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Distal Femur Fracture Fixation Solution

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Clinical Background

Clinical Problem

There are currently three main solutions for fixating a fracture of the distal femur: external fixation, internal fixation or an intramedullary implant.

External fixation or Ilizarov's method involves aligning the limb by placing metal rods, that are connected outside the body, to each fractured bone and compressing the surface of the fracture. The fracture unites as bone formation takes place within the existing tissue. (Elliot et al., 2016)

Internal fixation involves using a plate and screws to connect the fractured bones and stabilize them. However, the plate(s) need to be placed very carefully as fractured bones should be perfectly aligned, without compression, and no gap in between. (Elliot et al., 2016)

An intramedullary implant involves inserting a hollow metal rod into the medullary cavity of the bone through either the proximal or distal end of the bone in order to support the fracture while it heals. (Piétu & Ehlinger, 2017)

Current Solutions

Current methods have been proven to have multiple drawbacks, including slow healing, malunion, or deep infections.

External fixation is an inadequate solution as it leaves the patient very susceptible to infection due to the open wounds created in the skin. This would be especially dangerous for elderly patients who likely have weaker immune systems. Elliott et al. (2016) also found that using Ilizarov's method has a low strain amount, which meant no callus formation, and took a long time to heal.

Internal fixation is not an ideal solution because often the plate used to join the fragments bends when the patient puts their full weight on it for long periods of time, therefore most physicians have patients bed-ridden for the first few weeks or using crutches to avoid total weight-bearing. For elderly patients, who often have balance issues and thus could not use crutches, being immobile for so long increases the probability of mortality. "The effect of functional limitations (prolonged time of immobility) leading to decreased ambulation may be sufficient to impact patient mortality." (Streubel et al., 2011). Newman, et al. (2016) discussed the problems with internal plate fixation. They found that healing is slow, and there is no callus formation because of the low strain in the implant. At the same time, plates need to be placed very carefully, as fractured bones should be perfectly aligned, without any compression and no gaps in between.

An intramedullary implant, unlike internal fixation, requires a minimally invasive surgery which is ideal for minimizing infection and other surgical risks, such as mortality. Invasive surgical procedures and acute physiological stress were the most probable causes of complications such as bronchopneumonia, malignancy, ischemic heart disease, and sepsis during the early postoperative phase (Streubel et al., 2011).

Furthermore, Leider, et al. (2021) conducted a study on the effects depending on the amount of postoperative weight bearing elderly patients are prescribed. The study showed that, regardless of the weight-bearing, both intramedullary nail (IMN) and distal femoral locking plate treatments had the same primary outcomes after 6 months, including nonunion/malunion, deep infection, fixation failure, or change in alignment (and needing reoperation). Thus, the current solutions for non-invasive strategies are difficult to implement, have slow healing due to a low weight bearing, and could still lead to many drawbacks (such as malunion, fixation failure and need of reoperation).

Our Client

The specific client of this case is an 88-year old female patient suffering from a transverse comminuted distal femoral fracture on the same leg as a unicondylar knee replacement. The design solution will also apply to males with similar fractures, but it has been shown that the low-impact femoral fractures are most frequent in elderly women (Streubel et al., 2011). It is important to reduce postoperative immobilization time with elderly patients because lengthy immobilization may lead to muscle atrophy, which is a greater risk in patients aged 65+ years old due to “higher catabolism in skeletal muscle after surgery” (Huang et al., 2017). Similarly, diabetic patients may suffer from the same issue because increased hyperglycemia levels after surgery promote muscle atrophy (Huang et al., 2017). Additionally, once muscle atrophy has taken place, the ability to regain ambulatory ability is low in the elderly because their preoperative ambulatory ability and muscle mass levels are oftentimes low (Ogawa et al., 2008). Reducing immobilization time is also important for younger demographics because in general, mortality rates of patients with internal fixation procedures may increase with each extra day a patient is immobile after their operation (Pierre Guy, 2021).

