Femur Fracture Treatment Project: Summary of Project and Prototype Development

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1 Introduction

1.1 Background

The Femur Fracture Treatment Project (FFTP) was created by students from the University of British Columbia visiting Uganda and Kenya in 2015. Seeing the necessity for improvements in femur fracture treatment, a group of students took on the task of designing a femur traction device to meet the needs of medical professionals. This report outlines the research conducted to evaluate the problem, the development of a solution (device), as well as its verification and validation testing. The following sections will be discussed in further detail:

1. Background and research
2. Expressed need for the device
3. Development of device requirements & evaluation criteria
4. Prototype description, testing & conclusions
5. Recommendations

1.2 Femur Fractures

The femur is the largest and strongest bone in the body, hence high-energy trauma is required to cause fracture (1). Globally, between 20 and 50 million people suffer non-fatal injuries as a result of road traffic crashes (2). Ten percent of road injuries result in a femoral shaft fracture, with the young suffering a disproportionately higher incidence (3). Both the International Federation of Red Cross, Red Crescent Societies and the World Health Organization have declared road traffic injuries "among the most neglected health problems of the late 20th century", "hampering development and leaving millions in greater vulnerability." (4). Femoral shaft fractures, in particular, are associated with a high burden of disability due to poor alignment, limb shortening, and knee stiffness (5).

In low and middle income countries (LMICs), the incidence of femoral shaft fractures is estimated to be between 15.7-45.5 per 100,000 people compared to 9.9-12 per 100,000 people in high income countries (3; 5). Of motor vehicle accidents causing non-fatal injuries, fractures accounted for 66-69% of all injuries, with half of injuries related to fractures affecting the lower extremities, namely the femur, tibia, and fibula (6; 7).In LMICs such as Uganda, Rwanda, and Tanzania, a third of road traffic crashes involve boda bodas, a motorized two-wheeled vehicle making up the majority of transport in East Africa (8). In African LMICs, health burden is further accentuated by economic burden (9).

Femur fractures can occur in the neck, shaft, or head of the femur, often causing soft tissue damage that results in complications in managing the fracture (1). Femur fractures typically follow a common pattern:

1. The proximal bone segment typically displaces in the medial and anterior plane.
2. The distal fragment displaces in lateral and posterior plane. (10).

3. The distal fragment is pulled upwards to overlap with the proximal segment.

There are a number of different fracture types that can occur. These include straight line transverse fractures, spiral fractures, oblique fractures, and comminuted fractures, where the bone breaks into more than two pieces (10).

1.3 Skeletal Traction

In 2013, the World Health Organization reported that 94% of all traffic deaths and 90% of road traffic injury-related disability occurred in LMICs (11). In such settings, trauma care for femoral fractures is routinely conservative (i.e. non-surgical) and provided by non-specialists due to lack of surgical facilities, financial means, staffing, adequate training, or a combination thereof (12). This is in contrast to higher resource settings, where the majority of adult femoral fractures are treated with surgery. Early operative stabilization is thought to be beneficial to patient outcomes (13; 14).

For femoral fractures, non-surgical femoral traction treatment involves the application of an external force anchored to the skin or the bone of the leg. Traction operates under the primary principle of applying two equal and opposite forces on two fragments of the fracture to achieve and maintain fracture position for healing (10). Skin traction consists of adhesive padded tapes secured with bandage to the affected limb, but is poorly tolerated as it may result in local skin injury or may lose holding. Skeletal traction permits greater traction forces and can be tolerated for long-term treatment and is currently the standard of care for femoral shaft fractures in LMICs (10).

The application and management of skeletal traction requires on average 6-8 weeks of bed rest to achieve union in a reasonable orientation and daily attention to detail by both the staff and the patient during the healing period (15; 16). There are several different systems for skeletal traction, most involve the insertion of a traction pin either at the distal femur or proximal tibia under local anesthesia (10). Distal femoral pins are inserted at the level of the superior pole of the patella, outside the knee capsule. Proximal tibial pins are inserted posterior and inferior to the tibial tubercle. Pins used for adults are commonly Steinmann pins or Denham pins (10).

Shown in Figure 1, the simplest system of applying skeletal traction is to attach a rope to the traction pin, which is then passed over a pulley with a free weight hanging at the foot of the bed (10).

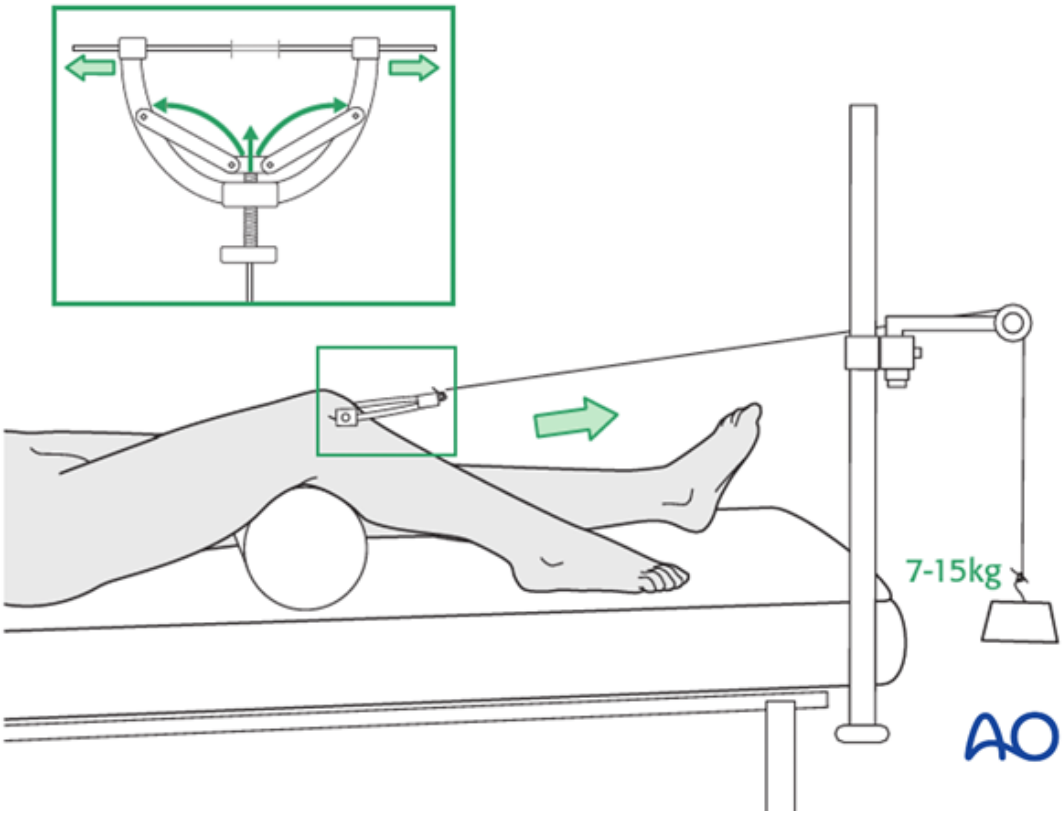

Figure 1: Typical Skeletal Traction Treatment (17)

The leg is then supported by resting it over a pillow such as in Russell traction (18) and Perkins traction (19). Perkins-type traction techniques are the preferred standard of care in LMICs and are commonly referred to as 'skeletal traction' or 'pin-based skeletal traction' (16). In Perkins traction, a single Steinmann pin is inserted distal and deep to the tibial tubercle under local anesthesia. Straight longitudinal traction with an initial weight of 3-4 kg is applied on an angle by elevating the foot of the bed with wooden blocks (20). During the course of the treatment, the weights are adjusted depending on the measured limb length of the fractured extremity. Perkins traction offers the advantage of knee mobilization, allowing the patient to undergo physiotherapy exercises beginning with range-of-motion exercises for the knee and graduating to active range of motion on the knee, hip musculature, and finally, the leg.(20) However, current skeletal traction systems do not have methods of monitoring and measuring the alignment process and as a consequence can cause misalignment (21)

1.4 Associated Problems with Traction

Management of traction requires more diligence, is more time consuming, and more technically demanding compared to surgical treatment (10). Skeletal traction for treating femoral shaft fractures is also associated with unwanted medical complications that can prolong treatment period and affect quality of healing. A systematic overview study done in 2016 by Kramer, Shearer, & Morshed (16) examined the rates of complications recorded in 455 adult cases of femur tractions from LMICs. Young, male patients who suffered high-trauma injuries represented a significant

portion of the data. Four categories of complications were identified: malunions (20%), non-unions (5%), infections (13%), and "other" (10%). In this study,

In a smaller study on 53 patients treated with Perkins traction, Gosselin and Lavaly (15) reported 9.3% of patients with malunion, 7.4% with nonunion, and 42.6% with pin tract infection. In general, it should be noted that comparisons between studies are difficult to make, as each study has its own definition and classification of traction associated problems. The studies are often limited by the observation period, so they may be unable to draw conclusions of long-term health effects and outcomes. According to Musajee (22), malunion of the femur can be defined as greater than 10°of varus or valgus deformation in the frontal plane, or 15°of anterior or posterior deformation in the sagittal plane. In general, the success rate of bone healing is influenced by the patient's general health profile, treatment administration time, severity of fracture, and patient compliance with treatment. In traction, insufficient reduction, slippage, or infections can cause malunions. Adverse effects of malunion include functional impairments to gait, limb shortening, and excessive stresses on other joints and body parts.

A study conducted by Tall et al. in 2012 (23) discussed using intramedullary (IM) nailing through open osteotomy surgery for correcting femoral shaft malunions in low income countries, and found 15 of 16 study subjects achieved union 3 months after surgical intervention. Musajee uses the clinical definition of nonunion as "motion at the fracture site after 8 weeks of traction". According to Ikpeme, Mkpanam, Abang, Ngim, and Udosen (24), patients with sub-par health profiles and nutrition are more likely to suffer from atrophic non-unions, which is classified as "failure of healing biology" and are usually treated with bone grafts. Fracture non-unions caused by over-distraction or the presence of soft tissue between bone segments are classified as hypertrophic and can be treated with just stabilization and compression. Infection can also play a role in causing septic non-union. In his study, Musajee (22) observed 75 femoral traction patients admitted to the Kenyatta National Hospital (KNH, Kenya) orthopedic unit over a three-month period. The study found that 24% of patients developed pin tract infection (PTI), which is strongly correlated with prolonged traction treatment time, with 6.7 weeks of hospitalisation as the average of patients who developed PTI and 4.2 weeks for the patients who did not. The paper defined PTI as the "infection of superficial or deeper soft tissues or by osteomyelitis", and can manifest through symptoms such as erythema, elevated temperatures, and drainage at the pin insertion site. The diagnosis of PTIs vary from study to study based on the severity, however minor infections could be as prevalent as 80% as reported by Clifford, Lyon, and Webb (25).

Due to the lack of mobility permitted during treatment using skeletal traction, patients often remain reclined in a supine position for long periods of time. Gefen (26) reports that pressure ulcers, which develop at deep muscles close to bony surfaces, propagate towards the surface and cause tissue necrosis if severe. The mechanism of pressure ulcer development is believed to be caused by ischemia (absence of blood supply to tissue). Alternatively, development may be caused by cellular deformation and strains as proposed by Breuls, Bouten, Oomens, Baijer & Baaijens (27). Previously the threshold "safe" pressure was believed to be 32 mmHg (4.3 kPa), measured from the surface, but this number has been challenged by Bouten, Oomens, Baaijens, Bader (28) due to the complexity of the ulcer formation process. However, it is understood that a time-pressure relationship exists, where high pressures can be safely applied for shorter time periods, and vice versa (26). According to Reenalda, Jannick, Nederhand & Ijzerman (29), other

factors that contribute to ulceration include moisture on the skin, obesity, malnutrition, mobility impairments, and shearing of the skin.

2 Expressed Need for Device

2.1 In-Country Context

In the Summer of 2015, members of the University of British Columbia's Biomedical Engineering Student Team (UBC BEST) travelled to Uganda and Kenya as part of an International Medical Device Initiative (IMDI). This initiative was created for the executive team of UBC BEST to identify and develop context-appropriate solutions to the medical and health care challenges being experienced in LMICs. During a number of visits to both higher and lower tiered health care facilities, the members witnessed an overwhelming number of orthopedic trauma caused by motor vehicle-accidents, particularly from boda bodas (motorcycle taxis). The increasing incidence of motor vehicle accidents have resulted in significant financial and resource strain on the health care and socio-economic systems across Uganda. One source notes that "[i]njury disproportionately affects the poor, with 83% of the 4.6 million global deaths from injury occurring in LMICs" (30).

Boda bodas have become a popular method of transportation in Uganda. Because of the large proportion of unemployed youth (62%) in Uganda and other similar developing nations, these youth have become reliant on this method of transportation as a source of income(31). The frequency of use coupled with the lack of road safety have contributed to the number of accidents and collisions increasing significantly. A healthcare professional from Uganda noted that 90% of patients admitted are vehicular accident victims and these accidents are most likely caused by boda bodas (32). With about 300,000 bodabodas operating in the capital, there are approximately 20 related medical cases daily at Mulago Hospital. A study by Kigera et al. calculated that yearly, treating patients from boda boda accidents in Uganda consumes 62.5% of the Directorate of Surgery's budget (33). This problem is not isolated to Uganda. Other countries such as Ethiopia, Kenya, Tanzania, India, and Mongolia would also benefit from improved femur fracture treatment practices.

