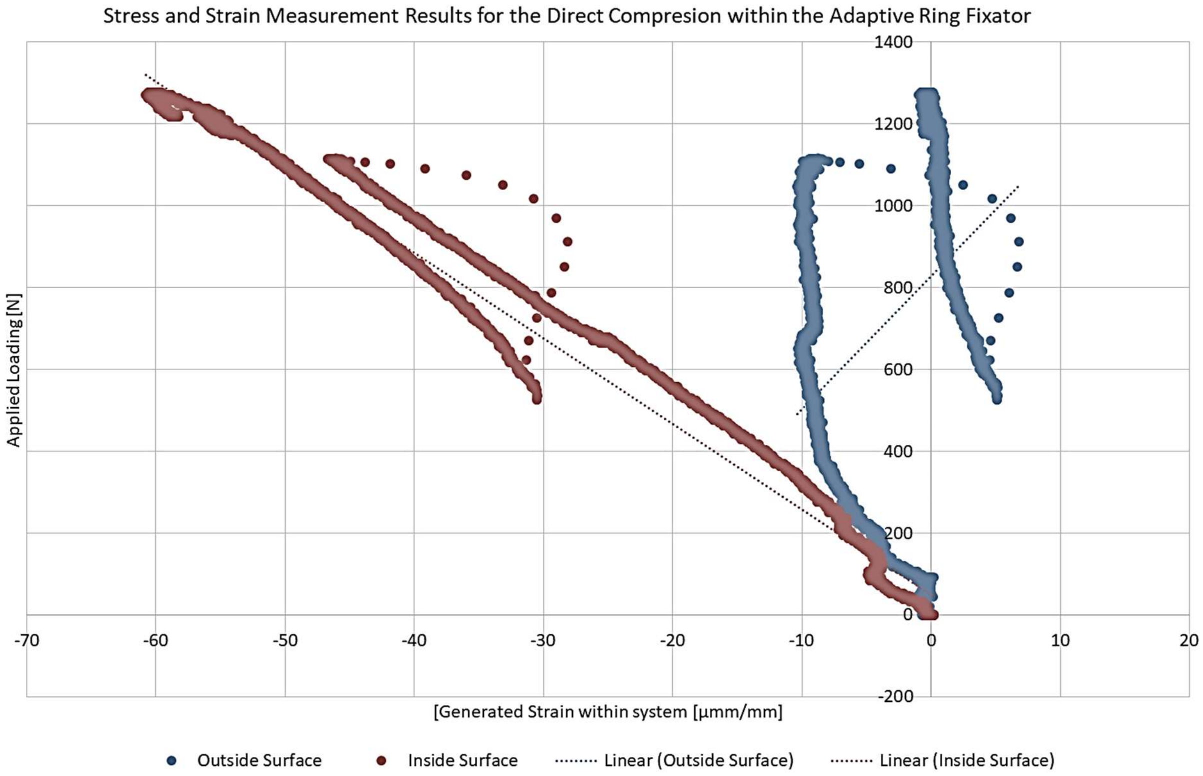


Figure 6.3: Stress and Strain Measurement Results for the compression within the Adaptive Ring Fixator

The image illustrates the Stress and Strain Measurement results for the compression within the Adaptive Ring Fixator system. The results indicate that the load had generated collapse and therefore component instability, once it had reached [1.1 kN].

The Adaptive Ring Fixator was effectively loaded to a maximum load of [1.1 kN], after evidence of assembly collapse and thus yielding was presented during the procedural testing. The ring fixator had been assembled into the stable (equal spacing) configuration with the strain gauges installed along a longitudinal element. The projection of the resultant internal strain has indicated that the device was structurally unstable, (as illustrated in Figure 6.3), indicating that the loading along the single element had demonstrated a point of specific assembly collapse and thus functional failure.

Figure 6.3 illustrates that the structural integrity of the Adaptive Ring Fixator, as assembled in the most stable configuration, can falter under a compressive load, with visual evidence of instability. The direct loading had produced substantial internal strain, as the loading was raised to [1.2 kN]. In addition, the load was unable to reach a magnitude comparable to the desired amount for an average human being when mobile. As illustrated previously, the device had maintained stability for a definite compressive load range, until the load had generated the initial collapse at [1.2 kN], and as such, the test results produced, indicate a design limitation in structural integrity. This design limitation may demand further device development for future experimental testing.

6.2.3. Compressive Test Discussion

The Adaptive Ring Fixator had performed unsatisfactorily for the procedural test pertaining to the direct compression. The Adaptive Ring Fixator was loaded under increasing compression until the load had generated structural instability, depictable as internal joint collapse. The load was not equivalent to the accumulated load due to weight bearing and mobility of a 95th percentile male. The strain data produced, had visually depicted possible yielding, by which had provided details that prove the design is structurally limited under certain stress conditions. The final compressive load, before the loading was stopped, was considerably lower than the defined maximum for the experimental procedure of [3.5 kN]. This has evidenced that the Adaptive Ring Fixator is weaker than the Ilizarov system and therefore would be weaker than the standard market ring fixator. As a conclusion to the procedural test, the stress conditions corresponding to weight bearing may produce destructive loading, as the structural integrity may be considered as inadequate.

Although the Adaptive Ring Fixator had produced measurement results that were unsatisfactory and exhibited signs that it is weaker under compression than the comparative market ring fixator, there were key visual factors in the test that may prove critical for further device development. The initial collapse was visually depicted as a sharp drop in the linear progression in strain for the Load-Deformation curve (as illustrated in both Figure 6.2 and Figure 6.3), producing clipping. This would be identified physically, as the collapse of the assembly joints and internal connections. Under the increasing influence of the compressive loading, the device had initially maintained a stable construct, evidencing graphically and physically, that the structural stability was sufficient. Furthermore, the results had shown that the Adaptive Ring Fixator had maintained this stability for a large compressive range before the immediate initial collapse, which would indicate that the structural failure may be unpredictable, as this was the result of instability within assembly joints. Therefore, the test had provided visual and physical evidence of limitations in the system’s design.

The Adaptive Ring Fixator’s structural integrity under the influence of compressive loading had therefore been experimentally verified to be limited by the design of the internal assembly joints. The experimental study had revealed that the design for co-active rapid and finite adjustment had introduced the problem of multiple joints and internal part connections within a single assembly. When fully assembled and fixed, the Adaptive Ring Fixator would be able to maintain stability for as long as the joints were static, and the load directed through the centres. From the direct stress, the joints may begin to collapse, and the increasing compressive load would result in a sabotage of the overall stability as the consecutive joints begin to buckle under the increasing loading. Thus, the study had proven that the structural integrity would be limited by these specific joints, and compression would produce multiple collapses as the overall assembly adjusts to the loading.

6.3. Tensile Loading Test

The test results from the direct axial tensile loading are detailed in the following section. The data pertaining to the loading and generated strain was translating into the following linear graphs. The tensile loading tests were successfully completed as loading had reached a defined maximum. The stress and strain measurements recorded by both the machine and strain gauges are shown.

6.3.1. External Strain Results

Figure 6.4 illustrates the results obtained from the Quasi-Static machine for the tensile loading of the two ring fixators (stable configuration). The figure shows the extent of each fixator's structural integrity, when placed under direct axial tension i.e. maintaining assembly stability. The test was completed by using a loading speed of [0.5 mm/s] with applied loading beginning from [0 N].

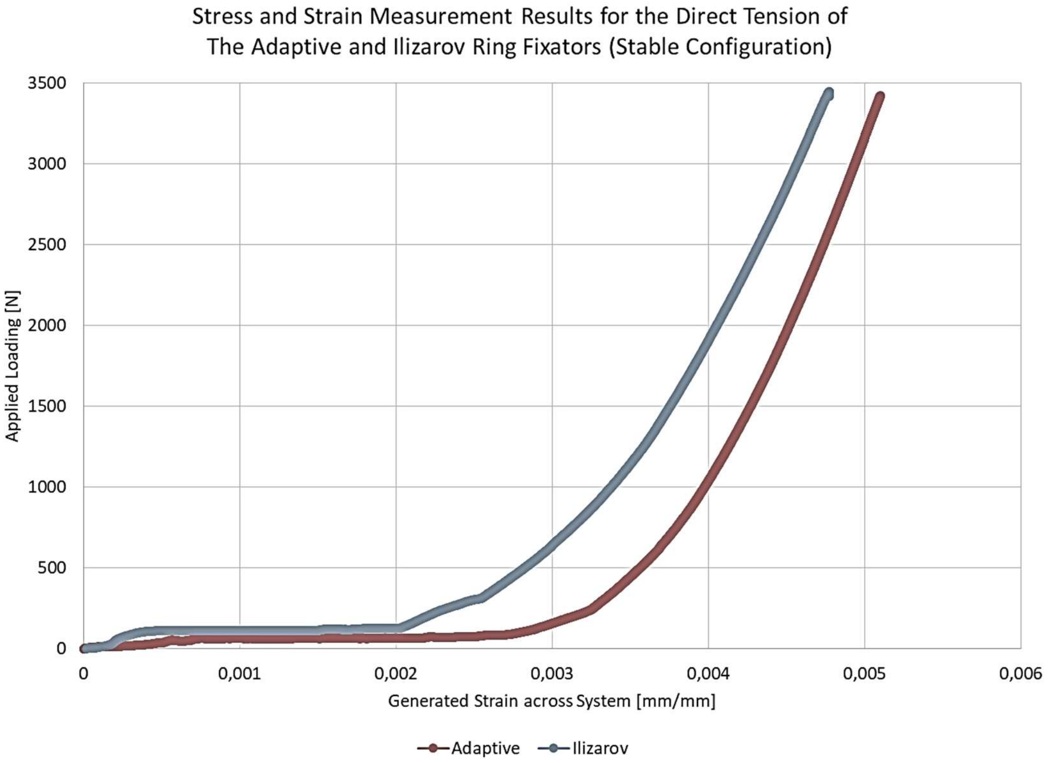


Figure 6.4: Stress and Strain Measurement Results for the tensile loading across the Ring Fixators

The image illustrates the Stress and Strain measurement results for the tensile loading of Adaptive and Ilizarov Ring Fixators. The results indicate that the Adaptive Ring Fixator had maintained stability for the test duration, maximum load of [3.5 kN].

The Ring Fixators were successfully loaded to a maximum tensile load of [3.5 kN]. The procedural test was successfully completed without complication or error, as the fixators maintained stability throughout the test. The Load-Deformation curves produced, had depicted stable behaviour from both fixators, demonstrating the Adaptive Ring Fixator's competitiveness under direct tension. The behaviours are depicted as demonstrating similar performances, as the differences become clearer as loading increased towards the maximum load of [3.5 kN]. The Adaptive Ring Fixator does demonstrate limitation in structural stability, as the Load-Deformation Curve show initial rapid strain generation until the fixator stabilised at [250 N], suggesting a partially limited design. In conclusion, the experimental test had demonstrated that the structural integrities of the two fixators are comparable, becoming more pronounce as the loading and resultant strain increases.

6.3.2. Internal Strain Results

Figure 6.5 illustrates the results obtained from the strain gauges for the tensile loading within the Adaptive Ring Fixator (stable configuration) i.e. the stress and strain measurement results across the opposing faces of a single longitudinal element. Figure 6.5 illustrates the structural behaviour of this element whilst the increasing tension is induced and distributed through the system.

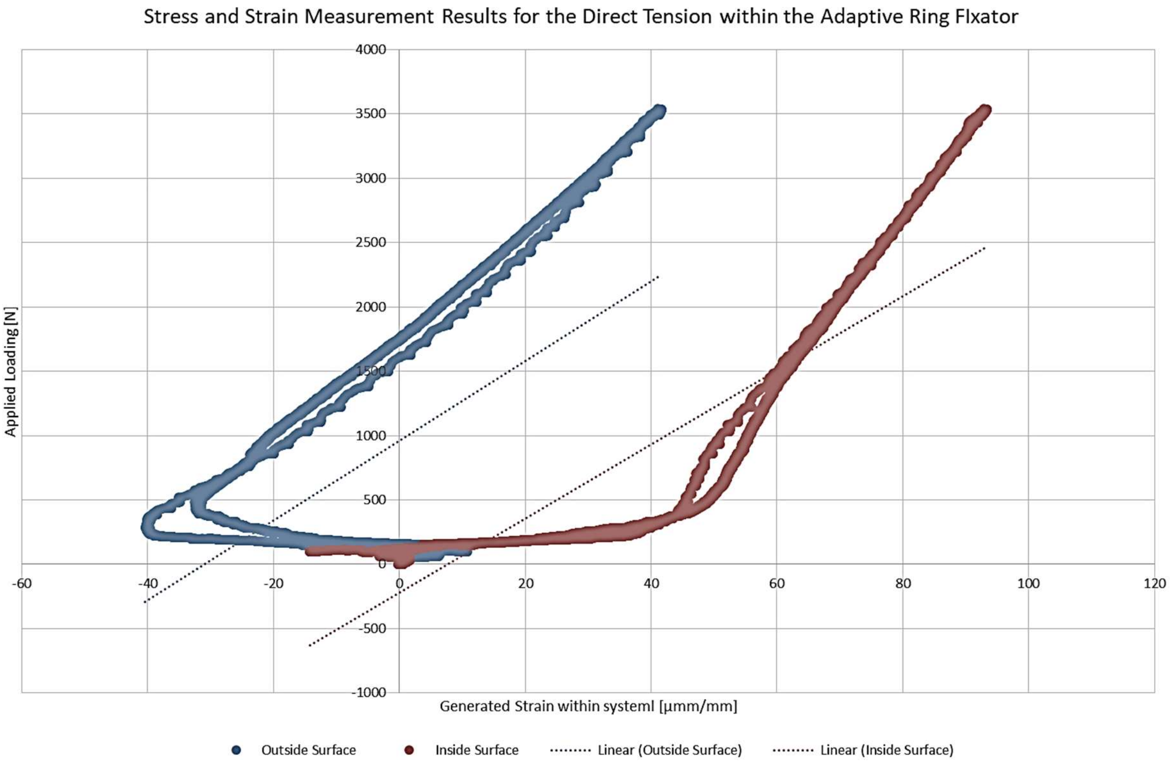


Figure 6.5: Stress and Strain Measurement Results for the tensile loading within the Adaptive Ring Fixator

The image illustrates the Stress and Strain measurement results for tensile loading within the Adaptive Ring Fixator system. The results indicate that the longitudinal elements had maintain stability after the load had passed the magnitude of [20 N].

The Adaptive Ring Fixator was effectively loaded to a maximum load of [3.5 kN], by which the loading was allowed to increase until the defined maximum tensile load had been reached. The strain data generated, had demonstrated visually that the Adaptive Ring Fixator had achieved and maintained enough structural stability to support the tensile loading (as illustrated by Figure 6.4). The longitudinal element, on the other hand, had eventually achieved enough assembly stability, as according to the stable configuration chosen for the procedural test. The projection from the Load-Deformation curve shows that the strain progression was successfully constrained [250 N].

Figure 6.5 indicates visually that the structural integrity of the Adaptive Ring Fixator system, as assembled in a stable configuration, is satisfactory when it is placed under increasing tensile load. The induced loading had produced strain along the length of a longitudinal element, comparable to weight bearing and body mobility, thus showing the stability comparable to a standard fixator. Although it was illustrated previously that the device had eventually achieved stability over time, its structural integrity could not constrain the rate of generated strain initially as its had tried to achieve enough stability and support for the tensile load. In conclusion, the test result has shown that the longitudinal element may only constrict strain once sufficient tensile loading is applied.

6.3.3. Tensile Test Discussion

The Adaptive Ring Fixator had performed satisfactorily for the procedural test pertaining to the direct tension. The Adaptive Ring Fixator was loaded under increasing tension until the load had reached a defined maximum of [3.5 kN]. The procedural test was successfully completed with minimal complication or error in loading. The load was allowed to increase to an equivalent load depictable of the accumulation of weight bearing and body mobility for the 95th percentile male. Although the Adaptive Ring Fixator had maintained structural stability for much of the test, there was visual evidence that the system had to mechanically adjust to the applied load as the progression of strain was non-linear and deviating rapidly. The test had evidenced that the ring fixator possesses a stable structure that is highly limited to only one type of load. As a conclusion to the procedural test, the Adaptive Ring Fixator is capable of maintaining structural stability for stress conditions correspondent of direct tension, however the stability may still unpredictable.

Although the Adaptive Ring Fixator had produced measurement results that were satisfactory and exhibited signs that the system is structurally stable, there was evidence that prove the fixator is structurally sound for only one loading type, which may prove critical for further development. As the tensile load was increased, the test had shown minimal error and sufficient stabilisation. The ring fixator was capable of maintaining stability, comparable to the market ring fixator, and validate compatibility for axial loads correspondent to limb lengthening and distraction. However, one particular aspect that may prove the device is still weaker to tensile loads, corresponds to its structural integrity during the initial stages of loading, by which may indicate that the joints were still adjusting under the loading to a point of structural stability. The Quasi-Static Machine reached the maximum at a much slower pace than the comparative model, indicating potential limitations. Therefore, under the influence of increasing tension, the Adaptive Ring Fixator is able to generate structural stability after the force has applied a sufficient magnitude of load to the assembly joints.

The Adaptive Ring Fixator may only be structurally stable for one directional load of enough force. This particular aspect in structural instability was visually depicted in the internal stress and strain measurement results (as illustrated in Figure 6.5). The figure shows that the initial strain was eventually constrained, indicating that stability may need to be attained by locking the joints. This was clearly evident for loads of a tensile nature, meaning that the joints would only be strong for tension not compression, proving the possibility that the ring fixator could fail to insufficient load. The Adaptive Ring Fixator's structural integrity under the influence of tensile loading would thus need to be experimentally verified by further diversifying the defined stress condition. A particular aspect that would need to be diversified would be the positioning of the tensile load, producing bending and shear stress that would clearly determine its strength for more destructive loading. The experimental study had revealed stability that would only be achieved once the assembly joints were sufficiently loaded, and therefore the further development of the ring fixator's design would need to be conducted with the addition of more diverse induced tensile loading conditions.

7. Discussion

7.1. Overall Design

The requirements for the Adaptive Ring Fixator were determined from a subsystem hierarchy. This approach ensured that the designs for each subsystem were intricate and independent such that any changes could be made efficiently, and any design requirement can be met categorically. In essence, the design outcomes can be individually evaluated, with respect to the full assembly.

The Adaptive External Ring Fixator was designed to offer rapid installation and control over the injury by permitting system shape change from specific structural adjustment and lengthening. The fixator rings were successfully designed to permit such expansion, by using hinge-and-lock systems incorporated into the full fixator ring structure. The assembly expansion is considerably simple, as it would only require the clinician to unlock the system by unloading a bolted-nut joint, and then rotate the segmented rings about the designated hinge. This simple setup had also ensured that the shape can be preserved, whilst the clinician encloses the device over the injury. The “expansion and closure” procedure was also timed, taking around [125 sec] to fully complete. The second key design requirement was also met from the addition of the longitudinal elements developed to offer either rapid or gradual lengthening. The longitudinal elements were designed to be unlocked and adjusted to achieve a desired length quickly to generate rapid shape changes. In addition, they could translate specific smaller movements, particularly rotational to translation, to induce gradual lengthening i.e. corrective adjustments. The success of this design has allowed the clinician the freedom to determine the choice of lengthening independently, and thus offered full injury control. This feature was verified, as movements were tested with minimal error.

The Adaptive External Ring Fixator was also designed to function as an effective external fixator, for which means it is should be able to support the weight and mobility of a 95th percentile male. The fixator rings were manufactured from 3mm mild steel sheet, while the longitudinal elements were manufactured from brass, both for their affordability, machinability and strong mechanical properties. The structural integrity for each of these components were evaluated, as they had gone under material analysis (as according to Appendix C) as well as a finite elements analysis using the Solidworks software. The inclusion of these materials had made the final design considerably cost effective as well as light-weight, approximating to an acceptable [2kg] weight.

However, during the direct loading procedure as part of the experimental validation of the device, the system had begun to buckle and collapse to the increasing load. This was evidently due to the compressive nature of the load as internal component meshes began to deteriorate. The collapse had begun after the load had rose beyond [1.2 kN], thus indicating that the system would be incapable of supporting the weight of a 95th percentile male, which is significantly less than a standard fixator. This evidence has primarily proven that the system requires further device development. Due to the scope and nature of the study, as well as the availability of resources and manufacturing, device development may only be done in future studies and experimentation.

7.2. Validation Experimentation

The experimental procedure of applying direct loading onto the external ring fixators was carried out by using the loading generated by a Quasi-Static Machine. The procedural tests followed the standard approach used by previous studies pertaining to validating the structural integrity of an external ring fixator. The loading was applied as an increasing load until a defined maximum was reached that would depict the weight of a 95th percentile male. In addition, the procedure tests were conducted in two variations (Adaptive and Ilizarov Ring Fixators) to make comparisons. This method is very simple and easy to follow, as it was designed for repeatability and reproducibility.

The Quasi-Static Machine was able to generate loads beyond the defined maximum and thus each ring fixator was loaded until either the maximum was reached or there were signs of yielding. The application of the direct loading had allowed the investigator to extrapolate the generated data for the strain across and within the systems, producing a visual picture of their behaviours under similar load conditions. All strain data was recorded and assigned according to the loading type. This particular method had clearly shown that the Adaptive Ring Fixator was structurally limited to one loading type as compression had induced collapse, while tension was applied to the system without complication. In addition, this would have been likely be considered as successful regarding the support of a 95th percentile male, however the generated strain data suggests the possibility of instability as the elements were shown to be adjusting under the loading. This method of loading had demonstrated a clear limitation in the design, and therefore the structural integrity of the assembly. The strain data resulting from the applied loading was captured by both the Quasi-Static Machine and strain gauges, generating data that could produce a clear picture. The application of direct loading proved useful along a certain direction however, the verification of the device's strength may require further diversity regarding the load direction and positioning.