People with balance issues, such as Parkinson's patients, are also potential clients because they likely find it challenging to bear most of their weight on their unaffected leg even with an aid such as crutches. Chou et al. (2020) demonstrate that after internal fixation operations, Parkinson’s patients have longer hospital stays and higher surgical failure rates, and they require a more rigid and stable fixator to heal their fractures (Chou et al., 2020). Osteoporosis affects 11% of females with similar femur fractures as the 88-year old client (Streubel et al., 2011) and is, therefore, an additional key characteristic of the target client.

Details of primary clients of this design are outlined above; however, in theory, any patient who requires a rapid recovery to full ambulatory ability after a comminuted femoral fracture may be a client of this implant design.

Design Requirements and Needs

NOTE: These are expressed needs ranked loosely (latent and threshold needs in Appendix B)

ID	SOURCE	NEED STATEMENT
1 - Weight bearing	**Dr. Pierre Guy** (expressed need): *Mortality rates increase with every day the patient is immobile after operation.* **Project Description** (expressed need): *"older patients respond poorly to immobilization... as they can develop significant medical complications… [they] have a high rate of medical comorbidities and a high rate of morbidity and mortality after a femoral fracture."*	Implant allows for standing and walking without mobility aids almost immediately after surgery.
2 - Minimally Invasive	**Dr. Pierre Guy** (expressed need): *Invasive surgeries, like total femur replacement, are very expensive and have a high chance of being unsuccessful. Minimally invasive surgery generally leads to better blood flow post-op. Benefits also include smaller incisions, less pain, and faster recovery.*	Implant does not disrupt the blood supply to bone and requires minimal incisions during surgery.
3 - Load-sharing	**Ganesh et al. (2005):** *"the big difference in modulus between the plate and bone… disturb the vascularity of the bone underneath the plate, causes bone resorption underneath the plate and reduction in strength."* **Lovald & Kurtz (2011):** *Wolff's Law → "The effects of stress shielding on a healed bone begin with the resorption of bone on the endosteal cortex, followed by a widening of the medullary canal and a thinning of the cortices. Clinically, stress shielding… may lead to either failure of the fixation or refracture of the bone after plate removal."* **Dr. Pierre Guy** (expressed need): *Fragment displacement decreases with increased rigidity.*	After the fracture is fixed with the implant, the femur bone still takes a fraction of load during weight bearing. Implant is still rigid enough so the healing process is undisturbed.
4 - Low moment	**Dr. Pierre Guy** (expressed need): *Internal fixation plates bend with time because of their lateral distance from the vertical force being applied on the greater trochanter (creates a moment)*	Device is not subjected to high bending moments during weight bearing.
5 - Minimal time under anesthesia	**Dr. Pierre Guy** (expressed need)***:*** *Less time under anesthesia leads to better postoperative outcomes. If it takes longer than the current solution, it must be justifiable.*	The length of the implantation is similar to or lower than current femur fracture fixation surgeries unless it performs tremendously well in other categories

Additional Requirements mentioned in Appendix B

ID	**DESIGN REQUIREMENT**	**JUSTIFICATION**
1 - Functional	The implant must allow for simple daily loading scenarios (ie. walking and standing) without breaking or permanently deforming. The implant must allow for at least 260% of the body weight.	The implant cannot bend or snap under full weight bearing pressure otherwise misalignment of fracture segments may result. During normal walking the forces affecting the lower limb can be as high as 260% of body weight (Bergmann et al., 2001).
2 - Constraints	The implant must not cause more than 5% strain on the bone.	More than 5% strain on the bone can interfere with bone healing The bone healing unit has 100% strain tolerance. Then, under lower strains, the unit yields to cartilage, which has 10%. At last, healed bone is formed and has a 2% to 5% tolerance. An excess strain causes bone to form nonunion and not heal (Elliot et al., 2016).
3 - Physical	The implant must not be placed greater than 1.5cm away from the central axis of the femur.	The moments on the distal femur about all axes are relatively small during walking (Bergmann et al., 2001) - we do not want to deviate the fixation device position too far from the bone. This way we do not subject the device to a large bending moment. 1.5cm comes from the average adult femur having an average diameter of 2.34cm (OrthopaedicsOne).
4 - Functional	The femur bone must share at least 10% of axial loading with the device during weight bearing.	The femur must share some of the load during walking or standing, otherwise new bone formation will be inhibited, causing non-unions of fractures, and the bone will weaken due to Wolff's Law.
5 - Functional	The implant must be able to align at least 4 bone fragments, both including regular and comminuted fractures.	According to an article from NCBI, the majority of bone fractures are related to a compression force. In general, ***4 distinct bone fragments*** are formed in bone fractures due to this force. (Bryan A. Hozack, 2019) These fragments can either be comminuted or partially aligned, depending on the amount of force, the direction of force, and more.
6 - Physical	The length of the implant must be smaller than 40cm (for general use in elderly patients).	The average buttock-popliteal distance for elderly women is 44cm (Kothiyal & Tettey, 2001) so any implant longer than this will not work for the primary client. It is assumed that most elderly males and adults will have longer femur lengths than this so the device will work for them.