In higher resource countries, the clinical practice for treating a femoral fracture follows an efficient streamline process to surgery. The Bone and Joint Health Network outlines the model flow of a health care continuum that aims to address 90% of hip fractures in surgery within a 48 hours timeline period(34) (Figure 2). In addition to a number of socioeconomic factors, that will be later discussed, treatment delays in LMICs are largely due to "bottlenecks" in the existing health system, which include a lack of adequate infrastructure, hospital beds, equipment, and specialised health care practitioners (35) .The time period between injury and treatment is when the body is most vulnerable to infection, thus it is imperative that patients receive immediate care. In Uganda alone, there is as few as one orthopedic surgeon per every 2 million people (36). In addition, LMIC hospitals and clinics are often unequipped with typical femur fracture surgical tools, such as the C-arm x-ray machine, due to its high cost and complexity.

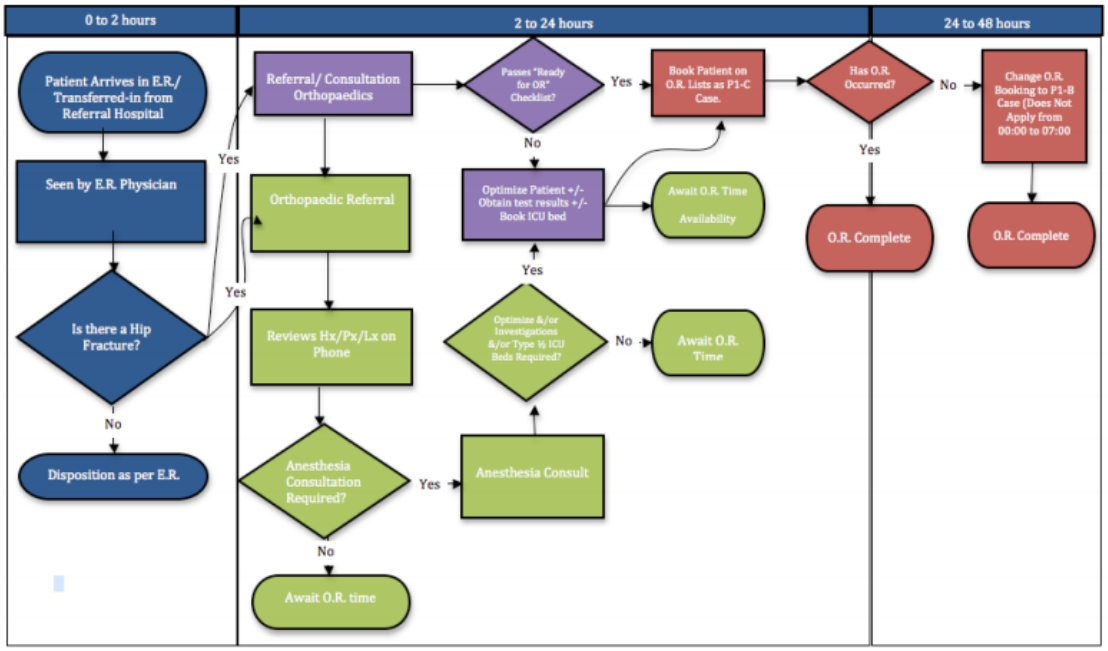

Figure 2: High-income Femoral Fracture Treatment Plan (37)

As a result, the Femur Fracture Treatment Project (FFTP) was started to improve treatment accessibility, reduce financial strain on patients and hospitals, and reduce treatment complications to allow patients to return to their everyday lives. We propose that the device be manufactured in-country, to provide additional benefits in terms of further stimulating the economic sector of the affected countries and improving the accessibility of the technology. To better assess the feasibility of adoption, acceptance and use, our team also emphasized the importance of testing product viability and identifying appropriate market places. This was done by establishing ongoing discussions with orthopedic and trauma surgeons, specialized researchers and end-users in country.

2.2 In-Country Validation of Device Need

There are many initiatives working on impacting the global burden of trauma in LMICs through improving surgical practice, access to surgery and more resource appropriate surgical technology; however there is only a small number of groups dedicated to improving treatment for patients who don't have the financial ability to obtain surgical treatment. As most femur fracture patients in LMICs are treated using traction, we believe that improvements in traction treatment are warranted in addition to improving accessibility to safe surgery.

The team prioritized early in-country collaboration in the design process in order to ensure that a context-appropriate solution could be developed. This consisted of developing a strong understanding the health care systems, infrastructures and the socioeconomic factors of different target segments. According to our research, the primary users and stakeholders of our device would be: orthopedic surgeons, orthopedic officers, and the patient. An orthopedic officer is a key healthcare worker in the Uganda medical system. They are specially trained in treatment and fracture care, and are key to the management of musculoskeletal injuries and management

of bone diseases. Orthopedic officers are particularly crucial in rural areas and lower tiered hospitals, due to the low number of trained orthopedic surgeons.

To better understand the needs of each of these stakeholders a formal collaboration with Biomedical Engineering Students at Makarere University in Uganda was started. With their help, we were able to conduct in-person interviews with orthopedic officers and orthopedic surgeons from the following hospitals: Jinja, Mulago, Arua, Entebbe, Hoima, Mbarara and Mbale.

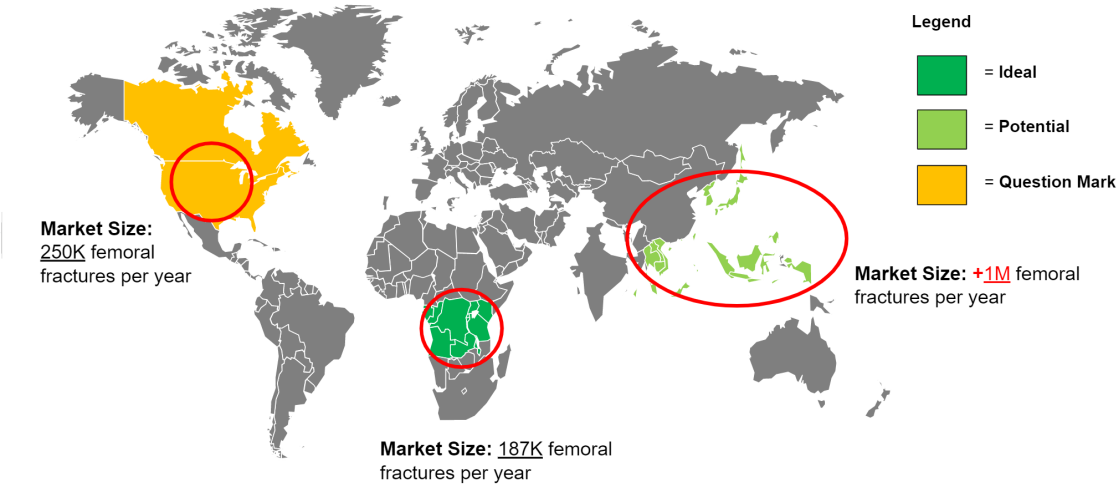

Figure 3: Internationally Identified Market Size

In addition to gaining a better understanding of the skeletal traction procedure, we were informed of the factors considered in choosing treatment options, as well as the typical demographics. For example, open fractures are almost always treated with surgery, and an external fixation is used in the case of clean open fractures. Although the best course of treatment for a femoral fracture is surgery, due to socioeconomic factors most patients do not have the financial means to finance it.

2.3 Improvements Offered by the Device

The original goal of the project was to improve patient outcomes through the design of a cost effective, clinically viable device for the treatment of femur fractures. It was deemed critical that our device offer a non-surgical solution to help alleviate some of the demand for orthopaedic surgeons, whom are scarce in many LMICs as described previously. Without the need for surgical intervention, our hope is that the device will make femur fracture treatment more accessible and affordable for patients. As well, reducing the hospital stay for patients suffering from femur fractures may allow medical resources to be reallocated to the treatment of other injuries, further reducing the burden on the healthcare system.

As well, mobilizing patients at earlier stages of recovery may present additional social and economic benefits as they can return to their families and return to the workforce earlier.Furthermore, we hope that the device can relieve some of the financial strain experienced by the healthcare system and its patients as a result of costly medical supplies and the long hospital stay that accompanies treatment. Ultimately, the goal of the device is to improve the healing process and

quality of post-trauma life of those who have suffered a femur fracture, without applying undue costs on the patient or their community.

3 Device Requirements and Evaluation Criteria

Outlining target specifications and device requirements is an essential step in clearly identifying the primary functions of the device. A full table outlining the device specifications and requirements is available in Appendix E. Table 1 is an excerpt of the table, highlighting the primary requirement specifications (RS) identified through collaboration with health care professionals, and literary research. The primary requirements may also be used as evaluation criteria when the correct verification tests are developed. Note that the specific shape of user satisfaction curves should be defined in coordination with end users, as suggested in the Recommendations section of this report.

Table 1: Needs and Requirements

RS	Need Statement	Requirements/Evaluation Criteria	Justification
1	Device must reduce and maintain fracture axially.	Axial gap between bone fragments is no more than 1mm, and is not overlapping more than 15mm after device use.	"[femoral shaft malunions] Become significant only if they result in shortening of $\geq$ 2.5 cm" (38) "In the opinion of some authors, even fractures initially presenting with $\geq$ 2.5 cm, limb shortening can be successfully treated conservatively, but according to others, the risk of limb shortening is 20.4 times as high as in cases presenting $\geq$ 30 mm overlap at the fracture site." (39) "Two essential criteria are to be considered in indicating external therapy: non-union site inter-fragment gap less than 10 mm, and stable osteosynthesis" (40)

Table 1: Needs and Requirements

RS	Need Statement	Requirements/Evaluation Criteria	Justification
2	Device is capable of altering lateral/medial angular fracture gap to acceptable angle relative to alignment before fracture (relative to longitudinal axis)	The maximum angle of varus/valgus alignment to lower limb's longitudinal axis to be between 0-10° after device use.	"When portable x-rays are available, AP and lateral views should be taken after 48–72h and weekly for the next 3 weeks. Overriding by 1–1.5 cm is acceptable as long as alignment in both the frontal and sagittal planes is adequate (less than 10° of varus/valgus and 15° of anterior/posterior angulation)." (41) "Acceptable reduction in the tibia is characterized as greater than 50% cortical contact, less than 10°angulation in any plane, less than 5°valgus or varus tilt, less than 10°of anterior or posterior angulation, less than 10°of rotation and less than 10mm leg length discrepancy." (24) "Healing with more than 10° of varus or valgus in the frontal plane, or 15° of anterior/posterior angulation in the sagittal plane will be considered a mal-union." (22) Max threshold: 10 degrees varus/valgus in frontal plane (38)

Table 1: Needs and Requirements

RS	Need Statement	Requirements/Evaluation Criteria	Justification
3	Device is capable of altering posterior/anterior angular fracture gap to acceptable angle relative to alignment before fracture (relative to longitudinal axis)	Maximum angle of of anterior/posterior angulation with respect to saggital plane is between 0-15° after device use	"Acceptable reduction in the tibia is characterized as greater than 50% cortical contact, less than 10°angulation in any plane, less than 5°valgus or varus tilt, less than 10°of anterior or posterior angulation, less than 10°of rotation and less than 10mm leg length discrepancy." (24) "Healing with more than 10° of varus or valgus in the frontal plane, or 15° of anterior/posterior angulation in the sagittal plane will be considered a mal-union." (22) "Overriding by 1–1.5 cm is acceptable as long as alignment in both the frontal and sagittal planes is adequate (less than 10° of varus/valgus and 15 of anterior/posterior angulation)." (41)

Table 1: Needs and Requirements

RS	Need Statement	Requirements/Evaluation Criteria	Justification
5	The device does not introduce any significant risks of pressure ulceration/deep tissue injury at the interface between the device and the patient	Pressure at interface region does not exceed 50mmHg (6.67kPa).	PUs [pressure ulcers] have great individual variance, but clinical studies show their onset begins after several hours of sustained pressure (26) 2 hours is the time threshold where the pressure limit seems to drastically decrease (in animal studies). (26) "Inverse (but undefined) relationship between pressure sustained and time." "Muscle damage can occur under high pressure, short time, but skin damage occurs under high pressure, long time." "Many extrinsic contributing factors." (42) "Found ulceration in mice with 50 mmHg of pressure, postulated that this would be similar in other mammals"(43) "Pressure greater than 50-60 mmHg can cause pressure ulcers". (Personal Communication, Rehabilitation healthcare professionals)

Table 1: Needs and Requirements

RS	Need Statement	Requirements/Evaluation Criteria	Justification
6	The device should for the allow the redistribution of pressure application in regular time intervals (passively or actively)	Immobilization time does not exceed 2 hours	PUs [pressure ulcers] have great individual variance, but clinical studies show their onset begins after several hours of sustained pressure (26) 2 hours is the time threshold where the pressure limit seems to drastically decrease (in animal studies). (26) "Inverse (but undefined) relationship between pressure sustained and time." "Muscle damage can occur under high pressure, short time, but skin damage occurs under high pressure, long time." "Many extrinsic contributing factors." (42) "Found ulceration in mice with 50 mmHg of pressure, postulated that this would be similar in other mammals"(43) "Pressure greater than 50-60 mmHg can cause pressure ulcers". (Personal Communication, Rehabilitation healthcare professionals)

4 Device Description, Testing & Conclusions

The current device incorporates a fibreglass cast with air bladders, straps, and a pneumatic piston system with the intention of achieving the requirements outlined above and in Appendix E (Figure 4).