The Adaptive Ring Fixator was effectively loaded to states that proved the system was acceptable or unacceptable for long bone fracture fixation, however to clearly demonstrate its capabilities, certain adjustments to the experimentation may need to be integrated. The Load-Deformation curves generated by the loaded cell machine and strain gauges depict the strain across all parts, however the application of bilateral strain gauges may assist in depicting the intricate behaviours. The introduction of the loaded cell machine made it possible to generate desired load conditions, however by employing the use of the test rig and other applicable mechanical tools, the loading can be diversified by alternating its direction and positioning as to induce more dynamic stresses. This method in device validation would produce absolute test results that would be able to categorically determine the limits in its structural integrity. This study was scoped to utilise the defined method to validate the newly designed system by correlating its structural integrity to its functionality, and therefore the conclusions made would suffice as valid evaluations of the design. The experimental procedure was deemed as successful at determining certain limitations in the system's design, however there is potential to conduct further experimentation in future studies. At its current state, the Adaptive Ring Fixator can perform adequately from a particular point of tensile loading, if not limited by its setup design, and may, from modification, be able to function effectively as a competitive external ring fixator for the application of long bone fracture fixation.

8. Conclusion and Recommendations

8.1. Conclusions

8.1.1. Fixator Rings

The Adaptive External Ring Fixator that was developed as part of this study was designed to offer rapid device installation and accommodate shape change as according to the clinician's actions. This feat was successfully achieved, in part. The fixator rings were designed as an arrangement of bolted-nut hinge joints and locks to allow for the expansion of the assembly, thus enclosing it over the injury circumventing damaged bone and soft tissue, eliminating the hindrances of installation. In addition, the fixator ring was manufactured from 3mm mild steel sheets, machined to shape (for its affordability, machinability and strength) to support the weight of a 95th percentile male. This in turn allowed the design to be light in weight as well as minimal in scale and assembly bulk. The fixator rings were designed to accommodate the intricate orientations and positioning of the longitudinal elements, focused in inducing gradual adjustment across the assembled system. The rings were evaluated to support the direct loads equivalent to the long bone fracture fixation, by employing material and finite element analyses for the loading applied by a longitudinal element. The fixator rings were designed successfully according to the design features desired however, its functionality would need to be further validated regarding its application as a fixator ring.

8.1.2. Longitudinal Elements

The longitudinal elements were designed to accommodate multi-directional system shape change and were manufactured from Brass for its corrosion resistance, machinability and mechanical properties. The longitudinal elements developed were to support the directional load distributed through the face of the fixator rings and thus stabilise the fracture. However, the longitudinal elements were somewhat capable of supporting the loading equivalent to that of the weight and mobility of a 95th percentile male (as verified by the procedural tests pertaining to direct loading). The ring fixator, when fully assembled, was able to provide sufficient stability for the tensile loads for [200N - 3.5 kN]. This Indicated that the stability was achieved once the longitudinal elements were sufficiently loaded. Another limitation in the structural design, is the device's inability to support compression, as loads beyond [1.2 kN] can led to buckling. The longitudinal elements were designed and developed to successfully allow both rapid and finite system adjustment, however the quality in maintaining stability for conditions of age, weight and mobility is still in question and may require further validation. The procedural tests were constructed to determine limitations in the design and clearly these tests have demonstrated such limitations. However, this study has shown that the elements can be further developed into more sophisticated designs.

8.1.3. Affordability, Weight, Adjustability, Safety and Ease of Application

The Adaptive External Ring Fixator was designed and developed successfully by achieving, in part, the areas of both user and patient ergonomics by employing a simple and efficient setup. The rings were manufactured from the accessible and affordable metal, mild steel, generating a total cost in material equivalent to R132.00 for $2\ \times \mathrm{square\ mild\ steel\ plates}$. The rings were formed from the square metal plates into the rings, using a standard turn lathe and mill. The artisans were able to achieve the shape very accurately. The hinges were made from standard tungsten steel. Together the total mass of the two fixator rings accumulated to 0.375 kg. The design of the rings can be regarded as proficient in allowing for full assembly expansion, when using the hinges and yet the defining quality is the semi-permeable state of the longitudinal elements when opening and closing the hinges, such that a desired shape can be kept and making the process of enclosing the device over the injury quick, easy and more important efficient. Since the rings are quite light in weight and thin in shape, the rings offer minimal intrusions and obstacles to the healing of the injury (swelling and muscle movement), specifically during daily domestic activities and therapy exercises. The rings are built from the C-joint hinges and the segmented rings, assembled together using standard fasteners, meaning the entire assembly is replaceable if need be and can be put through maintenance, cleaning of each component separately. The rings allow for one to remove the option of full assembly expansion via the anterior lock, simply using a lock or torque nut.

The longitudinal element was made from the non-ferrous material, free-machining brass, and the design was made cost effective by optimizing the material used to produce the component, and as such the accumulated cost in brass material was R1135.00. The material was chosen for their quality in machinability and it shows clearly, as the components were designed accurately and precisely with a very good surface quality. The total mass for the four longitudinal elements had resultant to 0.632 kgs and therefore the total mass was close to 1 kg for the entire assembly. The structural design and the internal components were manufactured accurately using the standard turn lathe, ensuring smooth surface texture along the cylindrical components, while the more intricate components such as the universal joints were formed through a mill. Together these components ensure smooth and efficient translations for both the rapid and gradual movements. The design was further improved from its original concept by allowing for the user the option to lock-and-switch between movements, employing grub screws within the adjustor head along the strut. The different mechanisms were successfully designed, maintaining the desired aim of ensuring the entire system is simple and accessible to the everyday medical attendee. In essence, the assembly was designed to assist the clinician’s decision making for the choice of shape change or amendments to the fixation of the injury, thus preserving the control over the fixation process.

The Adaptive External Ring Fixator as an assembled system, functions as expected regarding the structural adjustments (gradual and rapid) and the movements of the internal components. The operation of inducing shape changes and origin manipulation is quite effective and efficient. This was further improved by the smooth, multi-directional joints that could offer access to difficult angles and translations. However, enhancements to its versatility has made the system seemingly unstable and thus a balance between design and functionality is recommended in the near future.

8.2. Market Distribution and Pricing

8.2.1. Market Potential

Market potential of the product is in coordination of its product development and may even be considered in conjunction, as the product matures towards into a project worthy of investments. At the current point in time, the product is considered in the phase recognised as the conceptual design validation, whereby usability and innovation are regularly tested within current markets. Consequently, the product's market potential has been correlated to the following three factors: potential customer base, analyses of competition and investigation on environmental conditions.

The potential customer base for a newly designed external ring fixator can be categorised as the orthopaedic departments of the many accessible hospitals, located across the African continent. The growing interest in external fixator devices stems from the surgeons, looking for newer and more innovative designs that can further improve the external fracture fixation process. However, innovation can only offer some level of interest as factors such as simplicity and accessibility are a few of the major factors that are considered across Africa. As the populations of countries grow, the incident count rises in conjunction, by which factors of sophistication and accuracy may have to be sacrificed in order to maintain some level of efficiency within fracture fixation procedures.

The competition within the current markets is significant for newly designed external ring fixators, particularly for the devices that still employ the definitive principles established by Dr G. Ilizarov. The current markets possess the likes of the Ilizarov Ring Fixator, the original design, and more concurrently the Taylor Spatial Frame and the Hex-Lek Fixator, the modern developments. These devices are the popular and most market reliable products due to sophistication and accuracy by improving the deformity correction principles however, the differentiation predominantly stems from their strut designs and how they can further expand the application of the principles. The product currently would not revolutionize the processes, developed to employ the principles, but would reduce the complications, thus the product would cement its place in the market through operator convenience. An aspect that can be marketed to the customer as the basis for choice.

The current environmental conditions for a newly designed external ring fixator, favours devices that can provide the desired functionality without the excessive education and resources. Factors, such as functionality and cost may always be at conflict with one another and the African markets tends to support latter, as they continue to grow and develop with their evolving populations. Limitations in time and resources are intuitive when considering newer markets as orthopaedic departments attempt to cement their places within Africa, meeting the consistent demands. The need to access sophisticated and renown solutions when possible is often the frequent approach yet, they are always seeking for devices that require minimal learning such that a desired pace in procedures can be met, a factor that can fall along with the convenience that this device can provide. The available devices offer accuracy, repeatability and reproducibility at the cost of the operator's time and resources, such factors that are likely to be sacrificed when the cost is so high for newer markets and thus this product was designed, to circumvent these such considerations.

8.2.2. Stage of Commercialization

The product, at this current point in time, is in the stage of commercialization recognised as pre-product testing as the product development continues to progress towards the climatic preclinical trials, whereby the product's usability would be fully tested and validated. The product, which is continuing to be determined experimentally as a plausible and feasible product, is progressively developing and evolving through experimentation and prototyping, until it can produce adequate data that can successfully evidence an effective and feasible product for full commercialization.

The progression of the following study has allowed the product to progress from proof of concept, beyond the reduction to prototype, to the Pre-product testing as the product further develops until it is feasible to advance to the Alpha and Beta Testing. As shown in the following study, the scope was constructed to achieve initial validation of the product via relevant research reviewed and thereby generate a working model for serial prototype evaluation and experimentation. Thus, the scope of the study can be evaluated as a process in initiating and progressing the development of a new potential product however, due to the amount of time available, the study would only be able to progress the development and/or research to the point that one may be able to validate the product for the initial alpha testing i.e. pre-clinical trials, particularly serial cadaver testing.

The product at this current point of time has insufficient experimental data to validate some form of commercialization however, through more experimentation and prototyping in future studies, the potential product may be able to progress it development towards the Alpha and Beta Testing. Thus, the study has been concluded with relevant recommendations for the continuation of the experimentation that may need to be conducted upon the product to further refine its current design, functionality, operation and lastly its overall aesthetic appeal. The following study was established with the aim of constructing a potential product for commercialization and it has partially achieved its goal, as the product has the functionality to validate its existence but would need to be further refined with an extension to this study, as a considered future project or study.

8.2.3. Tentative Pricing

The product, in its current form, has an accumulated production cost of less than R500, excluding the service costs involved from the artisan services, as they operate according to assigned roles, a value that can be a benchmark for its price. The product is considerably cheaper when compared to standard models, which can even extend from over R10, 000 per ring. However, this production cost is still premature in the current stage of commercialization, as it is in pre-product testing. The product's final form has yet to be achieved due to continued experimentation and prototyping. The product is currently a commercial project with the potential of development as validation and approval is still the current goal in development and thus any commercialization is still premature. However, potential commercialization can still be projected and planned. The tested product was manufactured and built internally, employing the available artisan to acquire and form the chosen materials into components. The cost accumulation is a predictive value when regarding the use of such services, thus the final production value may only be established from the quotations of manufacturing and other services such as eventual electroplating. The production costs that can be verified, may be the accumulation of material cost and services, with a mark-up to this pricing.

8.3. Recommendations and Future Works

8.3.1. Design

For the development of the Adaptive External Ring Fixator, the design should require future modifications to reduce and ultimately rectify the limitations presented in the following study. The identified limitations that pose as significant opportunities for improvement would be the system's structural integrity and its strength along the three-dimensional space it encompasses. In addition, there is a need to determine the quality in accessibility when the device is fully operational. These ideas are further highlighted as the following design recommendations:

- Mild steel and Brass were materials selected for the rings and longitudinal elements due their affordability, accessibility and machinability. However, there is an opportunity to determine alternative core materials that would improve the structural integrity and thereby reduce the possibility of buckling. A possible consideration would be to partially integrate stainless steel; however, affordability would need to be carefully considered.

- A structural modification that could be considered in the case of improving the stability of the device would be to utilise pivot joints of limited mobility so as effectively transfer the loading and thereby reduce the joint failures. However, limited mobility would need to be accommodated by balancing or equating the interest in multi-planar deformity correction.

- The longitudinal elements developed for the ring fixator were still considerably large. The lengthening mechanism employed rapid and gradual mobility, however this design can be further improved from material optimisation. The longitudinal elements need to be more robust but finding a balance would need to be considered as functionality is still primary.

8.3.2. Experimentation

The experimental procedure was conducted to validate the structural integrity of the ring fixators was partially adequate in regard to determining their strengths for certain planar loads. However, the following recommendations were suggested as improvements to the outcomes of the study:

- Future iterations of device testing would be much improved through the design and development of a mechanism or test setup that could apply multiple planar stresses. If the design could also apply regulatory stress, one would be able to perform a statistical analysis, and thereby perform statistical validations.

- For future iterations, device testing through the application would need to be evaluated and validated by an expert orthopaedic surgeon, but in addition stress testing should be verified prior to cadaver study as to ensure surgeon safety and prevent test expenditure

- Implement the loading of the hinges of the device through the inclusion of a model replica of a bone held by wiring within the frames, thus determining a failure mode at the hinges

9. References

Al-Sayyad, M. J. (2008). Taylor spatial frame in the treatment of open tibial shaft fractures. *Indian J Orthop*, *42*(4), 431–438. https://doi.org/10.4103/0019-5413.43393

Bathgate, A., Best, J. P., Craig, G., & Jamieson, M. (2002). A prospective study of injuries to elite Australian rugby union players... including commentary by Wiley JP. *British Journal of Sports Medicine*, *36*(4), 265–269.

Beck, B. R. (1998). Tibial stress injuries. An aetiological review for the purposes of guiding management. *Sports Medicine*, *26*(4), 265–279. https://doi.org/10.2165/00007256-199826040-00005

Behrens, S. B., Deren, M. E., Matson, A., Fadale, P. D., & Monchik, K. O. (2013). Stress Fractures of the Pelvis and Legs in Athletes: A Review. *Sports Health*, *5*(2), 165–174. https://doi.org/10.1177/1941738112467423

Benjamin, J. B., Sheppard, J. E., & Hunter, T. B. (2003). <Human Screw & Plates.Pdf>, 1569–1590. https://doi.org/10.1148/rg.236035159

Brukner, P., & Khan, K. (2012). *Brukner and Khan's Clinical Sports Medicine* (4th ed.). Australia: McGraw-Hill Medical.

Chaudhuri, A., Datta, S., Chowdhury, A., Singh, A., Ghosh, S., & Roy, D. (2015). Ilizarov fixator in management of nonunited and infected tibial shaft fractures. *Medical Journal of Dr. D.Y. Patil University*, *8*(1), 35. https://doi.org/10.4103/0975-2870.148841

Clelland, S. J., Chauhan, P., & Mandari, F. N. (2016). The epidemiology and management of tibia and fibula fractures at Kilimanjaro Christian Medical Centre (KCMC) in Northern Tanzania. *Pan African Medical Journal*, *25*, 1–7. https://doi.org/10.11604/pamj.2016.25.51.10612

Court-Brown, C. M., Bugler, K. E., Clement, N. D., Duckworth, A. D., & McQueen, M. M. (2012). The epidemiology of open fractures in adults. A 15-year review. *Injury*, *43*(6), 891–897. https://doi.org/10.1016/j.injury.2011.12.007

Court-brown, C. M., & Caesar, B. (2006). Epidemiology of adult fractures : A review. https://doi.org/10.1016/j.injury.2006.04.130

Dammerer, D., Kirschbichler, K., Donnan, L., Kaufmann, G., Krismer, M., & Biedermann, R. (2011). Clinical value of the Taylor Spatial Frame: A comparison with the Ilizarov and Orthofix fixators. *Journal of Children's Orthopaedics*, *5*(5), 343–349. https://doi.org/10.1007/s11832-011-0361-3

Drugs.com. (2018). External Fixation for Leg Fracture in Children. Retrieved August 30, 2018, from https://www.drugs.com/cg/external-fixation-for-leg-fractures-in-children.html

Eidelman, M. (2017). Clinical utility of the Taylor spatial frame for limb deformities, 51–61. https://doi.org/10.2147/ORR.S113420

Eppenberger, M. (2009). Construction worker injuries and costs – a comparative study of older and younger workers, 6–13.

Fadel, M., & Hosny, G. (2005). The Taylor spatial frame for deformity correction in the lower limbs. *International Orthopaedics*, *29*(2), 125–129. https://doi.org/10.1007/s00264-004-0611-9

Farmanullah, Khan, M. S., & Awais, S. M. (2007). Evaluation of management of tibial non-union defect with Ilizarov fixator. *Journal of Ayub Medical College, Abbottabad : JAMC*, *19*(3), 34–36.

Feldman, D. S., Shin, S. S., Madan, S., & Koval, K. J. (2003). Correction of tibial malunion and nonunion with six-axis analysis deformity correction using the Taylor Spatial Frame. *Journal of Orthopaedic Trauma*, *17*(8), 549–554. https://doi.org/10.1097/00005131-200309000-00002

Ferreira, N. (2012). Circular external fixator application for midshaft tibial fractures : Surgical technique Reprint requests : *Saoj*, *11*(4), 39–43.

Fragomen, A. T., & Rozbruch, S. R. (2007). The mechanics of external fixation. *HSS Journal*, *3*(1), 13–29. https://doi.org/10.1007/s11420-006-9025-0

Geneva: World Health Organisation. (2018). Global Status report on road safety 2018, 2018.

HEARN, E. J. (1997). *MECHANICS OF MATERIALS I: An Introduction to the Mechanics of Elastic and Plastic Deformation of Solids and Structural Materials* (3rd ed.). Oxford: Butterworth Heinemann.

Holtrop, M. (1975). The ultra structure of bone. *Ann Clin*, *5*(4), 264–271.

Huelke, D. F., O'Day, J., & States, J. D. (1982). Lower extremity injuries in automobile crashes†. *Accident Analysis and Prevention*, *14*(2), 95–106. https://doi.org/10.1016/0001-4575(82)90076-8

Ilizarov, G. A. (1992). The Apparatus: Components and Biomechanical Principles of Application. In *ransosseous Osteosynthesis* (pp. 63–120). Berlin: Springer. https://doi.org/10.1007/978-3-642-84388-4 2

Juvinall, R. C., & Marshek, K. M. (2012). *Fundamentals of Machine Component Design* (Fifth). John Wiley & Sons, Inc.

Madadi, F., Vahid Farahmandi, M., Eajazi, A., Daftari Besheli, L., Madadi, F., & Nasri Lari, M. (2010). Epidemiology of adult tibial shaft fractures: a 7-year study in a major referral orthopedic center in Iran. *Medical Science Monitor*, *16*(5), CR217-R221. https://doi.org/878541 [pii]

Manner, H. M., Huebl, M., Radler, C., Ganger, R., Petje, G., & Grill, F. (2007). Accuracy of complex lower-limb deformity correction with external fixation: A comparison of the Taylor Spatial Frame with the Ilizarov ring fixator. *Journal of Children's Orthopaedics*, *1*(1), 55–61. https://doi.org/10.1007/s11832-006-0005-1

Menakaya, C. U., Rigby, A. S., Hadland, Y., Barron, E., & Sharma, H. (2014). Fracture healing following high energy tibial trauma: Ilizarov versus taylor spatial frame. *Annals of the Royal College of Surgeons of England*, *96*(2), 106–110. https://doi.org/10.1308/003588414X13824511650335

Metal Supermarkets - The Convenience Stores For Metal. (2016). What Is Mild Steel? Retrieved August 31, 2019, from https://www.metalsupermarkets.com/what-is-mild-steel/

Milner, C. E., Davis, I. S., & Hamill, J. (2006). Free moment as a predictor of tibial stress fracture in distance runners. *Journal of Biomechanics*, *39*(15), 2819–2825. https://doi.org/10.1016/j.jbiomech.2005.09.022

Monni, T., Birkholtz, F. F., de Lange, P., & Snyckers, C. H. (2013). Conversion of external fixation to internal fixation in a non-acute, reconstructive setting: A case series. *Strategies in Trauma and Limb Reconstruction*, *8*(1), 25–30. https://doi.org/10.1007/s11751-013-0157-8

Mullins, M. M., Davidson, A. W., Goodier, D., & Barry, M. (2003). The biomechanics of wire fixation in the Ilizarov system. *Injury*, *34*(2), 155–157. https://doi.org/10.1016/S0020-1383(02)00262-0

Murphy, D. F., Connolly, D. A. J., & Beynnon, B. D. (2003). Factors for Lower Extremity Injury: a Review of the Literature. *Br Med Doi101136bjsm37113*, *37 SRC-*, 13–29.

Neumann DA. (2010). *Kinesiology of the musculoskeletal system: Foundations for rehabilitation.* (2nd ed.). St. Louis: Mosby: Elsevier Ltd.

Non Ferrous Metals Works. (2018a). Aluminium Extrusions 6082. Retrieved August 31, 2018, from https://nfm.co.za/product/aluminium-extrusions-6082/

Non Ferrous Metals Works. (2018b). CDA385 (High Speed Free Machining Brass). Retrieved August 31, 2018, from https://nfm.co.za/product/cda385-high-speed-free-machining-brass/

OpenStax. (2013). Bones of the Lower Limb. Retrieved July 12, 2019, from https://opentextbc.ca/anatomyandphysiology/chapter/8-4-bones-of-the-lower-limb/

Pillai, A. (2015). The Use of an External Fixator to Heal a Pathological Tibial Shaft Fracture Osteoporosis & Physical Activity The Use of an External Fixator to Heal a Pathological Tibial Shaft Fracture, (December). https://doi.org/10.4172/2329-9509.1000140

Price, R. J., Hawkins, R. D., Hulse, M. A., & Hodson, A. (2004). The Football Association medical research programme: an audit of injuries in academy youth football. *British Journal of Sports Medicine*, *38*(4), 466–471. https://doi.org/10.1136/bjsm.2003.005165

Russell, T. A. (1996). *Fractures of the Tibial Diaphysis*. Rosemont: American Academy of Orthopaedic Surgeons.

Sharir, A., Barak, M. M., & Shahar, R. (2008). Whole bone mechanics and mechanical testing. *Veterinary Journal*, *177*(1), 8–17. https://doi.org/10.1016/j.tvjl.2007.09.012

Sheffield Limb Reconstruction. (2017). Let your frame take the strain. Retrieved January 16, 2019, from https://publicdocuments.sth.nhs.uk/pil633.pdf

Spiegelberg, B., Parratt, T., Dheerendra, S. K., Khan, W. S., Jennings, R., & Marsh, D. R. (2010). Ilizarov principles of deformity correction. *Annals of the Royal College of Surgeons of England*, *92*(2), 101–105. https://doi.org/10.1308/003588410X12518836439326

Tan, B., Shanmugam, R., Gunalan, R., Chua, Y., Hossain, G., & Saw, A. (2014). A Biomechanical Comparison between Taylor's Spatial Frame and Ilizarov External Fixator. *Malaysian Orthopaedic Journal*, *8*(2), 35–39. https://doi.org/10.5704/MOJ.1407.012

Taylor, J. C. (2002). Correction of General Deformity with The Taylor Spatial Frame Fixator TM.