Concept Generation

The team sat together and spent 10 minutes brainstorming individually and developing a preliminary design solution sketch. Once finished, each member presented their idea to the rest of the team. The team then had open discussions to see how each design might be improved or how separate ideas might be combined in order for each design to meet the design requirements set beforehand. Specifically, the requirements for weight-bearing, increasing load-sharing, alignment of 4 fragments, and working around a partial knee replacement were taken into consideration. Each member then spent time over the course of a week coming up with a clean sketch for their design, adding or refining the idea wherever they found it necessary. The concepts were ranked in order of plausibility, where high plausibility was defined as being similar to an existing solution. The intramedullary implant design was considered the most plausible due to its similarity to existing solutions and the double helix design was the least plausible due to the curved plates. This was a preliminary ranking and all designs were still moved on to the concept selection process without bias. Sketches of the following designs can be found in Appendix A.

1: Intramedullary (IM) Implant

This design uses a metallic rod that goes in the medullary cavity by way of antegrade insertion, so between the femoral head and the greater trochanter. This design could also be inserted from the distal end, for patients that do not have a partial knee replacement. The rod design should be able to support the weight of the patient and not deform as a result.

There are four large main screws that go all the way through the bone and rod to provide structure and to ensure the implant stays in place. There are optional smaller holes in the rod for screws as needed by the surgeon depending on the specifics of the fracture and bone porosity. These additional screws, which are closer to the fracture site than a traditional IM nail, allow for more stability and a stronger guarantee of fragment alignment during the healing process. This design lends itself to a minimally invasive surgery as several small insertion points can be made instead of full open leg surgery.

2: Ilizarov Method Vol.2

This design is the combination of the internal fixation plate and Ilizarov’s method (external fixation). Although the Ilizarov method does not involve an internal fixation plate to place the pins through it, this design provides additional stability with its plate. So, the plate can support excessive forces and not deform as a result, while protecting the fracture site. Furthermore, a number of screws (adjustable) are placed into the bone through the fixation plate to distribute the force on the femur caused by the weight, and to add additional resistance.

3: Plate and Pin combination

This design combines the use of pins through the femur and a secure plate locked with screws. It uses two pins, one with a hole to insert the other pin into, for a more secure hold on the fracture. The design also has a plate under the muscle, in contact with the bone to allow for greater security during the healing process. This design is quite invasive to insert, as it travels through the entire bone, however, it provides much more security, and rigidity, through a mechanism that makes the pins more inelastic. It would require precision to be able to insert one rod through another, being deep into the bone. There would need to be premade holes in one of the rods to allow for this, and precise plans to allow the angle and length of the rods to be right, so the two rods fit as needed.

4: Metal Covering

This design aims to distribute/relocate the weight-bearing force away from the fractured region as much as possible, so the patient can start using leg muscles while the weight-bearing force is not transferred (or significantly reduced) to the injured region.

The entire implant comprises multiple curved titanium (or stainless steel) plates inserted in the region between bone and the surrounding muscles. Eventually, the individual implants are ideally located and surrounding the fractured region. Those individual pieces will then be tightly locked to each other and work as one implant.

