FEMORAL FRACTURE FIXATION FOR DEVELOPING COUNTRIES

ENGR9700: MASTERS THESIS

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Declaration

I certify that this work does not incorporate without acknowledgment any material previously submitted for a degree or diploma in any university; and that to the best of my knowledge and belief it does not contain any material previously published or written by another person except where due reference is made in the text.

Christopher Lang
17th October 2016

I certify that I have seen and commented on this work, and approve its release for submission in partial fulfilment of the requirements for the degree of Bachelor of Engineering (Biomedical) (Honours)/Master of Engineering (Biomedical) conducted by Christopher Lang.

Professor Mark Taylor
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Abstract

Skeletal traction (Perkin's traction) is the most common form of femoral fracture fixation in the developing world (Bezabeh and Wamisho, 2010, Opondo et al., 2013, Sekimpi et al., 2011), with pin tract infection occurring in 42.6% of cases, while the patient remains bed ridden for seven weeks (Gosselin and Lavaly, 2007). First world femoral fracture fixation methods such as interlocking intramedullary nails are available in the developing world, however they are not affordable for a large majority of citizens who earn the minimal wage of $0.35 AUD per day (Besamusca et al., 2012), and are not customisable for the patient. This requires a low cost, customisable femoral fracture fixation method, with the scope of this project focusing on 0°-30° transverse femoral shaft fractures.

Femoral fracture fixation methods were reviewed and analysed to determine the best method to form the basis of the low cost, customisable fracture fixation method. Flexible intramedullary nails performed as well as interlocking intramedullary nails and better than skeletal traction in the range of knee joint mobility and complications, with a slightly longer time to full weight bearing compared to interlocking intramedullary nails. Flexible intramedullary nailing had the easiest manufacturing process as each nail is formed from single, solid rods of 316L stainless steel.

The low cost flexible intramedullary nails were designed to be easily customisable in regards to length and curvature, as well as being manufactured using readily available tools. The stainless steel rods can be cut using a tube cutter, while the bent tip of the nail can be formed using pliers to bend the nail over a stainless steel offcut. The nails can then be bent by hand by the surgeon to align the apex of the curve to the fracture site on the femur. The stainless steel costs between $1.80 - $4.90 AUD per meter, with the tooling provided by a single initial cost of $78.88, providing a low cost fracture fixation alternative.

Finite element analysis was performed to compare the stiffness of the low cost flexible intramedullary nails to a perfectly and imperfectly fitted interlocking intramedullary nail using a 4-point bend test, with the aim of the flexible intramedullary nails being at least 50% as stiff as the interlocking intramedullary nails. This is important as the stiffness of the nail

determines the stability it provides to the fracture, and, in association with callus formation at the fracture, determines when partial and full weight bearing can occur. The results showed that the flexible intramedullary nails produced a maximum of 32% of the stiffness of an imperfectly fitted interlocking intramedullary nail, which is below the desired stiffness.

Further investigations are recommended to determine the validity of the finite element analysis results should be conducted as simple models were used rather than complex, anatomically correct models for the flexible intramedullary nail and the femoral shaft. This will help determine if the flexible intramedullary nails can provide adequate stability to the fracture, and if further studies such as surgeon surveys, plastic and cadaver simulations, kit production, and clinical trials should be conducted.

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1. Introduction

1.1 Background

Fracture fixation, particularly of femoral shaft fractures, is common practice around the globe. There are many different forms of fracture fixation, however they all share a common goal: to provide stability to a fracture to allow it to heal back to its original anatomical position and function as quickly as possible. While a literature search for the ideology behind fracture fixation in the first world compared to the third world does not return any substantial results, from previous knowledge, the aim of first world fracture fixation is to get patients out of hospital and back to work as quickly as possible. Comparatively, due to the limitations of implant access in developing countries, the time taken for patients to return home and to work is limited by the available fracture fixation method, which for many years has been skeletal traction (Bezabeh and Wamisho, 2010, Opondo et al., 2013, Sekimpi et al., 2011).

Femoral shaft fractures are a common occurrence around the world, mainly resulting from traffic accidents. According to the World Health Organisation 2015 Global Status Report on Road Safety (WHO, 2015), the African region has the highest road traffic fatality rate, at 26.6 per 100,000 population. Due to this high fatality rate, and hence the high number of associated non-fatal injuries, there is a higher number of femoral shaft injuries that occur within the African region.

Skeletal traction has been the most common method of treatment for femoral shaft fractures in the African region for many years as it is cost effective and does not require major surgery (Bezabeh and Wamisho, 2010, Opondo et al., 2013, Sekimpi et al., 2011). However, it has been shown that complications such as delayed union, malunion, and length discrepancies leading to legs of differing length can occur due to the use of skeletal traction (Bezabeh and Wamisho, 2010, Opondo et al., 2013, Sekimpi et al., 2011).

Additional complications are associated with skeletal traction, with the most common form of complication being pin tract infection. Pin tract infection occurs in 42.6% of cases

(Gosselin and Lavaly, 2007), leading to damaged tissue around the infection site, as well as knee stiffness after the treatment is completed (Gosselin and Lavaly, 2007).

Patients who undergo skeletal traction remain in hospital for an average of seven weeks (Gosselin and Lavaly, 2007), and requires a bed for the entirety of the seven weeks, effectively removing a bed from availability for the rest of the hospital. In hospitals which are already short on available bedding, an alternative fracture fixation method which reduces the time the patient is in hospital will greatly benefit hospitals in developing countries. This shortened length of stay will also help to patients return to work faster, as work in developing countries is often dependent on the employee's physical ability to work to provide for themselves and their family.

Patients are often unable to afford first world femoral fracture fixation methods such as interlocking intramedullary nailing, especially when working on minimum wage (Besamusca et al., 2012). This is why a low cost, customisable fracture fixation method is required to provide a low cost alternative without the complications of skeletal traction.

1.2 Fracture Fixation Methods

Skeletal traction (Perkin's traction) involves the insertion of a traction pin in the tibial tuberosity, which is then attached to a stirrup and a weight which is set to reduce the femur, keeping the fractured femoral sections aligned and at the correct length (Demmer, 2007). This allows for the femoral sections to heal while the femur is held in a set position. While skeletal traction is a basic fixation method, it can result in various complications. An example of skeletal traction can be seen in Figure 1-1 below.

Figure 1-1 has been removed due to copyright restrictions

Figure 1-1 - Example of Skeletal Traction (Demmer, 2007)

Flexible intramedullary nails such as Ender's nails and titanium elastic nails are another form of fracture fixation. These are curved rods made of stainless steel or titanium, and are placed across the fracture site within the femoral canal, as seen in Figure 1-2. These nails are mainly used in paediatrics in regards to femoral shaft fractures as they do not damage the child's growth plates within the bone, which can occur when using an interlocking intramedullary nail.

Figure 1-2 has been removed due to copyright restrictions

Figure 1-2 – Example of a Titanium Elastic Nail (Flynn et al., 2001)

The gold standard of femoral fracture fixation is a hollow interlocking intramedullary nail, and it is also placed within the femoral canal, as seen in Figure 1-3. These nails are often held in place using interlocking screws to provide additional stability, and provides loading support across the fracture site, allowing for an earlier return to full weight bearing (Winquist et al., 1984, Thoresen et al., 1985).

Figure 1-3 has been removed due to copyright restrictions

Figure 1-3 - Example of an Interlocking Intramedullary Nail (Beaty et al., 1994)

External fixation is another possible fracture fixation method, involving placing rods either side of the fracture site which are held in place externally (Rommens and Hessmann, 2015). An x-ray of an external fixation device can be seen in Figure 1-4 below.

Figure 1-4 has been removed due to copyright restrictions

Figure 1-4 - Example of an External Fixation Device (Rommens and Hessmann, 2015)

1.3 Objectives

The purpose of this thesis is to develop a femoral shaft fracture fixation device that can be used in developing countries to allow a patient to have a smoother return back to full weight bearing activities compared to skeletal traction. This fracture fixation device must be fully customisable, low cost, and must be made from readily accessible materials and tools. The device must also be easily surgically inserted using readily available tools.

1.4 Scope

This thesis will focus only on the fixation of the femoral shaft, excluding the head and neck, and the proximal and distal ends of the femur. Only transverse fractures will be investigated, resulting in femoral shaft fractures from 0-30°, as seen in A3 of Figure 1-5 (Rommens and Hessmann, 2015).

Figure 1-5 has been removed due to copyright restrictions

Figure 1-5 - AO Classification: A simple fractures - A1 spiral, A2 oblique (≥30°), A3 transverse (<30°) (Rommens and Hessmann, 2015)

2. Literature Review

2.1 Purpose

The purpose of this literature review is to investigate different femoral shaft fracture fixation methods to determine which method will be able to provide adequate results while being easily customisable using standard tools. The selected fracture fixation methods will be assessed for their clinical results, particularly the time to full weight bearing, knee joint mobility, and complications. The ease of manufacture of each fracture fixation method will also be taken into consideration. This literature review will also briefly detail the biology of fracture healing.

2.2 Method

A Google Scholar and PubMed literature search was conducted using the keywords "femoral shaft fracture fixation", which was later refined to "femoral shaft intramedullary nail", "femoral shaft titanium elastic nail", "femoral shaft ender's nail", "femoral shaft Perkin's traction", and "biology fracture healing". The results were reviewed to ensure a portion of the reported data was in reference to the grade A fractures that are the focus of this review, as well as functional results such as knee flexibility, and time to weight bearing. There was no restriction on the year of publication.

2.3 Results

2.3.1 Biology of Fracture Healing

Inflammatory responses occur at the fracture site immediately following a fracture, resulting in indirect or direct fracture healing. Indirect fracture healing is the most common type of fracture healing, and does not require reduction or for the fracture to be rigidly stable (Marsell and Einhorn, 2011). This form of fracture healing is normally occurs in the presence of intramedullary nailing and external fixation femoral fracture fixation methods (Marsell and Einhorn, 2011).

A hematoma is created when the fracture occurs, consisting of peripheral and intramedullary blood cells, as well as bone marrow cells (Marsell and Einhorn, 2011). This results in an inflammatory response, causing coagulation around the ends of the fracture, as well as between them (Marsell and Einhorn, 2011). Specific mesenchymanl stem cells (MSCs) are then derived to form osteogenic cells to help facilitate bone regeneration. Fibrin-rich granulation tissue forms after the hematoma at the fracture site, allowing for endochondral formation between the fractured parts of the bone, which is then stabilised by the formation of cartilaginous tissue to form a soft callus. This soft callus forms 7-9 days after the fracture occurs (Marsell and Einhorn, 2011). Intramembranous ossification then occurs at the fracture ends, leading to the formation of a hard callus, providing enough structure and support to allow for weight bearing. This process is dependent on how quickly the MSCs are recruited (Marsell and Einhorn, 2011).