Tejwani, N., Polonet, D., & Wolinsky, P. R. (2015). External fixation of tibial fractures. *Journal of the American Academy of Orthopaedic Surgeons*, *23*(2), 126–130. https://doi.org/10.5435/JAAOS-D-14-00158

Tetsworth, K. D., & Paley, D. (1994). Accuracy of correction of complex lower-extremity deformities by the Ilizarov method. *Clinical Orthopaedics and Related Research*, (301), 102–110.

The Bone School. (2009). Taylor Spatial Frame. Retrieved January 16, 2019, from http://52.62.202.235/lower-limb/knee/tibia/ilizarov/taylor-spatial-frame

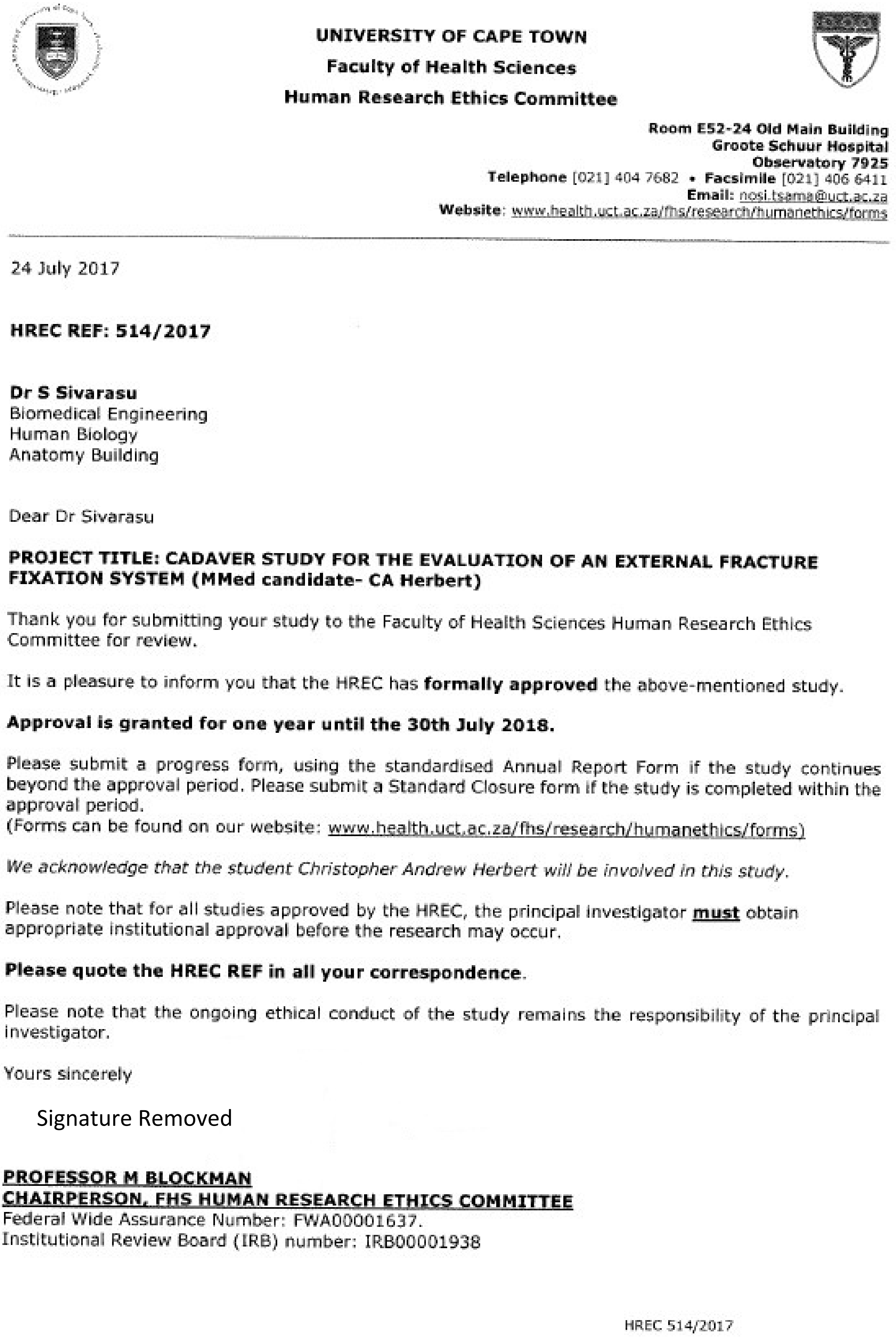
Uhthoff, H. K., Poitras, P., & Backman, D. S. (2006). Internal plate fixation of fractures: Short history and recent developments. *Journal of Orthopaedic Science*, *11*(2), 118–126. https://doi.org/10.1007/s00776-005-0984-7

Van Gent, R. N., Siem, D., Van Middeloop, M., Van Os, A. G., Bierma-Zeinstra, S. M. A., & Koes, B. W. (2007). Incidence and determinants of lower extremity running injuries in long distance runners: A systematic review. *Sport En Geneeskunde*, *40*(4), 16–29. https://doi.org/10.1136/bjsm.2006.033548

Voinescu, M., Soares, D., Castro, M., Mendes, E., Davidescu, A., & Machado, L. (2011). A STUDY OF MOMENTS ACTING ON THE TIBIA DURING GAIT IN THE ACTIVE ELDERLY POPULATION Mechanics Department , Politehnica University of Timisoara , Timisoara , CIFI2D , Faculty of Sport , University of Porto , Porto , Portugal 2. *Biomechanics in Sports*, *11*(29), 575–578.

Watson, M. A., Mathias, K. J., & Maffulli, N. (2000). External ring fixators: An overview. *Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine*, *214*(5), 459–470. https://doi.org/10.1243/0954411001535480

Appendices A- Ethics Approval Letter



UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 404 7682 • **Facsimile** [021] 406 6411
Email: nosi.tsama@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

24 July 2017

HREC REF: 514/2017

Dr S Sivarasu
Biomedical Engineering
Human Biology
Anatomy Building

Dear Dr Sivarasu

PROJECT TITLE: CADAVER STUDY FOR THE EVALUATION OF AN EXTERNAL FRACTURE FIXATION SYSTEM (MMed candidate- CA Herbert)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30th July 2018.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

We acknowledge that the student Christopher Andrew Herbert will be involved in this study.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval before the research may occur.

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Yours sincerely

Signature Removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

HREC 514/2017

Appendices B- Tables of Test Results

Table 5: The Generated Strain across the External Ring Fixators from Direct Compression

Adaptive Ring Fixator		**Ilizarov Ring Fixator**	
Applied Load	Strain	Applied Load	Strain
[N]	[mm/mm]	[N]	[mm/mm]
250,82	0,004161	250,34	0,002323
500,37	0,004999	500,8	0,002812
750,68	0,005812	750,05	0,003123
100,38	0,006592	1001,32	0,003376
1108,21	0,006984	1500,64	0,003752
516,51	0,006997	2000,14	0,004051
1270,02	0,011938	3001,29	0,004568

Table 6: The Generated Strain across the External Ring Fixators from Direct Tension

Adaptive Ring Fixator		**Ilizarov Ring Fixator**	
Applied Load	Strain	Applied Load	Strain
[N]	[mm/mm]	[N]	[mm/mm]
500,80	0,002821	501,45	0,003560
1001,32	0,003376	1000,77	0,003973
1500,64	0,003752	1500,37	0,004268
2000,14	0,004051	2000,51	0,004515
2500,23	0,004320	2501,09	0,004735
3001,29	0,004565	3000,79	0,004936
3421,23	0,004774	3421,24	0,005097

Table 7: The Generated Strain within the Adaptive External Ring Fixator from Direct Compression

Adaptive Fixator (Longitudinal Element)		
Applied Load	S1 Strain	S2 Strain
[N]	[µmm/mm]	[µmm/mm]
250	9,0940	17,6100
500	0,7354	45,8200
750	0,0038	0,0043
1000	0,0041	0,0045
1250	0,2848	57,7200
1277	0,2201	59,8200

Table 8: The Generated Strain within the Adaptive External Ring Fixator from Direct Tension

Adaptive Fixator (Longitudinal Element)		
Applied Load	S1 Strain	S2 Strain
[N]	[µmm/mm]	[µmm/mm]
500	31,8700	49,2300
1000	20,4400	55,3900
1500	7,1500	61,5400
2000	6,0690	69,2000
2500	18,2200	77,2400
3000	29,8500	85,0900
3500	40,8100	92,7000

Appendices C- Material Analysis

Introduction to Material Analysis

This study aims to design and develop an Adaptive Bone Fracture Fixation System, with key design features specific to full assembly expansion and rapid or finite longitudinal element lengthening. This device would be using intricate designs, specific to the subsystems of: the segmented fixator half ring and the longitudinal elements (translating struts). It is in this section that a detailed material analysis of the chosen materials will be provided and presented for the clarification upon their strength, structural integrity, affordability and feasibility for the final design of the device. This study is limited to the design and development of an accessible standard external ring fixator. This means that the design must meet parameters specific to Ø155 mm circular external fixators. This is specific to meeting the design parameters to make full use of the experimental study, as the experimental apparatus can only operate with the standard Ø155 mm circular external fixator. The identified parameters pertain to the structure of the fixator ring and its design requirements, particularly its internal diameter ring size as well as the positioning and number of clearance holes allocated about the fixator ring. The device is to be comprised of the components and parts built from accessible materials with aspects specific to affordability, machinability (accuracy), and lastly good mechanical properties. In addition, this study will be considering the appropriate materials that are available locally (Cape Town, South Africa) and would become the core materials for each component and subsystem. The materials that are to be evaluated and compared are as follows:

- Mild Steel – Low carbon steel, often used for structural engineering due the material's affordability and versatility in engineering practice –R35/kg [*Universal Steel Enterprises*]

- Aluminium 6061 T6 –Non-Ferrous Metal, often used for small and delicate items for its weight and corrosion resistance properties - R70/kg [*Non-Ferrous Metals Works (Pty) Ltd*].

- Brass CDA 385 – Non-Ferrous Metal, often used for smooth and accurate components for its machinability and corrosion resistance - R120/kg [*Non-Ferrous Metals Works (Pty) Ltd*].

These accessible materials will be analysed individually for each subsystem and will be limited to a load scenario that depicts a load conditions specific to a target component. The objective of this material analysis is to investigate the internal reactions of the component built from the material, by employing load scenarios, detailed by a free-body-diagram, to make applicable evaluations upon the following key design factors:

- Strength of Component
- Mass of Component
- Cost of Component

In conclusion, this section will provide details necessary to determine, which material would be most suitable in providing stability and still allow for micromotion to better bone reconstruction.

The Components for Material Analysis

This section will be investigating the two fundamental components that will form the basis for their subsystem. These components are specific to the segmented fixator ring and the internal components within the heart of the longitudinal element (shaft, housing and threaded turn head). The fixator ring is a segmented half ring within the complete ring assembly. The ring is integrated into the assembly by the hinge-and-lock systems fitted at each end, providing the rigid support.

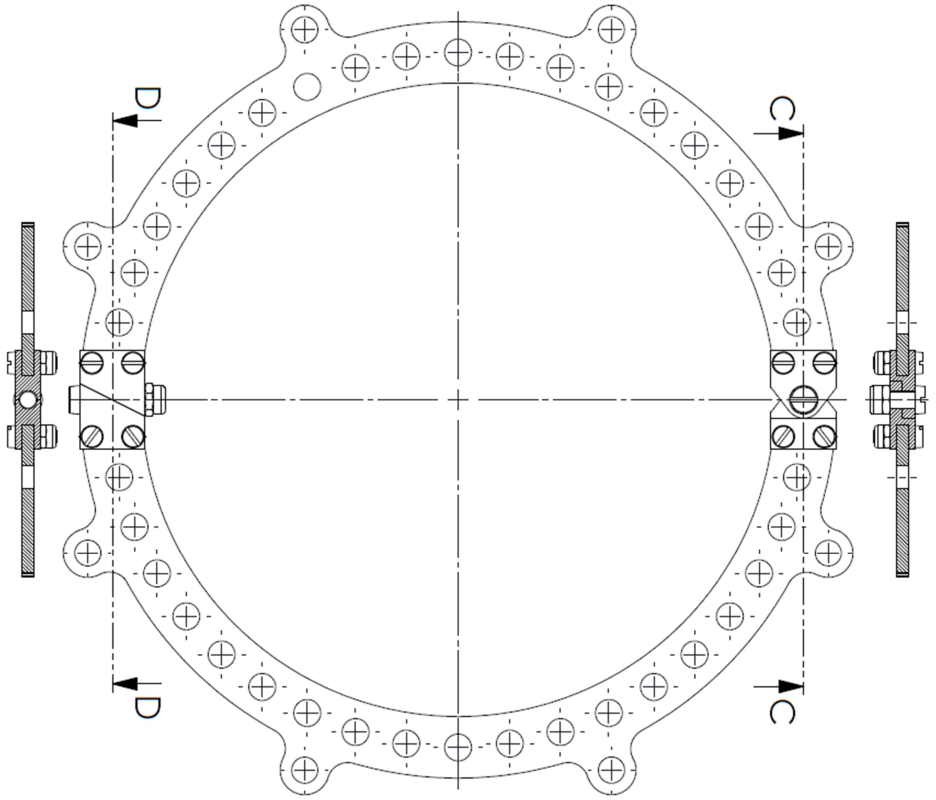


Figure 6: An image demonstrating the fully assembled fixator ring (segmented half rings with hinge-and-lock systems) as per the generated engineering drawings created using the Solidworks Software (Ref: Engineering Drawings in Appendix D)

The longitudinal elements are the extended supports of the system as well as the contributors to any adjustment to the fixed setup, thus they will consist of complex joints. These joints are specific to bolted/screwed joints that are introduced to effectively deliver the load through the element.

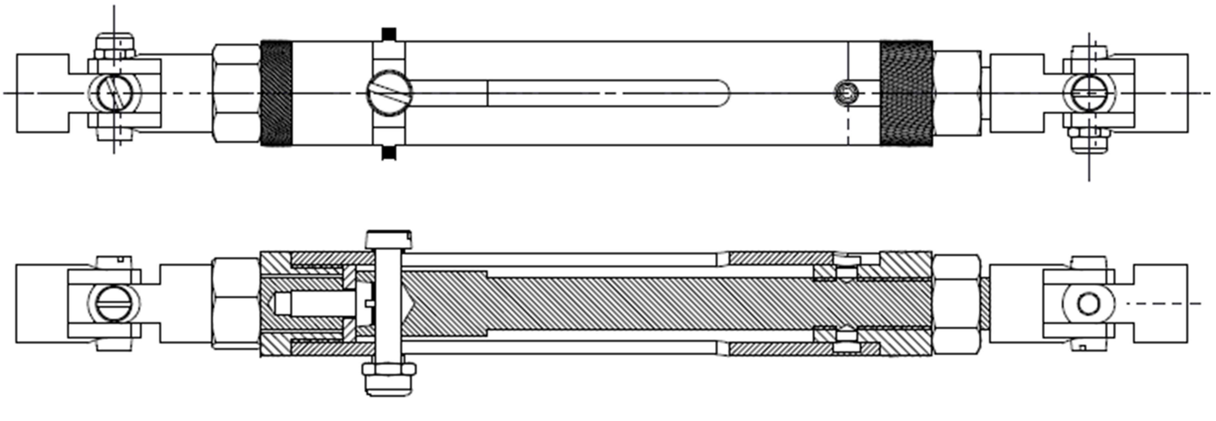


Figure 7: An image demonstrating the fully assembled longitudinal element (translating strut, turn heads and uni-joints) as per the generated engineering drawings created using the Solidworks Software (Ref: Engineering Drawings in Appendix D)

Description of Load Scenarios

The material analysis will investigate the generated deflection upon the parts by employing load scenarios equivalent to the operation and use of the device. These can be limited to the actions of the clinician upon the component or direct loading of the components during fixation i.e. fully assembled. Each component will be investigated by employing three applicable load scenarios

Scenario 1: The expansion (opening the mouth) of the fixator ring assembly (widening)

The first scenario was constructed to depict the process of expanding the assembled fixator ring. The expansion of the assembly is done by unlocking the bolted joint and widening the ring mouth. Th scenario details that the load is applied at the end of the ring, generating a loaded cantilever. This would also pertain to an attempt to break or forcibly open the lock by widening the joint.

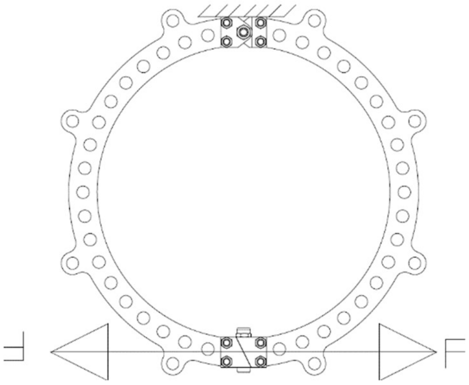


Figure 8: A detailed schematic of the load scenario: 1, whereby load is applied to the lock system to widen the ring's mouth

Scenario 2: The expansion (opening the mouth) of the fixator ring assembly (pulling)

The second scenario follows the previous sample by depicting a similar process for expanding the fixator ring assembly. This scenario depicts the attempt to break or open the bolted joint lock. This scenario includes the addition of a load generated from pulling the lock and stretching the ring across the face of the assembly. The load conditions specific to this scenario pertain to the application of a load at the lock system at away from the ring centre, thus stretching the half ring.

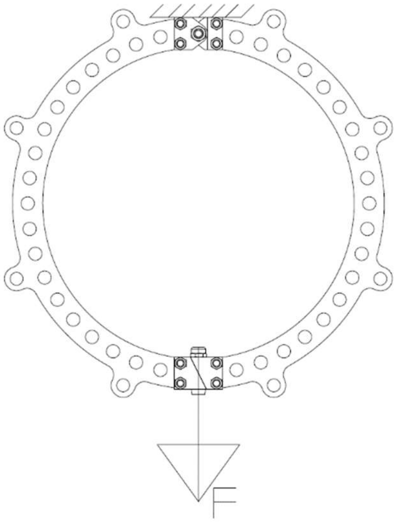


Figure 9: A detailed schematic of the load scenario: 2, whereby load is applied to the lock system to break or open the lock

Scenario 3: The loading applied from the attached longitudinal element (strut)

This scenario is simply the application of the transferred loading passed through the longitudinal elements upon the face of the ring. The scenario depicts the loading conditions as a curved beam cantilever with the hinge-and-lock systems as fixed rigid supports, whilst the loading is applied as a point load at the furthest end of the half ring. This would be applying both bending and torsional stress upon the ring however; this study will only detail the generation of the vertical deflection.

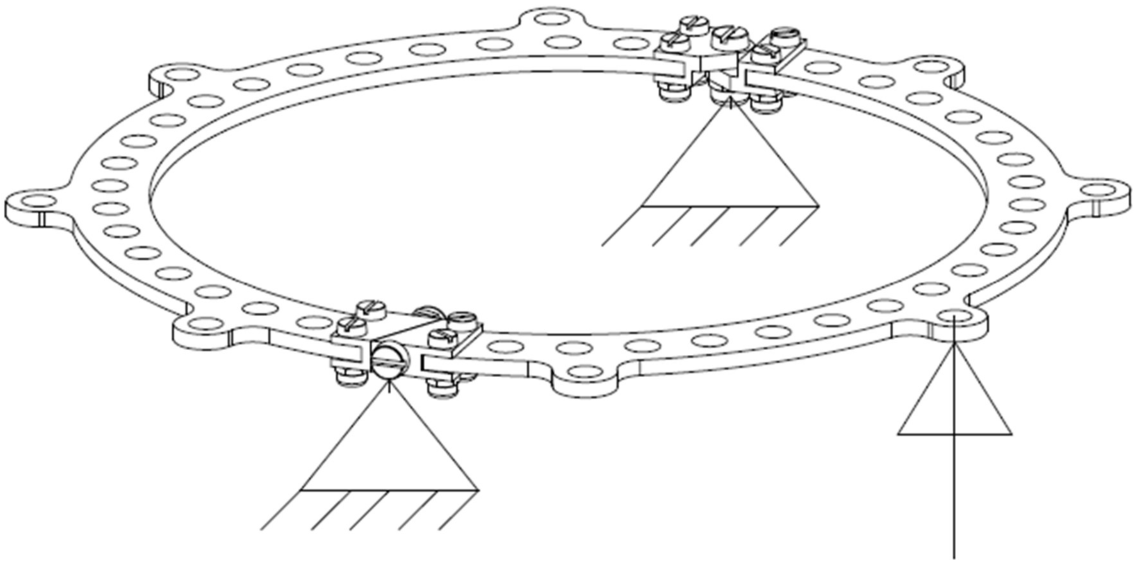


Figure 10: A detailed schematic of the load scenario: 3, whereby load is applied from the longitudinal element onto the ring

Scenario 4: The loading applied through the translating threaded shaft (length fixation)

This scenario details the application of loading applied through the entire longitudinal element. This would include the loading of the translating shaft. The shaft lies within the shaft housing and is translated along the length of shaft housing, to allow for the rapid lengthening of the element. The determination of a length is accomplished once the shaft is held in place within the housing.

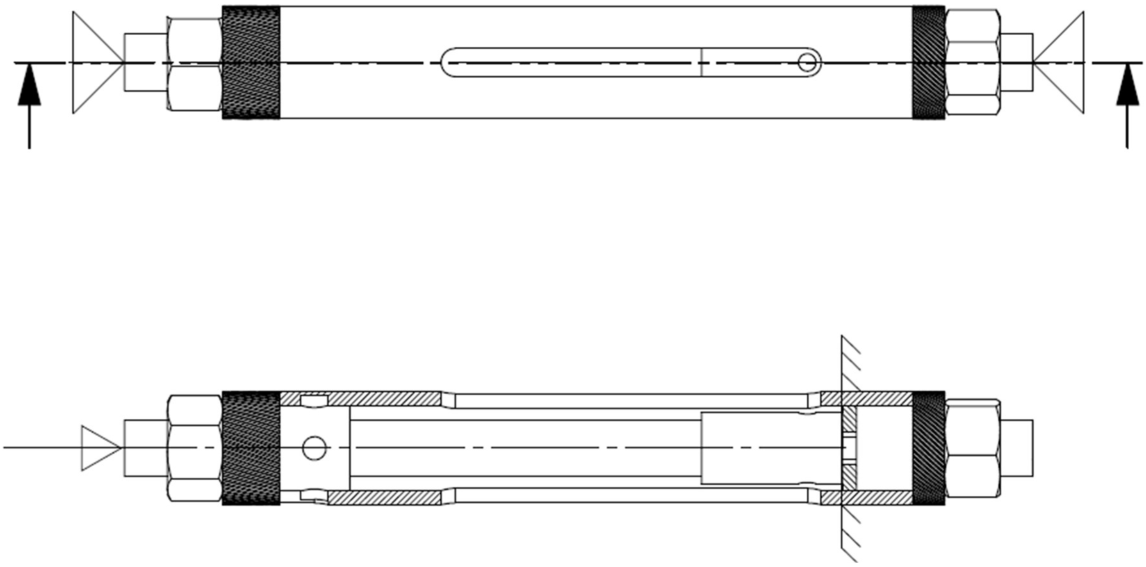


Figure 11: A detailed schematic of the load scenario: 3, whereby loading passes into the longitudinal element onto the strut

Scenario 5: The loading applied through the shaft housing (length fixation)

This scenario details the successful transfer of the load through the entire longitudinal element. The threaded turn head has delivered the loading through both the internal translating shaft and the shaft housing that are both loaded by opposing turn heads. The shoulders of the turn heads deliver the loading through the housing, generating a loaded cell scenario of direct axial loading. The loading is to be generated from the rigid support of the longitudinal elements between rings.