This design allows the distribution/relocation of the weight-bearing force away from the fractured region because it allows multiple intramedullary nailing/rod fixations sites to work in various locations. The mechanical analysis and the design of the fixations sites can be varied patient by patient, resulting in the use of different lengths, different placements, and orientations of intramedullary nails and rods. Those fixation sites perfectly cover (collectively) the entire 3-dimensional region of the fracture and the nearby location as the implant completely surrounds the bone. This will give much more flexibility and decision options for the surgeon/clinician to idealize and personalize the solution to individual patients. Fixation sites can be custom-made by surgeons/clinicians/engineers before performing surgery by simple drilling equipment. The fixations sites can be utilized to interact with nearby joints or any other implants.

Another aim of this design is a minimally-invasive surgical procedure. The incision only needs to allow one individual piece to go through at each time. Once the implant is placed and locked at the injured region further small incisions will be additionally made to insert the intramedullary nails or rods.

5: Compressible Internal Fixation Plate

This design is somewhat of a variation of the internal fixation plate. However, it contains two plates lateral to the bone, one above and one below the distal femur fracture. These plates are made of titanium and are drilled into the femur with titanium screws. The top plate has a narrower section that protrudes from it and inserts into the bottom plate. The bottom plate has an opening for a crank to be inserted in; the crank can be turned to tighten the protruding part of the top plate, effectively compressing the whole bone together with the bone segments of the fracture aligned. This creates an “artificial” weight bearing for the patient’s leg and promotes healthy bone healing of the fracture. Note that the crank is only temporary and is removed once the implant is fixed. A slightly more invasive but more balanced approach would be to put an additional similar compressible plate on the medial side of the femur.

6: Double Helix

The “Double Helix” consists of two plates wrapping the femur with a structure similar to a double helix. The metal plates are manufactured to rotate in the middle section so they can cross the femur and fixate on both the medial and lateral femur. One of the plates crosses the femur posteriorly while the other one crosses the femur anteriorly. Both plates are fixated with nails superior and inferior to the fracture site on both sides of the bone. This design is a patient-specific solution and can be modified by the surgeon according to the fracture. In some fracture cases, such as existing knee replacements or the size of the fracture, only one plate can be used, or the positioning of the plates/nails from the original design can be altered.

Concept Selection

All 6 concepts were first run through a pass/fail table (as seen below) using the requirements outlined in a previous section in order to narrow down possible designs. Note that there were several requirements (labeled as “Unknown” in the table below) that could not be accurately checked without testing of the designs so these were excluded from the results of the pass/fail requirements. From this table, the Intramedullary Implant and the Metal Covering were the only designs that passed all verifiable requirements. The Ilizarov Method Vol.2, Plate and Pin combination, Compressible Internal Fixation Plate, and Double Helix did not pass all pass/fail requirements, so they were eliminated.

ID	**1**	**2**	**3**	**4**	**5**	**6**
Supports 260% BW	☑	☑	☑	☑	☐	☐
<5% strain on bone	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Does not contact knee replacement	☑	☑	☐	☑	☑	☐
Non-toxic	☑	☑	☑	☑	☑	☑
<1.5cm lateral distance from femur central axis	☑	☐	☑	☑	☑	☑
Allows bone to support >10% of load	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Can align >= 4 bone fragments	☑	☑	☑	☑	☑	☑
Surgery takes less than 3 hours	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
<40cm length	☑	☑	☑	☑	☑	☑

Requirements pass/fail table: 1 - Intramedullary Implant, 2 - Ilizarov Method Vol.2, 3 - Plate and Pin Combination, 4 - Metal Covering, 5 - Compressible Internal Fixation Plate, 6 - Double Helix

