BMEG 230 Final Project: Fracture Fixation Plate

Group 22
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Clinical Background

Clinical Problem

To support healing of a fracture, a fracture plate is often surgically implanted into a patient to provide skeletal support and aid bone healing by allowing for early weight bearing. In the case of the elderly woman, the fracture we are dealing with is a comminuted extra-articular femoral fracture where the bone breaks straight across in the transverse direction into many pieces but does not extend to the knee joint ("American Academy of Orthopaedic Surgeons," n.d.). This injury is prominent with the elderly especially women due to their high susceptibility to osteoporosis. As bone is made of living tissue, to ensure its upkeep, the body breaks down old bone and replaces it with new bone, however, in the case of osteoporosis, the rate of bone resorption is greater than the rate of bone formation leading to a degradation of bone density over time making it more brittle (Harvey & Cooper, 2018).

The current solution involves a surgery where the fractured bone fragments are realigned and a locking plate is installed to provide stability as the bone heals. The locking plate is designed for light weight-bearing such as rehabilitation exercises or walking without significant weight bearing to the affected leg using crutches or walkers. Although they are viable recovery options for younger patients, they pose problems with the elderly as they often face balance problems due to deterioration of the vestibular system which comes with aging. The vestibular system is the sensory system which creates the sense of balance and spatial orientation (Jahn, 2019). For these reasons, the implant designed must be able support full weight bearing or the patient stands the risks of immobilization. The design of the implant also needs to be biocompatible and durable for a long period of time because due to the patient's age, the implant will likely not be taken out of the body to mitigate risks and recovery associated with another traumatic operation.

Current Solutions

As mentioned, there currently exist many solutions to allow for the best healing while also sustaining a high quality of life in patients following a femur fracture. With the specific demographic of elderly women, it is extremely important that this process is minimally invasive, and that patients be able to fully bear weight as soon as possible to prevent muscle and bone deterioration. Solutions such as plates, inserted along the lateral side of the bone, are not able to counter coronal plane moments, and tend to bend very quickly under the stress. Other solutions such as rods, inserted inside the bone, also have their faults. These, while they are not as susceptible to bending, do not always fix the bone fragments properly, allowing them to heal while aligned.

There is a large lack of research on femur implants for this specific demographic which is what results in the many complications with these surgeries. Current solutions that exist are not primarily designed for elderly women, meaning that often implants that are used for this group are not well supported. In successful surgeries, often implants come from a previously existing model that then needs to be adjusted to better the patient, meaning it is not always an accessible solution. With this study the goal is to create a design that is most suitable for the target patients, and that considers the needs that are specific to this group.

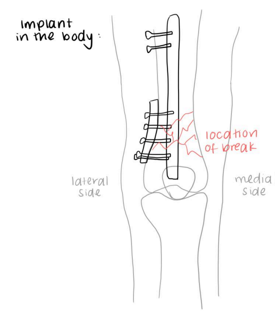
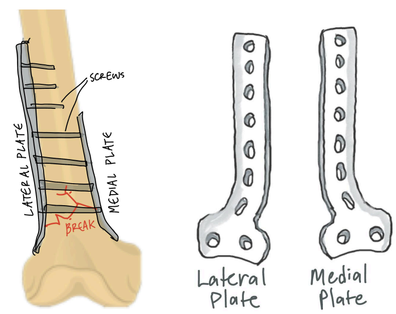
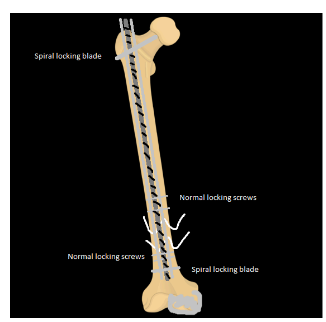
The Client