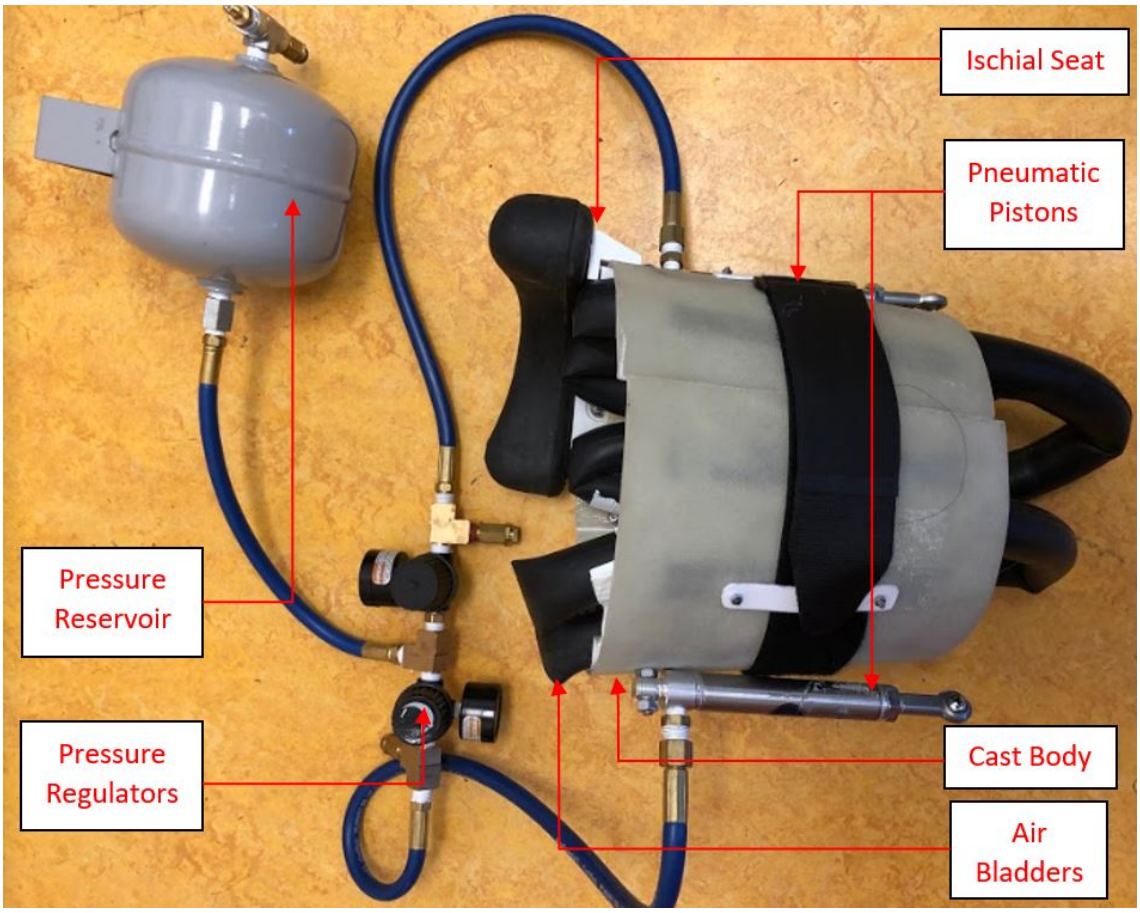

Figure 4: Femur Fracture Treatment Project Device

A force is applied through two pneumatic pistons, causing the distal fracture fragment to move away from the proximal segment (reduction). Each pneumatic piston is equipped with a separate pressure regulator to allow for lateral, medial adjustment of the distal fragment. Pistons are able to rotate about anchor points to the cast, allowing the physician to guide the rotational alignment of the distal fragment during reduction. The reactionary force from the pistons is grounded to the ischial tuberosity at the posterior ischium via the ischial seat. Air bladders are implemented inside the cast body to provide stability to the fracture site post-reduction, in conjunction with the rigid fibreglass cast. The modular air bladder compartments also allow for micro adjustment in posterior/anterior directions through alternating inflation. Another benefit that this design presents is that it allows for the redistribution of pressure at scheduled time intervals. A detailed list of parts used is included in Appendix F for reference.

A description of the current state of requirement verification testing is included in the sub-section below.

4.1 Device Verification Testing

In order to verify that the device is able to perform its intended functions, the sub-systems responsible for fulfilling major requirements were researched and tested using physical models. Note that additional verification testing is required to ensure that RS 1-14 are satisfied. Next

steps of the verification testing are discussed in the Conclusions and Recommendations section.

Pneumatic System Sealing: as described above, the force delivery system consists of two pistons connected to a pneumatic supply. It is essential that the system is appropriately sealed and can maintain force application to meet RS 1. The pneumatic system testing aimed to determine whether or not the pneumatic system leaked at operating pressure. The system was pressurized and pressure was monitored for increments of time up to 164 hours. No change in pressure was detected, which is a favorable result and suggests that there is no significant system leaking.

Force Testing: The design was tested to ensure that the system responsible for reduction was able to impart the appropriate amount of force given an input cylinder pressure, and maintain force application to meet RS 1 (Figure 5). It was found that input pressure (psi) and output force (kg) followed a linear relationship per Figure 6. A detailed testing procedure is included in Appendix A for reference.

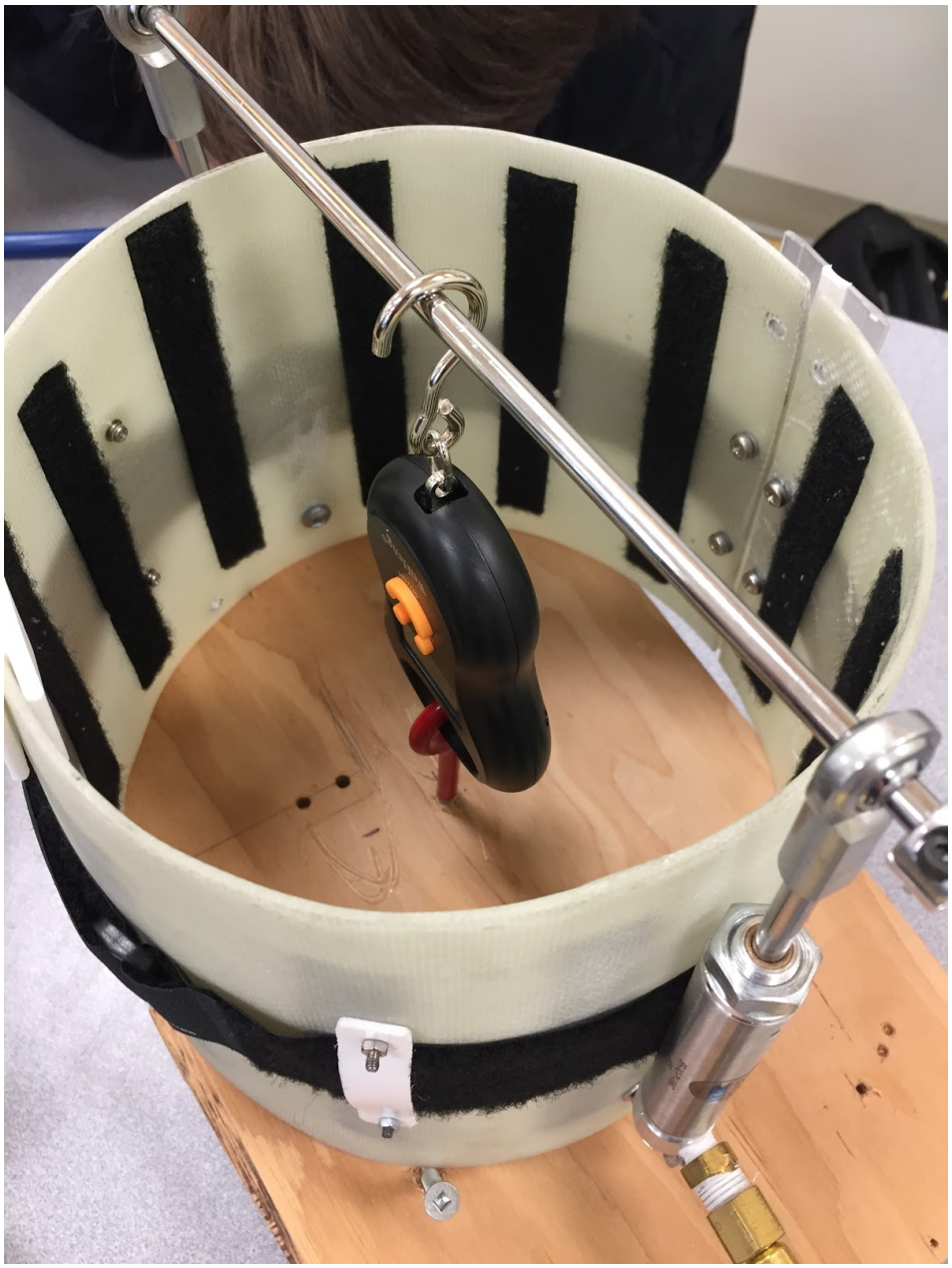

Figure 5: Applied Force Calibration Test Setup

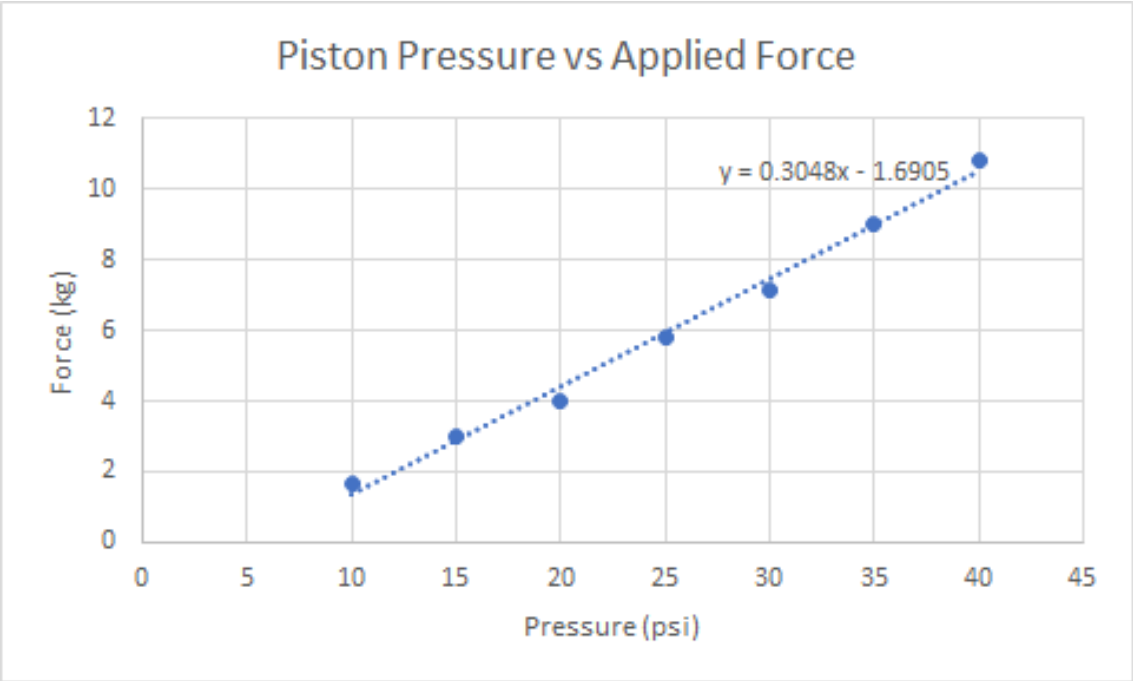

Figure 6: Applied Force Calibration Curve

Axial Reduction and Posterior/Anterior Alignment: axial reduction of the distal bone segment relative to the proximal segment is necessary to meet the criteria outlined in RS 1. As well, the device should be able to adjust the posterior/anterior fracture gap within an acceptable range per RS 3. Using a proof on concept test with a small test sled (Figure 7), blue arrows signify direction of force application and distal segment movement), it was confirmed that the distal segment moves in the intended direction when an axial force is applied from the device, and it is possible to adjust the posterior/anterior fracture gap through inflation of air bladders within the cast body. No resistance to mimic the effect of surrounding tissue was included in this model. Further testing including a model of the surrounding tissue and an accurate measurement method is required to verify that the device meets criteria outlined in RS 1 and 3.