After the hard callus is formed, further bone remodelling occurs to complete the final portion of fracture healing, allowing the biomechanical properties of the bone to return to their state pre-fracture. This occurs through the gradual resorption of the hard callus by osteoclasts, and the deposition of lamellar bone by osteoblasts, forming a lamellar bone structure with an intramedullary canal (Marsell and Einhorn, 2011). To ensure that this process is successful, revascularization occurs throughout the remodelling process, ensuring there is adequate blood supply to the fracture site, allowing for successful remodelling (Marsell and Einhorn, 2011).

2.3.2 Femoral Fracture Fixation Methods

A summary of the results from the literature reviewed can be seen in Table 2-1 below.

Table 2-1 - Summary of Femoral Shaft Fracture Fixation Results

Author	No. of Patients	Age (years)	Nail Type	Results
Goldie et al. (Goldie et al., 1983)	16	19-86 (mean: 69)	Ender Nails	5 of 7 trochanter patients: near normal knee joint mobility 1 stiff knee 1 above-knee amputation 6 of 9 femoral condyle patients: <90° knee joint mobility 3 died
Moehring (Moehring, 1988)	47	14-72	Ender Nails	43 patients: knee joint mobility returned to preoperative levels

Muckle & Siddiqi (Muckle and Siddiqi, 1982)	63	16-27 (mean: 19)	Ender Nails (35) Küntscher Nail (28)	Ender Nail: Partial weight bearing: 8-12 weeks (mean: 11) Knee flexion at 4 months (%): 85-90 28 Küntscher Nail patients Partial weight bearing: 8-16 weeks (mean: 12.5) Knee flexion at 4 months (%): 85-90
Moroz et al. (Moroz et al., 2006)	229 (234 fractures)	3-18	Titanium Elastic Nail	150 excellent 57 satisfactory 23 poor Time to full weight bearing: 6-18 weeks (mean: 10)
Flynn et al. (Flynn et al., 2001)	58	4-16 (mean: 9.5)	Titanium Elastic Nail	Patients walked without assistance 2-12 weeks (mean 8.5) 39 excellent results 18 satisfactory results 1 poor result
Luhmann et al. (Luhmann et al., 2003)	39 (43 fractures)	3.75-9.33 (mean: 6)	Titanium Elastic Nail	Patients without immobilisation: weight bearing after average 24.1 days Immobilised patients: weight bearing after average 52.7 days All patients: full knee joint mobility 8 patients with leg length discrepancy 2 major complications (septic arthritis, hypertrophic non-union) 18 minor complications (pain at nails, nail erosion through skin, delayed union)
Flynn et al. (Flynn et al., 2004)	83 (84 fractures)	6-16	Titanium elastic nail (48) Traction and spica cast (35)	80 patients: acceptable alignment 3 traction and spica cast patients: unacceptable angulation or leg length discrepancy Average time to independent mobility (days): Traction and spica cast: 106 Titanium elastic nail: 67
Carey and Galpin (Carey and Galpin, 1996)	25 (27 fractures)	5.9-10.9 (average: 8.5)	Flexible intramedullary nail	Average time to ambulation with crutches: 17.3 days All patients: full knee joint mobility

Winquist et al. (Winquist et al., 1984)	520	10.8-92 (mean 29.5)	Küntscher Nail	Isolated femoral fracture average patient hospital time: 13.3 days Average time to walking with crutches: 3.2 days Average time on crutches: 5.8 weeks 460 patients: knee joint mobility average = 132° 13 patients: knee joint mobility < 125° (minimum 90°) 47 patients lost to follow up 11 died – unrelated to femoral fracture
Botchu et al. (Botchu, 2005)	100	17-80	Küntscher Nail (60) Interlocking Intramedullary Nail (40)	73 patients: knee joint mobility > 110° 25 patients: knee joint mobility 60-110° 2 patients: knee joint mobility < 60° No cases of non-union 3 cases of infection 2 implant failures (Küntscher Nail)
Boopalan et al. (Boopalan et al., 2014)	17	22-70 (median: 27)	Küntscher Nail (6) Interlocking Intramedullary Nail (11)	16 patients regained original femoral length 14 patients: full knee joint mobility 3 patients with knee stiffness Full weight bearing: 4 months
Beaty et al. (Beaty et al., 1994)	30 (31 fractures)	10-15 (average: 12)	Interlocking Intramedullary Nail	Average 17 day hospital stay Leg length discrepancy: -1.8 – 3.2 cm (average 0.51cm)
Thoresen et al. (Thoresen et al., 1985)	47	15-87 (median 28)	Grosse-Kempf interlocking intramedullary nail	14 fractures considered stable enough for immediate weight bearing All others: partial weight bearing with crutches for 2 months 30 fractures = excellent 8 = good 7 = fair 2 = poor
Sekimpi et al. (Sekimpi et al., 2011)	70	15-50+	SIGN Interlocking Intramedullary Nail	20 patients lost to follow up No leg length discrepancy > 2cm 47 patients: full knee joint mobility 3 patients: >20° decrease in knee joint mobility

Stans et al. (Stans et al., 1999)	81 (85 fractures)	6-16	Early spica (25) Traction/spica (10) External fixation (22) Flexible rods (11) Plates (4) Reamed rod (13)	No patient had leg length discrepancy > 2cm Average time to full weight bearing (weeks): Early spica: 10 Traction/spica: 12 External fixation: 22 Flexible rods: 7.9 Plates: 10 Reamed rod: 4.3 Major complications: 9 external fixation patients
Gosselin & Lavaly (Gosselin and Lavaly, 2007)	53 (54 fractures)	16-71 (average: 34.2)	Perkins Traction	Mean traction duration: 45 days 23 patients: full knee joint mobility 11 patients: good knee joint mobility 20 patients lost to last follow up 23 patient pin tract infection 4 non-union 5 malunion 3 >2.5cm shortening 2 re-fracture
Buxton (Buxton, 1981)	50	11-70	Perkins Traction	30 patients: full knee joint mobility All patients: >120° knee joint mobility 18 patient pin tract infection 3 non-union 2 malunion 3 >2.5cm shortening 4 re-fracture

2.3.3 Ender's Nails, Titanium Elastic Nails & Flexible Intramedullary Nails

Ender's nails, titanium elastic nails, and flexible intramedullary nails were studied across multiple investigations, as seen in Table 2-1. Ender's nails are a specific form of flexible intramedullary nailing, usually using slightly thicker nails without a bent tip, as seen in Figure 2-1 below. Titanium elastic nails and flexible intramedullary nails also work on the same principle, with titanium elastic nails specifically being made of titanium, while flexible intramedullary nails are made of either titanium or stainless steel. An example of this can be seen in Figure 1-2 above.

Figure 2-1 has been removed due to copyright restrictions

Figure 2-1 - Example of Ender's Nails (Muckle and Siddiqi, 1982)

Patients treated with Ender Nails had near normal knee joint mobility (Goldie et al., 1983, Moehring, 1988, Muckle and Siddiqi, 1982), while patients were able to perform partial weight bearing from 8-12 weeks after surgery (Muckle and Siddiqi, 1982).

The majority of patients treated with titanium elastic nails (TENs) also displayed excellent results, with the 150 excellent cases detailed by Moroz et al. (2006) resulting in anatomical or near-anatomical alignment with no peri-operative problems, while Flynn et al. (2001) classified their 39 excellent results as having < 1cm leg length inequality, 5 degrees of malalignment, and no pain or complications. The classification for satisfactory and poor results by Flynn et al. (2001) can be seen in Figure 2-2. Luhmann et al. (2003) also classified their fractures as defined by Flynn et al. (2001), resulting in 12 excellent, 26 satisfactory, and 5 poor results. The average time to full weight bearing or time to independent mobility as reported by Moroz et al. (2006), Flynn et al. (2001) and Flynn et al. (2004) were 10 weeks, 8.5 weeks, and 9.6 weeks respectively, while Luhmann et al. (2003) reported that patients without immobilisation were able to bear weight after an average of 24.1 days (3.4 weeks), while immobilised patients could bear weight after an average of 52.7 days (7.5 weeks). There were minimal major complications or poor results reported by Luhmann et al. (2003) and Flynn et al. (2001) however, Moroz et al. (2006) reported major complications in 17.4%

of the patients studied. Minor complications were reported by all studies, including pain at the nails and surrounding soft tissue and inflammatory reaction (Flynn et al., 2001, Flynn et al., 2004, Luhmann et al., 2003, Moroz et al., 2006).

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Figure 2-2 – Classification of Excellent, Satisfactory, and Poor Titanium Elastic Nail Outcomes (Flynn et al., 2001)

Unspecified flexible intramedullary nails were used by Carey and Galpin (1996) to treat 25 patients with 27 fractures. The average time to ambulation with crutches was 17.3 days (2.5 weeks), and all patients were reported to have full knee joint mobility. Leg length discrepancies ranged from 6mm shorter to 17mm longer, while any alignment differences were of no clinical concern. There were minimal major complications, while no minor complications were reported (Carey and Galpin, 1996).

2.3.4 Küntscher Nail, Interlocking Intramedullary Nail & SIGN Intramedullary Nail

Küntscher nails were used exclusively in the study conducted by Winquist et al. (1984), while Botchu et al. (2005) and Boopalan et al. (2014) used both Küntscher nails and interlocking intramedullary nails. Winquist et al. (1984) reports that patients were able to walk without crutches after an average of 5.8 weeks, while knee joint mobility averaged 132°, which was considered excellent. Only 13 patients of the 460 patients available for follow-up had knee joint mobility <125°. 4 patients developed an infection, non-union was displayed in 4 patients, while shortening of the leg >2cm occurring in 10cm, and shortening of 1-2cm occurred in 37 patients (mainly in comminuted fractures). Patients with shortening of 2cm or less generally did not display any back or limb pain (Winquist et al., 1984).

Results shown by Botchu et al. (2005) grouped the results of both the use of the Küntscher nail and the interlocking intramedullary nail. 73 patients had knee joint mobility > 110° which was considered good, while 25 patients had knee joint mobility between 60-110°, and 2 patients had knee joint mobility <60°. There were minimal complications, with no cases of non-union and only 3 cases of infection. There were 2 cases of Küntscher nail implant failure, and these nails were replaced by interlocking intramedullary nails (Botchu, 2005). Similarly, Boopalan et al. (2014) grouped the results of the use of both nails. 16 patients were able to regain their original femoral length, 14 patients had full knee joint mobility, and patients with isolated femoral fractures were able to walk with full weight bearing after 4 months. 3 patients suffered from knee stiffness, while 3 patients underwent reoperation due to complications.

Beaty et al. (1994) reported that leg length discrepancies averaged 0.51 cm, with a range from -1.8-3.2 cm from 30 patients. Most complications were minor and were resolved, however one patient developed asymptomatic segmental avascular necrosis of the femoral head.

Thoresen et al. (1985) used the Grosse-Kempf interlocking intramedullary nail. 14 fractures were considered to be stable enough for immediate weight bearing, while the other patients were required to only perform partial weight bearing with crutches for two months, after which full weight bearing was allowed. Of the 47 patients reported, there were 30 excellent results, 8 good, 7 fair, and 2 poor results. The classification criteria for these results can be seen in Figure 2-3 (Thoresen et al., 1985).