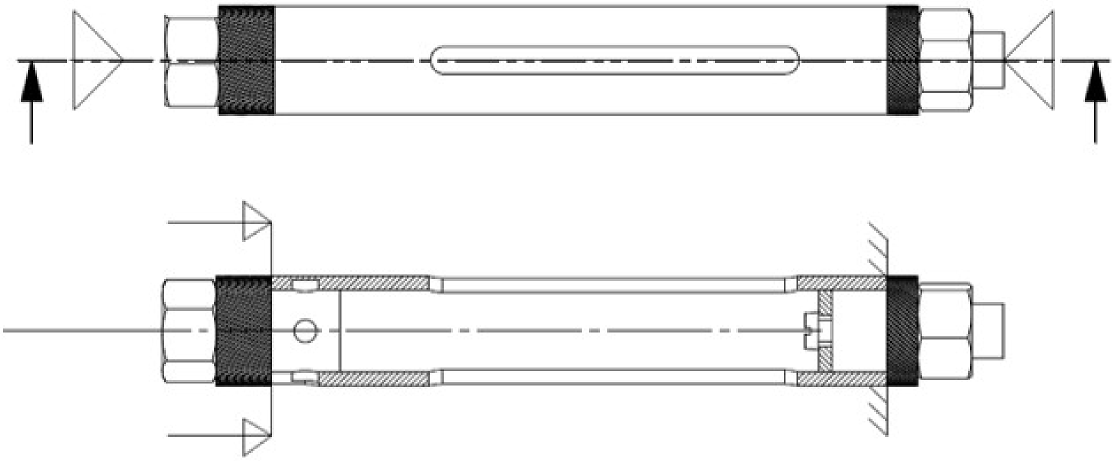


Figure 12: A detailed schematic of the load scenario: 3, whereby loading passes through the entire shaft housing

Scenario 6: The loading applied through the threaded turn head (modified bolted joint)

This scenario details the application of the threaded turn head as a modified bolted joint, whereby the loading conditions pertain to bolt calculations correspondent to the loading and stabilisation of bolted joint equivalent. However, this component is designed to be threaded into the assembly as a screw as well as threaded housing for the translating shaft thus the application of both the bolted joint and axial loading calculations would need to be considered for this particular scenario.

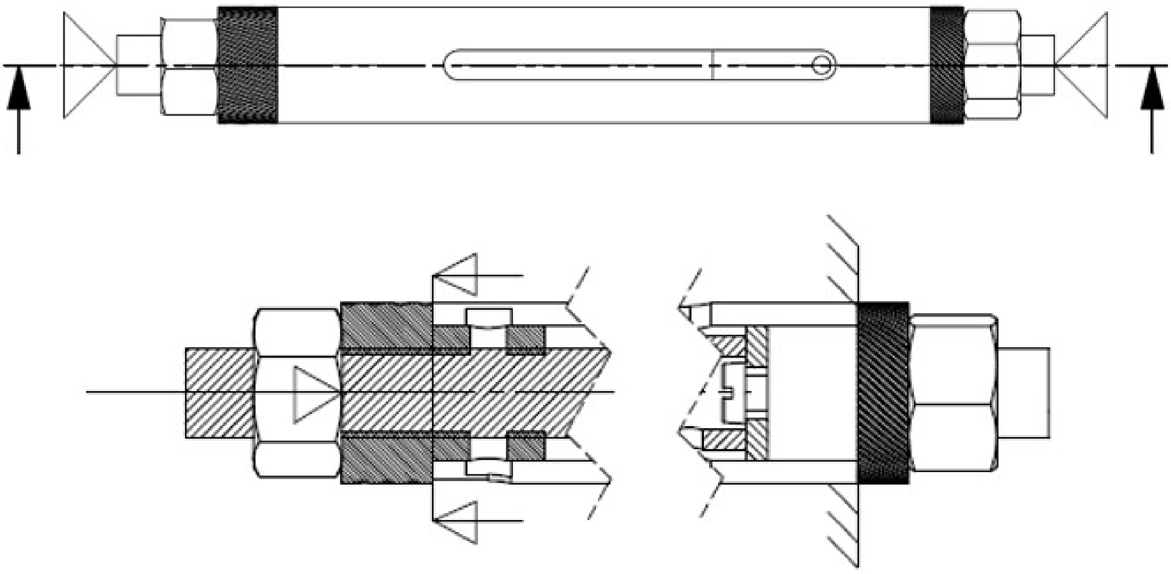


Figure 13: A detailed schematic of the load scenario: 3, whereby loading passes through the threaded turn head

Equations for Load Scenarios

This section details the construction of the equations for each of the described load scenarios. The load scenarios, defined in the previous section, is to be analysed using equations applicable to the structure of the loaded item and the defined loading conditions used for each scenario.

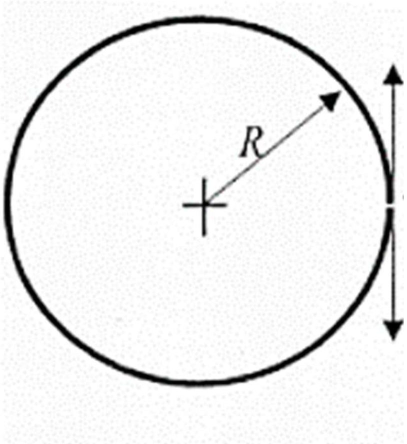
The equations that are to be constructed to follow Castigiliano's First Theorem (HEARN, 1997) , which states that *"If the total strain energy expressed in terms of the external loads is partially differentiated with respect to one of the loads the result is the defection of the point of application of that load and in the direction of that load*". Each equation is to employ the application of a point load to determine the generated deflection across or along the subjected component analysed. Lastly, the final equation is to be shown in full such that the assumption can be followed.

Alternative equations pertaining to load calculations for known items such as fasteners (Juvinall & Marshek, 2012) are to follow their rules and concepts such that the final equation can clearly display the intention. These equations have utilized the calculations pertaining to calculations for clamped joints. The final equation integrates these calculations with the assumptions made for the definition of the defined load scenario, thus the final equation clearly demonstrates this aim.

Scenario 1: The expansion (opening the mouth) of the fixator ring assembly (widening)

The following scenario will be treating the ring as a double curved beam cantilever with the load applied at the end of the ring resulting in bending along the x-axis, away from the ring's centre. The equation that was constructed follows the concepts of Castigiliano's First Theorem, by using one half of the fixator ring assembly as a single cantilever and the deflection as the sum of two.

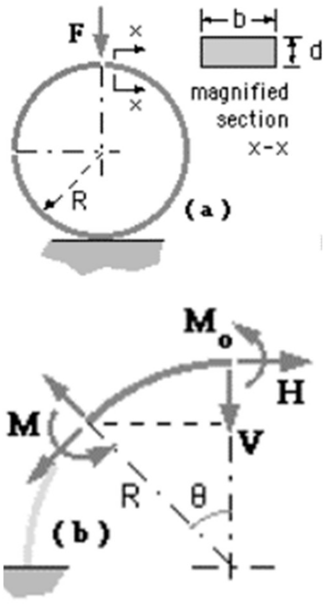
Equation 1: The expansion (opening the mouth) of the fixator ring assembly (widening)

Equations for Deflection (x) (Point Load @ End of Ring)	*Diagram for Load Scenario: 1*
$M_x = PR\ (1-\cos\theta)$ $U_x = \int_0^R \frac{M_x^2}{2EI}\,dR$ $U_x = \int_0^\pi \frac{[PR(1-\cos\theta)]^2}{2EI}\,Rd\theta$ $U_x = \frac{P^2R^3}{2EI}\int_0^\pi (1+\cos^2\theta-2cos\theta)d\theta$ $U_x = \frac{P^2R^3}{2EI}\times\frac{3\pi}{2}$ $\delta_x = \frac{\delta U}{\delta P} = \frac{\delta U}{\delta P}\frac{3P^2R^3}{4EI} = \frac{3PR^3}{2EI}$	

Scenario 2: The expansion (opening the mouth) of the fixator ring assembly (pulling)

The following scenario will be treating the ring again as a double curved beam cantilever with the load applied at the end of the half ring however, the resultant bending will act along the y-axis. The equation that was constructed follows the concepts of Castigiliano's First Theorem, by using one half of the fixator ring assembly as a single cantilever and the deflection as the sum of two.

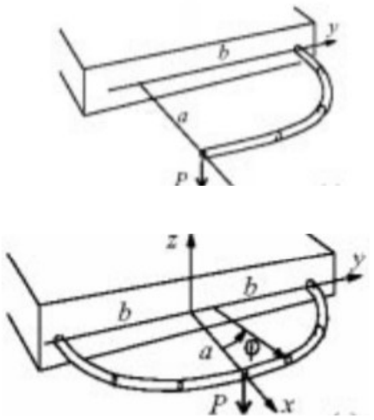
Equation 2: The expansion (opening the mouth) of the fixator ring assembly (pulling)

Equations for Deflection (y) (Point Load @ End of the Ring)	*Diagram for Load Scenario: 2*
$\sum M_{cut\ at\ \theta} = M + M_o - VRsin\theta - HR(1 - cos\theta) = 0$ $M = VRsin\theta + HR(1 - cos\theta) - M_o \rightarrow VRsin\theta - M_o, H = 0$ $\frac{\partial M}{\partial V} = Rsin\theta; \frac{\partial M}{\partial H} = R(1 - cos\theta); \frac{\partial M}{\partial M_o} = -1$ $\delta V = \frac{1}{EI}\int_0^L M\frac{\partial M}{\partial V}\,dS = \frac{1}{EI}\int_0^{\frac{\pi}{2}}(VRsin\theta - Mo).Rsin\theta.R\,d\theta$ $\delta V = \left(\frac{\pi}{4}VR - Mo\right)\frac{R^2}{EI} \rightarrow M_o = \frac{2}{\pi}VR$ and $F = \frac{V}{2}$ $V = \left(\frac{\pi}{4}VR - \frac{2}{\pi}VR\right)\frac{R^2}{EI} = \left(\frac{\pi}{2} - \frac{1}{\pi}\right)\frac{FR^3}{EI}$	

Scenario 3: The loading applied from the attached longitudinal element (strut)

The following scenario will be treating a half ring as curved beam cantilever with the load applied at the end of the half ring from the longitudinal element, resulting in bending along the z-axis.

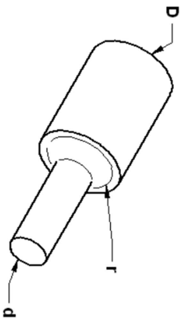
Equation 3: The expansion (opening the mouth) of the fixator ring assembly (pulling)

Equations for Deflection (z0 (Point Load @ End of the Ring)	*Diagram for Load Scenario: 3*
$\sum M_x = PRcos\theta$ $\frac{\partial M}{\partial P} = Rsin\theta;$ $\delta V = \frac{1}{EI}\int_0^R M\frac{\partial M}{\partial P}\,dR = \frac{1}{EI}\int_0^{\frac{\pi}{2}}(PRsin\theta).Rsin\theta.R\,d\theta$ $\delta V = \frac{\pi PR^2}{3EI}$	

Scenario 4: The loading applied through the translating threaded shaft (length fixation)

This scenario details the application of loading applied through the entire longitudinal element. This implies that there exists axial loading along the translating shaft. The equation is a simplified method for the determination of deflection for a rounded shaft under direct axial loading. The equation stems from the relationships between the key material factors that pertain to stability.

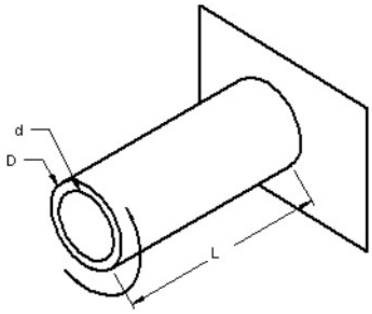
Equation 4: The loading applied through the translating threaded shaft (length fixation)

Equations for Deflection (Point Load through Shaft)	**Diagram for Load Scenario: 4**
$P = \frac{F}{4}$ $\sigma = \frac{F}{A} = \frac{4F}{\pi D^2}; \; E = \frac{\sigma}{\varepsilon}$ $\delta = \sigma EL = \frac{4F}{\pi D^2} \times EL$ $\delta = \frac{4FLE}{\pi D^2}$	

Scenario 5: The loading applied through the shaft housing (length fixation)

This scenario also details the similar application of loading applied through the entire longitudinal element however, the assumption corresponds to the rigidity to the entire longitudinal element. The equation quantifies the deflection for a cylinder under direct axial loading through the centre. The equation follows the previous equation by equating the relationships of key material factors.

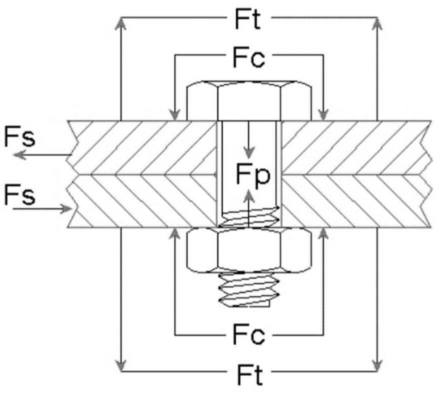
Equation 5: The loading applied through the shaft housing (length fixation)

Equations for Deflection (Point Load through Housing)	*Diagram for Load Scenario: 5*
$P = \frac{F}{4}$ $\sigma = \frac{F}{A} = \frac{4F}{\pi (D - d^2)^2}; \; E = \frac{\sigma}{\varepsilon}$ $\delta = \sigma EL = \frac{4F}{\pi (D - d^2)^2} \times EL$ $\delta = \frac{4FLE}{\pi (D - d^2)^2}$	

Scenario 6: The loading applied through the threaded turn head (modified bolted joint)

The equation for this scenario details the application of bolt calculations for clamped joints with the aim of determining the applied load and therefore the deflection of the threaded turn head. Since the threaded turn head is considered as a modified bolt-and-nut, the conditions pertain to the stabilisation of the clamped joint and the loading induced through the longitudinal element. The equation thus follows the bolt calculations and the relationships of specific material factors.

Equation 6: The loading applied through the threaded turn head (modified bolted joint)

Equations for Vertical Deflection (Point Load @ End of Ring)	*Diagram for Load Scenario: 6*
$F_b = F_i + \frac{1}{1+ R}F_e; R = \frac{k_c}{k_b}; k = \frac{AE}{l}$ $A_c \approx d^2 + 0.68dg + 0.065g^2; F_i = k_i A_t S_p$ $R = \frac{k_c}{k_b} = \frac{A_t}{A_b}; F_b = F_i + \frac{A_b}{A_t + A_b}F_c$ $\delta = \frac{4F_bLE}{\pi(D-d^2)^2} = \frac{4LE\left(0.75A_tS_p + \frac{A_b}{A_t+A_b}F\right)}{\pi(D-d^2)^2}$	

Results from the Material Analysis

The results produced from a completed material analysis for each component are demonstrated within this section. The generated deflection from the loading are visually depicted as clear linear graphs with progression in loading and deflection. These results are also produced from scenarios of preserved parameters such as: ring thickness [3mm] and translating shaft diameter [12 mm]

Figure 14: The Loading applied from the lock system to the half ring during the fixator ring assembly expansion. Deflection is generated from the bending of the half ring along the y-axis as the moment arm increases as the half ring is covered

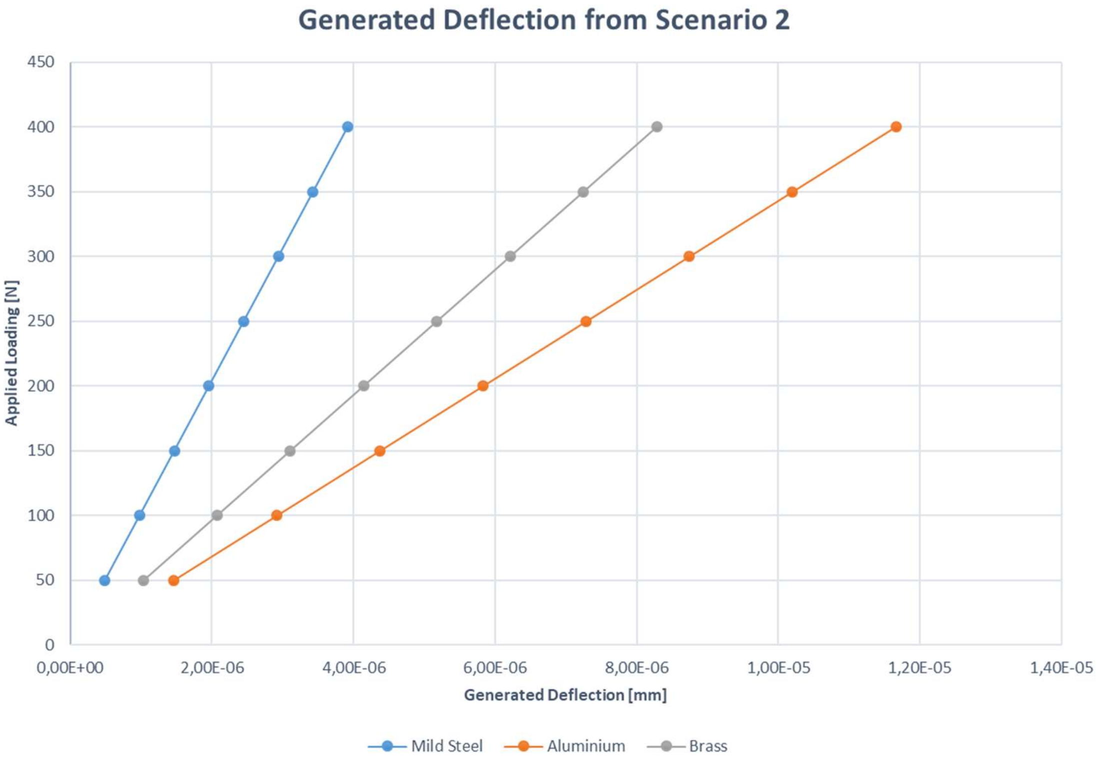


Figure 15: The Loading applied from the lock system to the half ring during the fixator ring assembly expansion. Deflection is generated from the bending of the half ring along the x-axis as the ring is stretch along the diameter of the ring

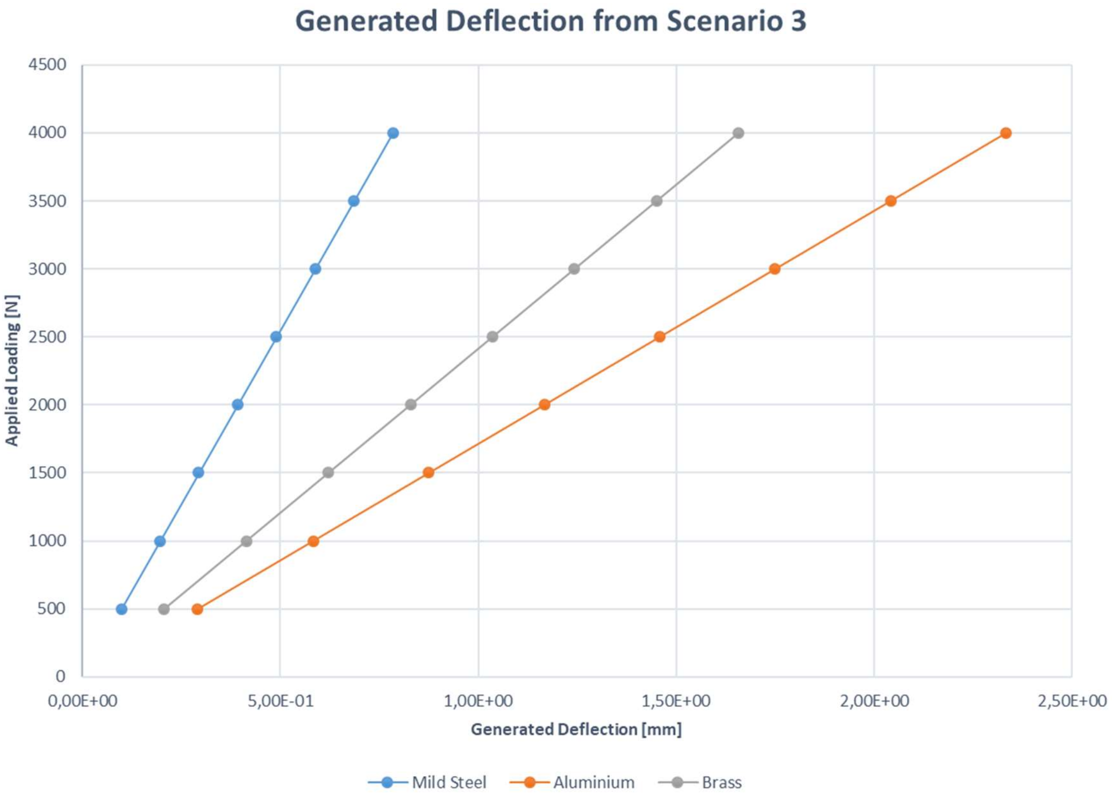


Figure 16: The Loading applied from the longitudinal element upon the face of the ring during fracture fixation. Deflection is generated from the bending of the half ring along the z-axis as the moment arm increases as the half ring is covered