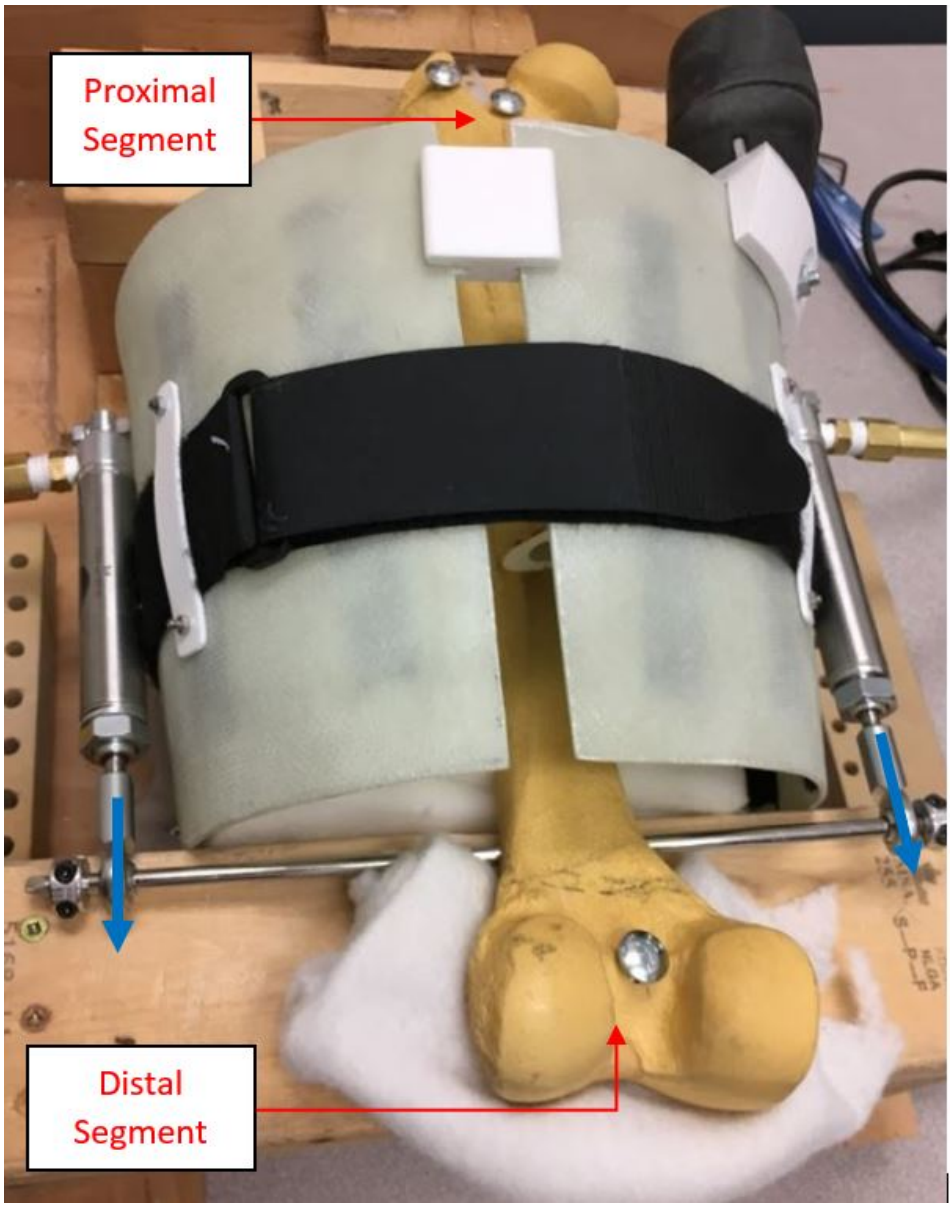

Figure 7: Axial Reduction, Posterior/Anterior Alignment Proof of Concept Test Setup

Lateral/Medial Alignment: correcting lateral/medial misalignment of the bone segments is important to positioning the bone in such a way that it will heal correctly. The device should be able to adjust the lateral/medial fracture gap per RS 2. The lateral/medial alignment test served as a proof of concept that the dual action of the pistons at non-proportional pressures can correct such an alignment (Figure 8). Rubber bands were used to simulate tissue resistance. The test was found to be successful in adjusting the alignment angle of the distal bone segment. Further testing that includes a model of the surrounding tissue and an accurate measurement method is required to verify RS 2.

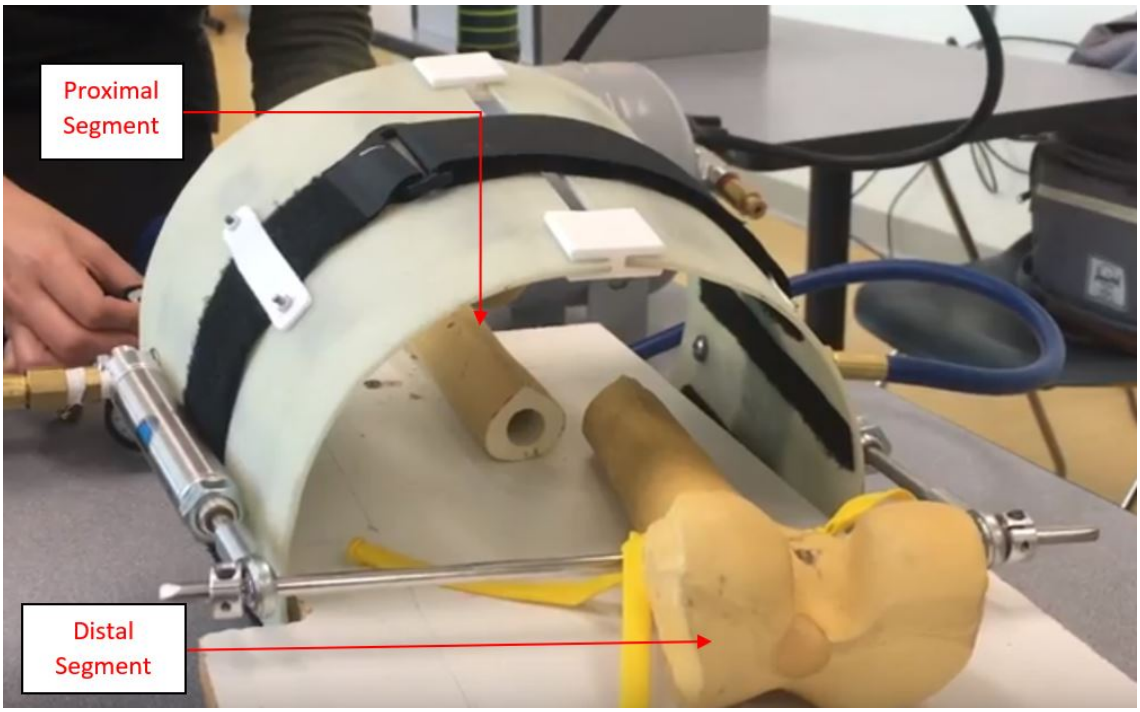

Figure 8: Lateral/Medial Alignment Proof of Concept Test Setup

4.2 Device Verification Testing, Pressure Testing

4.2.1 Introduction

One major area of concern that was identified by specialists in the field (doctors, surgeons, in-country health care personnel) was the introduction of pressure ulcers. Since the device is intended to apply traction to the leg, it must be strapped around the thigh for up to 6 weeks as constant pressure from the surrounding air bladders holds the device in place. The formation of pressure ulcers is a function of both the magnitude of applied pressure and the time that it is applied, as outlined in the requirement specifications (Appendix E). Specifically, RS 5 suggests that the interface pressure between the device and tissue should be less than 50 mmHg (6.67 kPa) to avoid tissue necrosis or damage. The device was anchored to rigid anchor points to facilitate pressure application, which are circled in red in Figure 9.

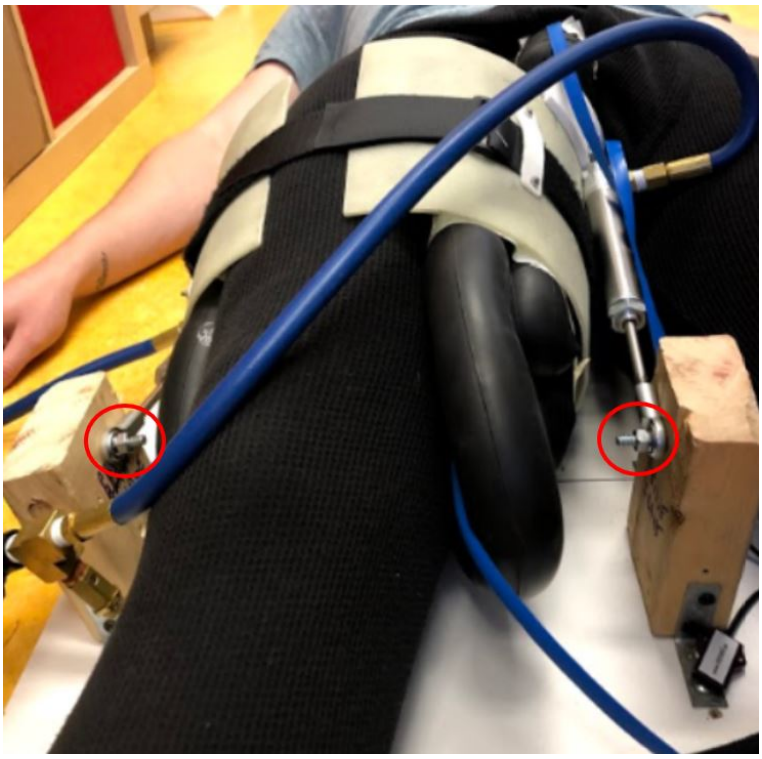

Figure 9: Device Anchor Points

4.2.2 Summary of Methods

The Novel Pliance-X system was used for testing, and MATLAB was used for post-processing of the data. Pressure sensors were placed at the following locations in both supine and seated positions (Figure 10):

1. Insertion point of adductor longus to the pelvis (Position A)
2. Ischial tuberosity (Position B)
3. External surface of thigh, inside cast (Position C)

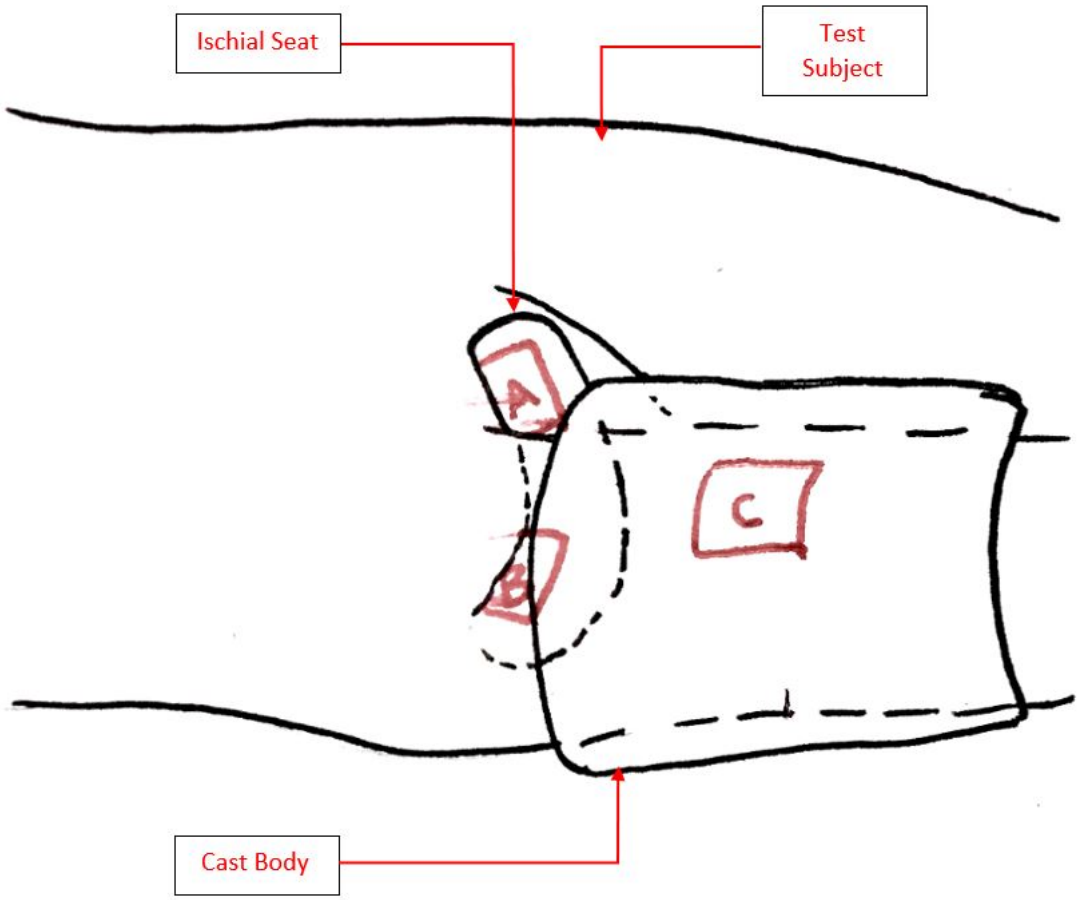

Figure 10: Pressure Testing Positions on Ischial Seat and Air Bladder Interface

Figure 11 shows a photo of the sensors fixed in place. The position 'A' sensor is visible at the top of the photo, while the position 'B' sensor is visible near the bottom. The position 'C' sensor is not visible and is located within the cast.