Figure 2-3 has been removed due to copyright restrictions

Figure 2-3 - Fracture Result Classification Criteria (Thoresen et al., 1985)

From this classification criteria, it can be seen that the majority of patients recovered excellent knee joint mobility, with minimal shortening and malalignment of the femur. There were 3 intraoperative complications, and 3 fractures needed to be re-operated due to poor reduction (Thoresen et al., 1985).

Sekimpi et al. (2011) investigated the use of SIGN interlocking intramedullary nails in developing countries in 70 patients. While 20 patients were lost to follow up, 47 patients had full knee joint mobility postoperatively, while 3 patients had >20° decrease in knee joint mobility. While there were no cases of non-union or leg length discrepancies >2cm, there were 2 infections, and 2 cases of the interlocking screw missing the nail (Sekimpi et al., 2011).

2.3.5 Multiple Fixation Study

Stans et al. (1999) conducted a study investigating the results of different fracture treatments, covering early spica, traction then spica, external fixation, flexible rods, plates, and reamed rods. While no patients had clinically effected gate and there were no cases of shortening >2cm, 28 patients had shortening of >1cm of the fractured femur, while 3 cases of overgrowth occurred using external fixation. Reamed rods gave the best result in regards to time to full weight bearing with 4.3 weeks, followed by 7.9 weeks for flexible rods. External fixation resulted in the longest average time to full weight bearing with 22 weeks, while traction then spica was 12 weeks, with early spica resulting in 10 weeks. External fixation had the largest amount of major and minor complications, while reamed rods had 1 major and 1 minor complications, and flexible rods had 1 major complication (Stans et al., 1999).

2.3.6 Perkins Traction

Gosselin and Lavaly (2007) investigated the use of Perkins traction in 53 patients in Sierra Leone. The average time in traction was 45 days, 23 patients had full knee joint mobility, and 11 patients had good knee joint mobility at the final follow up (data for remaining 20 patients was unavailable for knee range of motion). Perkins traction did however result in many complications, with 4 cases of non-union, 5 cases of malunion, 3 cases of >2.5cm shortening, 3 cases for re-fracture, and 23 pin tract infections (Gosselin and Lavaly, 2007).

Similarly, Buxton (1981) reports 3 cases of non-union, 2 cases of malunion, 3 cases of >2.5cm shortening, 4 cases of re-fracture, and 18 cases of pin tract infection in 50 patients.

30 patients had full knee joint mobility, and no patient had knee joint mobility <120° (Buxton, 1981).

2.4 Discussion

The time to full weight bearing, knee joint mobility, and complications for each form of fracture fixation are discussed below. Population considerations for the studies are also discussed, with the average BMI distribution of first world and developing countries taken into account.

2.4.1 Time to Full Weight Bearing

Intramedullary nailing using a Küntscher nail, interlocking intramedullary nail, or a SIGN intramedullary nail has the shortest average time to full weight bearing, with Winquist et al. (1984) reporting that patients using a Küntscher nail were able to walk without crutches after an average of 5.8 weeks, while Thoresen et al. (1985) reported that patients were able to conduct full weight bearing after 2 months of partial weight bearing (approximately 8 weeks). Stans et al. (1999) reported that the use of reamed rods allowed for an average time to full weight bearing of 4.3 weeks, while flexible rods allowed full weight bearing after 7.9 weeks.

Flexible intramedullary nailing and Enders nails allowed for independent mobility after 8-12 weeks, which on average is longer than that of intramedullary nailing (Beaty et al., 1994, Boopalan et al., 2014, Botchu, 2005, Carey and Galpin, 1996, Flynn et al., 2001, Flynn et al., 2004, Goldie et al., 1983, Luhmann et al., 2003, Moehring, 1988, Moroz et al., 2006, Muckle and Siddiqi, 1982, Sekimpi et al., 2011, Thoresen et al., 1985, WHO, 2015, Winquist et al., 1984).

The average time to full weight bearing for traction then spica was 12 weeks, while external fixation averaged 22 weeks (Stans et al., 1999). No data was available for Perkins traction.

Although intramedullary nailing has the shortest average time to full weight bearing, forms of flexible intramedullary nailing are not considerably longer, ranging from 0-6 weeks longer.

The data recorded for time to full weight bearing may be dependent on patient follow up frequency, and if patients were suffering from other injuries, however as the studies averaged this time over multiple patients, this helps to eliminate these variables.

2.4.2 Knee Joint Mobility

All forms of fracture fixation reported the majority of fracture cases resulting in satisfactory to excellent degrees of knee joint mobility (Beaty et al., 1994, Boopalan et al., 2014, Botchu, 2005, Buxton, 1981, Carey and Galpin, 1996, Flynn et al., 2001, Flynn et al., 2004, Goldie et al., 1983, Gosselin and Lavaly, 2007, Luhmann et al., 2003, Moehring, 1988, Moroz et al., 2006, Muckle and Siddiqi, 1982, Sekimpi et al., 2011, Stans et al., 1999, Thoresen et al., 1985, WHO, 2015, Winquist et al., 1984).

2.4.3 Complications

Perkins traction has the largest amount of complications, particularly with pin tract infections being prevalent in 42.6% of cases (Gosselin and Lavaly, 2007). External fixation also had a large number of complications (Stans et al., 1999). Intramedullary nails and flexible intramedullary nails had similar amounts of complications (Beaty et al., 1994, Boopalan et al., 2014, Botchu, 2005, Carey and Galpin, 1996, Flynn et al., 2001, Flynn et al., 2004, Goldie et al., 1983, Luhmann et al., 2003, Moehring, 1988, Moroz et al., 2006, Muckle and Siddiqi, 1982, Sekimpi et al., 2011, Thoresen et al., 1985, Winquist et al., 1984).

2.4.4 Population Considerations

While two studies investigating Ender nails covered ages from teenagers to the elderly, the study by Muckle and Siddiqi (1982), as well as the studies investigating titanium elastic nails and flexible intramedullary nails were mainly focused on paediatrics (Carey and Galpin, 1996, Flynn et al., 2001, Flynn et al., 2004, Luhmann et al., 2003, Moroz et al., 2006). This is compared to the studies conducted into interlocking intramedullary nailing and Küntscher nails, which covered young adults to the elderly.

The change over time of the use of flexible intramedullary nails from older patients to exclusively paediatrics may have resulted from a number of factors. The use of flexible intramedullary nails does not affect the growth plates within the femur, and hence this is a benefit of the use of flexible intramedullary nails in paediatrics where possible, as femoral growth will not be stunted.

Additionally, interlocking intramedullary nails are capable of providing more support of the fracture compared to flexible intramedullary nails, hence the prevalence of the use of interlocking intramedullary nails in older and hence larger patients (compared to the weight of paediatric patients). This must be taken into consideration when selecting a fracture fixation method.

The World Health Organisation provides a database of global body mass index (BMI) values, providing data for the percentage of the population from each country that fit into the following categories:

- Underweight (BMI < 18.5)
- Normal (BMI 18.5 – 24.99)
- Pre-Obese (BMI 25-29.99)
- Obese (BMI ≥ 30)

Due to the lack of information regarding BMI data from the developing world, the results from Ghana are used as an indication of the percentage of the developing world population that fits into each of the BMI categories. Australia and the United States of America are taken as representatives of the first world. These results are shown in Table 2-2 below. The results do not add up to 100% in each case, as the results for the database are taken from numerous studies rather than a single study.

Table 2-2 - Ghana, Australia, USA % Population for BMI Ranges

Country	% Underweight (<18.5)	% Normal (18.5 – 24.99)	% Pre-Obese (25 – 29.99)	% Obese (≥ 30)
Ghana	16.4	72.4	8.1	3.1
Australia	1	39.2	39	16.4
USA	2.4	35.7	32.2	33.9

From the results seen in Table 2-2, 88.8% of the population of Ghana are at a normal BMI or lower, while 45.4% of Australians and 66.1% of Americans are pre-obese to obese. These general population factors play a role in influencing the type of fracture fixation required, and the use of interlocking intramedullary nails over flexible intramedullary nails in the first world can be correlated to a larger, heavier general population. As the population of Ghana, and then extrapolating this data to the rest of the developing world, are either at a normal BMI or lower, there is a larger portion of the population, including adults, where flexible intramedullary nails could provide adequate support for their weight.

2.5 Final Recommendation & Fixation Method Selection

As the project is focused on creating a form of fracture fixation that is customisable and can be made easily for a low cost, while still delivering acceptable knee joint mobility with minimal complications, a technique based on titanium elastic nails and Enders nails will be selected for further investigation and work. Although fracture fixation based on this technique does not deliver the average time to full weight bearing that interlocking intramedullary nailing does (Beaty et al., 1994, Boopalan et al., 2014, Botchu, 2005, Carey and Galpin, 1996, Flynn et al., 2001, Flynn et al., 2004, Goldie et al., 1983, Luhmann et al., 2003, Moehring, 1988, Moroz et al., 2006, Muckle and Siddiqi, 1982, Sekimpi et al., 2011, Thoresen et al., 1985, Winquist et al., 1984), the results of using titanium elastic nailing is better than the results shown by traction then spica, and external fixation (Stans et al., 1999). A method based on flexible intramedullary nails will also result in less complications than Perkin's traction (Buxton, 1981, Carey and Galpin, 1996, Flynn et al., 2001, Flynn et al., 2004, Goldie et al., 1983, Gosselin and Lavaly, 2007, Luhmann et al., 2003, Moehring, 1988, Moroz et al., 2006, Muckle and Siddiqi, 1982), removing the potential for pin tract infection.

Rods of 316 stainless steel will be easier to customise to form the elastic nails required compared to hollow interlocking intramedullary nailing, which also requires screws to fix the nail in place, requiring additional custom tooling (Sekimpi et al., 2011). Despite the tendency in first world fracture fixation to use interlocking intramedullary nails over flexible intramedullary nailing for adults, this is partially due to the stability that interlocking intramedullary nailing can provide for adults where the majority of adults have a high BMI. Using the population of Ghana as an approximation for the rest of the developing world, the BMI of the developing world is much lower than that of the first world, and hence flexible intramedullary nailing could provide adequate support for their weight.

3. Flexible Intramedullary Nail Design

3.1 Design Requirements

Flexible intramedullary nails are relatively simple in design, as they are solid nails rather than the hollow design of standard intramedullary nails. As they are created from a solid body, there are no design requirements apart from the length and the shaping of the nails. These minimal design requirements allow the flexible intramedullary nails to be manufactured so easily.

One design requirement of the flexible intramedullary nail is that the tip of the nail is bent slightly, as seen in Figure 3-1. This needs to occur to help the nail move into the medullary canal (Lascombes et al., 2012), as it provides a smoother, curved edge for the nail to move against the wall, rather than a sharper edge which could catch on bone in the medullary canal, stopping the nail from moving further up the canal. The length of the bent tip is to be approximately 2.2 times the diameter of the nail (Lascombes, 2010).