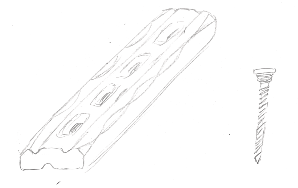
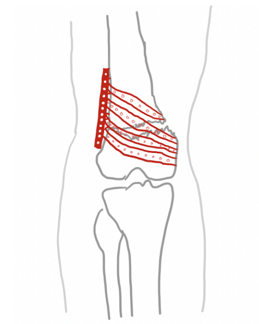
In this study, the target population for the implant is elderly women. Among the elderly, distal femur fractures are among the most common types of femur fractures (Streubel et al., 2011). Currently, the one-year mortality rate following surgery of patients over the age of 60, with distal femur fractures, was found to be around 23% (Streubel et al., 2011). This suggests a need for improvement in the design and process of inserting implants. As mentioned previously, there have been a lot of issues with bending in current implant designs when patients begin to fully bear weight too soon after surgery. Concerning the target group of elderly women, bearing weight following surgery is not only beneficial but essential to healing. As found in another study on full versus partial weight bearing in elderly patients following distal femur fracture surgery, by Paulsson et al. (2021), immediate weight bearing encourages bone healing, while also being a key factor in preventing muscle atrophy and other negative health implications. In addition to the need for the implant to allow immediate full-weight bearing, other factors need to be considered when creating a solution for this particular group. Moreover, for older patients, less invasive surgeries, with smaller incisions are better for recovery.

Concept Generation

Over the course of a week, team members individually came up with preliminary design ideas. These initial concepts were a result of ideas that came up during the seminar from Dr. Pierre Guy on the shortcomings of the designs and techniques used today, and conversation about viability of potential concepts with Dr. Guy afterward. When each team member finished their sketch and brief idea description, the team met to discuss each of our design features, reasoning for design choices we made, and to share opinions on each other's designs.

Table 1. Preliminary Designs.

<table>
<tr><td>Rod-Plate Combination</td><td rowspan="2">
</td></tr>
<tr><td>An intramedullary rod that runs the length of the femur used in conjunction with a small locking plate inserted along the lateral side of the femur at the location of the break. The rod is inserted to prevent bending of the plate under loading while the plate provides additional support to stabilize the healing bone fragments as well as anchors the rod.</td></tr>
<tr><td>Two Plates in Conjunction</td><td rowspan="2">
</td></tr>
<tr><td>Two plates used in parallel on lateral and medial sides of the distal femur with screws securing the plates to each other through the bone and to the bone itself. The lateral plate is longer and thicker as more bulk can be tolerated here, while the medial plate is slimmer and shorter, primarily reinforcing the lateral plate to prevent bending.
*Two team members came up with similar concepts which were combined.</td></tr>
<tr><td>Updated Intramedullary Nail</td><td rowspan="2">
</td></tr>
<tr><td>A proposed update to the traditional intramedullary nail. By threading the shaft of the nail, turning it into a screw, and tapping the medullary cavity, we should be able to attain a more stable fixation in comparison to the traditional nail.</td></tr>
</table>

Grooved Plate	
A plate with grooves and indentations on the side in contact with the femur. This design reduces the contact area between the implant and the bone, improving blood circulation. Locking screws are used to reduce compression on the bone surface.	
Internal Spiral Cast	
Cage-like wire cast which wraps around the fracture site, securing the area of affected bone and a supporting plate placed on the lateral femur at location of break. Both the plate and wrapped components have holes throughout to allow vascularity. Wrap component is comprised of two separate pieces that are fused together during implant insertion	

Needs and Requirements

In order to select the best design, lists of needs and requirements were formulated based on stakeholder needs (primarily from Dr. Guy), industry standards, and biomechanical data.

As a team we came up with and refined the following seven needs. Justification for each need can be found in Table A1.

1. The implant is strong enough and securely fixed to allow full weight bearing before the bone completely heals.
2. The procedure is minimally invasive due to the patient's age.
3. The width of the implant is small enough to comfortably fit between the patient's femur and the soft tissue of their thigh without causing any problems.
4. Implant is lightweight and promotes the natural bone healing process. The design minimizes contact area with the femur.
5. The implant is made out of biocompatible material and will not be rejected by the body.
6. The implant is cost-efficient.
7. The implant minimizes stress shielding while still being able to bear the pre-designated stress.