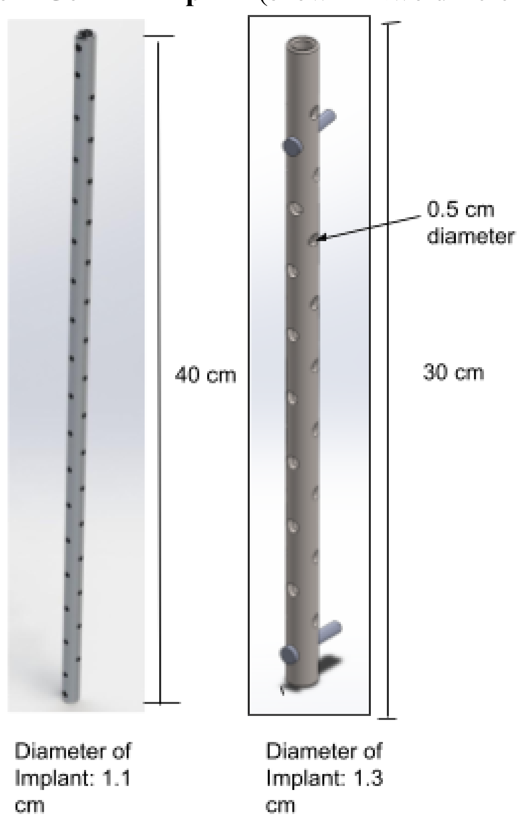
Some of these requirements are justified in Appendix B

Following the pass/fail elimination system, the 2 remaining concepts (Intramedullary Implant, and Metal Covering) were ranked on a more qualitative basis. In other words, they were ranked according to the needs table. The higher ranking concept was the Intramedullary Implant because of its ability to take on load, its minimal bending moment, its minimally invasive surgery approach, and its lack of interference with blood supply and with the partial knee replacement. The Metal Covering approach was deemed unrealistic because of the highly invasive surgery it would require. However, the holes spread across the Metal Covering were seen as an advantage because they would reduce stress shielding on the bone compared to a solid implant according to the mathematical relationships between cross-sectional area, Young's modulus, and force distribution between two different materials. These holes were therefore combined with the Intramedullary Implant design to create the final design proposal, as outlined in the next section.

Final Design

Our final design is the Next-Gen Intramedullary (IM) Implant, a hollow IM nail lined with many additional holes throughout the rod. The implant allows for a minimally invasive surgery as it is inserted into the medullary cavity of the femur. Since it is an intramedullary nail, it can be inserted through either the distal or proximal end of the femur allowing the design to be used in patients with a unicondylar or even a total knee replacement. The holes allow for a decrease in stress-shielding as they decrease cross-sectional area throughout the length of the nail. In addition, the holes allow for the implant to be lighter than other implants.

CAD design images of the Next-Gen IM Implant (shown in two different sizes)



Future Work

The next step of our design would consider incorporating biodegradable materials, with growth factors to promote bone regeneration. The integration of biomaterials to the implant can accelerate bone growth/healing and lead to the bone being full weight-bearing in a shorter time period post-operation. Choosing a biomaterial that is biodegradable inside the bone tissue will allow for a timed release throughout the early stages of bone regeneration. The degradation rate and dosage of the chosen biomaterial can be tested with reference to existing literature in biodegradable scaffolds. Furthermore, making the Next-Gen IM implant itself biodegradable can have many advantages in terms of the biocompatibility of the implant, as well as eliminating the negative biomechanical and surgical implications of current implants such as stress-shielding, secondary surgery and permanent physical irritation. He et al. (2021) found that biodegradable porous scaffolds with an inner layer of iron and an outer layer of zinc show similar mechanical properties to the cancellous bone while having a controllable degradation rate. The Next-Gen IM implant design can be tested with similar materialistic properties to improve the current design.

Further physical prototyping of the implant would focus on testing the mechanical features of the implant. These tests include: measuring the stress and strain on the implant and the implant-femur complex under loading conditions associated with walking and standing, measuring the strain on the femur after the implant has been placed to ensure the bone tissue is not under a strain more than it can tolerate, measuring the distribution of the loading force between the femur and the implant to ensure the bone is supporting at least 10% of the load and the implant does not cause a substantial stress-shielding effect. Additionally, the surgery to place the implant, in theory, should be minimally invasive and thus require a minimal amount of time under anesthesia. There is no way of determining the actual time frame for implantation without performing the procedure in clinical trials, so this theory has to be further validated during future testing steps for the implant.