Figure 3-1 has been removed due to copyright restrictions

Figure 3-1 - Flexible Intramedullary Nails with Bent Tips (Flynn et al., 2001)

Another design requirement is to ensure that the nail can be easily bent by hand, as the surgeon must be able to bend the nail to allow for the apex of curvature of the nail to be across the fracture sight (Barry and Paterson, 2004). Being able to bend the nail by hand allows the surgeon to customise the nail on the spot in the theatre without needing specific tools, also decreasing the number of tools needed to manufacture the flexible intramedullary nails.

The sourcing of the materials must come from local hardware stores or local internet store, and hence all materials and manufacturing tools are standard, regular materials and tools. This will help to reduce the overall cost of the fracture fixation device, as there is no need for custom materials or tools.

The flexible intramedullary nails should also aim to produce 50% or more of the stiffness of an interlocking intramedullary nail, which would not be able to provide enough support for weight bearing straight away, but would allow for earlier partial weight bearing compared to Perkin's traction due to the additional support of the flexible intramedullary nails. This benefits the patient by allowing them to get out of bed earlier, reducing their time in hospital.

The design of this flexible intramedullary nail assumes that the hospital possesses the ability to sterilise the nails after they have been manufactured, as a non-sterile cannot be introduced into the body due to the risk of infection. The design also assumes that the hospital has access to an image intensifier, as this is a critical aspect in the initial design of the flexible intramedullary nail, as the thickness and curvature of the rods are dependent on the size of the intramedullary canal.

3.2 Flexible Intramedullary Nail Material Selection

Flexible intramedullary nails can be manufactured from titanium alloys or from 316L stainless steel, both of which are currently used clinically. Stainless steel has a higher elastic modulus and lower elasticity than titanium, and hence stainless steel has a higher bending stiffness compared to titanium (Lascombes, 2010). Stainless steel has a higher elastic restoring force than titanium, which is important in cases concerning an overweight adolescent (Lascombes, 2010). As stainless steel is the suggested material for overweight adolescents, this should also translate to adults with normal weights and BMI, which can be the equivalent of overweight adolescents. 316L stainless steel is also a biocompatible material, allowing it to be accepted into the body without an adverse immune response towards its presence.

3.3 Manufacturing Process

316L stainless steel can be purchased in metre lengths, which then need to be cut to size. This allows the surgeon to vary the length of the nail to suit the patient. The stainless steel can be cut using a tube cutter, as seen in Figure 3-2, which allows the length of the nail to be changed without altering the geometry of the nail.

Figure 3-2 - Rod cutter used to customise the flexible intramedullary nails

Using two hand grip clamps, the stainless steel nail can be held in place on a bench or table, preventing rotation of the nail while it is cut to size. The tube cutter can then be placed on the nail at the desired length to cut the nail to size. Initially the tube cutter was tightened by hand, however this prolonged the cutting process, and trying to tighten the cutter often resulted in blisters on the hands of the user. To prevent the formation of blisters and to allow the tube cutter to be tightened sufficiently and hence decrease the time taken to cut the nail, a set of pliers was used to tighten the tube cutter. This setup can be seen in Figure 3-3.

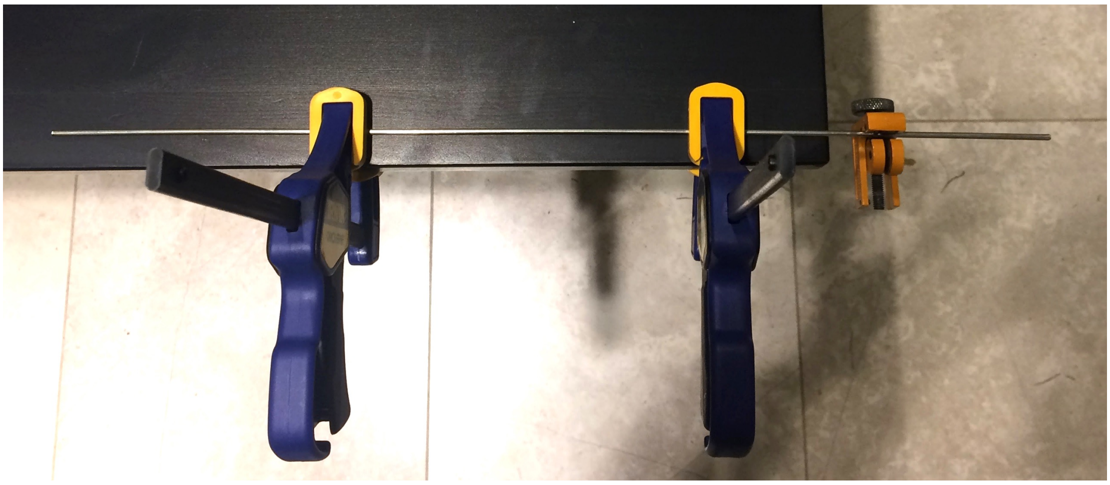

Figure 3-3 - Cutting flexible intramedullary nail setup

Due to the circular cutting that results from using the tube cutter to cut the stainless steel nail, a slight burr is formed when the nail is cut. This can be removed using a metal file, allowing for the cut end of the nail to be smoothed out. This removes any risk of adverse biological effect from the microenvironment that could form around the burr if the burr was left on the nail.

After the nail is cut to the desired length and the burr is filed back, the tip of the nail must then be bent to allow an easy transition into the medullary canal (Lascombes et al., 2012). To create this bent tip, an offcut of steel is clamped to the bench, ensuring that a portion of the steel offcut is hanging over the edge of the bench. The nail is then clamped onto the steel offcut, with the tip of the nail to be bent hanging over the edge of the steel offcut. The length of the nail hanging off the edge of the steel offcut, and hence the length to be bent, should be approximately 2.2 times the diameter of the nail (Lascombes, 2010). This tip is then clasped with pliers, and bent to shape around the edge of the steel offcut to form the bent tip, as seen in Figures 3-4 and 3-5 below.

Figure 3-4 - Setup of steel offcut and flexible intramedullary nail to bend the nail tip

Figure 3-5 - Bent nail tip

The nail must then be taken by hand and bent into shape to allow the apex of the curve of the nail to be placed at the fracture site (Barry and Paterson, 2004). This allows for the maximum amount of opposing force and hence stability across the fracture site. Bending the nail by hand allows the surgeon to change the apex point of the curvature of the nail to ensure this occurs across the fracture site, and hence this must be calculated with reference to an x-ray of the patient's femur. A bent nail can be seen in Figure 3-6 below.

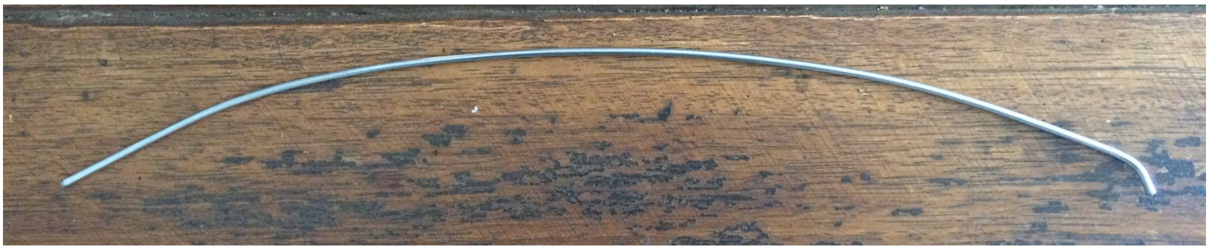

Figure 3-6 - Bent Flexible Intramedullary Nail

Manufacturing the flexible intramedullary nails in this way allows for the surgeon to fully customise the nails used for each patient, allowing for alterations in the diameter, length, and curvature of the nail to best suit the patient. The nails are quick to manufacture, taking approximately 10-15 minutes to cut the nail, bend the tip, and bend the nail into shape.

3.4 Surgical Procedure

The surgical procedure for the insertion of flexible intramedullary nails has already been defined by different surgeons and companies, including Barry and Paterson (2004) and DePuy Synthesis (2015). The diameter of the nail to be used is determined from x-rays of the patients femoral shaft, where the diameter of the nail should be approximately one third of the diameter of the canal (DePuy, 2015). Two nail entry locations are made 1-2cm proximal to the distal physis, which are then opened to allow entry for the nail into the canal (DePuy, 2015). The first nail is then inserted with the bent tip of the nail at 90° to the shaft, after which the nail is rotated 180° and inserted until it approximately reaches the fracture site. This process is then repeated using the second nail. The insertion of the nails is performed using a T-handle or insertor and slotted hammer as seen in Figure 3-7 (Lascombes, 2010)**,** assuming that these tools are available at the hospital from previous surgeries or within surgical tool supplies. If these are not available, a set of adjustable pliers may be used to grip and rotate the nail, which can then be struck by a hammer to help insert the nail, however this task is easier if the T-handle or insertor and slotted hammer tools are available.

Figure 3-7 has been removed due to copyright restrictions

Figure 3-7 - T-handle (Top) and Insertor with Slotted Hammer (Bottom) Tools (Lascombes, 2010)

An image intensifier is then used to check the alignment of the two nails, to ensure they have crossed over, and that they are positioned correctly to cross over the fracture site (DePuy, 2015, Barry and Paterson, 2004). The nails are then pushed over the facture site one at a time, and then imaged again to ensure they have entered the canal on the other side of the fracture site rather than exiting through the fracture into the soft tissue surrounding the bone. The image intensifier is also used to ensure that one nail has remained below the other at both points where the nails cross over, otherwise the nails will not be able to be aligned correctly (DePuy, 2015).

3.5 Costs

Cost is an important part of the design of the flexible intramedullary nails, as the tools need to be cheap and readily available, allowing the device to be affordable for patients in developing countries. The costs of the tooling and materials to create the flexible intramedullary nails can be seen in Table 3-1 below.

Table 3-1 - Tooling and Material Costs

Tool/Material	Purchase Location	Cost
316 Stainless Steel Rod – 3mm	All Things Stainless Steel - Online	$1.80 per metre
316 Stainless Steel Rod – 4mm	All Things Stainless Steel - Online	$2.65 per metre
316 Stainless Steel Rod – 5mm	All Things Stainless Steel - Online	$4.90 per metre
Steel Angle Bar Offcut	Bunnings Warehouse	$20.50 per metre
4PCE Quick Grip Clamp Set	Bunnings Warehouse	$29.90
3-22mm Tube Cutter	Bunnings Warehouse	$8.50
Multigrip Pliers	Bunnings Warehouse	$19.98
Total for Tooling		$78.88
Total including 1m of 3, 4, 5mm 316 Stainless Steel Rods		$88.23

As the tooling for manufacturing of the flexible intramedullary nails is a once off purchase which can be used to manufacture multiple intramedullary nails, the initial cost of $78.88 can be considered relatively cheap. The 316 stainless steel rods are also cheap, with 1m of stainless steel able to produce two nails for implantation. If the cost of a set of nails to the patient was set to $10, the hospital purchasing the tooling and stainless steel would recuperate the initial outlay for the tooling after 16 patients when using a 5mm rod of 316 stainless steel, after 11 patients when using a 4mm rod, and after 10 patients when using a 3mm rod. The only potential recurring cost for tooling is the eventual wear of the tube cutter, which would eventually need to be replaced to ensure adequate cutting of the nails.