We then isolated the following five design requirements. Justification can be found in Table A2.

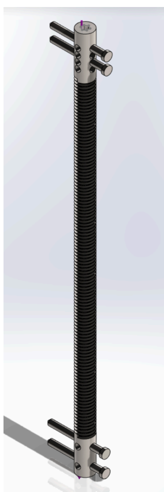
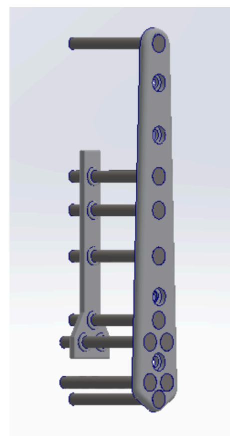
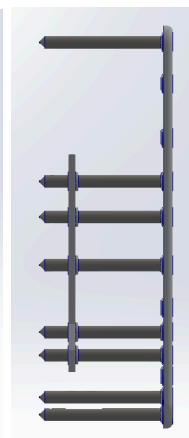
1. The implant must be able to bear an axial force of 773.98N without experiencing plastic deformation.
2. The implant should not increase the knee thickness by more than 5.6 mm. The implant should not exceed the length and width of the shaft of the patient's femur (328.3 mm and 32.5 mm respectively).
3. The material used for the implant must become biologically inert and should not shed, or metabolize in the body.
4. The implant must have a lifetime of at least twelve years.
5. The implant should have a smooth surface with no sharp protrusions.

Concept Selection

After finalizing the needs and requirements, two of the five designs (the Grooved Plate and the Internal Spiral Cast) were screened out as they did not meet enough requirements to compete with the other concepts.

The remaining three designs were then modeled in SolidWorks, along with a mock femur constructed with the bone properties of an elderly person. The bone properties were sourced from academic literature and studies on the mechanical properties of bone (see Table D1).

Table 2. CAD Models.

Updated Intramedullary Nail	**Rod-Plate Combination**	**Two Plates in Conjunction**
 	 	 

Requirements that were not pass/fail were used to create a weighted decision matrix (WDM) and corresponding weights were decided by first having each team member allocate percentages individually, then discussing differences and redistributing weights as a team. The resulting WDM was then used to evaluate the performance of the remaining designs along with SolidWorks stress simulations for quantitative stress data. Each of the three designs was also tested using a variety of materials, shown below is the analysis of each design using titanium alloy (Ti-6Al-4VSolution treated and aged). The designs were also tested using other materials (solid steel and aluminum), however the other materials did not perform as well as the titanium; with the aluminum designs failing stress testing entirely. Tables B1 and B2 show WDMs analyzing the designs using other materials.

Table 3. WDM Analysis of Concepts Using Titanium Alloy (Ti-6Al-4VSolution).

		Updated Intramedullary Nail	Rod-Plate Combination	Two Plates in Conjunction
Criteria	Weight			
Bear load > 773.98N without significant strain	45%	0.72	0.96	0.86
Does NOT increase knee thickness by >5.6mm (implant thickness)	20%	0.55	0.02	0.38
Blood needs to circulate through the bone, (% of surface area of bone NOT covered)	25%	1.00	0.97	1.00
Price per kg	10%	0.92	0.93	0.98
Total satisfaction rating	100%	77.57%	77.06%	80.77%

The first criteria (ability to bear load) was evaluated by running stress simulations on each design in SolidWorks. The implants were attached/inserted into the femur model and 773.98 N of force was applied tangentially to the femoral head. The value is expressed as a ratio of the max stress experienced by the implant to the yield strength of the material. Stress distribution models of each design can be found in Table C1. A lower ratio is considered a more favorable result.

The second criteria (implant thickness) was determined by finding the thickest section of each design that protrudes from the femur, and comparing it to our max allowance. A lower thickness is considered a more favorable result.

The third criteria (surface area contact) was determined by finding the surface area of the implant that contacts with the femur and comparing it to the total femoral shaft surface area. A lower surface area is considered a more favorable result.