Contributions

Raghav Madhwal- Current Solutions
Enda Cakmak - Future Work
Alperen Celik - Brochure
Krishma Singla - Intramedullary Implant Design, Clinical Problem
DongWoo Han- Clinical Problem, Current Solutions, Brochure
Latif Dhalla- Current Client, Final Design, Concept Selection

All members contributed equally to the research for Clinical Background, Design Requirements, and Concept Generation.

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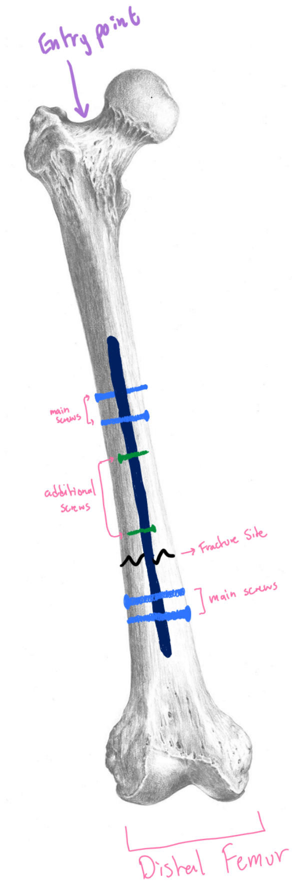
Appendix A: Concept Generation Designs