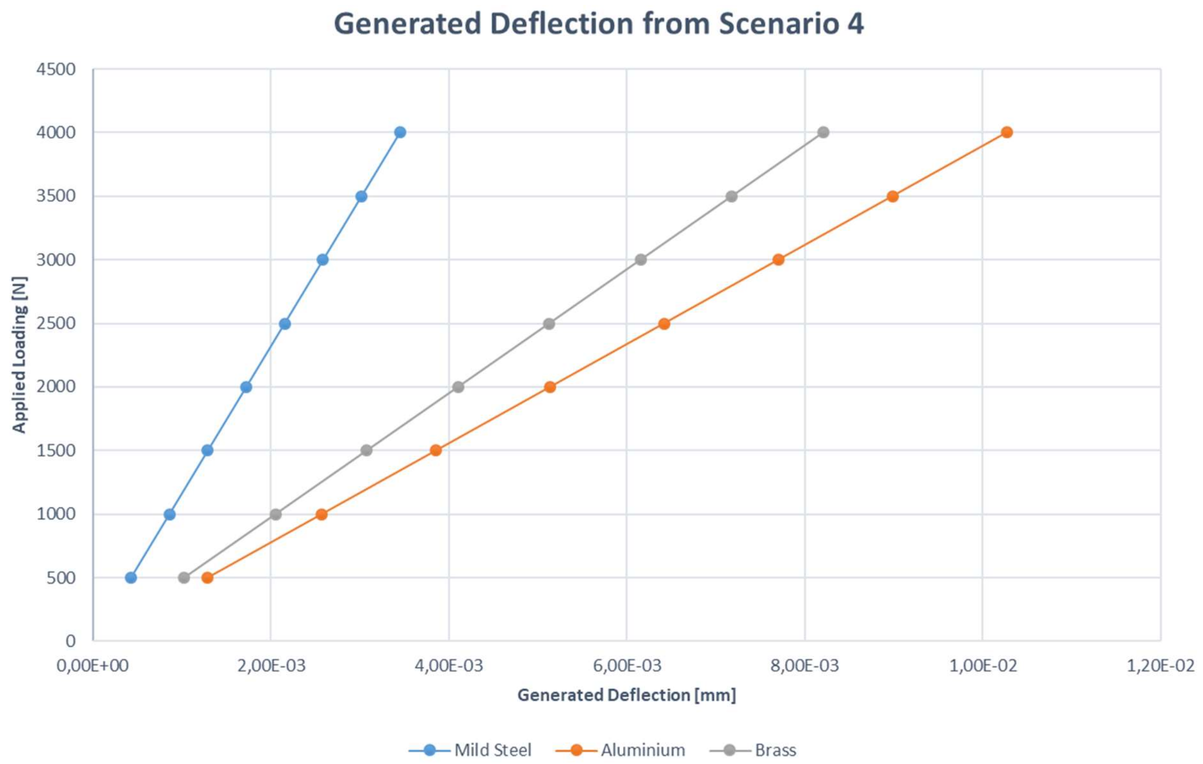


Figure 17: The direct axial loading of the threaded translating shaft during the loading of the entire fracture fixation system. Deflection is generated from the transfer of the load from the turn head to the shaft as the loading acts upon the face

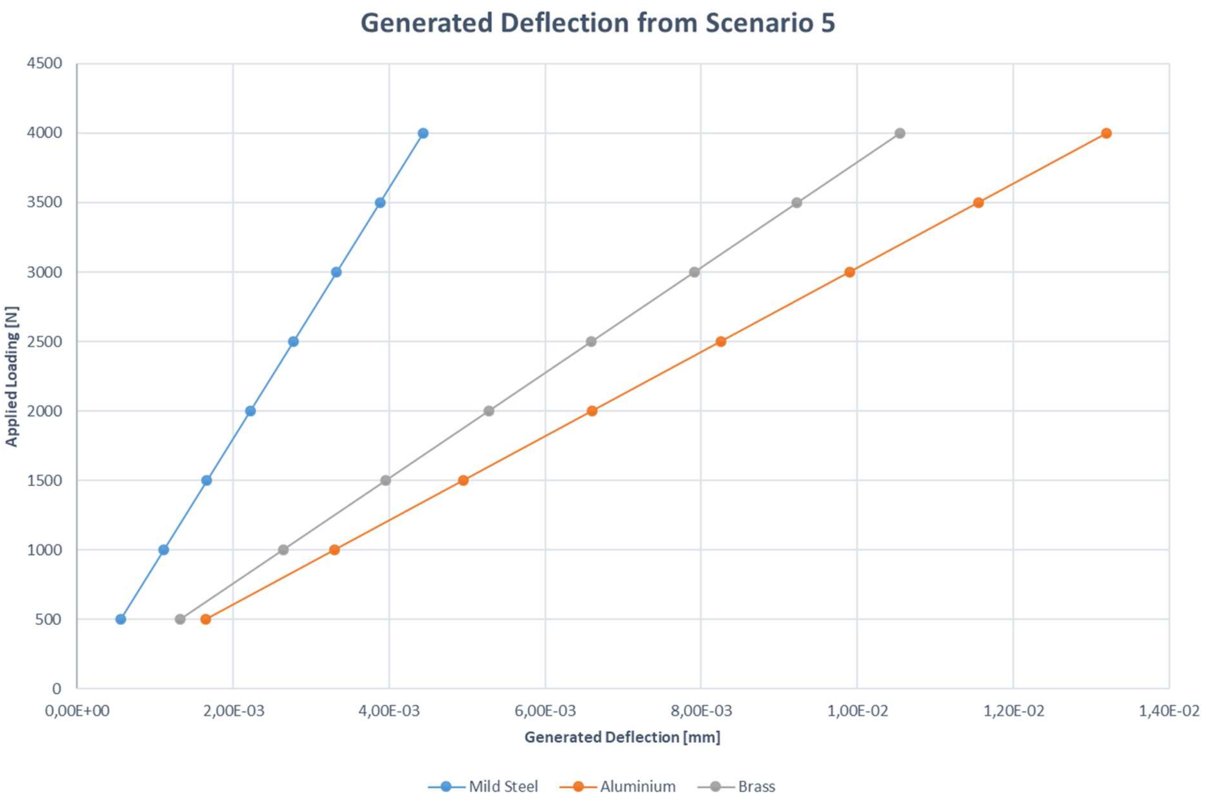
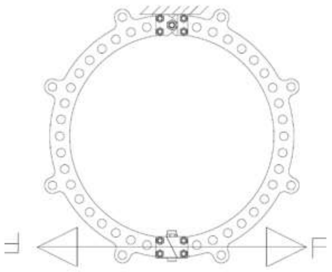


Figure 18: The direct axial loading of the translating shaft housing during the loading of the entire fracture fixation system. Deflection is generated from the transfer of the load from the turn head to the housing through the turn head's shoulder

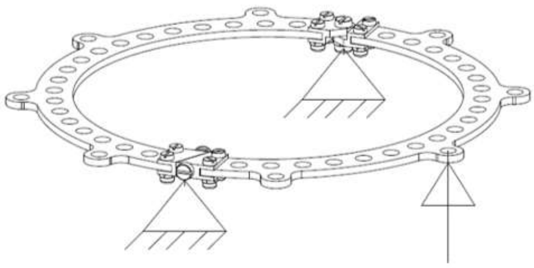
The Fixator Ring - Mild Steel

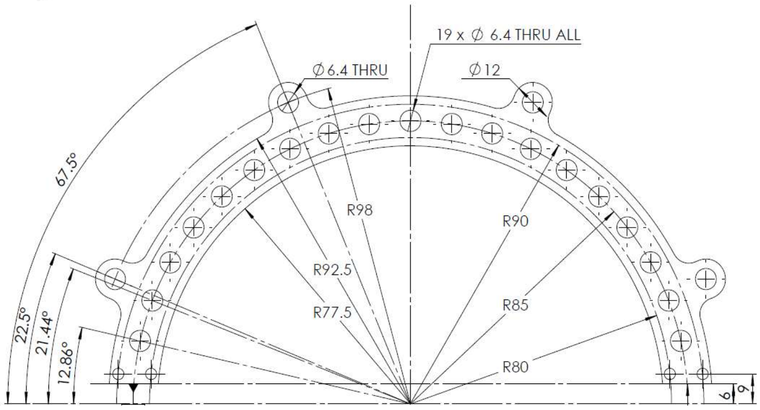
***Scenario 1:** Assembly expansion (widening)*



Scenario 2: Assembly expansion (pulling)

***Scenario 3:** The loading at the edge of the half ring (strut)*





Fixator Ring Dimensions		*155 mm Ring*	
Inner Diameter	=	155	mm
Outer Diameter	=	195	mm
Middle Diameter	=	170	mm
Ring Width	=	20	mm
Metal Area	=	10995,57	mm2

Mechanical Properties:		*Mild Steel*	
Mass Density	=	7,87E-06	kg/mm3
Poissons Ratio	=	0,29	
Brinell Hardness	=	126	
Elastic Modulus	=	2,05E+11	Pa
Shear Modulus	=	8,00E+10	Pa
Yield Strength	=	3,70E+08	Pa

Moment of Inertia (Ring (Ix))	=	6,67E-07	m/m
Moment of Inertia (Ring (Iy))	=	1,67E-03	m
Moment of Inertia (Ring (J))	=	3,33E-07	m3

The Fixator Ring - Mild Steel

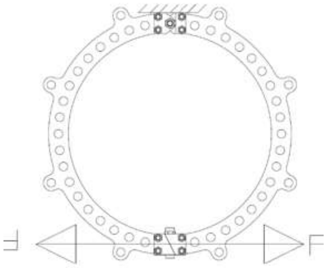
		Transverse(x) Deflection (Point Load @ End of Ring)					
		Ring Thickness [mm]					
		1	2	3	4	5	6
POINT LOADING (N)	50	1,06E+00	5,29E-01	3,53E-01	2,65E-01	2,12E-01	1,76E-01
	100	2,12E+00	1,06E+00	7,06E-01	5,29E-01	4,24E-01	3,53E-01
	150	3,18E+00	1,59E+00	1,06E+00	7,94E-01	6,35E-01	5,29E-01
	200	4,24E+00	2,12E+00	1,41E+00	1,06E+00	8,47E-01	7,06E-01
	250	5,29E+00	2,65E+00	1,76E+00	1,32E+00	1,06E+00	8,82E-01
	300	6,35E+00	3,18E+00	2,12E+00	1,59E+00	1,27E+00	1,06E+00
	350	7,41E+00	3,71E+00	2,47E+00	1,85E+00	1,48E+00	1,24E+00
	400	8,47E+00	4,24E+00	2,82E+00	2,12E+00	1,69E+00	1,41E+00
		Internal Reaction [mm]					

		Transverse(y) Deflection (Point Load @ End of Ring)					
		Ring Thickness [mm]					
		1	2	3	4	5	6
POINT LOADING (N)	50	5,44E-08	2,18E-07	4,90E-07	8,71E-07	1,36E-06	1,96E-06
	100	1,09E-07	4,35E-07	9,80E-07	1,74E-06	2,72E-06	3,92E-06
	150	1,63E-07	6,53E-07	1,47E-06	2,61E-06	4,08E-06	5,88E-06
	200	2,18E-07	8,71E-07	1,96E-06	3,48E-06	5,44E-06	7,84E-06
	250	2,72E-07	1,09E-06	2,45E-06	4,35E-06	6,80E-06	9,80E-06
	300	3,27E-07	1,31E-06	2,94E-06	5,23E-06	8,16E-06	1,18E-05
	350	3,81E-07	1,52E-06	3,43E-06	6,10E-06	9,53E-06	1,37E-05
	400	4,35E-07	1,74E-06	3,92E-06	6,97E-06	1,09E-05	1,57E-05
		Internal Reaction [mm]					

	Strut No.	Vertical Deflection (Point Load from Strut)					
		Ring Thickness [mm]					
	4	1	2	3	4	5	6
POINT LOADING (N)	500	2,94E-01	1,47E-01	9,80E-02	7,35E-02	5,88E-02	4,90E-02
	1000	5,88E-01	2,94E-01	1,96E-01	1,47E-01	1,18E-01	9,80E-02
	1500	8,82E-01	4,41E-01	2,94E-01	2,21E-01	1,76E-01	1,47E-01
	2000	1,18E+00	5,88E-01	3,92E-01	2,94E-01	2,35E-01	1,96E-01
	2500	1,47E+00	7,35E-01	4,90E-01	3,68E-01	2,94E-01	2,45E-01
	3000	1,76E+00	8,82E-01	5,88E-01	4,41E-01	3,53E-01	2,94E-01
	3500	2,06E+00	1,03E+00	6,86E-01	5,15E-01	4,12E-01	3,43E-01
	4000	2,35E+00	1,18E+00	7,84E-01	5,88E-01	4,71E-01	3,92E-01
		Internal Reaction [mm]					

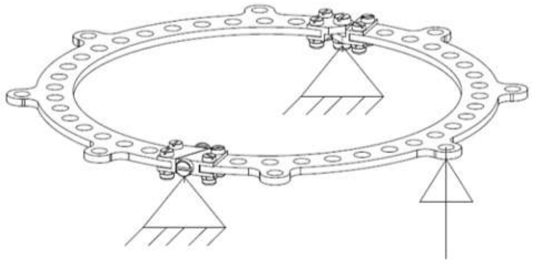
The Fixator Ring - Aluminium

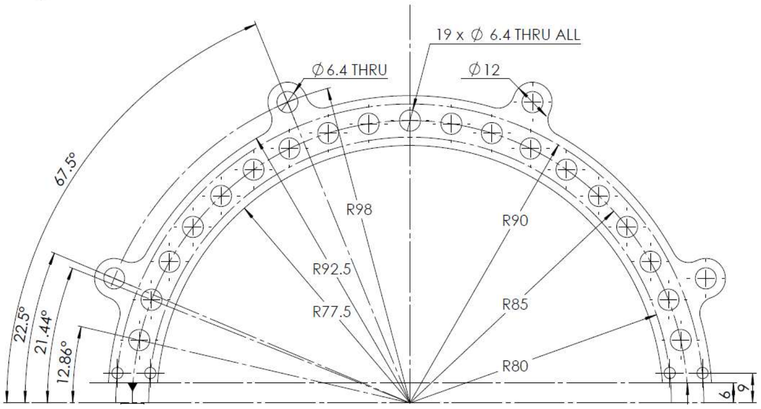
***Scenario 1:* Assembly expansion (widening)**



Scenario 2: Assembly expansion (pulling)

***Scenario 3:* The loading at the edge of the half ring (strut)**





Fixator Ring Dimensions		*155 mm Ring*
Inner Diameter	=	155 mm
Outer Diameter	=	195 mm
Medium Diameter	=	170 mm
Ring Width	=	20 mm
Metal Area	=	10995,57 mm2

Mechanical Properties:		*Alu 6061 T1*
Mass Density	=	2,70E-06 kg/mm3
Poissons Ratio	=	0,29
Brinell Hardness	=	95
Elastic Modulus	=	6,89E+10 Pa
Yield Strength	=	2,76E+08 Pa
Ult Yield Strength	=	6,07E+08 Pa
Moment of Inertia (Ring (Ix))	=	6,67E-07 m/m
Moment of Inertia (Ring (Iy))	=	1,67E-03 m
Moment of Inertia (Ring (J))	=	3,33E-07 m3

The Fixator Ring - Aluminium

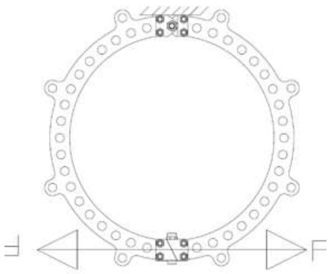
		Transverse(x) Deflection (Point Load @ End of Ring)					
		Ring Thickness [mm]					
		1	2	3	4	5	6
POINT LOADING (N)	50	3,15E+00	1,58E+00	1,05E+00	7,88E-01	6,30E-01	5,25E-01
	100	6,30E+00	3,15E+00	2,10E+00	1,58E+00	1,26E+00	1,05E+00
	150	9,45E+00	4,73E+00	3,15E+00	2,36E+00	1,89E+00	1,58E+00
	200	1,26E+01	6,30E+00	4,20E+00	3,15E+00	2,52E+00	2,10E+00
	250	1,58E+01	7,88E+00	5,25E+00	3,94E+00	3,15E+00	2,63E+00
	300	1,89E+01	9,45E+00	6,30E+00	4,73E+00	3,78E+00	3,15E+00
	350	2,21E+01	1,10E+01	7,35E+00	5,51E+00	4,41E+00	3,68E+00
	400	2,52E+01	1,26E+01	8,40E+00	6,30E+00	5,04E+00	4,20E+00
		Internal Reaction [mm]					

		Transverse(y) Deflection (Point Load @ End of Ring)					
		Ring Thickness [mm]					
		1	2	3	4	5	6
POINT LOADING (N)	50	1,62E-07	6,48E-07	1,46E-06	2,59E-06	4,05E-06	5,83E-06
	100	3,24E-07	1,30E-06	2,92E-06	5,18E-06	8,10E-06	1,17E-05
	150	4,86E-07	1,94E-06	4,37E-06	7,77E-06	1,21E-05	1,75E-05
	200	6,48E-07	2,59E-06	5,83E-06	1,04E-05	1,62E-05	2,33E-05
	250	8,10E-07	3,24E-06	7,29E-06	1,30E-05	2,02E-05	2,92E-05
	300	9,72E-07	3,89E-06	8,75E-06	1,55E-05	2,43E-05	3,50E-05
	350	1,13E-06	4,53E-06	1,02E-05	1,81E-05	2,83E-05	4,08E-05
	400	1,30E-06	5,18E-06	1,17E-05	2,07E-05	3,24E-05	4,66E-05
		Internal Reaction [mm]					

	Strut No.	Vertical Deflection (Point Load from Strut)					
		Ring Thickness [mm]					
	4	1	2	3	4	5	6
POINT LOADING (N)	500	8,75E-01	4,38E-01	2,92E-01	2,19E-01	1,75E-01	1,46E-01
	1000	1,75E+00	8,75E-01	5,83E-01	4,38E-01	3,50E-01	2,92E-01
	1500	2,63E+00	1,31E+00	8,75E-01	6,56E-01	5,25E-01	4,38E-01
	2000	3,50E+00	1,75E+00	1,17E+00	8,75E-01	7,00E-01	5,83E-01
	2500	4,38E+00	2,19E+00	1,46E+00	1,09E+00	8,75E-01	7,29E-01
	3000	5,25E+00	2,63E+00	1,75E+00	1,31E+00	1,05E+00	8,75E-01
	3500	6,13E+00	3,06E+00	2,04E+00	1,53E+00	1,23E+00	1,02E+00
	4000	7,00E+00	3,50E+00	2,33E+00	1,75E+00	1,40E+00	1,17E+00
		Internal Reaction [mm]					

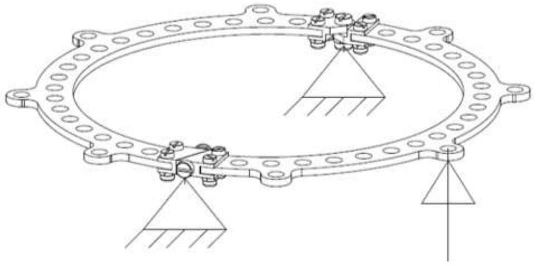
The Fixator Ring - Brass

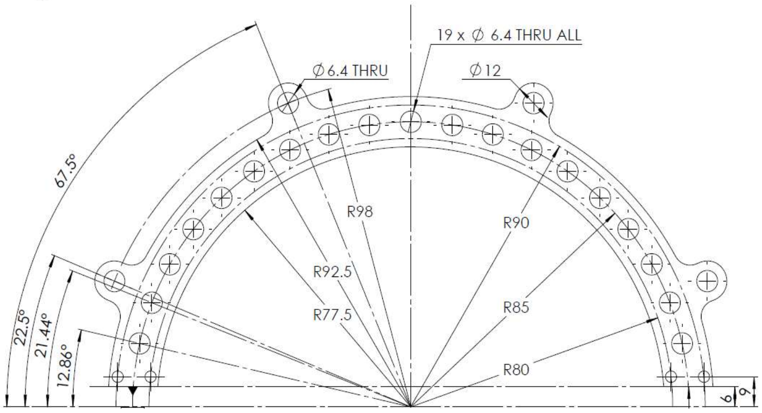
Scenario 1: Assembly expansion (widening)



Scenario 2: Assembly expansion (pulling)

Scenario 3: The loading at the edge of the half ring (strut)





Fixator Ring Dimensions	■	*155 mm Ring*
Inner Diameter	=	155 mm
Outer Diameter	=	195 mm
Medium Diameter	=	170 mm
Ring Width	=	20 mm
Metal Area	=	10995,57 mm2

Mechanical Properties:	■	*Brass*
Mass Density	=	8,49E-06 kg/mm3
Poissons Ratio	=	0,31
Brinell Hardness	=	60
Elastic Modulus	=	9,70E+10 Pa
Yield Strength	=	1,24E+08 Pa
Ult Yield Strength	=	3,38E+08 Pa

Moment of Inertia (Ring (Ix))	=	6,67E-07 m/m
Moment of Inertia (Ring (Iy))	=	1,67E-03 m
Moment of Inertia (Ring (J))	=	3,33E-07 m3

The Fixator Ring - Brass

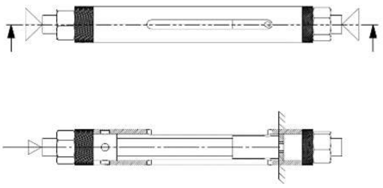
		Transverse(x) Deflection (Point Load @ End of Ring)					
		Ring Thickness [mm]					
		1	2	3	4	5	6
POINT LOADING (N)	50	2,24E+00	1,12E+00	7,46E-01	5,59E-01	4,48E-01	3,73E-01
	100	4,48E+00	2,24E+00	1,49E+00	1,12E+00	8,95E-01	7,46E-01
	150	6,71E+00	3,36E+00	2,24E+00	1,68E+00	1,34E+00	1,12E+00
	200	8,95E+00	4,48E+00	2,98E+00	2,24E+00	1,79E+00	1,49E+00
	250	1,12E+01	5,59E+00	3,73E+00	2,80E+00	2,24E+00	1,86E+00
	300	1,34E+01	6,71E+00	4,48E+00	3,36E+00	2,69E+00	2,24E+00
	350	1,57E+01	7,83E+00	5,22E+00	3,92E+00	3,13E+00	2,61E+00
	400	1,79E+01	8,95E+00	5,97E+00	4,48E+00	3,58E+00	2,98E+00
		Internal Reaction [mm]					