The final criteria (price) was determined by finding the weight of the entire implant and finding the price of each material per gram. A lower cost is considered a more favorable result.

We found that the two plates in conjunction, made of titanium alloy would provide the greatest satisfaction to our stakeholders, hence why we chose it to be our final design.

Final Design

This design sought to build on and solidify Dr. Guy's improvised solution that was discussed in class. A traditional locking plate is affixed to the lateral side of the femoral diaphysis using 10, 5 mm screws, seen in Figure E1. On the medial side of the femur, a thinner, shorter locking plate is affixed using the same screws that were inserted through the lateral side, seen in Figure E2. Both plates are made of a titanium alloy (Ti-6Al-4VSolution). This design seeks to minimize recovery time by implementing buffers on the face of the plate, at the screw holes, minimizing surface area contact between the plate and the femur, and allowing for more blood to flow.

The smaller plate on the medial side of the femur is what truly allows this design to excel. With the addition of this plate, the moment experienced by the lateral plate, which is caused by the patient's body weight (expressed as a downwards force acting at the femoral head) is greatly reduced, preventing it from bending as it has in the past, without the medial plate reinforcing it.

Figure 1. Final design of double fixation plate. Image was developed using CAD methods in order to realistically simulate our projected design.

A potential surgical approach with Less Invasive Stabilization System (LISS) is devised based on "MIO - less invasive stabilization system (LISS)" by Gebhard et al. (2020):

1. Reduce the fracture
2. Insert the lateral plate with the LISS insertion guide and secure it with the three most distal and the one most proximal screws.
3. Insert the other screws halfway through in preparation for the alignment of the medial plate.
4. Insert the medial plate with another insertion guide and align it with the lateral plate.
5. Tighten the screws through the threaded holes of the medial plate.
6. Close the wounds

Future Work

The next steps for our design would be to discuss the viability of the necessary surgery in order to implement the plates with a specialist assuring that the procedure is minimally invasive. Once our design has been considered feasible, we would then begin prototyping. We would be using titanium alloy to create a lifesize model of our design in order to begin testing it and evaluating it under real-life conditions. Our testing methods would include applying a force that reflects the load that it would experience when implanted to the prototype in order to evaluate the resulting stress and strain values. Testing on human-like models or cadavers could also be beneficial in order to simulate similar conditions to when the plates are used by real patients.

While in-depth research, brainstorming, and evaluation processes were conducted before the design of this implant was finalized, there are ways in which these steps could have been improved. As part of the process, when deciding on the design model that was going to be adapted for the final product, a stress analysis was conducted using a CAD model of a femur, with each implant on it. The resulting stress on the bone when a force was applied was examined. A bone model was created using simple shapes available in CAD, and the properties of cortical and trabecular bone were manually inputted based on findings from previous studies. To improve this, there could have been more research done on bone material properties specifically in elderly women as this was the target patient group. As this may be difficult considering the lack of specific research on this, to improve the process further, there is potential to do our own study on this or evaluate trends in bone degradation with age to input a more accurate value.

Along with verifying the bone properties for the simulation, the successfulness and applicability of the implant for a variety of patients could be tested by altering the size of the gap between bone fragments in CAD to ensure that the device will work to treat different degrees of femur fractures.

Another potential source of error in the process stems from the assumptions made in relation to some of the design requirements. For instance, for our first design requirement which looked at the minimum axial force that the implant should be able to bear, the paper where the value was found used data from young people and does not include data for any strenuous activities such as running or jumping. After the age of 50, bone density starts to degrade which leads to it having a lower resilience to axial force. An assumption made in relation to the weighted decision matrix was that the price per kilogram for the manufacturing of our design does not include labor costs, which is another factor that should be further researched.

Looking back at the process in which we reached our final design, while choosing a design, various models were tested. However, once a model had been chosen we did not perform a lot of alterations. In future studies, we would likely want to test variations of the model by altering, for example, different screw placements.