Figure 11: Verification Pressure Testing Positions on Ischial Seat and Air Bladder Interface, Positions 'A' and 'B'

The test subject was an adult male of 92kg (200 lbs). The typical traction force applied for skeletal traction maintenance is 10-15% of the patient's body weight (44; 45), which corresponds to a 90-136N applied force range for the test subject weight. Tests were conducted with 10%, 15% and 20% of the patient body weight in separate trials. The detailed test procedure is included in Appendix B for reference. The full set of results are included in Appendix C.

4.2.3 Results

Results: Initial Long-Term Application Interface Pressure Measurement

An initial test was conducted to explore how interface pressure may vary during long-term application. Results are shown in Figure 12 below.

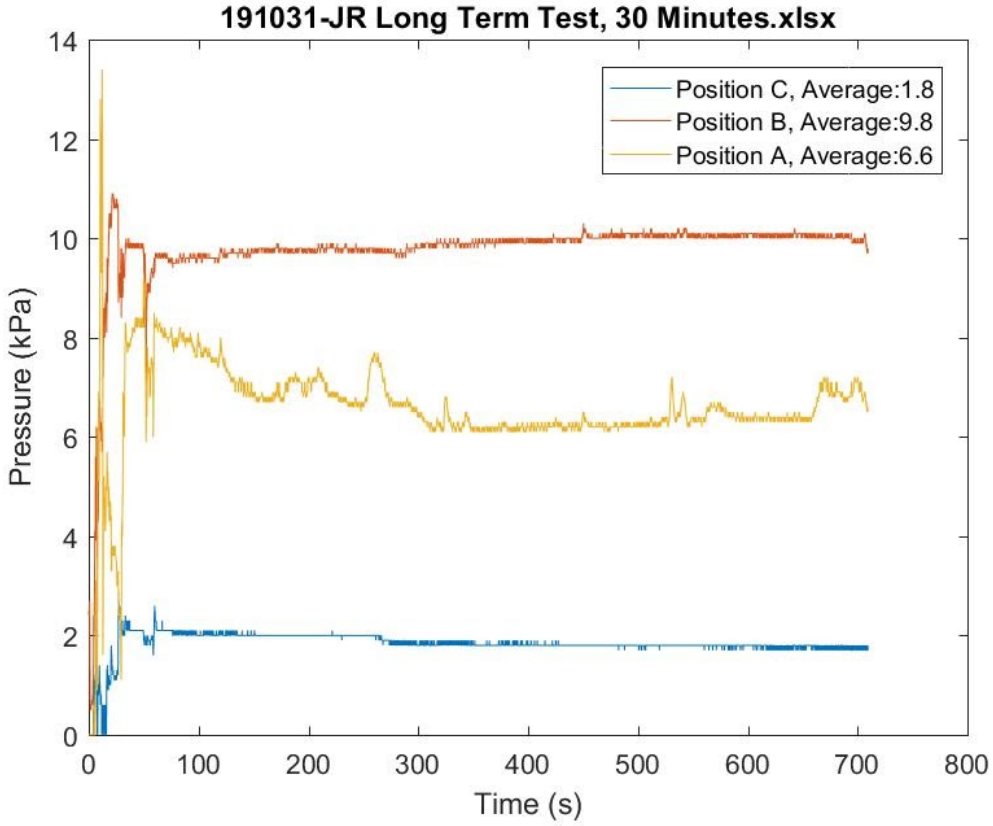

Figure 12: Pressure (kPa) vs. Time (Seconds). 30 Minute Trial. Supine Position, 10% Body Weight

Results: Interface Pressure Measurements

Average pressure values for each position are shown below in Tables 2 and 3. Graphs for each case are included in Appendix C.

Table 2: Average Pressure Over Test Interval, Supine Position. Locations, A, B and C.

-	Position A, kPa [mmHg]	Position B, kPa [mmHg]	Position C, kPa [mmHg]
10% B.W	3.1 [23.3]	8.3 [62.2]	2.1 [15.8]
15% B.W	8.8 [66.0]	9.7 [72.8]	2.4 [18.0]
20% B.W	3.1 [23.3]	14 [105.0]	2.6 [19.5]

Table 3: Average Pressure Over Test Interval, Seated Position. Locations, A, B and C.

-	Position A, kPa [mmHg]	Position B, kPa [mmHg]	Position C, kPa [mmHg]
10% B.W	12 [90.0]	11 [82.5]	1.6 [12.0]
15% B.W	16 [120.0]	6.8 [51.0]	2.5 [18.8]
20% B.W	19 [142.5]	9.1 [68.3]	2.8 [21.0]

4.3 Discussion and Conclusions

Conclusions from verification testing were as follows:

4.3.1 Verification Test Results

Initial verification tests to explore the ability of the device to satisfy RS 1-3, 5 were conducted. It was shown that the device is capable of providing the axial force necessary to illicit fracture reduction, as well as posterior/anterior and medial/lateral forces necessary to align the fracture under simplified conditions.

4.3.2 Verification Test Results, Pressure Testing

Pressure testing was conducted to explore the device's ability to satisfy RS 4. Results and limitations of this testing were as follows:

Initial Long-Term Application

Figure 12 suggests that pressure tends to remain constant or decrease over time following device application.

Supine Position

Measured interface pressure values for 10-20% B.W cases in position B (ischial tuberosity) were found to exceed the 50mmHg (6.67 kPa) threshold. the 15% B.W case in position A (medial leg/groin) was also found to exceed the threshold. As % B.W increased in the trials, it was found that a greater proportion of pressure, and corresponding applied force was concentrated on the ischial tuberosity (position B).

Seated Position

Measured interface pressure values for 10-20% B.W cases in positions A and B were found to exceed the 50mmHg (6.67 kPa) threshold. The magnitude of pressure values were found to be generally greater in the seated position than in the supine position.

Sources of Error

Some potential sources of error were identified during the pressure testing:

1. The measured pressure values for the initial long-term application trial (position A) were found to be approximately 72% greater than values found in Part B trials (Supine condition, 10% B.W; Sample Calculation 1, Appendix D). As well, significant transient variation between 0-400 seconds was also noted at this position. These discrepancies may be due to different seat positioning and movement between trials. This result may suggest that pressure at the device interface may vary depending on patient size and position.

2. We assumed that anchoring the device to the test setup via the piston rod ends was sufficient to model the attachment of the device to the distal pin under actual treatment conditions (Figure 9). This method may introduce error due to patient movement and interactions with the device.

4.4 Plan for Device Validation Testing

Validation testing will be conducted to assess the device performance against user needs through end user feedback. It will also be used to assess the usability of the device and evaluate the user's satisfaction with the final prototype. This open ended feedback may also help the design team in identifying additional opportunities for design improvement. The following topics will be explored as part of validation testing:

- Device usability
- Device ergonomics
- Axial fracture reduction
- Lateral/medial alignment
- Posterior/anterior alignment

Device ergonomics and usability can be tested by allowing the user to use the device and provide feedback. Device reduction and alignment capability will be confirmed through verification testing before being tested as part of validation testing. IEC 62366-1 (Application of Usability Engineering to Medical Devices), FDA usability engineering guidelines and any other guidelines used in the relevant LMIC should be consulted in designing the final validation test.

4.4.1 Users

The intended users of this device are orthopaedic surgeons or orthopaedic officers working in LMICs. User recruitment may be conducted by contacting local orthopaedic surgeons and residents through physicians that have already consulted on the project. If access to physicians is limited, the usability of the design and device ergonomics may be evaluated using non-technical users that are not involved with the project to remove bias. Contacts in Uganda may assist in recruiting surgeons and orthopaedic officers in target LMICs.

A sample methodology for validation testing is presented in the sub-section below.

4.4.2 Methods

Present the device to the users and give a brief description of what the device does:

"This is a femoral traction device used to treat femur fractures by applying a force with the use of two pneumatic pistons. The pneumatic pistons are controlled using separate pressure regulators to allow for lateral and medial adjustment of the distal fragment. Air bladders contained within the cast are used to provide stability as well as posterior and anterior adjustments on the bone segments."

Place the device in a simulated set-up with a pin rigidly attached to a model fractured femur (similar to the set-up in Section 4.1 Device Verification Testing). The team should only provide guidance when prompted. Make observations throughout the process and note when the user requires assistance. It should be noted whether the procedure outlined below is followed. A list of observations and questions are listed below.

After giving the brief description above to the user, ask them to perform the following tasks:

1. Fill the tank with compressed air using bike pump
2. Apply equal force to reduce the distal fragment per RS 1
3. Align the distal fragment in the lateral/medial direction to meet RS 2
4. Align the distal fragment in the posterior/anterior direction to meet RS 3

4.4.3 List of Observations and Questions

Observations:

1. Note the profession of the user. Do they have previous knowledge of the device?

Task 1:

2. Note the pressure inside the air tank after it has been filled.
3. Did the user experience any difficulties attaching/detaching the bike pump to the tank?

Task 2:

4. Note the pressure in each piston after task 2 in section 4.3.2 is completed.
5. Did the user adjust the pressure regulators simultaneously or independently?

Task 3:

6. Note the pressure in each piston after task 3 in section 4.3.2 is completed.
7. Note the displacement, in mm, of the distal fragment from the proximal segment in the lateral/medial direction.

8. Did the user adjust one or both pistons? In which order?

Task 4:

9. Note the displacement, in mm, of the distal fragment from the proximal fragment in the posterior/anterior direction after task 4 in section 4.3.2 is completed.
10. Note which air bladders were filled.
11. Did the user require any guidance during this step?

Usability:

12. Did the tank run out of air and have to be refilled before all tasks were completed?
13. Assess how intuitive the design is and whether it is used as intended. How long did the procedure take to complete?
14. How many steps did they use to complete the procedure?
15. How many times did the user ask the team for help?
16. Were the steps followed in the correct order?
17. Did the user miss any steps required to complete the tasks?

Additional Questions for the user:

1. How simple did you find the process? Gather general feedback.
2. How sensitive did you find the control of the pistons? (i.e. too sensitive, not sensitive enough or just right)
3. How useful do you think this device is?
4. Would you use this device as an alternative to surgery?
5. Would you use this device as an alternative to a traction table?
6. Do you have any suggestions on how to improve the device?

5 Recommendations

Based on the verification testing conclusions and current state of the device, the following are recommended as the next steps in project development:

1. As the verification tests described for RS 1-3 were preliminary, revised tests should be developed to include accurate tissue models and methods of measurement. Results of additional verification testing should motivate device modifications to achieve ideal function.
2. Pressure testing (RS 5) should be revised to include either an ex-vivo or tissue model that allows insertion of the traction pin per the actual procedure. Multiple trials should be used to reduce variation in results.

3. Additional verification tests should be developed to ensure that RS 4, and RS 6-14 are satisfied. Results of additional verification testing should motivate device modifications to achieve ideal function.

4. The most important requirements (Table 1) should be used as evaluation criteria and a measure of device performance. Satisfaction curves should be developed in coordination with end users.

5. The validation testing proposed in the above sections should be reviewed per IEC 62366-1 (Application of Usability Engineering to Medical Devices), FDA usability engineering guidelines and any other relevant guidelines. Validation testing should be conducted to test device function against end-user expectations.

6. In-country clinical trials in compliance with applicable regulatory standards should be conducted on completion of the final design. Pending the conclusions of the clinical trials, the device may advance to the design-for-manufacturing stage, at which point the device may be optimized for production, storage, and distribution in mass quantities.

7. A partner organization interested in carrying forth with further verification and validation testing, design optimization, and implementation should be sought. The support of people who are knowledgeable of the regulatory process and can provide guidance on implementation strategies is critical for the device to be able to make its intended impact in-country. Another possible direction could be to open-source the technology to the public, thereby making documentation from previous stages in the process available for other groups to review and proceed with advancement.

8. Implementation of the device in-country is the ultimate goal. Upon implementation, it is important that this treatment method be culturally adopted, which would most likely occur through widespread use and as successful cases inspire the confidence and trust of local communities, and physicians.

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[60] T. Byrne, *Zimmer Traction Handbook: 9th Addition.* Zimmer Orthopaedic Surgical Products Inc., 2005.

7 Appendix A: Force Calibration Procedure

7.1 Introduction

The purpose of this test is to determine the equivalent output force from the pneumatic pistons for specific input pressures. Results will be used to create a calibration curve of input pressure vs. output force, which will allow for correct setting of traction force based on patient body mass.