Wages in developing countries are a critical factor that must be considered when determining the cost of the flexible intramedullary nails. A study by Besamusca et al. from WageIndicator.org reported that in Uganda in 2012, the median wage for informal employment (the cheapest form of employment) was 894 Ugandan Shillings per day, equating to $0.35 AUD. The price of an intramedullary nail is quoted at $125.03 AUD ($95 US) by Kramer et al. (2016), with each interlocking screw costing $19.74 AUD ($15 US), which puts interlocking intramedullary nails out of each for a large portion of people in developing countries. By pricing the flexible intramedullary nails at approximately $10 AUD or cheaper allows access to this form of fracture fixation for a large portion of the population living on minimum wage.

3.6 Assumptions and Limitations

The surgical procedure for the flexible intramedullary nails assumes that the hospital and surgeon performing the operation has a basic set of surgical tools such as scalpels and drills that can provided access to the femur and perform the opening in the bone to allow the nails entry into the intramedullary canal. Additionally, this procedure assumes that the hospital is able to provide an image intensifier for use during the surgery to allow the surgeon to image key checkpoints throughout the operation, such as the alignment of the bone and the nails within the femoral canal.

As the nails will be manufactured in a non-sterile environment, it is assumed that the hospital is in possession of an autoclave or another form of sterilisation. This is a critical requirement, as a sterile nail set must be used to perform the fracture fixation to reduce the risk of infection.

The design and customisation options of the flexible intramedullary nails are limited by the available diameters of 316 stainless steel, and the smallest diameter the tube cutter is able to cut effectively, which, using the currently selected tube cutter, is specified to be 3mm.

4. Flexible Intramedullary Nail Finite Element Analysis

4.1 Objectives

The main objective of performing finite element analysis of the flexible intramedullary nails is to produce a comparative study between the flexible intramedullary nails and an interlocking intramedullary nail. This is a critical clinical test that can be used to determine whether the current stiffness of the fracture allows for full or partial weight bearing. The modelling of the flexible intramedullary nails and the intramedullary nails was to be performed using parts created in Autodesk Inventor, as well as the stress analysis tool also provided within the software. It was decided that a 4-point bend test would be used, with loads of 500N as used by (Abosala et al., 2010). The material properties and dimensions of the femoral shaft will be determined through literature, while the thickness of the interlocking intramedullary nail model will be determined from an existing interlocking intramedullary nail.

4.2 Initial Modelling

As the flexible intramedullary nails are only applied to the femoral shaft, a simple shaft model can be used rather that an anatomically correct model, which will still provide an accurate estimate of an anatomical model.

Average dimensions of an adult femoral shaft were used to construct the model of the femoral shaft. This included an inner radius of 10.05mm and an outer radius of 14.2mm according to Huang et al. (2012). A new material was created in Autodesk Inventor to provide the material properties of the femoral bone, with a Young's Modulus of 14.8 GPa (Rho et al., 1993), and a Poisson's ratio of 0.3 (Wirtz et al., 2000).

The interlocking intramedullary nail will initially have an outer radius of 10.05mm, simulating a perfect fit within the intramedullary canal of the femoral shaft model. This will later be changed to 9.8mm to simulate an imperfect fit, leaving a 0.25 mm gap between the nail and the wall of the femoral canal. The width of the nail will remain at 1.15mm, giving an initial inner radius of 8.9mm for a perfectly fitted nail, and an inner radius of 8.65mm for the imperfectly fitted nail.

4.3 Initial Calculations

Based on the initial model and the 4-point bend test created to compare the stiffness of the flexible intramedullary nails and interlocking intramedullary nails, the maximum displacement of the femoral shaft and of the interlocking intramedullary nail can be calculated using Equations 4-1 and 4-2 as seen bellow.

Equation 4-1 - Calculation of Moment of Inertia of Cylinder

$$I = 0.78(r_o^4 - r_i^4)$$

Equation 4-2 - Calculation of Maximum Displacement

$$\Delta_{\max} = \left(\frac{Pa}{24EI}\right) * (3l^2 - 4a^2)$$

Equation 4-1 calculates the moment of inertia of a cylinder, where r_o is the outer radius of the cylinder, and r_i is the inner radius of the cylinder, as seen in Figure 4-1.

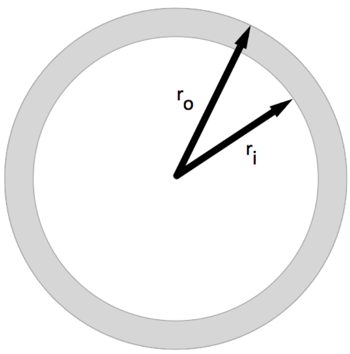

Figure 4-1 - Moment of Inertia Diagram

Equation 4-2 calculates the maximum displacement of the cylinder when loaded with a force P, at a length a from the edge of the cylinder. L is the length of the cylinder, while I is the moment of inertia, and E is the modulus of elasticity of the cylinder, as seen in Figure 4-2.

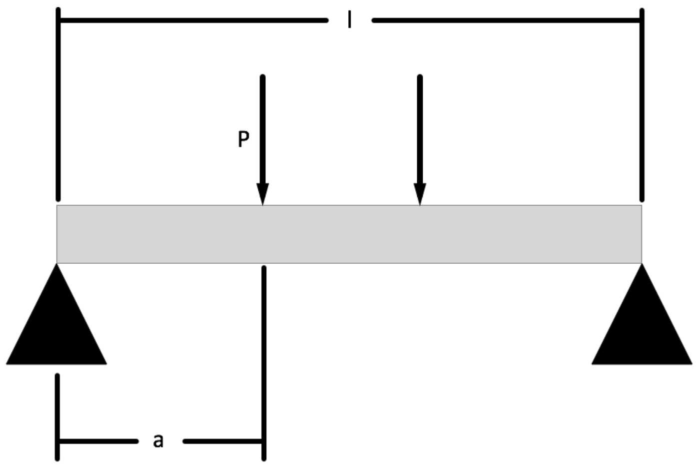

Figure 4-2 - 4-point Bend Test Diagram

4.3.1 Femoral Shaft Initial Calculation

Using Equations 4-1 and 4-2, the moment of inertia and the maximum displacement of the femoral shaft can be calculated.

$$I = 0.78(r_o^4 - r_i^4)$$
$$I = 0.78(0.0142^4 - 0.01005^4)$$
$$I = 2.3757\times10^{-8}\ kg.m$$

$$\Delta_{\max} = \left(\frac{Pa}{24EI}\right) * (3l^2 - 4a^2)$$
$$\Delta_{\max} = \left(\frac{500\times0.127.5}{24\times14.8\times10^9\times2.3757\times10^{-8}}\right) * (3\times0.335^2 - 4\times0.1275^2)$$
$$\Delta_{\max} = 2.052mm$$

4.3.2 Interlocking Intramedullary Nail Calculation

Using Equations 4-1 and 4-2, the moment of inertia and the maximum displacement of the interlocking intramedullary nail can be calculated.

$$I = 0.78(r_o^4 - r_i^4)$$
$$I = 0.78(0.01005^4 - 0.0089^4)$$
$$I = 3.0633\times10^{-9}\ kg.m$$

$$\Delta_{\max} = \left(\frac{Pa}{24EI}\right) * (3l^2 - 4a^2)$$

$$\Delta_{\max} = \left(\frac{500\times0.127.5}{24\times190\times10^{9}\times3.0633\times10^{-9}}\right) * (3\times0.335^{2} - 4\times0.1275^{2})$$

$$\Delta_{\max} = 1.2398mm$$

4.4 Finite Element Analysis

Autodesk Inventor was used to perform the finite element analysis of the 4-point bend tests, using the configuration seen in Figure 4-3 below, correlating to the configuration seen in Figure 4-2, and the values used in the initial maximum displacement calculations.

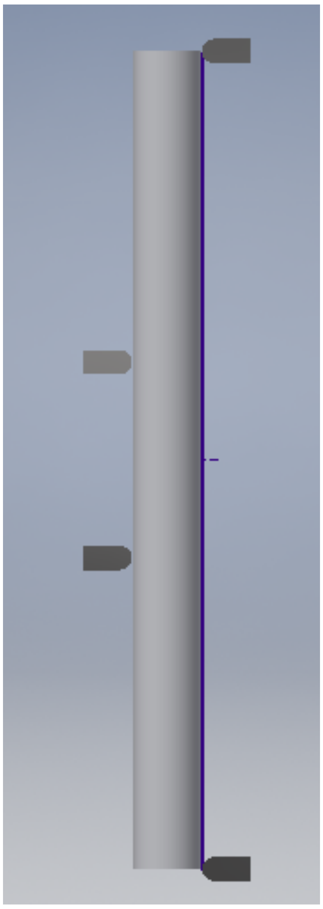

Figure 4-3 - Autodesk Inventor 4-point Bend Test Setup

The contacts between the supports and loads and the femoral shaft were defined as separation contacts. A fixed constraint was applied to the edge supports, while the loads were given frictionless constraints forcing them to only move in one direction rather than tilting after the force was applied, producing inaccurate results.

4.4.1 Unfractured Femoral Shaft

The unfractured femoral shaft was tested to determine the settings that will cause convergence at approximately the expected values, providing confidence in the results calculated.

The results for the unfractured femoral shaft can be seen in Figure 4-4 below.

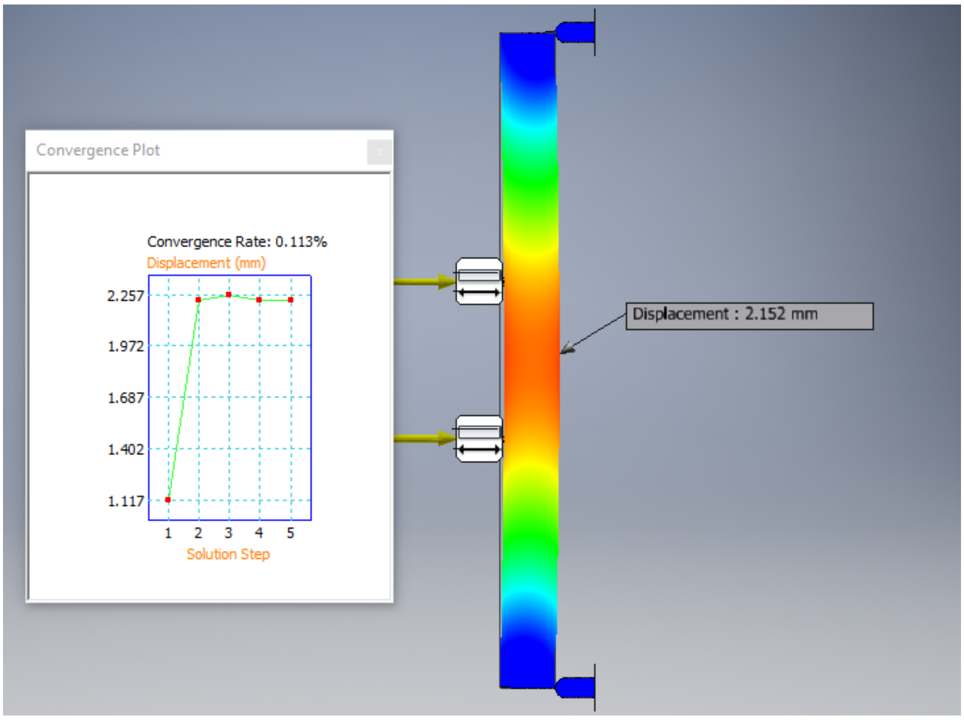

Figure 4-4 - Unfractured Femoral Shaft Test

This test produced a convergence rate of 0.113%, and a resulting displacement of 2.152mm. Compared to the calculated maximum displacement for the femoral shaft of 2.052mm, the finite element analysis resulted in a difference of 4.87%, which is an acceptable approximation.