References

1060 Grade Aluminium Alloy Plate. (n.d.). indiamart.com. https://www.indiamart.com/proddetail/1060-grade-aluminium-alloy-plate-19302574248.html

American Academy of Orthopaedic Surgeons. (n.d.). *Distal femur (thighbone) fractures of the knee*. OrthoInfo. Retrieved December 4, 2022, from https://orthoinfo.aaos.org/en/diseases--conditions/distal-femur-thighbone-fractures-of-the-knee/

Bagheri, Z. S., Tavakkoli Avval, P., Bougherara, H., Aziz, M. S. R., Schemitsch, E. H., and Zdero, R. (2014, June 26). "Biomechanical Analysis of a New Carbon Fiber/Flax/Epoxy Bone Fracture Plate Shows Less Stress Shielding Compared to a Standard Clinical Metal Plate." ASME. *J Biomech Eng*. September 2014; 136(9): 091002. https://doi.org/10.1115/1.4027669

Barua, B. (2019, May 27). Survey reveals Canadian health-care concerns. The Fraser Institute Blog. https://www.fraserinstitute.org/blogs/survey-reveals-canadian-health-care-concerns

BMEG 230 project – Design a fracture fixation plate [Class Handout]. (2022). School of Biomedical Engineering, University of British Columbia, Vancouver, British Columbia.

Cakir, F., Özkal, F. M., & Sensoz, E. (2022, June 8). Performance Assessment of Biocompatible Metals Used in the Treatment of Femoral Neck Fractures. *ACS Applied Bio Materials*, 5(6), 3013–3022. https://doi.org/10.1021/acsabm.2c00321

Carretta, R., Stüssi, E., Müller, R., & Lorenzetti, S. (2013). Within subject heterogeneity in tissue-level post-yield mechanical and material properties in human trabecular bone. *Journal of the Mechanical Behavior of Biomedical Materials*, *24*, 64–73. https://doi.org/10.1016/j.jmbbm.2013.04.014

D'Angeli, V., Belvedere, C., Ortolani, M., Giannini, S., & Leardini, A. (2013). Load along the femur shaft during activities of daily living. *Journal of Biomechanics, 46*(12), 2002-2010. https://doi.org/10.1016/j.jbiomech.2013.06.012

Endo, D., Ogami-Takamura, K., Imamura, T., Saiki, K., Murai, K., Okamoto, K., & Tsurumoto, T. (2020). Reduced cortical bone thickness increases stress and strain in the female femoral diaphysis analyzed by a CT-based finite element method: Implications for the anatomical background of fatigue fracture of the femur. *Bone Reports*, *13*, 100733. https://doi.org/10.1016/j.bonr.2020.100733

Fryar, C. D., Carroll, M. D., Gu, Q., Afful, J., & Ogden, C. L. (2021, January). Anthropometric reference data for children and adults: United States, 2015–2018. *Vital Health Stat, 3*(46). National Center for Health Statistics. https://www.cdc.gov/nchs/data/series/sr_03/sr03-046-508.pdf

Gebhard, F., Phil Kregor, Oliver, C., Nousiainen, M. T., & Höntzsch, D. (2020). *MIO - less invasive stabilization system (LISS)*. AO Foundation Surgery Reference. Retrieved December 6, 2022, from https://surgeryreference.aofoundation.org/orthopedic-trauma/adult-trauma/distal-femur/basic-technique/mio-liss-less-invasive-stabilization-system

Guy, P. (2022). *Distal femur implant design* [PowerPoint slides]. https://canvas.ubc.ca/courses/101160/files/22811342?module_item_id=5004516

Hart, N. H., Newton, R. U., Rantalainen, T., Ireland, A., & Siafarikas, A. (2017). Mechanical basis of bone strength: influence of bone material, bone structure and muscle action. *Journal of Musculoskeletal & Neuronal Interactions*, *17*(3), 114–139.