7.2 Materials and Part Numbers

- Pressure regulator with gauge (Mcmaster part: 1000841264)
- Right-Angle Tee Adapter (Mcmaster part: 50785K222)
- Two (2) Lightweight Air Hoses (Mcmaster part: 50475K49)
- High-Pressure threaded pipe fittings (Mcmaster part: 5485K31)
- Pistons (Mcmaster part:6498K524)

7.3 Assembly Notes

Teflon tape is used to create air tight fittings. Piston connections to the cast body are rigidly fixed in axial, with one degree of freedom (rotational). Note that an applied force of 80lbs (36 kg) is expected at 200 psi from the piston datasheet.

7.4 Methods

The body of the cast is placed upright on piece of plywood and fixed in place using wood screws. A scale is screwed into the plywood and centered at the middle of the cast body. The pressurized pneumatic system was attached to the pin, and connected to a scale (Figure 5).

1. Screw the force gauge into plywood; sit cast body onto the plywood so the force gauge is centered. Insert several screws into the wood surrounding the cast body to hold it in place.
2. Insert the pin through pistons rod ends, fix with clamps, attach the other end of the force gauge to the pin.
3. Slowly apply the same amount of pressure into the pistons until the pistons extend and the force gauge reads a non-zero force. This is the datum (0) value of the set up and record as 0kg in a table.
4. Increase the pressure in each piston by 5 psi and record the corresponding force value in the results table.
5. Repeat until 60 psi is reached (or maximum value for force gauge is reached).
6. Plot the results to obtain a pressure vs. force calibration curve.

8 Appendix B: Pressure Testing Procedure

8.1 Introduction

The test subject is an adult male of 92kg (200 lbs). The typical traction force applied for skeletal traction maintenance is 10-15% of the patient's body weight (44; 45), which corresponds to a 90-136N applied force range. Per Equation 1 below (developed from force calibration testing, Appendix A), 20psi is selected to produce a force of 90N:

$$(m/2 + 1.69)/(0.3048) \tag{1}$$

The resolution of the gauge on the pressure regulator is 5psi resulting in an uncertainty in output force of +- 5.5N. In the example case of a 92kg subject, this represents 20 +- 2.5psi, or approximately 90.2 +- 5.5N. The calculated force is from the combined effect of both pistons.

An initial 30 minute test will be performed to determine the fluctuation of pressure experienced over an extended period of time. If the pressure is found to remain constant or decrease over time, the remainder of the data points will be recorded shortly after the force application. If the pressure is found to increase over time, all data points will be recorded when the pressure stabilizes.

8.2 Methods

8.2.1 Test Setup and Assembly

1. Pressurize the air compressor tank to 80psi using the bike pump. The tank pressure is monitored using the bike pump pressure gauge.

2. Refer to the Novel Pliance-X Operating Procedure for system setup procedure. Note: do not insert leg into cast until sensors have been unloaded.

3. Insert the leg through the air bladder cast and use velcro straps to secure.

8.2.2 Test Procedure

Tests are performed with the person lying on a flat surface with shoulder anchors fixed. The force applied to the subject through the device pistons is transmitted through fasteners into supports mounted on the platform, as shown in Figure 9. The piston force tends to move the test subject backwards, which would not occur were the pin inserted through the patient's leg and acting as a second grounding point. Two padded blocks at the test subject's shoulder level prevent backwards motion, as shown in Figures 13, 14 below.

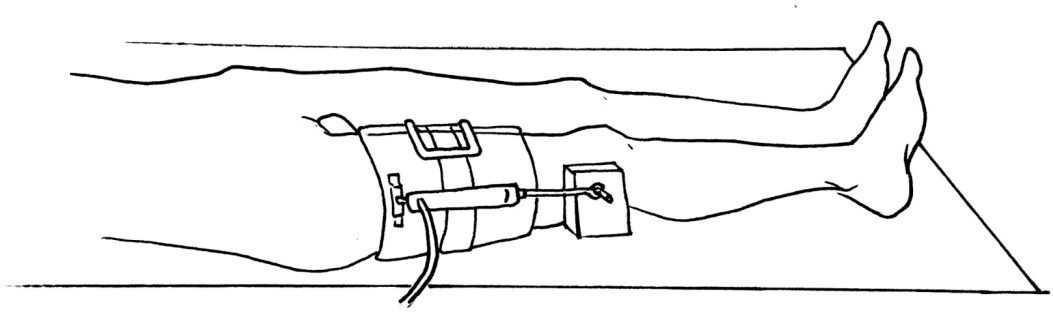

Figure 13: Verification Pressure Testing, Supine Position Configuration (Side View)

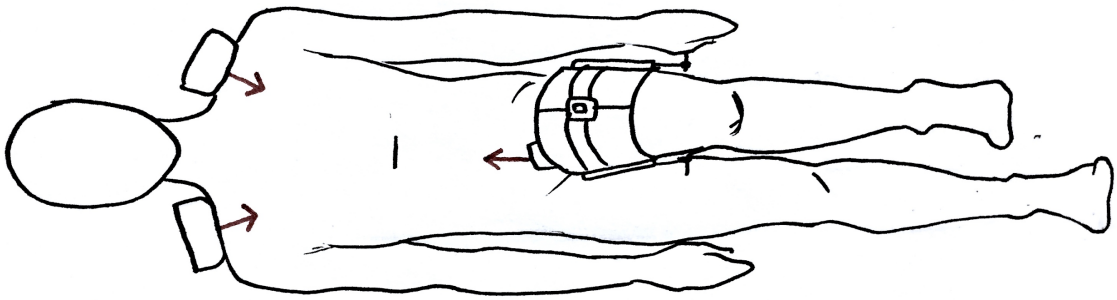

Figure 14: Verification Pressure Testing, Supine Position Configuration (Top View)

8.2.3 Initial Measurements

1. Place sensors at all positions and fix firmly to test subject with tape.
2. Ensure connection of piston rod ends to the anchor points on the plywood base (Figure 9).
3. Attach the prototype to test subject using the strap, and inflate all air bladders to comfort level of test subject. The device should fit snugly on the test subject's thigh.
4. Secure test subject's location relative to device using anchor points at the shoulders (Figure 14).
5. Apply traction force by slowly turning the pressure regulator valves simultaneously and checking the display for the appropriate pressure. Ensure equal force is applied in each piston.
6. Start recording data as per the attached Novel Pliance-X Operating Procedure. Record data for 30 minutes. Movement of the test subject should be as limited as much as possible

during this time. Measurements will be taken starting at twenty (20) seconds after initial force application. Measure pressure until the measured pressure value has been stable for ten (10) minutes.

7. Rename .csv output file according to convention date-locationx-data.

8. Disconnect power from Novel module.

8.2.4 Initial Measurement Analysis

1. Graph the pressure recorded during the 30 minute testing interval outlined in the 'Initial Measurements' section to evaluate the change in pressure over time.

2. If pressure decreases over time, follow the steps outlined below in the 'Supine Position' section, recording pressure values for two (2) minutes in Step 5. Take the average pressure value over this 2 minute period.

3. 3 If pressure increases, follow the steps outlined below in the 'Supine Position' section, recording pressure values until stable for 10 consecutive minutes in Step 5. Take the average pressure value over this 10 minute period.

8.2.5 Supine Position

1. Ensure connection of piston rod ends to the anchor points on the plywood base (Figure 9).

2. Attach the prototype to test subject using the strap, and inflate all air bladders to comfort level of test subject. The device should fit snugly on the test subject's thigh.

3. Secure test subject's location relative to device using anchor points at the shoulders (Figure 14).

4. Apply traction force by slowly turning the pressure regulator valves simultaneously and checking the display for the appropriate pressure. Ensure equal force is applied in each piston.

5. Start recording data as per the attached Novel Pliance-X Operating Procedure. Record data for the time determined in the 'Initial Measurement Analysis' section. Movement of the test subject should be as limited as much as possible during this time. Measurements will be taken starting at twenty (20) seconds after initial force application.

6. Rename .csv output file according to convention date-locationx-data.

7. Disconnect power from Novel module.

8.2.6 Seated Position

Modify the test setup such that the person is in a seated position. The steps to do so are listed below (Figure 15):

1. Disconnect piston rod anchors from plywood base.

2. Remove shoulder anchors.

3. Move location of piston rod anchors so that the test subject is supported against a wall and the cast is around the subjects thigh.

4. Fix piston rod anchors to base.

5. Insert leg into cast.

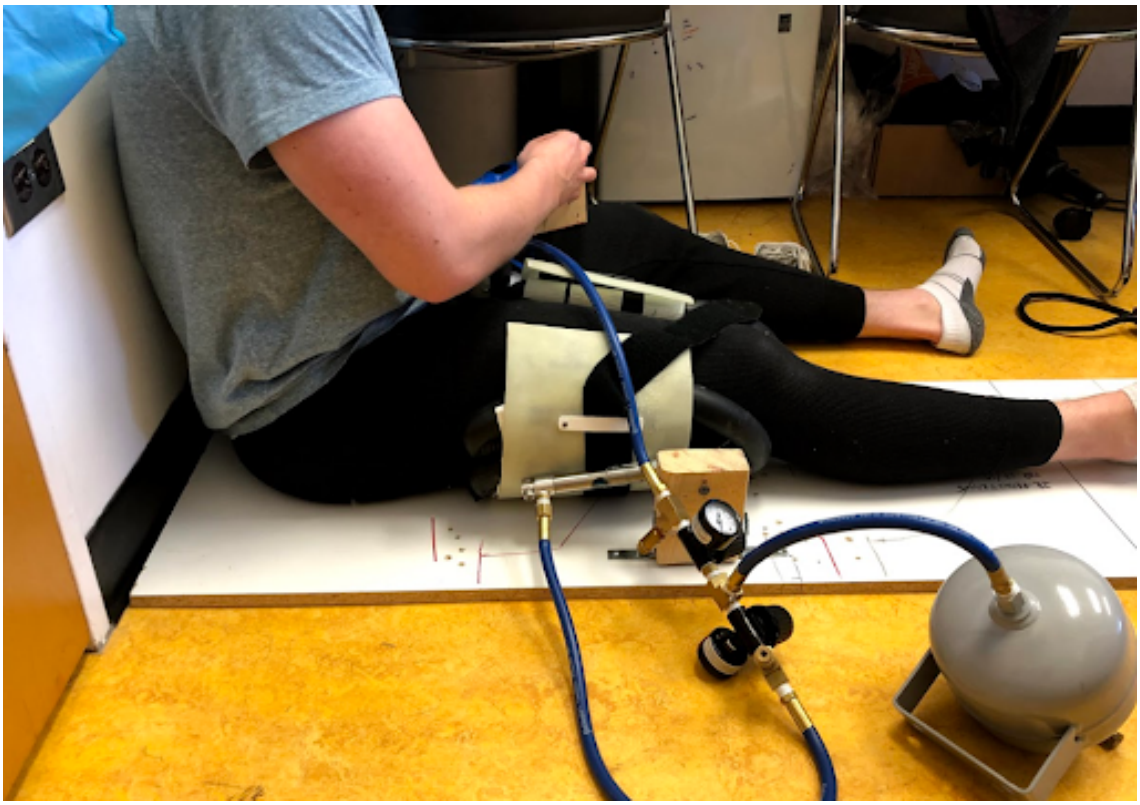

Figure 15: Verification Pressure Testing, Seated Position Configuration (Side View)

Repeat steps 1-7 from the 'Supine Position' section with test subject in the seated position.