		Transverse(y) Deflection (Point Load @ End of Ring)					
		Ring Thickness [mm]					
		1	2	3	4	5	6
POINT LOADING (N)	50	1,15E-07	4,60E-07	1,04E-06	1,84E-06	2,88E-06	4,14E-06
	100	2,30E-07	9,20E-07	2,07E-06	3,68E-06	5,75E-06	8,28E-06
	150	3,45E-07	1,38E-06	3,11E-06	5,52E-06	8,63E-06	1,24E-05
	200	4,60E-07	1,84E-06	4,14E-06	7,36E-06	1,15E-05	1,66E-05
	250	5,75E-07	2,30E-06	5,18E-06	9,20E-06	1,44E-05	2,07E-05
	300	6,90E-07	2,76E-06	6,21E-06	1,10E-05	1,73E-05	2,48E-05
	350	8,05E-07	3,22E-06	7,25E-06	1,29E-05	2,01E-05	2,90E-05
	400	9,20E-07	3,68E-06	8,28E-06	1,47E-05	2,30E-05	3,31E-05
		Internal Reaction [mm]					

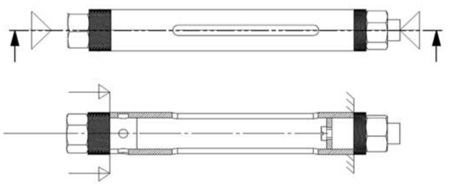
	Strut No.	Vertical Deflection (Point Load from Strut)					
		Ring Thickness [mm]					
	4	1	2	3	4	5	6
POINT LOADING (N)	500	6,22E-01	3,11E-01	2,07E-01	1,55E-01	1,24E-01	1,04E-01
	1000	1,24E+00	6,22E-01	4,14E-01	3,11E-01	2,49E-01	2,07E-01
	1500	1,86E+00	9,32E-01	6,22E-01	4,66E-01	3,73E-01	3,11E-01
	2000	2,49E+00	1,24E+00	8,29E-01	6,22E-01	4,97E-01	4,14E-01
	2500	3,11E+00	1,55E+00	1,04E+00	7,77E-01	6,22E-01	5,18E-01
	3000	3,73E+00	1,86E+00	1,24E+00	9,32E-01	7,46E-01	6,22E-01
	3500	4,35E+00	2,18E+00	1,45E+00	1,09E+00	8,70E-01	7,25E-01
	4000	4,97E+00	2,49E+00	1,66E+00	1,24E+00	9,95E-01	8,29E-01
		Internal Reaction [mm]					

The Longitudinal Element - Mild Steel

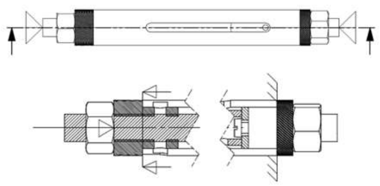
***Scenario 4:** The loading applied through the translating threaded shaft (length fixation)*

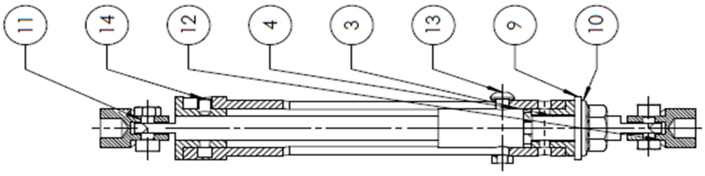


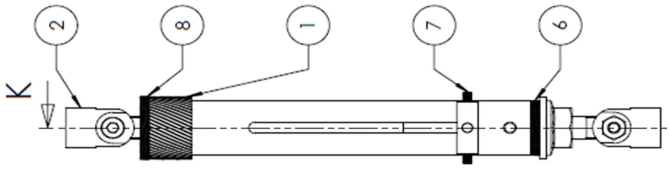
***Scenario 5:** The loading applied through the shaft housing (length fixation)*



***Scenario 6:** The loading applied through the threaded turn head (modified bolted joint)*







Dimensional Constants	■	*Strut*
Threaded Strut Length	=	80 mm
Piston Head Length	=	5 mm
Strut Housing Length	=	90 mm
Threaded Strut Support Length	=	10 mm
Shoulder Radius (Strt-Piston Hd)	=	2 mm
Housing Thickness	=	2 mm

Mechanical Properties	■	*Mild Steel*
Mass Density	=	7,87E-06 kg/mm3
Poissons Ratio	=	0,29
Brinell Hardness	=	126
Elastic Modulus	=	2,05E+11 Pa
Yield Strength	=	3,70E+08 Pa
Ult Tensile Strength	=	4,40E+08 Pa
Price	=	35 R/kg

The Longitudinal Element - Mild Steel

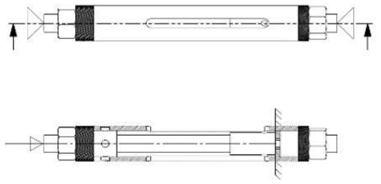
		Deflection of the Shaft (Threaded)				
		Diameter [mm]				
		4	6	8	10	12
		Mass [kg]				
		0,008	0,018	0,032	0,049	0,071
Strut No.		Cost [R]				
	4	0,276913	0,623053	1,10765	1,730703	2,492213
AXIAL LOADING [N]	500	3,88E-03	1,73E-03	9,70E-04	6,21E-04	4,31E-04
	1000	7,76E-03	3,45E-03	1,94E-03	1,24E-03	8,63E-04
	1500	1,16E-02	5,18E-03	2,91E-03	1,86E-03	1,29E-03
	2000	1,55E-02	6,90E-03	3,88E-03	2,48E-03	1,73E-03
	2500	1,94E-02	8,63E-03	4,85E-03	3,11E-03	2,16E-03
	3000	2,33E-02	1,04E-02	5,82E-03	3,73E-03	2,59E-03
	3500	2,72E-02	1,21E-02	6,79E-03	4,35E-03	3,02E-03
	4000	3,11E-02	1,38E-02	7,76E-03	4,97E-03	3,45E-03
		Internal Reaction [mm]				

		Deflection of the Housing				
		Diameter [mm]				
		4	6	8	10	12
		Mass [kg]				
		0,024	0,042	0,063	0,089	0,119
Strut No.		Cost [R]				
	4	0,830738	1,453791	2,2153	3,115266	4,153688
AXIAL LOADING [N]	500	1,29E-03	9,70E-04	7,76E-04	6,47E-04	5,55E-04
	1000	2,59E-03	1,94E-03	1,55E-03	1,29E-03	1,11E-03
	1500	3,88E-03	2,91E-03	2,33E-03	1,94E-03	1,66E-03
	2000	5,18E-03	3,88E-03	3,11E-03	2,59E-03	2,22E-03
	2500	6,47E-03	4,85E-03	3,88E-03	3,23E-03	2,77E-03
	3000	7,76E-03	5,82E-03	4,66E-03	3,88E-03	3,33E-03
	3500	9,06E-03	6,79E-03	5,43E-03	4,53E-03	3,88E-03
	4000	1,04E-02	7,76E-03	6,21E-03	5,18E-03	4,44E-03
		Internal Reaction [mm]				

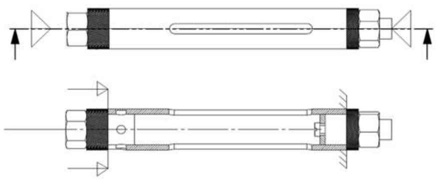
		Deflection on the Turn Head				
		Diameter [mm]				
		4	6	8	10	12
		At [mm2]				
		8,78	20,1	36,6	58	84,3
		Fi [N]				
		2,44E+03	5,58E+03	1,02E+04	1,61E+04	2,34E+04
Strut No.		R = Ac/At				
	4	0,17666	0,241297	0,293034	0,332378	0,363206
AXIAL LOADING [N]	500	9,87E-03	1,10E-02	1,33E-02	1,57E-02	1,82E-02
	1000	1,03E-02	1,12E-02	1,34E-02	1,58E-02	1,83E-02
	1500	1,07E-02	1,14E-02	1,35E-02	1,59E-02	1,84E-02
	2000	1,11E-02	1,16E-02	1,36E-02	1,60E-02	1,84E-02
	2500	1,15E-02	1,18E-02	1,38E-02	1,61E-02	1,85E-02
	3000	1,19E-02	1,20E-02	1,39E-02	1,62E-02	1,86E-02
	3500	1,23E-02	1,22E-02	1,40E-02	1,63E-02	1,87E-02
	4000	1,28E-02	1,24E-02	1,41E-02	1,63E-02	1,87E-02
		Internal Reaction [mm]				

The Longitudinal Element - Aluminium

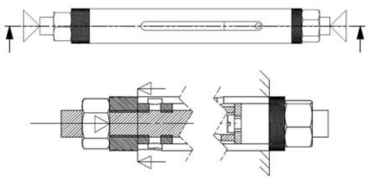
Scenario 4: The loading applied through the translating threaded shaft (length fixation)

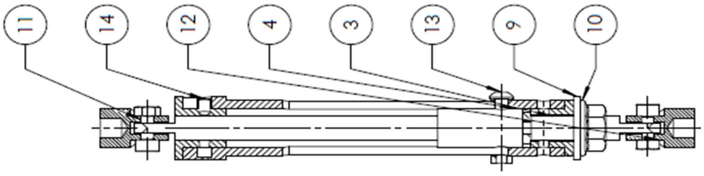


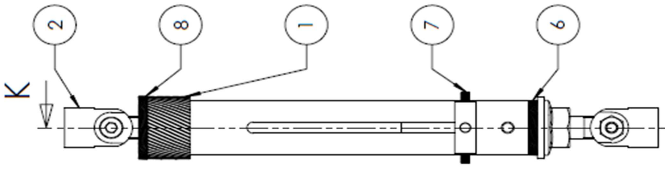
Scenario 5: The loading applied through the shaft housing (length fixation)



Scenario 6: The loading applied through the threaded turn head (modified bolted joint)







Dimensional Constants		Strut	
Threaded Strut Length	=	80	mm
Piston Head Length	=	5	mm
Strut Housing Length	=	90	mm
Threaded Strut Support Length	=	10	mm
Shoulder Radius (Strt-Piston Hd)	=	2	mm
Housing Thickness	=	2	mm

Mechanical Properties		Alu 6061 T1	
Mass Density	=	2,70E-06	kg/mm3
Poissons Ratio	=	0,33	
Brinell Hardness	=	95	
Elastic Modulus	=	6,89E+10	Pa
Yield Strength	=	2,76E+08	Pa
Ult Tensile Strength	=	3,10E+08	Pa
Price	=	70	R/kg

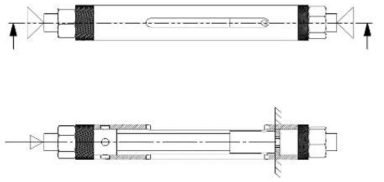
The Longitudinal Element - Aluminium

		Deflection of the Shaft (Threaded)				
		Diameter [mm]				
		4	6	8	10	12
		Mass [kg]				
		0,003	0,006	0,011	0,017	0,024
Strut No.		Cost [R]				
	4	0,190004	0,427508	0,760014	1,187522	1,710032
AXIAL LOADING [N]	500	1,15E-02	5,13E-03	2,89E-03	1,85E-03	1,28E-03
	1000	2,31E-02	1,03E-02	5,77E-03	3,70E-03	2,57E-03
	1500	3,46E-02	1,54E-02	8,66E-03	5,54E-03	3,85E-03
	2000	4,62E-02	2,05E-02	1,15E-02	7,39E-03	5,13E-03
	2500	5,77E-02	2,57E-02	1,44E-02	9,24E-03	6,42E-03
	3000	6,93E-02	3,08E-02	1,73E-02	1,11E-02	7,70E-03
	3500	8,08E-02	3,59E-02	2,02E-02	1,29E-02	8,98E-03
	4000	9,24E-02	4,11E-02	2,31E-02	1,48E-02	1,03E-02
		Internal Reaction [mm]				
		Deflection of the Housing				
		Diameter [mm]				
		4	6	8	10	12
		Mass [kg]				
		0,008	0,014	0,022	0,031	0,041
Strut No.		Cost [R]				
	4	0,570011	0,997518	1,520028	2,13754	2,850053
AXIAL LOADING [N]	500	3,85E-03	2,89E-03	2,31E-03	1,92E-03	1,65E-03
	1000	7,70E-03	5,77E-03	4,62E-03	3,85E-03	3,30E-03
	1500	1,15E-02	8,66E-03	6,93E-03	5,77E-03	4,95E-03
	2000	1,54E-02	1,15E-02	9,24E-03	7,70E-03	6,60E-03
	2500	1,92E-02	1,44E-02	1,15E-02	9,62E-03	8,25E-03
	3000	2,31E-02	1,73E-02	1,39E-02	1,15E-02	9,90E-03
	3500	2,69E-02	2,02E-02	1,62E-02	1,35E-02	1,15E-02
	4000	3,08E-02	2,31E-02	1,85E-02	1,54E-02	1,32E-02
		Internal Reaction [mm]				

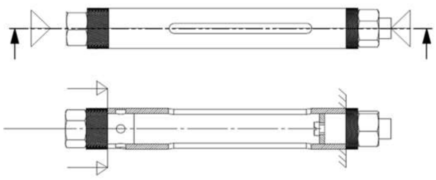
		Strain on the Turn Head				
		Diameter [mm]				
		4	6	8	10	12
		At [mm2]				
		8,78	20,1	36,6	58	84,3
		Fi [N]				
		2,44E+03	5,58E+03	1,02E+04	1,61E+04	2,34E+04
Strut No.		R = Ac/At				
	4	0,17666	0,241297	0,293034	0,332378	0,363206
AXIAL LOADING [N]	500	2,94E-02	3,28E-02	3,95E-02	4,67E-02	5,42E-02
	1000	3,06E-02	3,34E-02	3,98E-02	4,70E-02	5,45E-02
	1500	3,18E-02	3,40E-02	4,02E-02	4,73E-02	5,47E-02
	2000	3,30E-02	3,45E-02	4,06E-02	4,76E-02	5,49E-02
	2500	3,43E-02	3,51E-02	4,10E-02	4,78E-02	5,51E-02
	3000	3,55E-02	3,57E-02	4,13E-02	4,81E-02	5,53E-02
	3500	3,67E-02	3,63E-02	4,17E-02	4,84E-02	5,55E-02
	4000	3,80E-02	3,69E-02	4,21E-02	4,86E-02	5,57E-02
		Internal Reaction [mm]				

The Longitudinal Element - Brass

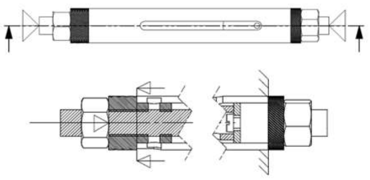
Scenario 4: The loading applied through the translating threaded shaft (length fixation)

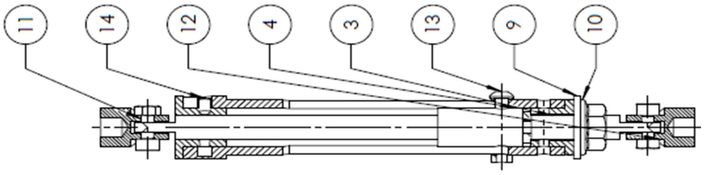


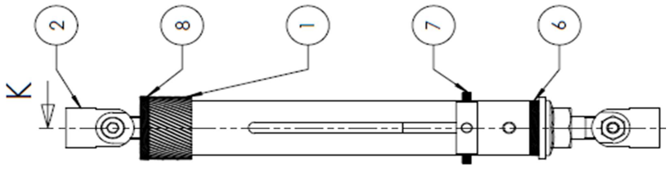
Scenario 5: The loading applied through the shaft housing (length fixation)



Scenario 6: The loading applied through the threaded turn head (modified bolted joint)







Dimensional Constants	■	*Strut*
Threaded Strut Length	=	90 mm
Piston Head Length	=	20
Strut Housing Length	=	90 mm
Threaded Strut Support Length	=	10 mm
Shoulder Radius (Strt-Piston Hd)	=	2 mm
Housing Thickness	=	2 mm

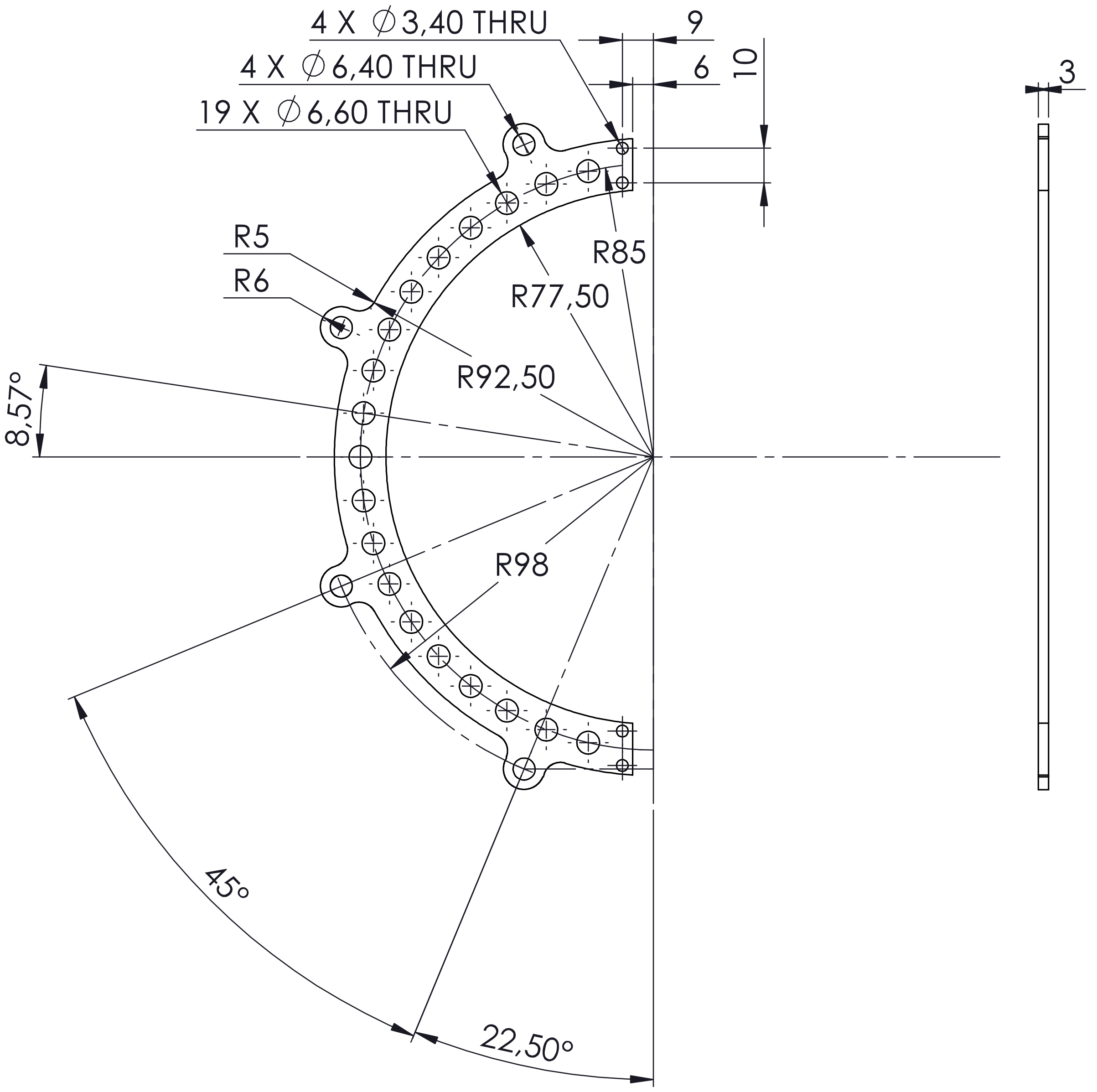
Mechanical Properties	■	*Brass*
Mass Density	=	8,49E-06 kg/mm3
Poissons Ratio	=	0,31
Brinell Hardness	=	126
Elastic Modulus	=	9,70E+10 Pa
Yield Strength	=	1,24E+08 Pa
Ult Tensile Strength	=	3,38E+08 Pa
Price	=	120 R/kg