Intramedullary Implant



Ilizarov Method Vol.2

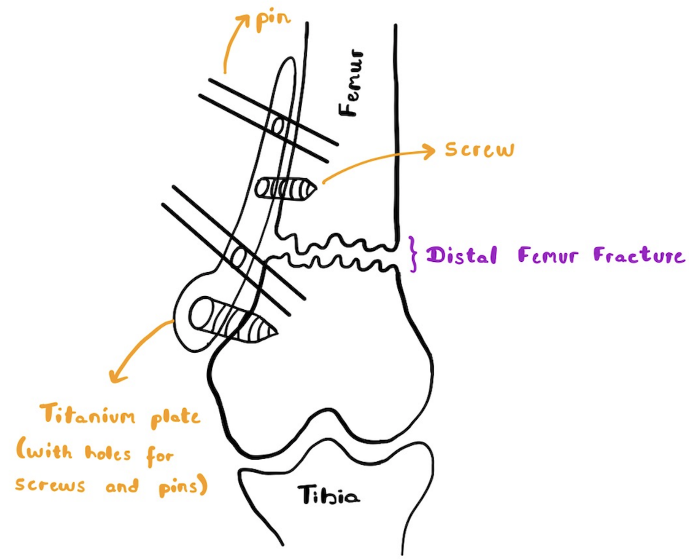
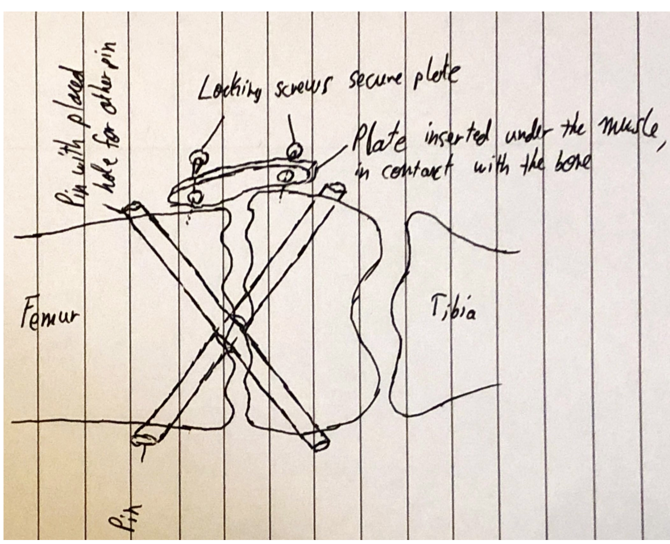
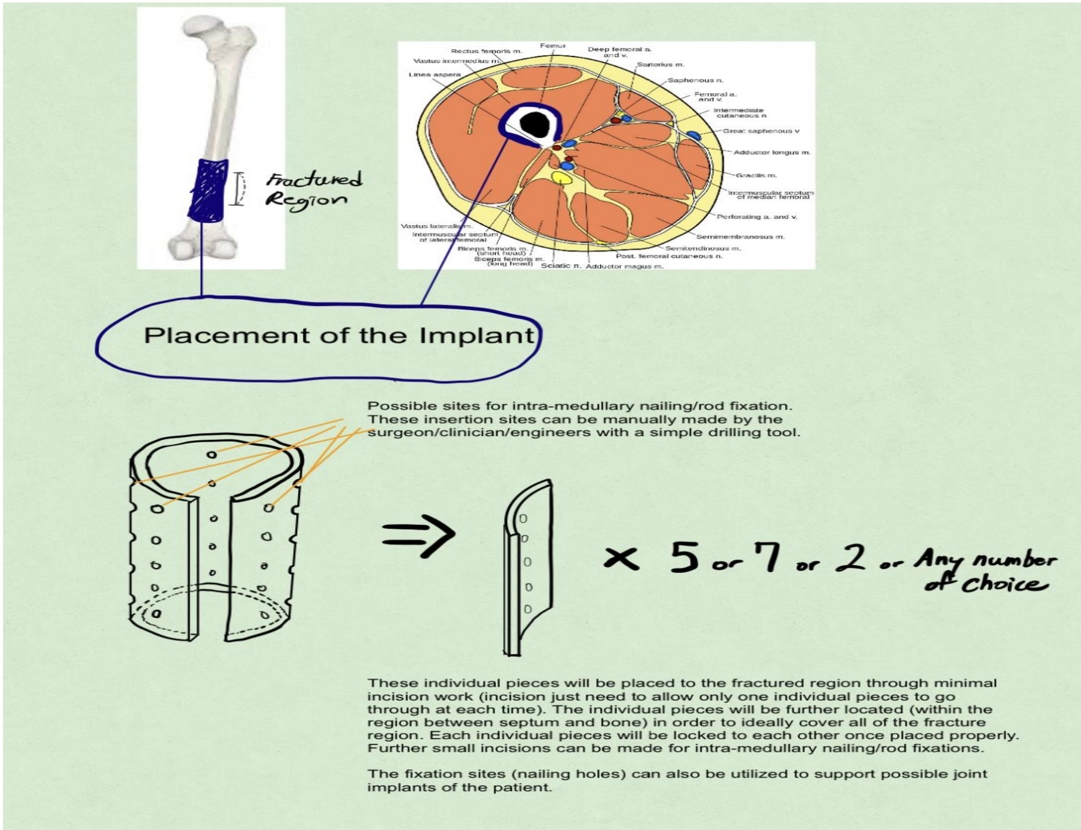