9 Appendix C: Pressure Testing Results

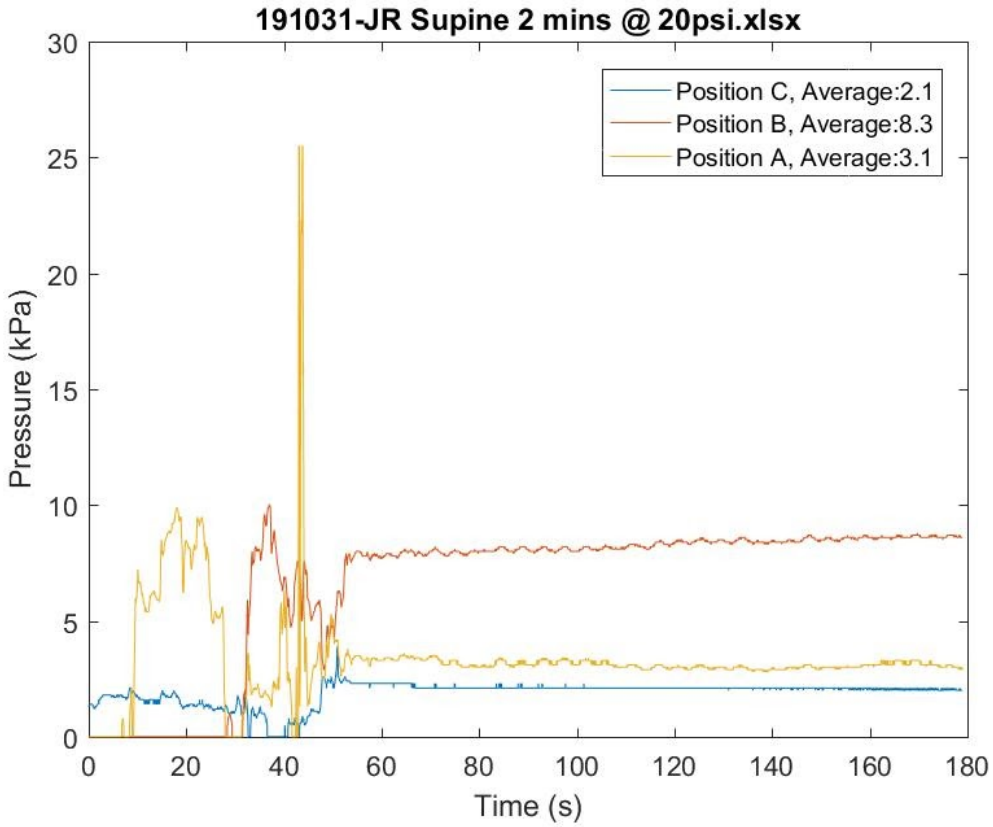

Figure 16: Pressure (kPa) vs. Time (Seconds). 2 Minute Trial. Supine Position, 10% Body Weight

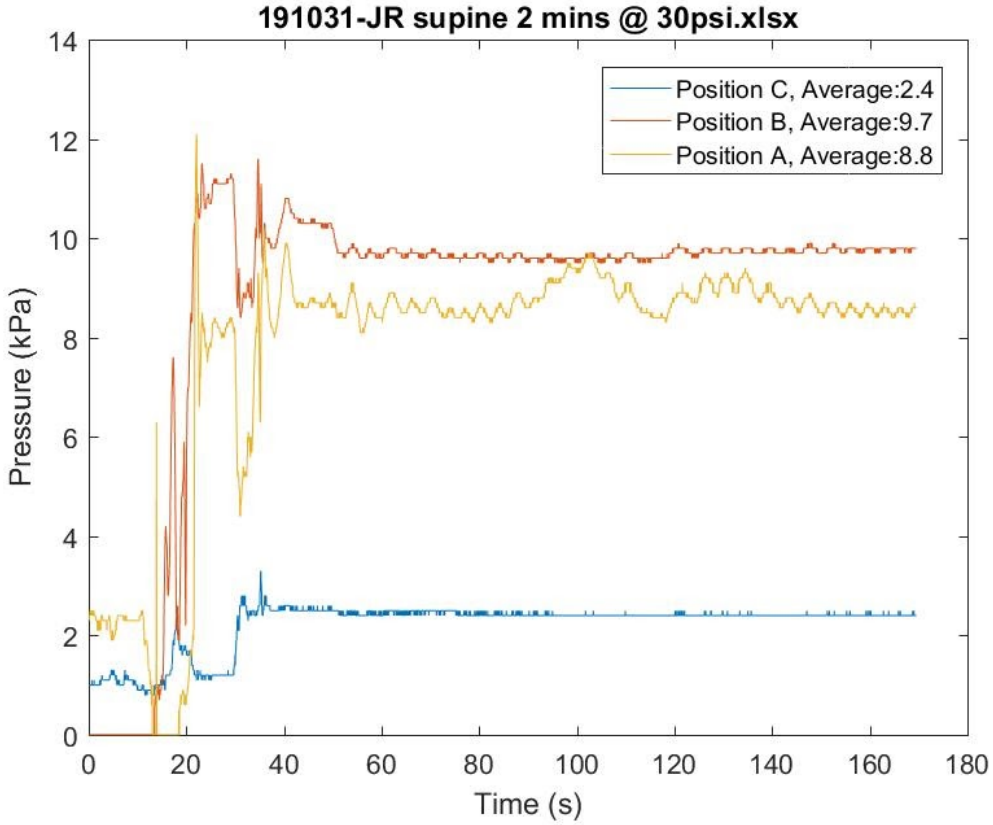

Figure 17: Pressure (kPa) vs. Time (Seconds). 2 Minute Trial. Supine Position, 15% Body Weight

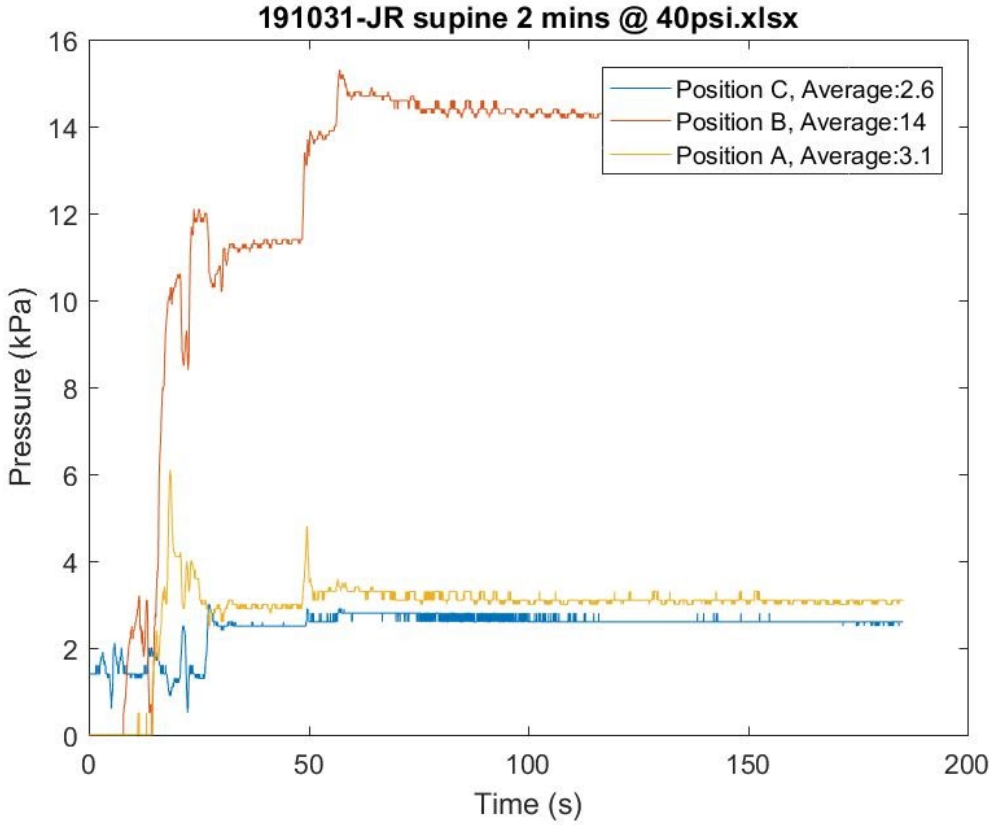

Figure 18: Pressure (kPa) vs. Time (Seconds). 2 Minute Trial. Supine Position, 20% Body Weight

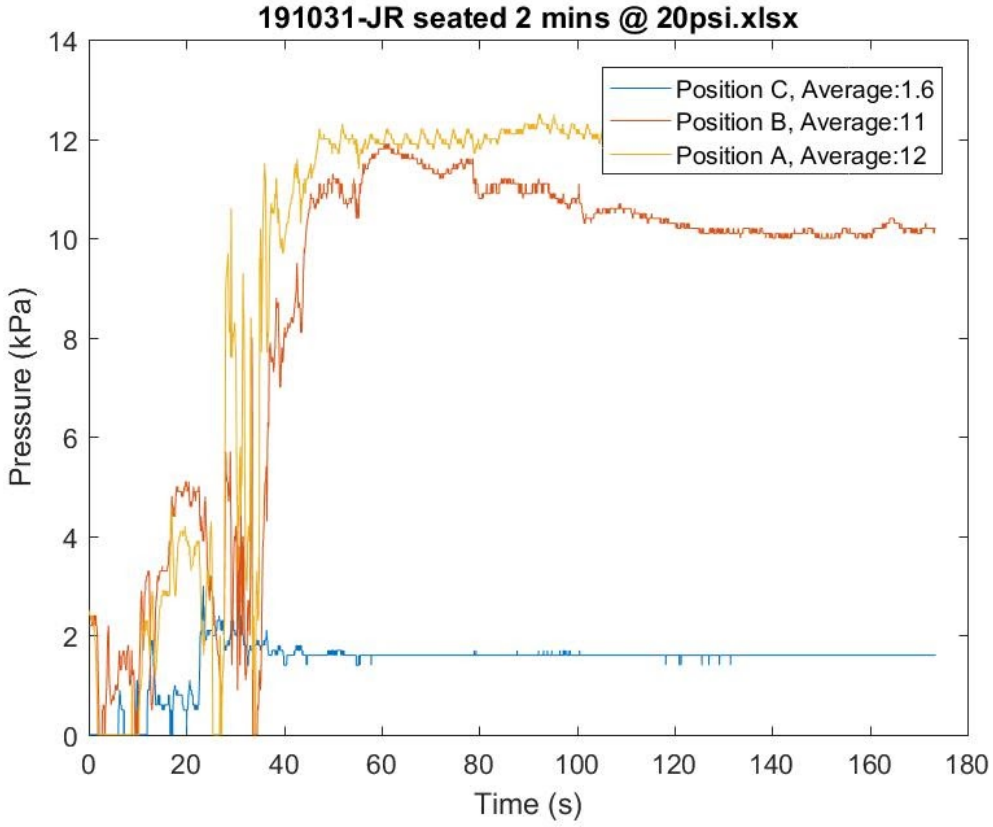

Figure 19: Pressure (kPa) vs. Time (Seconds). 2 Minute Trial. Seated Position, 10% Body Weight

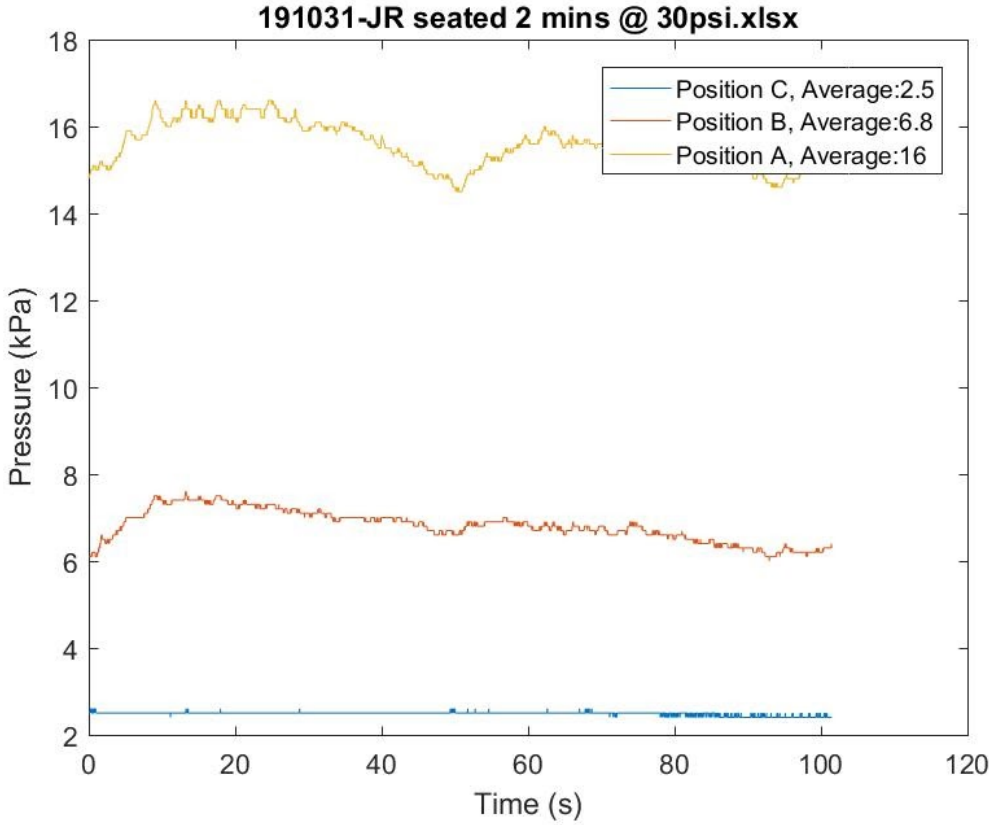

Figure 20: Pressure (kPa) vs. Time (Seconds). 2 Minute Trial. Seated Position, 15% Body Weight