The Longitudinal Element - Brass

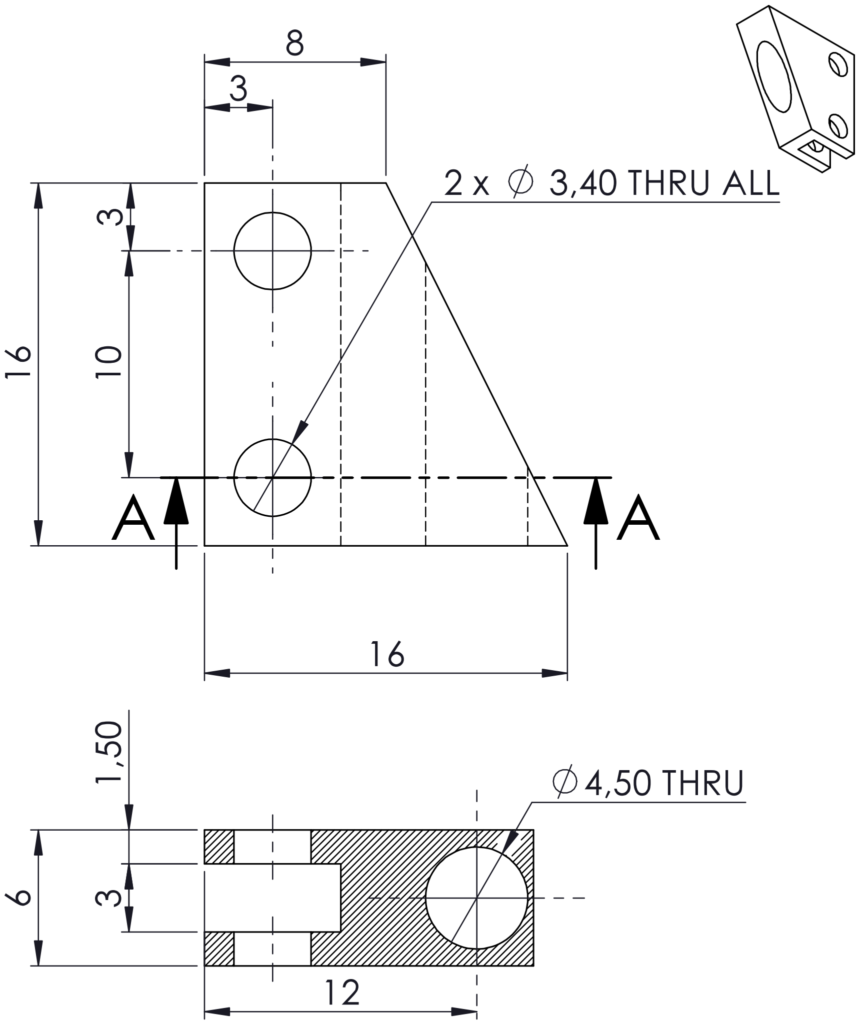
		Deflection of the Shaft (Threaded)				
		Diameter [mm]				
		4	6	8	10	12
		Mass [kg]				
		0,010	0,022	0,038	0,060	0,086
Strut No.		Cost [R]				
	4	1,152	2,593	4,609	7,201	10,370
AXIAL LOADING [N]	500	9,23E-03	4,10E-03	2,31E-03	1,48E-03	1,03E-03
	1000	1,85E-02	8,20E-03	4,61E-03	2,95E-03	2,05E-03
	1500	2,77E-02	1,23E-02	6,92E-03	4,43E-03	3,08E-03
	2000	3,69E-02	1,64E-02	9,23E-03	5,91E-03	4,10E-03
	2500	4,61E-02	2,05E-02	1,15E-02	7,38E-03	5,13E-03
	3000	5,54E-02	2,46E-02	1,38E-02	8,86E-03	6,15E-03
	3500	6,46E-02	2,87E-02	1,62E-02	1,03E-02	7,18E-03
	4000	7,38E-02	3,28E-02	1,85E-02	1,18E-02	8,20E-03
		Internal Reaction [mm]				

		Deflection of the Housing				
		Diameter [mm]				
		4	6	8	10	12
		Mass [kg]				
		0,029	0,050	0,077	0,108	0,144
Strut No.		Cost [R]				
	4	3,456707	6,049237	9,217885	12,96265	17,28353
AXIAL LOADING [N]	500	3,08E-03	2,31E-03	1,85E-03	1,54E-03	1,32E-03
	1000	6,15E-03	4,61E-03	3,69E-03	3,08E-03	2,64E-03
	1500	9,23E-03	6,92E-03	5,54E-03	4,61E-03	3,96E-03
	2000	1,23E-02	9,23E-03	7,38E-03	6,15E-03	5,27E-03
	2500	1,54E-02	1,15E-02	9,23E-03	7,69E-03	6,59E-03
	3000	1,85E-02	1,38E-02	1,11E-02	9,23E-03	7,91E-03
	3500	2,15E-02	1,62E-02	1,29E-02	1,08E-02	9,23E-03
	4000	2,46E-02	1,85E-02	1,48E-02	1,23E-02	1,05E-02
		Internal Reaction [mm]				

		Strain on the Turn Head				
		Diameter [mm]				
		4	6	8	10	12
		At [mm2]				
		8,78	20,1	36,6	58	84,3
		Fi [N]				
		2,44E+03	5,58E+03	1,02E+04	1,61E+04	2,34E+04
Strut No.		R = Ac/At				
	4	0,17666	0,241297	0,293034	0,332378	0,363206
AXIAL LOADING [N]	500	2,09E-02	2,33E-02	2,80E-02	3,32E-02	3,85E-02
	1000	2,17E-02	2,37E-02	2,83E-02	3,34E-02	3,87E-02
	1500	2,26E-02	2,41E-02	2,86E-02	3,36E-02	3,88E-02
	2000	2,35E-02	2,45E-02	2,88E-02	3,38E-02	3,90E-02
	2500	2,43E-02	2,49E-02	2,91E-02	3,40E-02	3,91E-02
	3000	2,52E-02	2,54E-02	2,94E-02	3,42E-02	3,93E-02
	3500	2,61E-02	2,58E-02	2,96E-02	3,44E-02	3,94E-02
	4000	2,70E-02	2,62E-02	2,99E-02	3,45E-02	3,96E-02
		Internal Reaction [mm]				

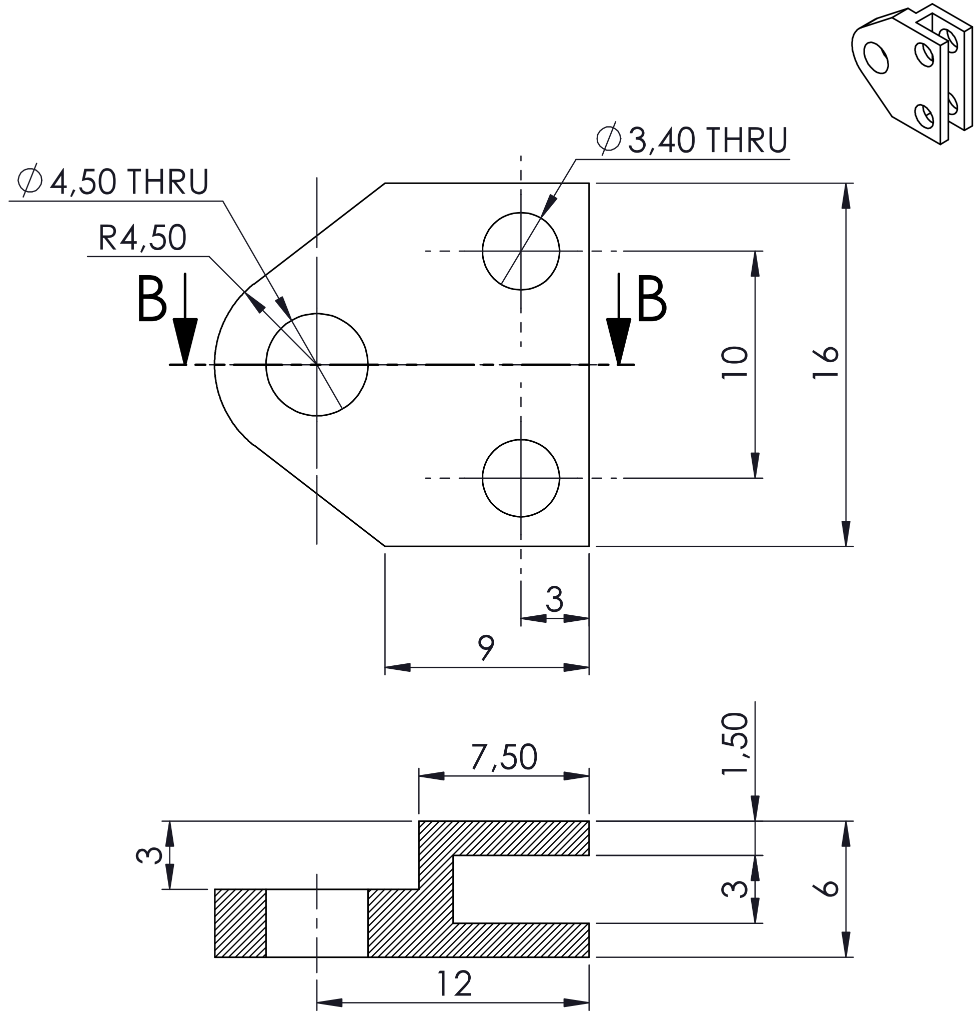


A4 Landscape	University of Cape Town Department of Mechanical Engineering				
	Title: C-Jointed Ring				
Quantity: 4	Part Finish	Date: 2019/02/07	Scale: 1:2	Sheet1	of 3
Material: Steel	Drawn By: Christopher Herbert HRBCHR001			Drawing Number CJFR - 001	



C-Joint (Lock)
Mtl - Key Steel

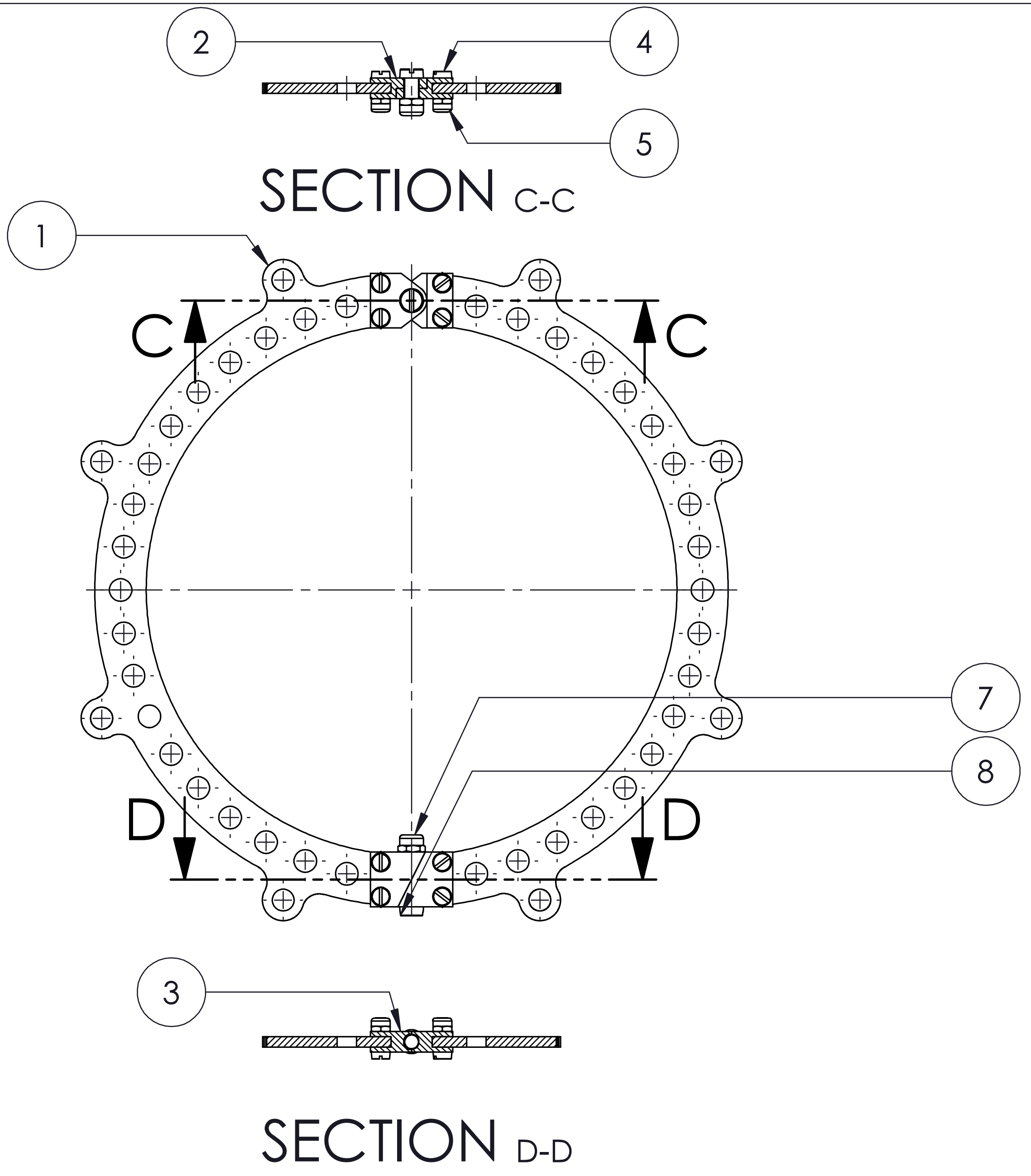
SECTION A-A



C-Joint (Hinge)
Mtl - Key Steel

SECTION B-B

A4 Landscape	University of Cape Town Department of Mechanical Engineering				
	Title: Hinge-and-Lock System				
Quantity: 2	Part Finish	Date: 2019/02/07	Scale: 3:1	Sheet2	of 3
Material: Steel		Drawn By: Christopher Herbert HRBCHR001		Drawing Number CJFR - 002	



ITEM NO.	PART NAME	MATERIAL/ DESCRIPTION	QTY.
8	M4 x 20 - Slotted Cheese Head	ISO 1207 - M4 x 20 - 20C	1
7	M4 - Lock Nut	ISO 10511-M4-C	2
6	M4 x 10 - Slotted Cheese Head	ISO 1207 - M4 x 10 - 10C	1
5	M3 - Lock Nut	ISO 10511-M3-C	8
4	M3 - Slotted Cheese Head	ISO 1207 - M3 x 10 - 10C	8
3	C-Joint (Lock)	KEY STEEL	2
2	C-Joint (Hinge)	KEY STEEL	2
1	C-Joint (Ring)	MILD STEEL	2

A4
Landscape

University of Cape Town
Department of Mechanical Engineering

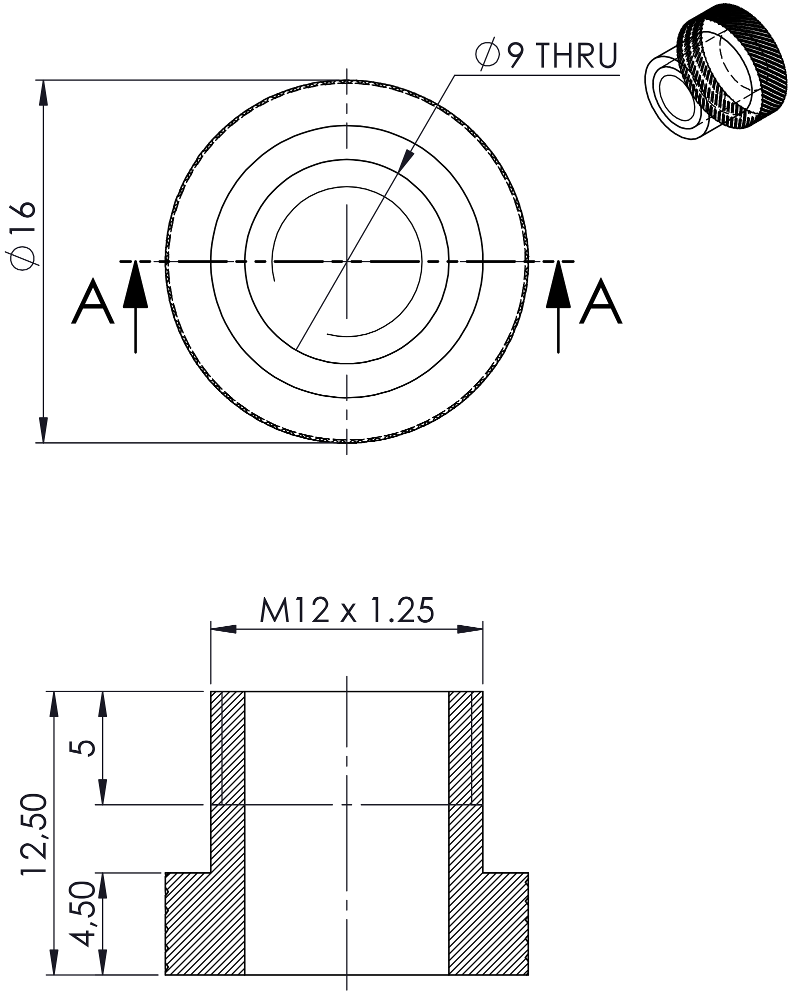
Title:
C-Joint (Ring)

Assembly
Drawing

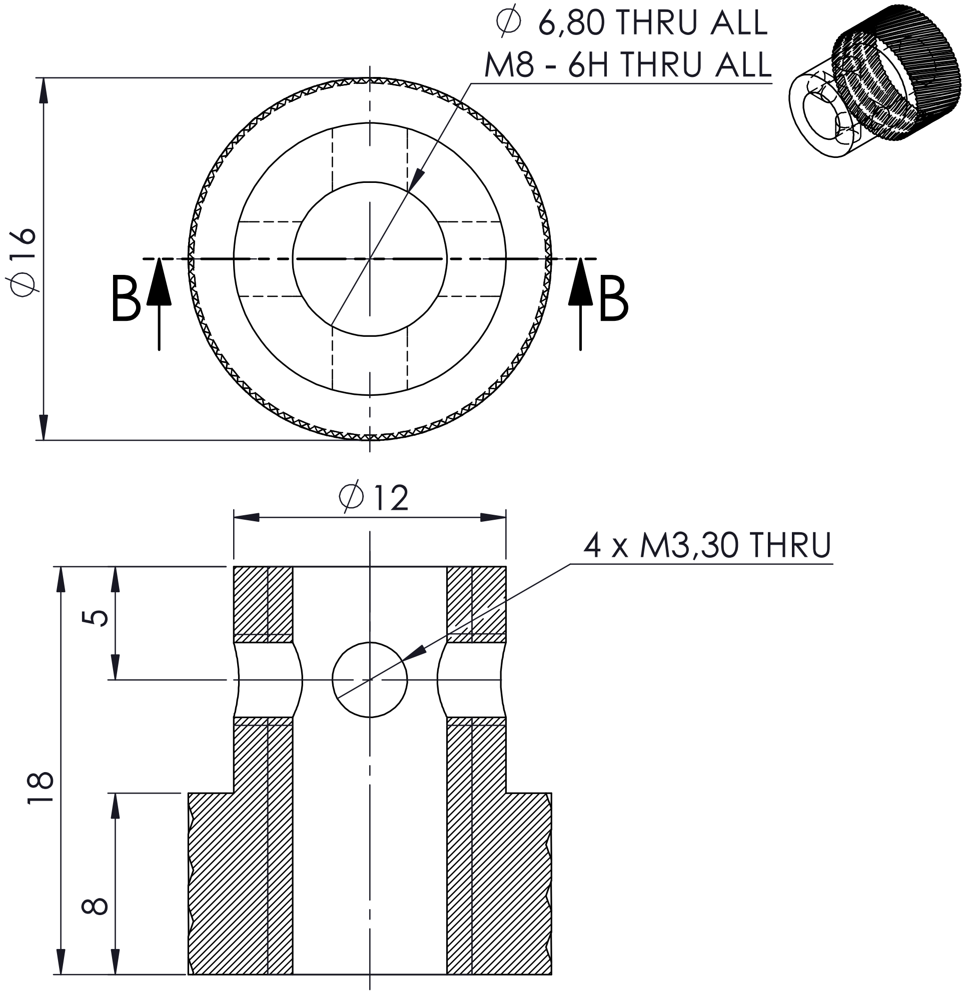
Scale: 1:2
Date: 2019/02/07
Sheet3 of 3

Drawn By:
Christopher Herbert
HRBCHR001

Drawing Number
CJFR - 003

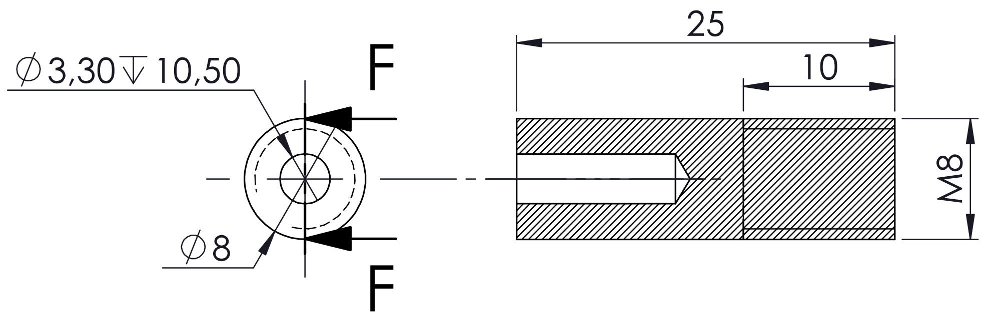


Turn Head (Lock)
Mtl - Brass
SECTION A-A



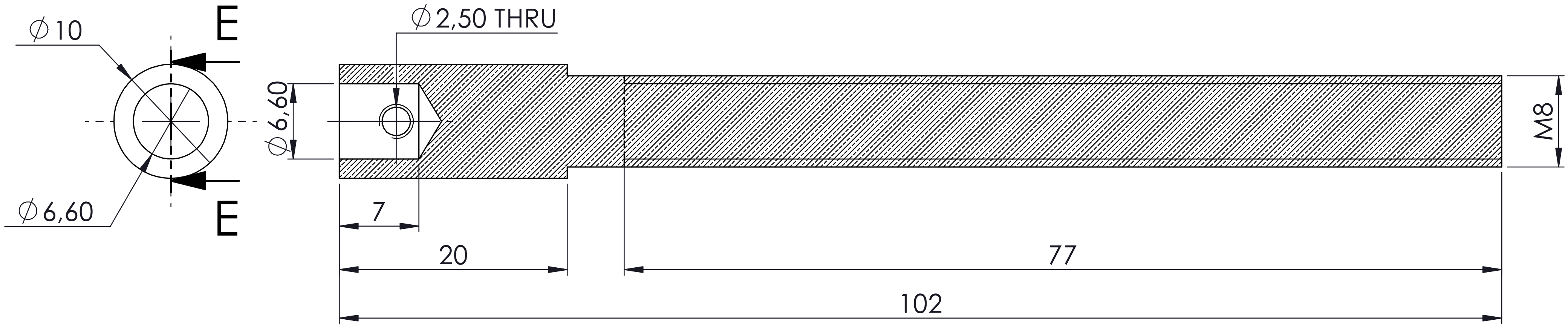
Turn Head (Adjustor)
Mtl - Brass
SECTION B-B

A4 Landscape	University of Cape Town Department of Mechanical Engineering				
	Title: Threaded Turn Heads				
Quantity: 4	Part Finish 0.2	Date: 2019/02/07	Scale: 3:1	Sheet 1	of 7
Material: BRASS		Drawn By: Christopher Herbert HRBCHR001		Drawing Number RFLE - 001	