The settings for the finite element analysis were refined through trial and error until the analysis converged to a result that was approximately the same as that calculated using Equations 4-1 and 4-2. The mesh and convergence settings used in each trial and error test case were varied within the parameters suggested by Autodesk on the Autodesk Inventor Knowledge Network.

The final mesh and convergence settings were:

Mesh Settings

- Average element size (as a fraction of bounding box length) – 0.075
- Minimum Element Size (as a fraction of average size) – 0.12
- Grading Factor – 1.500
- Maximum Turn Angle – 45.00 degrees
- Create Curved Mesh Elements – on

Convergence Settings

- Maximum number of h Refinements – 5
- Stop Criteria (%) – 1.000
- h Refinement Threshold (0 to 1) – 0.75
- Results to Converge – Displacement

4.4.2 Interlocking Intramedullary Nail

The interlocking intramedullary nail was tested to ensure the settings produced during the testing of the unfractured femoral shaft were translatable to other finite element analyses. Using these settings, the results seen in Figure 4-5 were achieved.

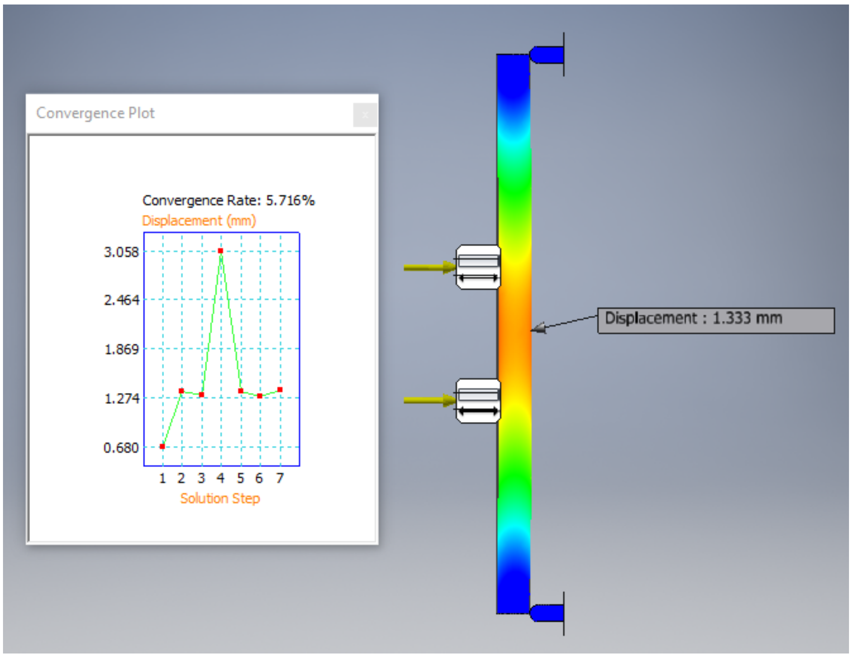

Figure 4-5 - Interlocking Intramedullary Nail Finite Element Analysis

This test produced a convergence rate of 5.716%, and a resulting displacement of 1.333mm. Compared to the calculated maximum displacement for the interlocking intramedullary nail of 1.2398mm, the finite element analysis resulted in a difference of 6.99%, which is an acceptable approximation, and hence these settings will be used for the remainder of the finite element analyses.

4.4.3 Perfectly Fitted Intramedullary Nail Results

Using the settings previously defined, the perfect intramedullary nail fitting was tested for different fracture angles around the midpoint of the femoral shaft. The maximum displacement was recorded, and the width of the fracture opening was calculated using Equation 4-3. The points used in Equation 4-3 are determined using the probe tool within Autodesk Inventor's stress analysis package. As the coordinates of a point on the deformed model could not be acquired directly, two probes were attached to the tip of both fracture ends at the largest opening point of the fracture. The x, y, and z displacement values were observed at these points. An example of these points can be seen in Figure 4-6 below. These values give the position of the fracture ends relative to its initial start point, as the two probed points are the same point on the fracture when the structure is undeformed, and hence the displacement values can provide coordinates for the fracture opening, allowing for the calculation of the fracture opening width. The results of the finite element analysis are summarised in Table 4-1 below.

Equation 4-3 – Calculation of Fracture Width

$$Width = \sqrt{(x_1 - x_2)^2 + (y_1 - y_2)^2 + (z_1 - z_2)^2}$$

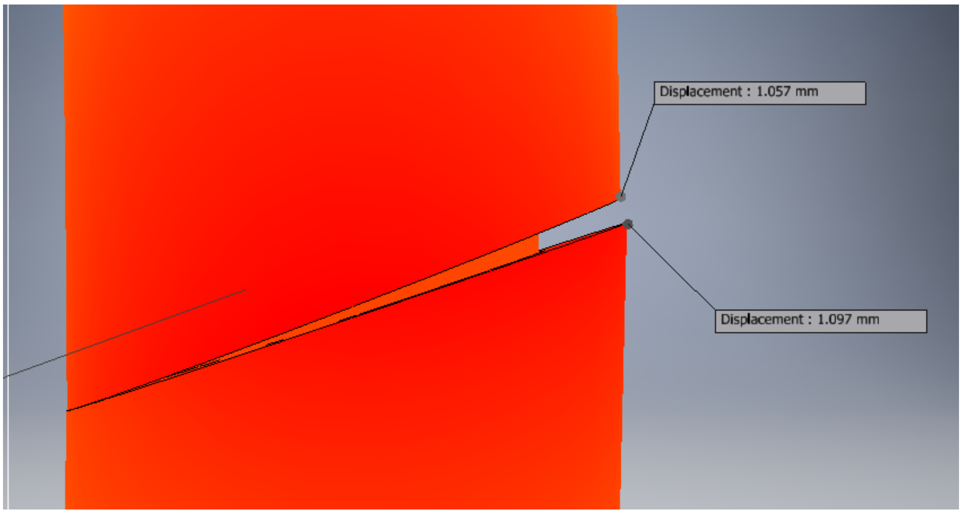

Figure 4-6 - Example Placement of Probes to Calculate X, Y, and Z Displacements for Fracture Width Calculation

Table 4-1 - Perfectly Fitted Intramedullary Nail Finite Element Analysis Results

Test	Max Displacement (mm)	Converged?	Convergence Rate (%)	Fracture Width (mm)
Unfractured + Femoral Nail	0.7296	Y	0.289	N/A
0º Fracture + Femoral Nail	1.095	Y	0.016	0.1590
10º Fracture + Femoral Nail	1.075	Y	0.022	0.1576
20º Fracture + Femoral Nail	1.097	Y	1.902	0.1668
30º Fracture + Femoral Nail	0.8978	Y	0.405	0.1578

4.4.4 Imperfectly Fitted Intramedullary Nail Results

The results of the finite element analysis of the imperfectly fitted intramedullary nail can be seen in Table 4-2 below.

Table 4-2 - Imperfectly Fitted Intramedullary Nail Finite Element Analysis Results

Test	Max Displacement (mm)	Converged?	Convergence Rate (%)	Fracture Width (mm)
0º Fracture + Small Femoral Nail	1.761	Y	0.003	0.4426
10º Fracture + Small Femoral Nail	1.783	Y	0.075	0.4511
20º Fracture + Small Femoral Nail	1.848	Y	0.92	0.4529
30º Fracture + Small Femoral Nail	0.8978	Y	0.405	0.4962

The mesh was additionally refined in some cases, as a mesh density of 0.075 did not produce a converging result, and hence the mesh was refined to 0.05.

An example of the results seen from the finite element analysis of the imperfectly fitted intramedullary nail can be seen in Figure 4-7 below. This figure is adjusted x0.5 to show clearer separation at the fracture site.

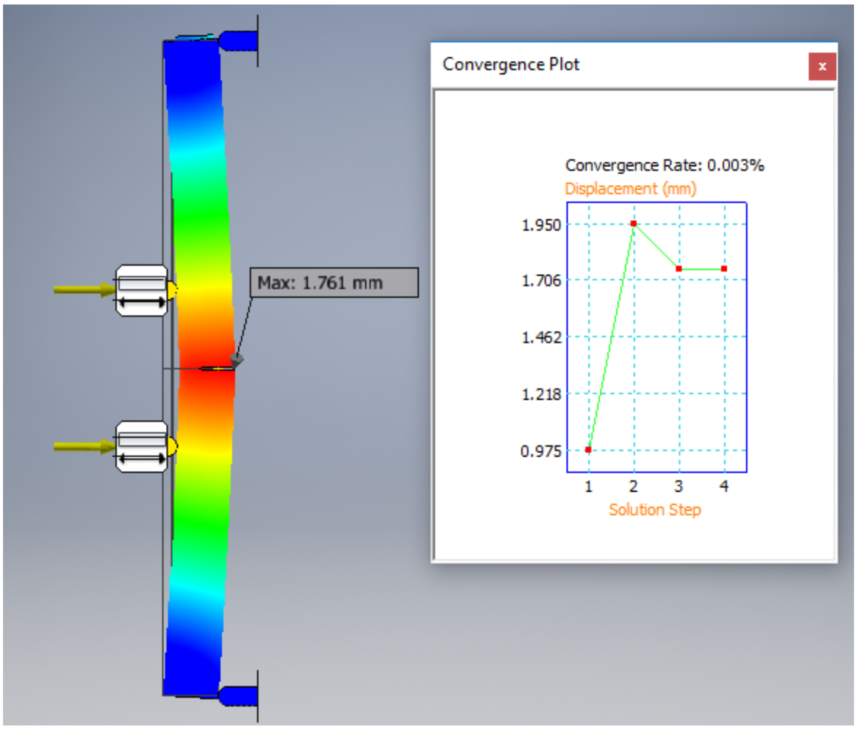

Figure 4-7 - Imperfectly Fitted Intramedullary Nail Finite Element Analysis - Adjusted x0.5

4.4.5 Flexible Intramedullary Nail Results – 3mm

Two 3mm flexible intramedullary nails were modelled as simple, curved stainless steel rods without a bent tip which sit next to each other within the femoral shaft model, as seen in Figure 4-8, to be tested at fracture degrees from 0°- 30° around the midpoint of the femoral shaft.