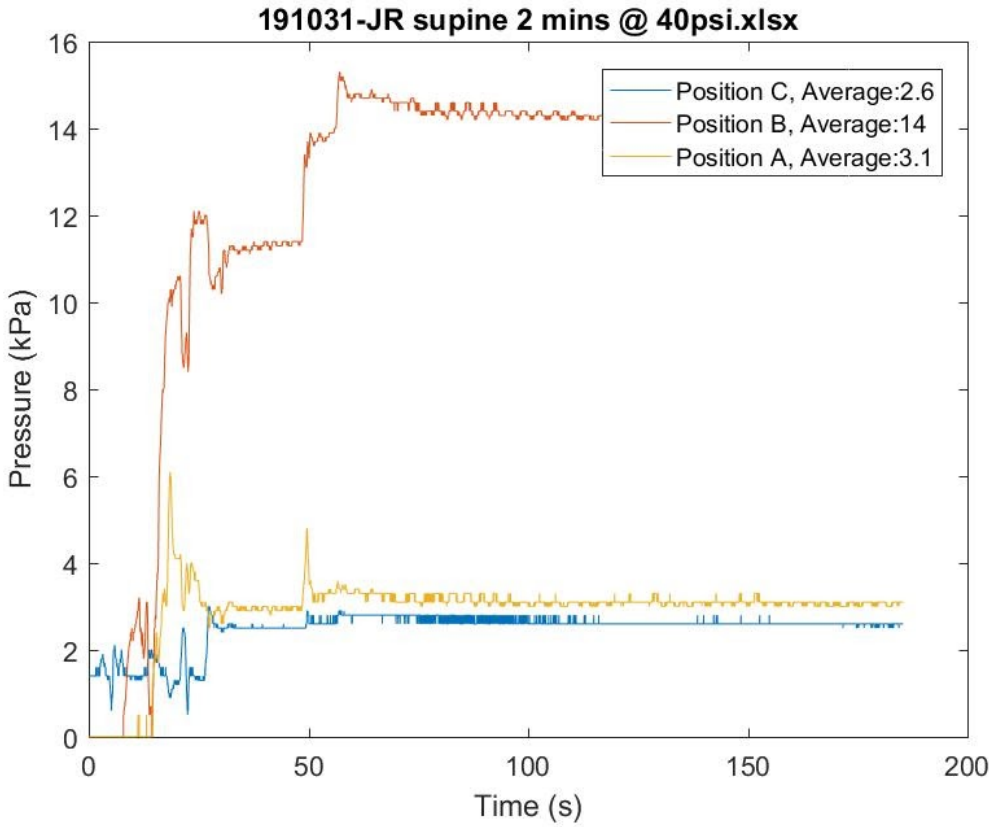

Figure 21: Pressure (kPa) vs. Time (Seconds). 2 Minute Trial. Seated Position, 20% Body Weight

10 Appendix D: Sample Calculations

Calculation 1: Percent Difference

$$(V1 - V2)/(V1 + V2)/2 * 100 = PercentDifference \tag{2}$$

$$(6.6 - 3.1)/(6.6 + 3.1)/2 * 100 = 72\% \tag{3}$$

11 Appendix E: Requirement Specifications

Table 4: Needs and Requirements

RS	Need Statement	Requirements/Evaluation Criteria	Justification
1	Device must reduce and maintain fracture axially.	Axial gap between bone fragments is no more than 1mm, and is not overlapping more than 15mm after device use.	"[femoral shaft malunions] Become significant only if they result in shortening of $\geq$ 2.5 cm" (38) "In the opinion of some authors, even fractures initially presenting with $\geq$ 2.5 cm, limb shortening can be successfully treated conservatively, but according to others, the risk of limb shortening is 20.4 times as high as in cases presenting $\geq$ 30 mm overlap at the fracture site." (39) "Two essential criteria are to be considered in indicating external therapy: non-union site inter-fragment gap less than 10 mm, and stable osteosynthesis" (40) "Overriding by 1–1.5 cm is acceptable as long as alignment in both the frontal and sagittal planes is adequate (less than 10° of varus/valgus and 15° of anterior/posterior angulation)." (41)

Table 4: Needs and Requirements

RS	Need Statement	Requirements/Evaluation Criteria	Justification
2	Device is capable of altering lateral/medial angular fracture gap to acceptable angle relative to alignment before fracture (relative to longitudinal axis)	The maximum angle of varus/valgus alignment to lower limb's longitudinal axis to be between 0-10° after device use.	"Overriding by 1–1.5 cm is acceptable as long as alignment in both the frontal and sagittal planes is adequate (less than 10° of varus/valgus and 15° of anterior/posterior angulation)." (41) "Acceptable reduction in the tibia is characterized as greater than 50% cortical contact, less than 10°angulation in any plane, less than 5°valgus or varus tilt, less than 10°of anterior or posterior angulation, less than 10°of rotation and less than 10mm leg length discrepancy." (24) "Healing with more than 10° of varus or valgus in the frontal plane, or 15° of anterior/posterior angulation in the sagittal plane will be considered a mal-union." (22) Max threshold: 10 degrees varus/valgus in frontal plane (38)
3	Device is capable of altering posterior/anterior angular fracture gap to acceptable angle relative to alignment before fracture (relative to longitudinal axis)	Maximum angle of of anterior/posterior angulation with respect to saggital plane is between 0-15° after device use	"Acceptable reduction in the tibia is characterized as greater than 50% cortical contact, less than 10°angulation in any plane, less than 5°valgus or varus tilt, less than 10°of anterior or posterior angulation, less than 10°of rotation and less than 10mm leg length discrepancy." (24) "Healing with more than 10° of varus or valgus in the frontal plane, or 15° of anterior/posterior angulation in the sagittal plane will be considered a mal-union." (22) "Overriding by 1–1.5 cm is acceptable as long as alignment in both the frontal and sagittal planes is adequate (less than 10° of varus/valgus and 15 of anterior/posterior angulation)." (41)

Table 4: Needs and Requirements

RS	Need Statement	Requirements/Evaluation Criteria	Justification
4	Device is capable of altering angle of rotational alignment relative to the healthy leg	maximum angle of femoral anteversion relative to the healthy leg is between 0-10° after device use	"Torsional deformities above 15° may cause problems of clinical significance. In particular, external malrotation of the femur is tolerated less than internal malrotation." (46) Found rotational discrepancies to be less than 10° in 76/80 test samples (47)
5	The device does not introduce any significant risks of pressure ulceration/deep tissue injury at the interface between the device and the patient	Pressure at interface region does not exceed 50mmHg (6.67kPa).	PUs [pressure ulcers] have great individual variance, but clinical studies show their onset begins after several hours of sustained pressure (2 hours suggested as a threshold) (26) "The observation that the amount of pressure needed to cause injury decreases significantly at approximately 2 hours post-loading indicates that loaded muscle tissue becomes more vulnerable to PU development and DTI [deep tissue injury] at that time"(26) "Most of studies revealed an inverse relationship between magnitude of external force and duration of loading crucial to initiate tissue breakdown"(42) Found ulceration in mice with 50mmHg of pressure, postulated that this would be similar in other mammals"(43) Pressure greater than 50-60mmHg can cause pressure ulcers. (Personal Communication, Rehabilitation healthcare professionals)

Table 4: Needs and Requirements

RS	Need Statement	Requirements/Evaluation Criteria	Justification
6	The device should for the allow the redistribution of pressure application in regular time intervals (passively or actively)	Immobilization time does not exceed 2 hours	PUs [pressure ulcers] have great individual variance, but clinical studies show their onset begins after several hours of sustained pressure (2 hours suggested as a threshold)(26) "The observation that the amount of pressure needed to cause injury decreases significantly at approximately 2 hours post-loading indicates that loaded muscle tissue becomes more vulnerable to PU development and DTI [deep tissue injury] at that time"(26) "Most of studies revealed an inverse relationship between magnitude of external force and duration of loading crucial to initiate tissue breakdown"(42) Found ulceration in mice with 50mmHg of pressure, postulated that this would be similar in other mammals"(43) Pressure greater than 50-60mmHg can cause pressure ulcers. (Personal Communication, Rehabilitation healthcare professionals)
7	The device is composed of reusable components.	Device is composed of at least 60% by volume reusable components	"many organisations in developed countries provide medical equipment as donations to them, to help alleviate the problem. However, a significant portion of donated medical equipment becomes unserviceable on arrival and/or after brief use. Repair is also, often difficult because OEM's technical support is usually already spent by the time a medical equipment is shipped to developing countries either as a donation or as a used product." (48)

Table 4: Needs and Requirements

RS	Need Statement	Requirements/Evaluation Criteria	Justification
8	Tissue at pin insertion area must be accessible and sterilizable.	Device does not have components that impede access to the pin site	"Since the pin is a foreign body auto claving was the recommended method of sterilization and cleaning of the wound at the site of pin entry in the body should be done at least twice a day to avoid infection." (49)

Table 4: Needs and Requirements

RS	Need Statement	Requirements/Evaluation Criteria	Justification
9	System should be stiff enough to prevent large interfragmentary movements over 1 mm to prevent malunion and promote secondary bone healing	The stiffness of device cast material is greater than 400N/mm	To promote secondary/indirect healing, movement of fragments along axes is beneficial for the formation of soft callus (kept within 0.2 - 1 mm of amplitude, 2 mm of gap)(50) "The healing process was inferior when the [interfragmental] gap was larger than 2 mm" "Larger interfragmentary movements and strains...stimulated larger callus formation for small gaps (1-2 mm)" (51) "highest biomechanical stability of the healed bone and mineral density of the gap tissue was achieved with an IFM [interfragmental movement] of 0.4 mm, although the differences were not significant" (52) "The stiffness of the external fixation highly influences the fracture healing pattern" "A physiological load of 500N was applied and three different stiffnesses of the external fixator were simulated (2300, 1725, and 1150N/mm)" "After the first 3 weeks, the interfragmentary strain decreased due to the callus formation and the appearance of new cartilage and bone around the fracture gap" "Assuming the steady state to be reached when the load supported by the callus was about 450N, or 90% of the total load applied, this state was achieved at 56, 60, and 64 days after fracture for the 2300, 1725, and 1150N/mm fixators, respectively" (53)

Table 4: Needs and Requirements

RS	Need Statement	Requirements/Evaluation Criteria	Justification
10	Device is adjustable in pistons length and in inner cast (air bladder) diameter.	Device is adjustable in pistons length and in inner cast (air bladder) diameter.	"Eight studies directly reported that the males were at far greater risk of being involved in a RTI [road traffic injury] than the females. All road users: passengers, pedestrians, motorists and cyclists were noted to be prone to RTIs in 10 studies. However, children aged 0 -15 years were cited in 8 studies as being highly vulnerable to RTIs especially in the urban setting. Boda-bodas (commercial motorcycles) were cited as a significant cause of RTIs in Uganda in 7 studies."(54) "Boda Boda injuries accounted for a quarter (25%) of cases. Pedestrians and the motorcyclists themselves were injured in 78% of Boda Boda "accidents" (Table 2). There were 146 males and 36 females (Male: Female ratio = 4:l). The ages of the injured Boda Boda cyclists ranged between 14 and 28 with a mean of 24 years."(55) Table 6 contains average physiognomic leg lengths and thigh circumference for multiple African countries(56)
11	The device should not cause additional damage from shear stress.	Shear stress between air bladder and thigh remains less than 9.8kPa [73.5mmHg] over treatment	See graph in results for combined shear and normal pressure loading. Blood flow rate was found to decrease with addition of shear loads(57) "At a sufficiently high level of shear (roughly 100 g/cm2 [9.8 kPa]) the pressure necessary to produce occlusion was half that required when little shear was present [at the thenar eminence]"(58)

Table 4: Needs and Requirements

RS	Need Statement	Requirements/Evaluation Criteria	Justification
12	Market cost of treatment is lower than current standard.	Cost/ patient is less than $175CAD	"The average cost of treatment for patients who underwent surgery was Ksh 9761 [$125.71 CAD] compared to those managed conservatively Ksh 13594 [$175.07 CAD]."(59)
13	Only trained personnel will have access to adjusting the device.	Only trained personnel will have access to adjusting the device.	"Challenges [associated with treatment] include: lack mobile x-ray, uncooperative patients, lack of materials and equipment to use, long hospitalization, lack of ward space, and disturbance of fracture site by bone-setters who infiltrate the hospital at night." (Personal Communication, June 2017, Ugandan healthcare professional) "In the developing world, traditional bone-setting practices are popular and these often result in a host of preventable complications."(24)
14	Applied pressure on medial side of leg should be avoided.	No applied pressure on medial side of leg.	Avoid medial side pressure application (Personal Communication, April 2018, Canadian healthcare professional) Injury to peroneal nerve is referenced as a potential side-effect of prolonged pressure application in the Zimmer Traction Handbook: "Make sure pressure is kept off the peroneal nerve...or foot drop may occur" (60)

12 Appendix F: Bill of Materials

1. 1x Custom 3D printed ischial seat attachment
2. 1x Custom fibre glass cast body
3. 2x Recycled bike inner tubes
4. 1x Minto Sager Emergency Bilateral Traction Splint replacement ischial seat
5. 2x Mcmaster-Carr rod ends (PN: 59915K43)

6. 1x Mcmaster-Carr pressure relief valve (PN: 98905K15)
7. 2x Mcmaster-Carr pneumatic pistons (PN: 6498K524)
8. 2x Mcmaster-Carr pressure regulator and gauge (PN: 1000841264)
9. 1x Mcmaster-Carr air fill valve (PN: 8063K37)
10. 2x Mcmaster-Carr high pressure threaded pipe fittings (PN: 51205K191)
11. 1x Mcmaster-Carr right angle t-adapter (PN: 50785K222)
12. 2x Mcmaster-Carr light weight air hose (PN:54075K18)
13. 1x Viaircorp 5 gallon air tank