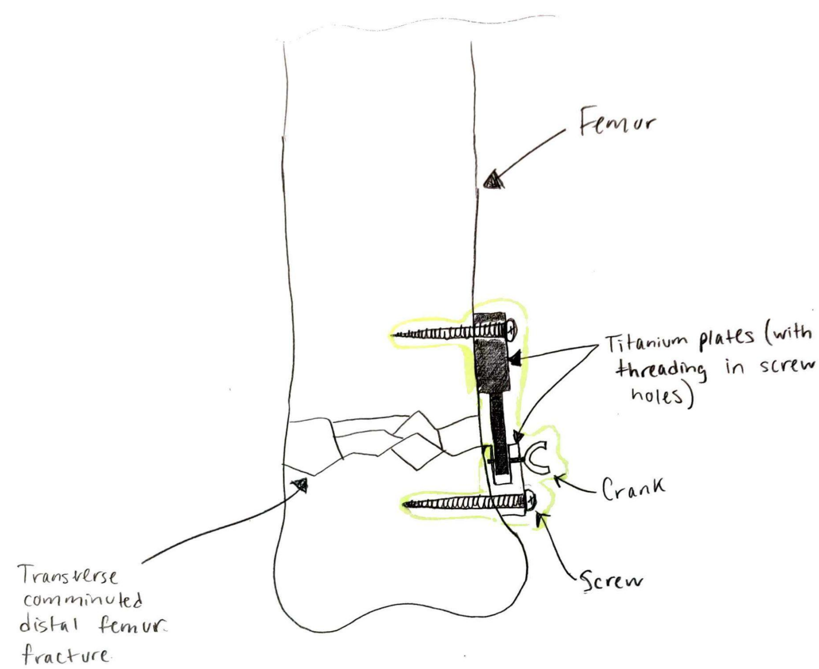
Plate and Pin combination



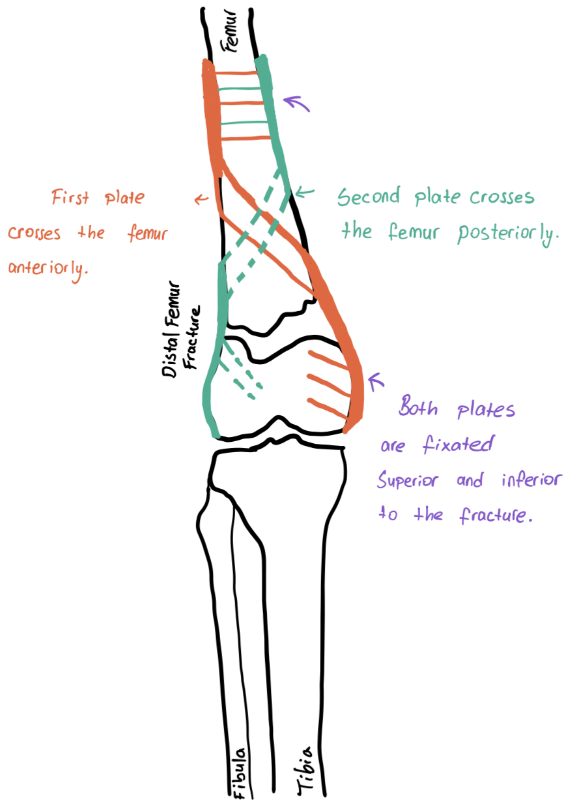
Metal Covering



Compressible Internal Fixation Plate



Double Helix



Appendix B: Additional Needs and Requirements

Threshold and Latent needs of the patients and surgeons:

ID	SOURCE	NEED STATEMENT
6 - Not prominent	**Dr. Pierre Guy** (expressed need): *prominent implants may get too near the skin and will then need to be removed (not ideal for healing)* **Patient** (threshold need)	The implant does not cause any physical pain or emotional discomfort. It does not lie too close to the surface. It is not prominent enough to make the patient feel isolated from society.
7 - Adaptable	**Surgeons** (threshold need): *not ideal to modify the implant or the surgery procedure in order to get the implant to fit the patient.* **Hospital** (threshold need): *buying many different custom sizes of the implant for patients with different body types is not cost-effective.*	Implant size is suitable for most elderly (with focus on female) patients
8 - Cost Effective	**Hospital** (threshold need), **Patient** (latent need) ***these are assumed needs*	Implant does not cost an extraordinary amount relative to current fixation plates.

ID	DESIGN REQUIREMENT	JUSTIFICATION
7 - Regulatory	The fixation surgery does not take more than 3 hours.	Current internal fixation surgeries take around 1-2 hours ((Alberta Health Services, 2021)) so it does not make sense to make a device that takes a much longer time to fix. A long surgery time would negatively impact the patient (longer time under anesthesia and likely more invasive) as well as the hospital and surgeon (longer surgeries are not ideal).
8 - Regulatory	The material must be biocompatible and non-toxic to the body. Any material used in the implant proven to be toxic to humans fails this criteria.	Prevent deep infections and material decay. General Health Canada Guideline. "Reasonable measures shall be taken to ensure that every material used in the manufacture of a medical device… shall not pose any undue risk to a patient, user or other person." (Legislative Service Branch, 2021)
9 - Physical	There must not be contact between the implant and a partial knee replacement throughout fixation.	Patient has a partial knee replacement which may be damaged if subjected to direct loads from the fixation device, or which may prevent the surgeon from fixing the implant in the first place.