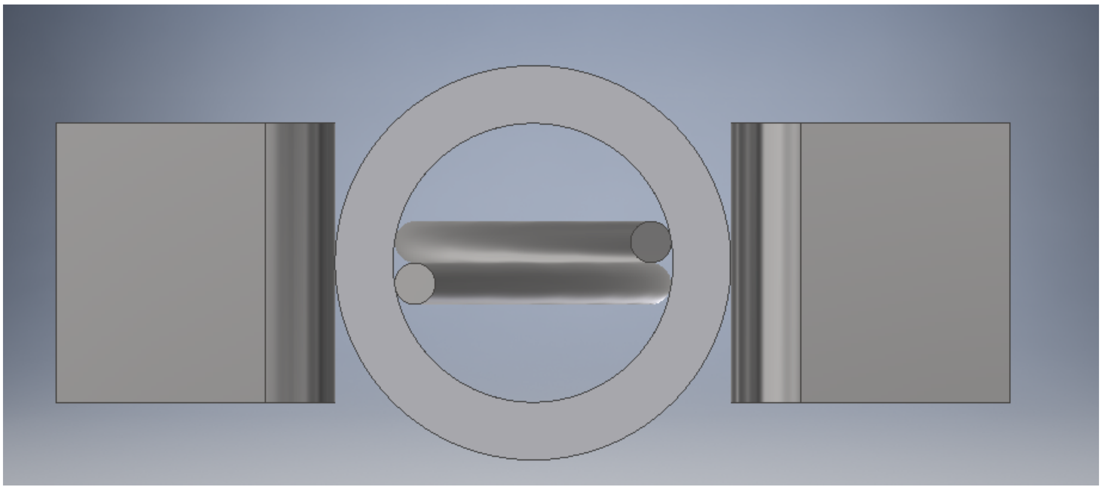

Figure 4-8 - 3mm Flexible Intramedullary Nails within Femoral Shaft Model

These results can be seen in Table 4-3 below. The fracture width measurement for the analysis of the 10° fracture could not be taken as the data was replaced when performing a secondary analysis attempting to cause convergence.

Table 4-3 - 3mm Flexible Intramedullary Nail Finite Element Analysis Results

Test	Max Displacement (mm)	Converged?	Convergence Rate (%)	Fracture Width (mm)
0º Fracture + 3mm Stainless Steel Nails	3.107	N	14.67	0.5253
10º Fracture + 3mm Stainless Steel Nails	3.547	N	2.244	N/A
20º Fracture + 3mm Stainless Steel Nails	5.635	Y	0.243	1.1395
30º Fracture + 3mm Stainless Steel Nails	5.949	Y	0.781	1.593

5. Discussion

5.1 Finite Element Analysis Discussion

5.1.1 Perfectly Fitted Intramedullary Nail

The maximum displacement of the perfectly fitted intramedullary nail decreased as the fracture angle increased with the exception of the maximum displacement of the 20° fracture, following the expected trend as increasing the fracture angle should decrease the maximum displacement as there is additional contact between the two halves of the femoral bone in the direction of the applied force. These forces ranged from 1.097mm to 0.8989mm.

All of the results calculated for the perfectly fitted intramedullary nail reached convergence using the same settings used calculating the maximum displacements of the unfractured femoral shaft and the intramedullary nail. However, the 20° fracture only reached a convergence rate of 1.902%, which is higher compared to the convergence rates ranging from 0.405% to 0.022% for the remaining fracture angles, and results in a slightly higher maximum displacement than expected.

The resulting fracture width was also calculated, with these results remaining relatively consistent, differing by a maximum of 0.0014mm. However this was again with the exception of the 20° fracture results, which resulted in a fracture width of 0.1668mm.

5.1.2 Imperfectly Fitted Intramedullary Nail

The imperfectly fitted intramedullary nail produced results that were opposite to what was expected, with the maximum displacement of the femoral shaft increasing with an increasing fracture angle. However, the maximum displacement only increased by 6% from a 0° fracture to a 30° fracture, and so while there is an increase in maximum displacement, it is not significantly large.

All of the results for the imperfectly fitted intramedullary nail converged at convergence rates below 1%, with the result for the 0° fracture resulting in a 0.003% convergence rate.

As the results have a low convergence rate, there can be high confidence about the validity of these results.

The calculated fracture width also increased with the increase in maximum displacement, with these results increasing by 12%.

5.1.3 Flexible Intramedullary Nails – 3mm

The finite element analysis of the flexible intramedullary nails initially performed poorly, with convergence rates ranging from 13.34% to 79.051%, and hence these results could not be trusted to be accurate. The finite element analysis settings had to be changed to produce any form of convergence.

The settings were originally altered to have an average element size of 0.05 rather than 0.075, increasing the mesh density, which can help to lead to convergence of the results. While this alteration helped to decrease the convergence rate, it did not lead to the convergence of the maximum displacement results.

When analysing the deformed structures that resulted from the finite element analysis, it was noted that the flexible intramedullary nails within the femoral shaft often showed the largest displacement, with the nails rotating slightly. Due to the nature of the analysis, the computation of the maximum displacement was focusing on converging the maximum displacement of the flexible intramedullary nails rather than the femoral shaft. In order to cause the analysis to focus on the maximum displacement of the femoral shaft rather than the flexible intramedullary nails, the convergence settings were changed to exclude the flexible intramedullary nails from the convergence calculations.

The exclusion of the flexible intramedullary nails from the convergence calculations allowed the analysis to converge for the 20° fracture and 30° fracture, however convergence was still not reached for the 0° fracture and the 10° fracture. To help the analysis converge, the h refinement threshold was altered from 0.75 to 0.85. This change tightens the criteria for mesh refinement through Inventor's mesh refinement process, as the areas to be refined must now be within 15% of the maximum displacement value for that analysis rather than 25%, resulting in the refinement of less area of the model. This did not result in the convergence of the maximum displacement results for the 0° and 10° fracture model, however it did decrease the convergence rate percentage compared to previous results.

While a comparison of the maximum displacement across the different fracture angles cannot be performed with the results for the 0° and 10° fracture models not reaching convergence, the maximum displacements for the 20° and 30° fractures models are considerably higher than the displacements seen using the perfectly and imperfectly fitted intramedullary nails. This is also observed in the fracture width.

5.1.4 Intramedullary Nail Comparison

As seen in the results for the perfectly fitted intramedullary nail, the imperfectly fitted intramedullary nail, and the flexible intramedullary nails, the maximum displacement and convergence rate can vary unexpectedly for every fracture angle. This can be explained through the finite element analysis mesh refinement process that Autodesk Inventor utilises.

Inventor utilises triangular mesh elements, and performs both P and H refinements, where P refinements refer to a change in the polynomial formula used to "describe displacements", while H refinements refer to "the size of the circumscribed circle of the triangle". In the first and second refinement iteration, only P refinements are used, and any refinement after this is defined through H refinements. The h refinement threshold is used to determine the size of the area that will be refined as a percentage of the maximum displacement calculated for that refinement, while the number of h refinements determines the number of times this refinement process will occur. As this refinement process and the size of the area refined is determined by the maximum displacement calculated in that refinement step, this can cause variations between the refinement of the mesh at each fracture angle. This is a potential cause of the unexpected results seen in the tables above.

Despite these unexpected results, comparisons can still be drawn between the different forms of intramedullary nailing. The flexible intramedullary nails resulted in a larger maximum displacement compared to the perfectly fitted intramedullary nails and the imperfectly fitted intramedullary nails. This was expected as the flexible intramedullary nails only contact the bone at three points rather than the entire surface area of the nail, and hence the provided stability and stiffness is lower than that of the interlocking intramedullary nails. Also, as there is an increased amount of space between the centre of the nail and the opposite wall of the intramedullary canal, there will be increased displacement, similar to the increase in displacement seen between the maximum displacement results displayed by the imperfectly fitted intramedullary nail compared to the perfectly fitted intramedullary nail due to the additional intramedullary canal space that the femoral shaft could utilise to displace.

A comparison of the maximum displacements of each fracture type and form of fracture fixation can be seen below in Table 5-1. Results in italics indicate that they did not converge.

Table 5-1 - Comparison of Maximum Displacements for Each Fracture Fixation Method for Fracture Angles 0° - 30°

Fracture Angle	Maximum Displacement (mm)		
	Perfectly Fitted Intramedullary Nail	Imperfectly Fitted Intramedullary Nail	Flexible Intramedullary Nails
0° Fracture	1.095	1.761	*3.107*
10° Fracture	1.075	1.783	*3.547*
20° Fracture	1.097	1.848	5.635
30° Fracture	0.972	1.869	5.949

From Table 5-1 using the converged results of the 20° and 30° flexible intramedullary nail models, it can be seen that the 3mm flexible intramedullary nails are able to produce approximately 32% of the stiffness of the imperfectly fitted intramedullary nails, and approximately 18% of the stiffness of the perfectly fitted intramedullary nail. This stiffness comparison does not meet the design requirements specified in section 3.1, however, 3mm nails would not be used clinically in a femur with the width seen in the model.

As a comparison, a 5mm flexible intramedullary nail was tested using a 30° fracture model to determine if the use of a larger diameter nail would produce a smaller maximum displacement. The maximum displacement observed using an average element size of 0.04 was 7.989mm, with a convergence rate of 0.887%, as seen in Figure 5-1.