Shaft (Drill Tapped)
Mtl - Brass

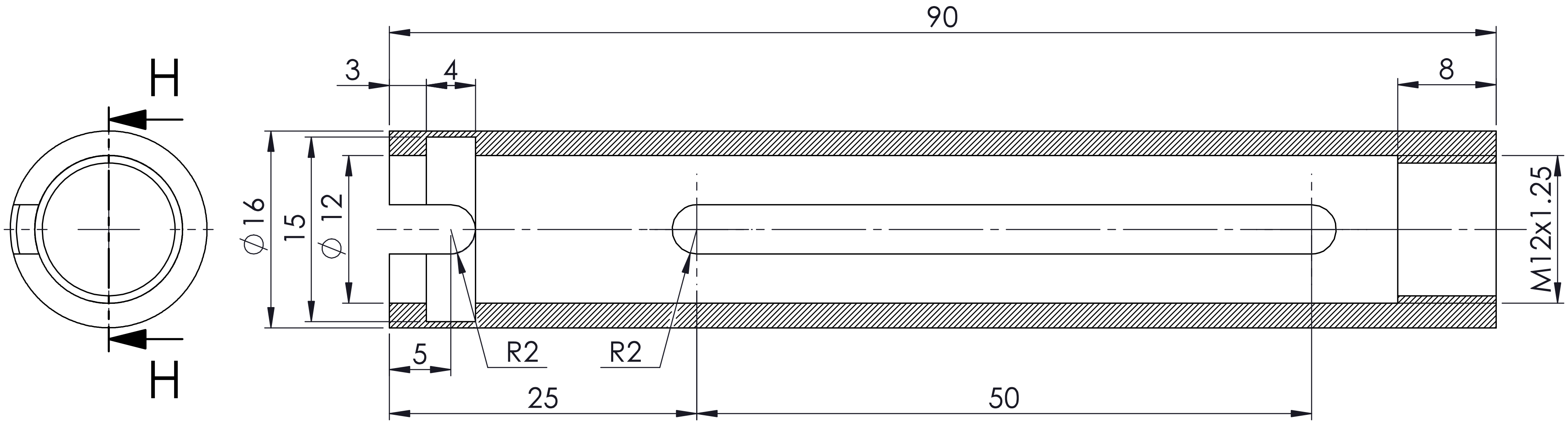
SECTION F-F



Shaft (Threaded)
Mtl - Brass

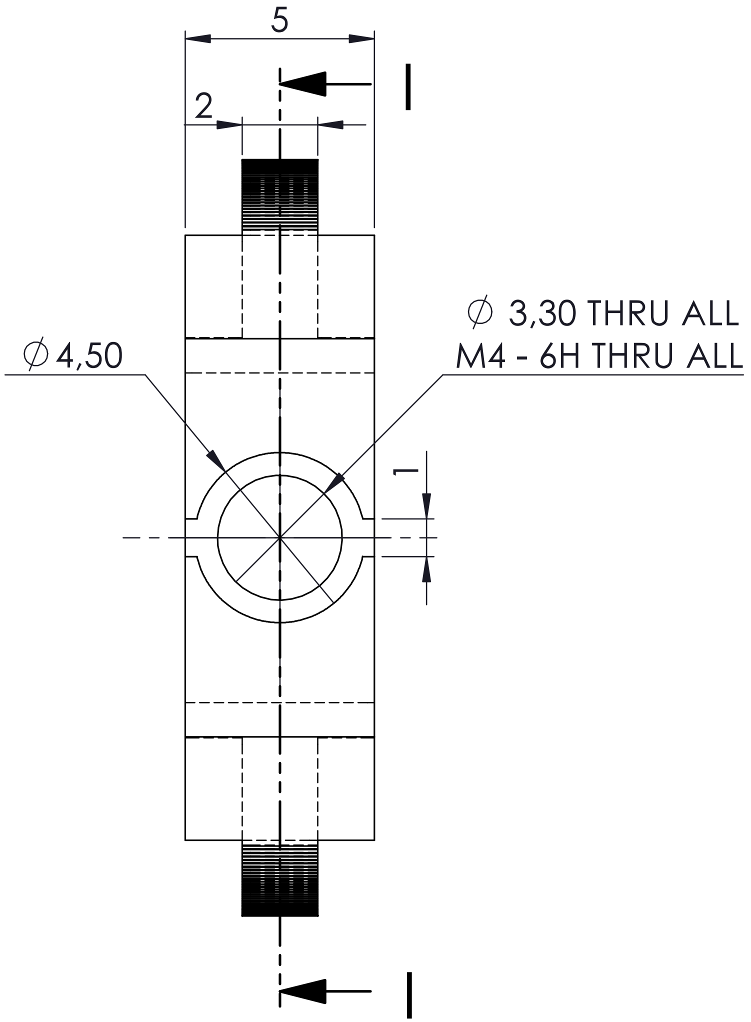
SECTION E-E

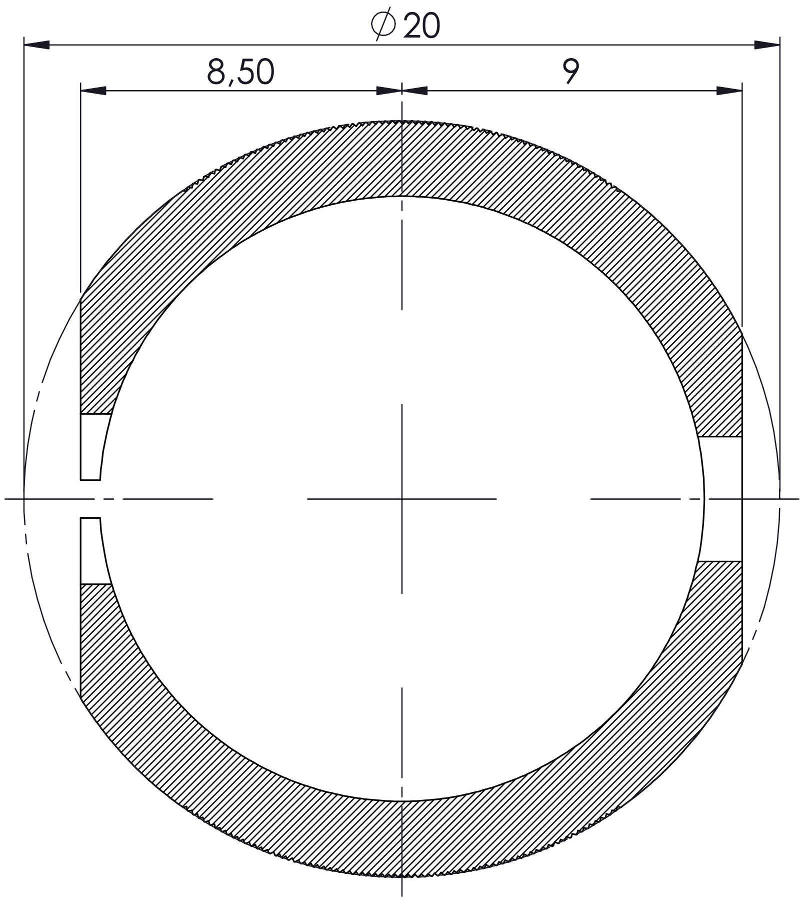
A4 Landscape	University of Cape Town Department of Mechanical Engineering				
	Title: Element Shafts				
Quantity: 4	Part Finish 0.2	Date: 2019/02/07	Scale: 2:1	Sheet 2	of 7
Material: BRASS	Drawn By: Christopher Herbert HRBCHR001			Drawing Number RFLE - 002	



SECTION H-H

A4 Landscape	University of Cape Town Department of Mechanical Engineering				
	Title: Shaft Housing				
Quantity: 4	Part Finish 0.2	Date: 2019/02/07	Scale: 2:1	Sheet 3	of 7
Material: BRASS	Drawn By: Christopher Herbert HRBCHR001			Drawing Number RFLE - 003	





SECTION I-I

A4 Landscape	**University of Cape Town** Department of Mechanical Engineering				
	Title: Retaining Ring (Modified)				
Quantity: 4	Part Finish 0.2	Date: 2019/02/07	Scale: 5:1	Sheet 4	of 7
Material: BRASS	Drawn By: Christopher Herbert HRBCHR001			Drawing Number RFLE - 004	

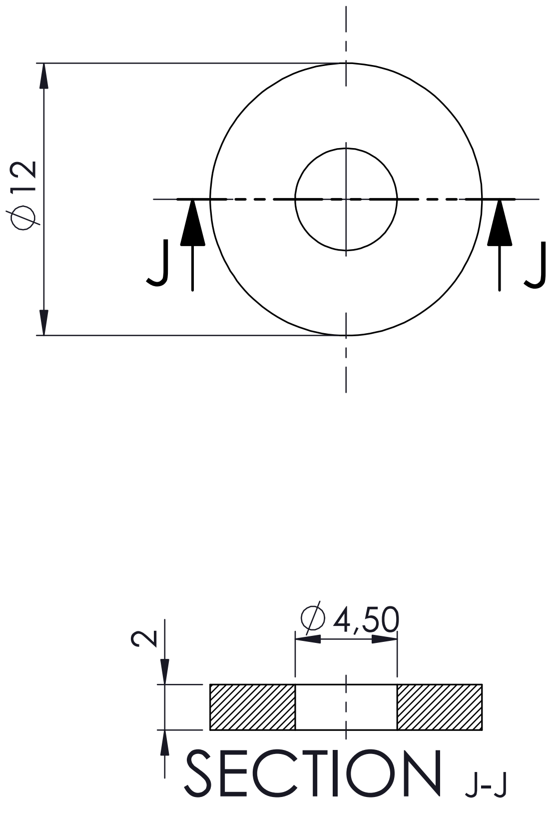
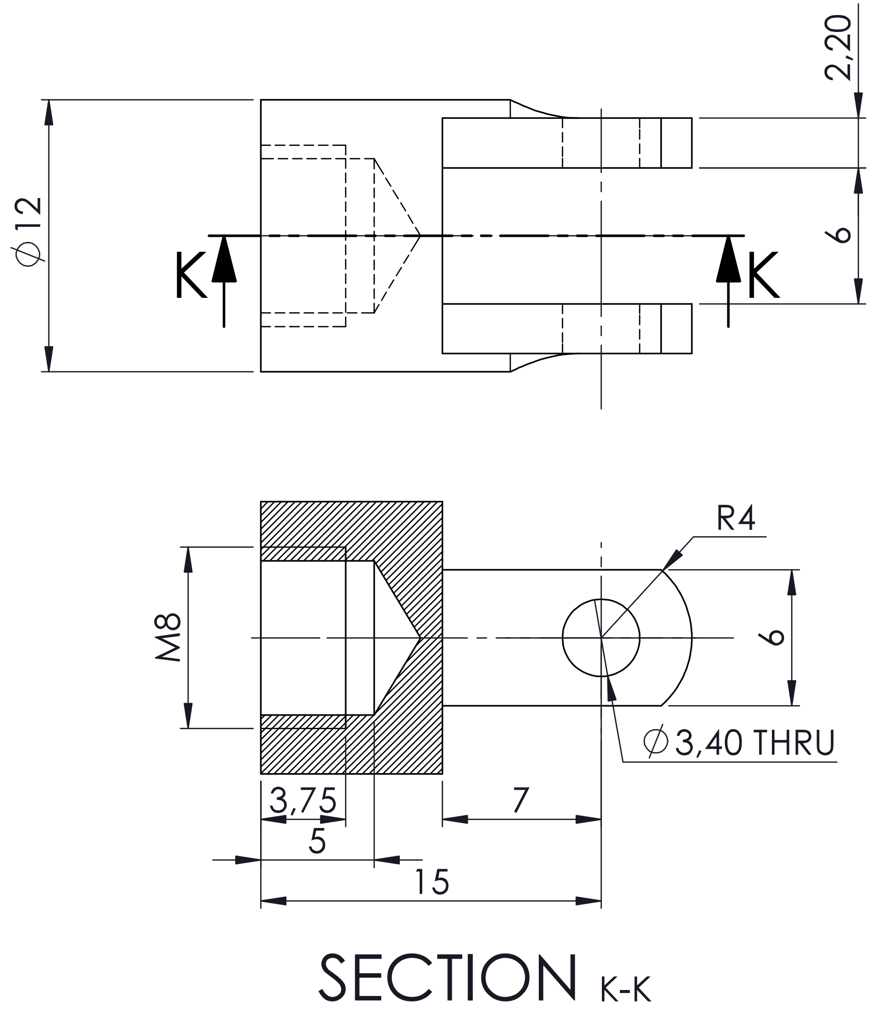
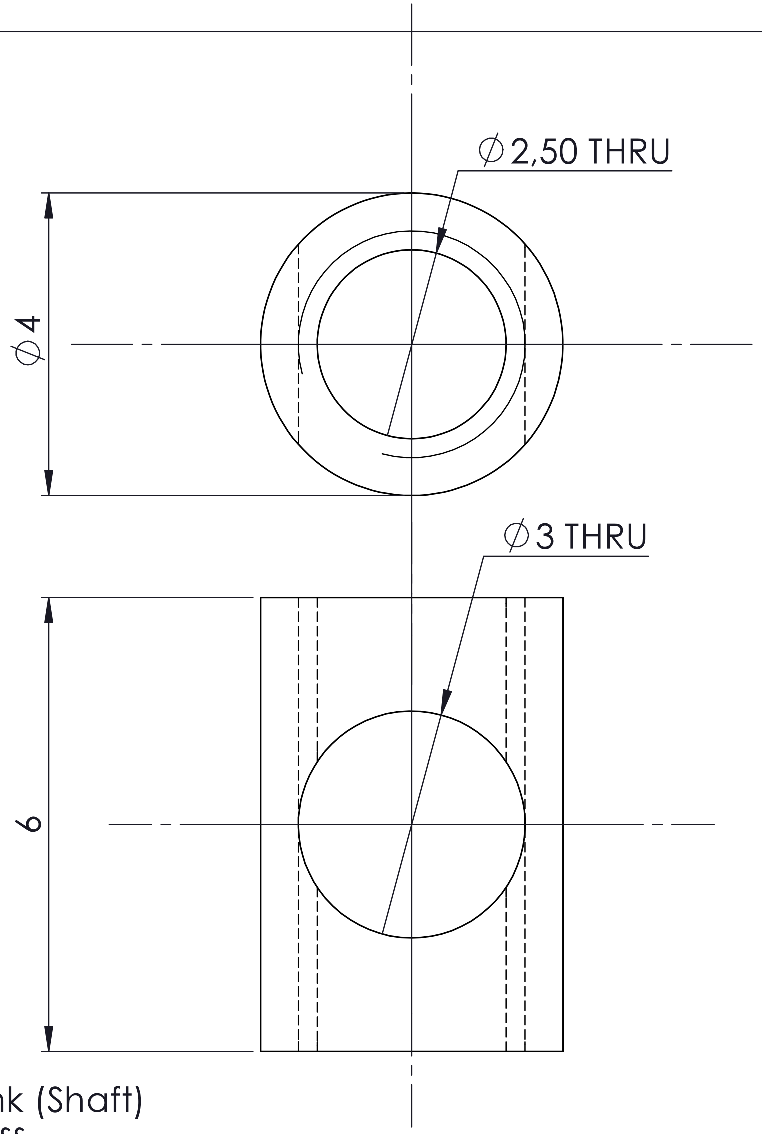


Plate (Thick Washer)
Mtl - Brass

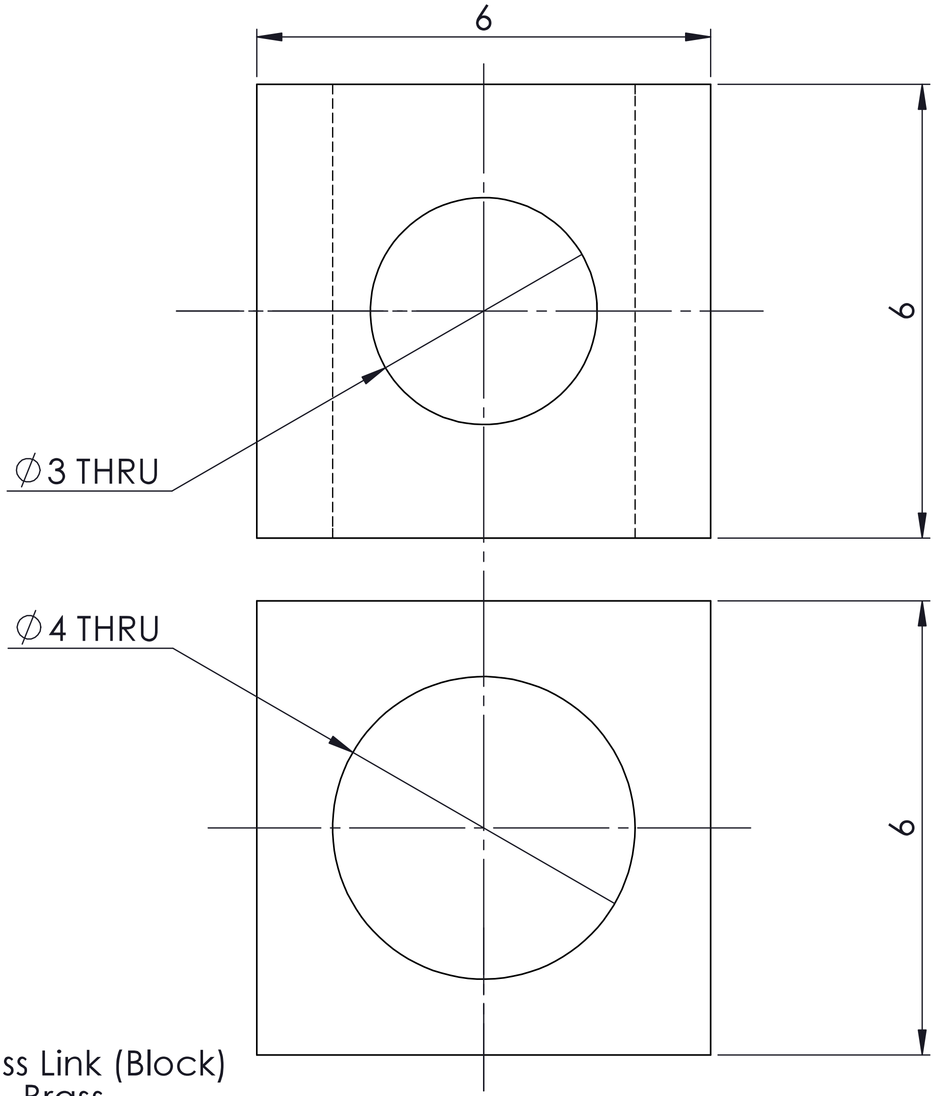


Universal Joint
Mtl - Brass

A4 Landscape	**University of Cape Town** Department of Mechanical Engineering				
	Title: Plate and Universal Joint				
Quantity: 4	Part Finish 0.2	Date: 2019/02/07	Scale: 3:1	Sheet 5	of 7
Material: BRASS	Drawn By: Christopher Herbert HRBCHR001			Drawing Number RFLE - 005	

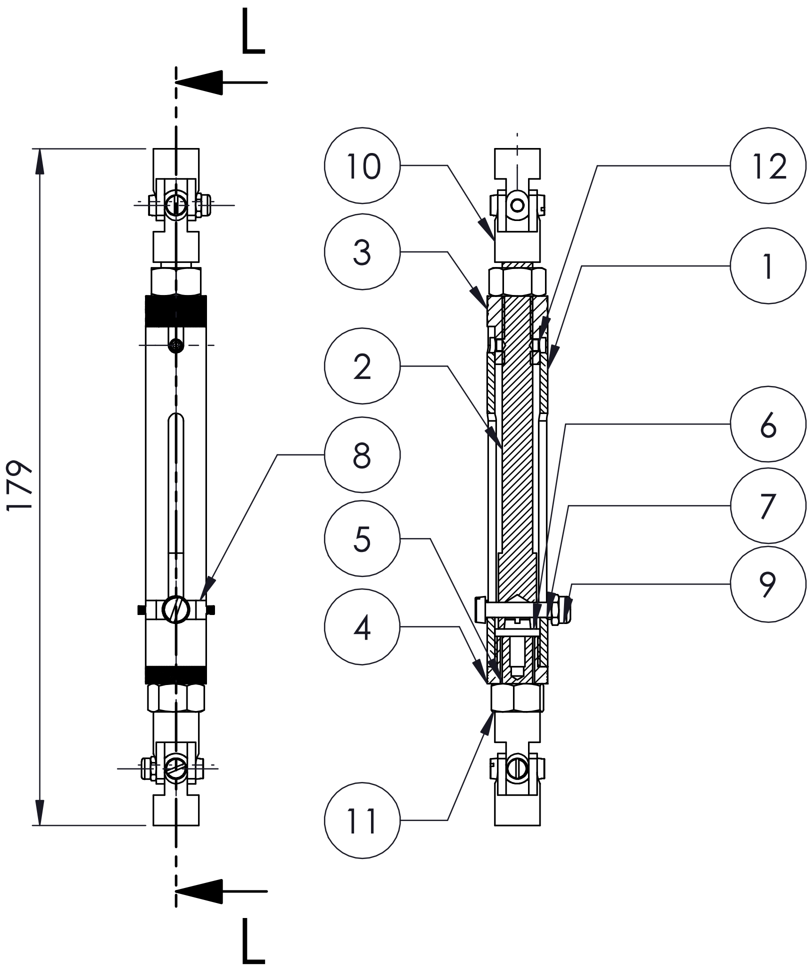


Cross Link (Shaft)
Mtl - Brass



Cross Link (Block)
Mtl - Brass

A4 Landscape	University of Cape Town Department of Mechanical Engineering				
	Title: Cross Link				
Quantity: 4	Part Finish 0.2	Date: 2019/02/07	Scale: 10:1	Sheet 6	of 7
Material: BRASS	Drawn By: Christopher Herbert HRBCHR001			Drawing Number RFLE - 006	



SECTION L-L

ITEM NO.	PART NAME	MATERIAL/DESCRIPTION	QTY.
12	M3 - Grub Screw	ISO 4027 - M3 x 2.5-N	4
11	M8 Nut	ISO - 4033 - M8 - D - C	2
10	Universal Joint	BRASS	2
9	M4 - Lock Nut	ISO 10511-M4-C	1
8	Retaining Ring (Modified)	BRASS	1
7	M4 x 20 - Slotted Cheese Head	ISO 1207 - M4 x 20 - 20C	2
6	Plate (Thick Washer)	BRASS	1
5	Shaft (Drill Tapped)	BRASS	1
4	Turn Head (Lock)	BRASS	1
3	Turn Head (Adjuster)	BRASS	1
2	Shaft (Threaded)	BRASS	1
1	Shaft (Housing)	BRASS	1

A4
Landscape

University of Cape Town
Department of Mechanical Engineering

Title:
Turn Head (Lock)

Assembly
Drawing

Scale: 1:2
Date: 2019/02/07
Sheet 7 of 7

Drawn By:
Christopher Herbert
HRBCHR001

Drawing Number
RFLE - 007