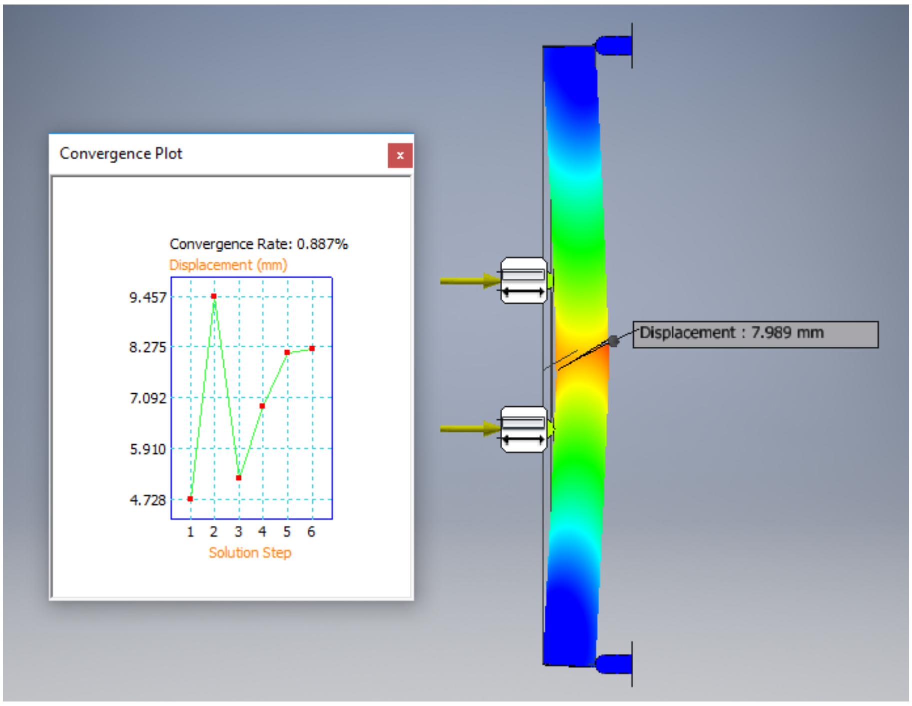

Figure 5-1 - 30° Fracture with 5mm Nail Analysis

The displacement shown from this analysis using 5mm flexible intramedullary nails is higher than that of the same fracture angle using 3mm nails, which is contradictory to the theory that the displacement would decrease with nails of increasing diameter. The 5mm flexible intramedullary nails possess a higher moment of inertia than the 3mm flexible intramedullary nails, and hence the displacement should decrease, increasing the comparable stiffness between the more clinically suited 5mm nails and the perfectly and imperfectly fitted intramedullary nails. As this was not reflected in the analysis performed in Autodesk Inventor, it suggests that the model may be too simplistic in regards to the modelling of the flexible intramedullary nails, also taking into account the variability of the mesh refinement performed by Inventor. A more detailed model and analysis of the flexible intramedullary nails should be conducted in the future to determine whether it is a form of fracture fixation worth pursuing.

5.2 General Discussion

As seen in section 5.1, the flexible intramedullary nails do not meet the design specifications set in section 3.1, and the interlocking intramedullary nails are clearly stiffer than the flexible intramedullary nail. As the interlocking intramedullary nails are stiffer than the flexible intramedullary nails, weight bearing can be achieved earlier. However, as discussed in section 3.4, average families on minimum wage will not be able to afford to purchase an interlocking intramedullary nail, whereas the use of the designed low cost flexible intramedullary nail is more affordable. The low cost of the designed intramedullary nail is a considerable benefit of this form of fracture fixation over the interlocking intramedullary nails, however the use of the flexible intramedullary nails brings its own additional considerations.

As the flexible intramedullary nails do not provide the same amount of stability as the interlocking intramedullary nails, additional considerations must be made regarding the time to weight bearing. Due to the stability provided by the interlocking intramedullary nails, patients are able to weight bear very early during fracture healing before the formation of the hard callus. Weight bearing with the use of the flexible intramedullary nails may not be able to occur until after the formation of the hard callus, as the formation of the hard callus will provide additional stability to the fracture, however only partial weight bearing may be possible until lamellar bone formation has started to occur. Additional support will be required, potentially in the form of a cast to provide more support until the fracture is stable enough to weight bear without additional support. This time to partial and full weight bearing is an area of study that could be further investigated in future work.

Despite the time to full weight bearing is longer than that of interlocking intramedullary nailing, it is shorter than that of Perkin’s traction. This decreases the patient’s length of stay at the hospital, helping to free up bed within the hospital. As the patient has an earlier time to partial and full weight bearing, this also aids in an earlier return to work for the patient, however this is still job dependent. Yet the potential for an earlier return to work compared to Perkin’s traction provides the patient with a more positive outlook compared to being bed bound during Perkin’s traction.

As the time when a patient can return to partial and full weight bearing is dependent on what stage of fracture healing the fracture is in, an image intensifier is critical in the use of flexible intramedullary nails as a fracture fixation method. Not only will it be used to determine when the patient can return to some form of weight bearing, but an image intensifier is used to determine the size of the nails to be used, and to observe the surgery at checkpoints such as aligning the nails to cross the fracture site. Additionally, the clinical environment must have a form of sterilisation available to sterilise the nails after they have been customised, as well as basic surgical tools.

The use of flexible intramedullary nails also has the added benefit of lower complications than the currently used method of Perkin's traction. The main benefit in regards to these complications is being able to avoid the pin tract infection rate of 42.6% that is seen in Perkin's traction (Gosselin and Lavaly, 2007).

The flexible intramedullary nails are easily manufactured, as seen in section 3.3, meeting the design requirement of customisable length and curvature. This benefits the patient, as they are not only receiving a considerably cheaper fracture fixation device, but the device is customised to their specific needs. Further surgery would also be recommended for the removal of the flexible intramedullary nails, however patients may be lost to follow up. If a considerable number of patients are lost to follow up, further studies could be conducted to determine if the removal of the nails is necessary assuming that there are no symptoms of discomfort or reduced hip and knee movement.

These benefits and considerations are all dependent on whether the flexible intramedullary nails can provide enough stability, as the current analysis results show that the nails can provide up to 32% of the stiffness of an imperfectly fitted intramedullary nail. This is below the desired design specifications detailed in section 3.1. Despite these results, as stainless steel flexible intramedullary nails are available for use currently, it would be beneficial to conduct further finite element analysis using a more detailed model of the low cost flexible intramedullary nails which include surgical incision points and the bent tip of the nail, as well as using a finite element analysis tool which allows for greater control over mesh density and convergence analysis. If these results return the same as the analysis seen earlier, the benefits of the use of flexible intramedullary nails over skeletal traction must be considered, however these benefits may not be able to overcome the low stability provided by the nails.

6. Further Recommendations

As the results seen through the finite element analysis of the flexible intramedullary nail did not meet the design requirements specified in section 3.1 and further analysis of a 5mm nail produced unexpected results of a maximum displacement higher than the 3mm nail analysis of the same fracture type, it is suggested that further analysis is performed before a final decision is made on whether to continue development of a low cost intramedullary nail. This analysis would benefit to either confirm the results displayed in section 4, or to provide results that are more in line with the expected results. This analysis would be performed using a more complex flexible intramedullary nail and anatomical femur model compared to the simplistic modelling performed in section 4.

Additionally, the variation in the mesh refinement between the models for each fracture angle may have caused the variations in the results obtained. The next step in this process would be to conduct a similar finite element analysis using the flexible intramedullary nail and anatomical femur model of increased complexity in different software that allows for full control over the mesh density, and how and where the mesh is refined to ensure that a higher level of confidence can be placed in the results obtained. This will remove the variability between the models at various fracture angles, and hence will produce more accurate results.

Assuming that after further investigation the comparable stiffness of the flexible intramedullary nails is at the 50% design requirement specified in section 3.1, further studies could be conducted to determine at which point of fracture healing would the callus formed provide enough stability to perform partial and full weight bearing occur. A finite element model with the inclusion of soft and hard callus formation, as well as callus resorption and lamellar bone deposition, could simulate the fracture healing process from haematoma formation to full bone remodelling. This would allow the surgeon to dictate clearly when weight bearing can occur.

While it is outside the scope of this particular project, additional studies could be conducted to determine the maximum fracture angle that the flexible intramedullary nails could adequately support. The focus of this project has been to investigate transverse fractures, and additional work could be undertaken to investigate whether the flexible intramedullary nails could support a spiral femoral shaft fracture or a basic comminuted fracture assuming there is adequate reduction of the fracture, as successful results in these studies could broaden the use of this fracture fixation method.

Assuming the flexible intramedullary nails meet the design requirements after additional more complex finite element analysis, further investigations should be conducted to determine physical results through testing the flexible intramedullary nails in plastic femoral bone models and cadaver femoral bones. This will provide data to support that found through the finite element analysis.

While there is an indication that this form of customisable fracture fixation device is required, as observed by Professor Mark Taylor, additional surveys of surgeons in developing countries could be conducted to provide feedback on the current system and potential changes that could be useful.

Provided the approval of the required ethics, the device could be tested in a small number of cases in a clinical trial through a hospital in a developing country, allowing the efficiency of the device to be observed. This could then help lead to wide spread access to this form of customisable fracture fixation device.

Ideally the flexible intramedullary nails would be marketed and sold in a kit containing all of the tools required for manufacture, as well as 1 meter lengths of stainless steel at varying diameters to provide enough material for the surgeon to perform the fracture fixation method after receiving the kit. Further investigations need to be performed to determine if it is cheaper to collate the tools and materials in Australia to then be distributed in the developing world through local suppliers, or whether it is more beneficial to provide local suppliers or the hospital with the list of tools and materials required to perform the surgeries. This decision would be influenced by the availability of the tools within the developing world, as the kits could easily be constructed within Australia as the tools are available from Bunnings Warehouse, and the stainless steel is available from a local store online. Ideally the kits would be sold at cost price or for minimal profit to the developing world as the aim of the project is to provide a cheaper fracture fixation method rather than using a need to create a profit.

While the surgical method is already established, surgeons would need to be trained in how to customise the flexible intramedullary nails to suit each patient, as well as slight variations in the surgical procedure, or teaching of the entire procedure if the surgeon is not familiar with the surgery. Additional clinical studies could be conducted to investigate whether the flexible intramedullary nails can remain implanted or if they need to be removed. While removal of the nails is suggested, if a large portion of patients are lost to follow up and hence the nails remain implanted, a study investigating the potential symptoms and effects of not removing the implant may be beneficial.

7. Conclusion

Femoral shaft fractures are a common occurrence in motor vehicle accidents, with Africa having the highest prevalence of motor vehicle accidents in the world. The most common form of fracture fixation, skeletal traction, results in many complications including a 42.6% infection rate and leave patients bed ridden for approximately seven weeks (Gosselin and Lavaly, 2007). While first world fracture fixation methods such as interlocking intramedullary nailing provide the best results and are available in the developing world, they are expensive and are outside the price range of patients working for minimal wage (Besamusca et al., 2012, Kramer et al., 2016) and are not customisable for patients.

Flexible intramedullary nails have been used for femoral shaft fracture fixation, and provide adequate time to full weight bearing and knee joint mobility with minimal complications. As the flexible intramedullary nails are made of single, solid rods, these can be easily customised to suit each patient. These nails can be created from 316L stainless steel rods of varying diameter, which can be cut to a desired size and curved to allow the maximum point of curvature to cross the fracture site, allowing for individual patient customisation.

Finite element analysis comparing flexible intramedullary nails to a perfect and imperfectly fitted interlocking intramedullary nail show that the flexible intramedullary nails can only provide a maximum stiffness of 32% of the stiffness of the imperfectly fitted interlocking intramedullary nail. This does not meet the required design specification of the low cost flexible intramedullary nail, and hence further finite element analysis must be performed using a more complex flexible intramedullary nail and femur model with full control over the mesh density and convergence analysis to confirm if the low cost flexible intramedullary nails can provide enough stability to merit their use in fracture fixation. If the low cost flexible intramedullary nails are shown to provide enough stability to merit their use, then additional studies investigating the nail performance in physical plastic and cadaver models, as well as clinical trails, surgeon training, and the development and distribution of a kit containing the required tools and materials should be conducted.

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