Harvey, N.C., & Cooper, C. (Eds.). (2018). Osteoporosis: A Lifecourse Epidemiology Approach to Skeletal Health (1st ed.). CRC Press. https://doi.org/10.1201/9781351234627

Høiseth, A., Alho, A., & Husby, T. (1990). Femoral Cortical/Cancellous Bone Related to Age. *Acta Radiologica*, *31*(6), 626–627. https://doi.org/10.1080/02841859009173111

Ito, M., Nakata, T., Nishida, A., & Uetani, M. (2011). Age-related changes in bone density, geometry and biomechanical properties of the proximal femur: CT-based 3D hip structure analysis in normal postmenopausal women. *Bone*, *48*(3), 627–630. https://doi.org/10.1016/j.bone.2010.11.007

Jahn K. (2019). The Aging Vestibular System: Dizziness and Imbalance in the Elderly. *Advances in oto-rhino-laryngology*, *82*, 143–149. https://doi.org/10.1159/000490283

Keramaris, N. C., Calori, G. M., Nikolaou, V. S., Schemitsch, E. H., & Giannoudis, P. V. (2008). Fracture vascularity and bone healing: a systematic review of the role of VEGF. *Injury*, *39 Suppl 2*, S45–S57. https://doi.org/10.1016/S0020-1383(08)70015-9

Liang, B., Ding, Z., Shen, J., Zhai, W., Kang, L., Zhou, L., Sha, M., & Liang, D. (2012, May 13). A distal femoral supra-condylar plate: biomechanical comparison with condylar plate and first clinical application for treatment of supracondylar fracture. *International Orthopaedics*, *36*(8), 1673–1679. https://doi.org/10.1007/s00264-012-1529-2

Milligan, D. J., O'Brien, S., Bennett, D., Hill, J. C., & Beverland, D. E. (2013). The effects of age and gender on the diameter of the femoral canal in patients who undergo total hip replacement. *The Bone &Amp; Joint Journal*, *95–B*(3), 339–342. https://doi.org/10.1302/0301-620x.95b3.30882

Mirzaali, M. J., Schwiedrzik, J. J., Thaiwichai, S., Best, J. P., Michler, J., Zysset, P. K., & Wolfram, U. (2016). Mechanical properties of cortical bone and their relationships with age, gender, composition and microindentation properties in the elderly. *Bone*, *93*, 196–211. https://doi.org/10.1016/j.bone.2015.11.018

Nikodem, A. (2011). Correlations between structural and mechanical properties of human trabecular femur bone. *Acta of Bioengineering and Biomechanics*, *14*(2), 37–46.

Orthopedic Implants Price List at best rates. (2022, August 8). Vast Ortho. https://www.vastortho.com/orthopedic-implants-price-list/

Paulsson, M., Ekholm, C., Jonsson, E., Geijer, M., & Rolfson, O. (2021). Immediate Full Weight-Bearing Versus Partial Weight-Bearing After Plate Fixation of Distal Femur Fractures in Elderly Patients. A Randomized Controlled Trial. *Geriatric orthopaedic surgery & rehabilitation*, *12*, 21514593211055889. https://doi.org/10.1177/21514593211055889

Polguj, M., Bliźniewska, K., Jędrzejewski, K., Majos, A., & Topol, M. (2013). Morphological study of linea aspera variations - proposal of classification and sexual dimorphism. *Folia morphologica*, *72*(1), 72–77. https://doi.org/10.5603/fm.2013.0012

Prime Quality ASTM F138 304L Stainless Steel Round Bar for Surgical Implant. (n.d.). Made-in-China.com. https://zytcstainless.en.made-in-china.com/product/kSwEbVgrCWYI/China-Prime-Quality-ASTM-F138-304L-Stainless-Steel-Round-Bar-for-Surgical-Implant.html

Reilly, D. T., Burstein, A. H., & Frankel, V. H. (1974). The elastic modulus for bone. *Journal of Biomechanics*, *7*(3), 271–275. https://doi.org/10.1016/0021-9290(74)90018-9

Statistics Canada. (2022, January 24). *Table 13-10-0114-01 Life expectancy and other elements of the complete life table, three-year estimates, Canada, all provinces except Prince Edward Island.* https://doi.org/10.25318/1310011401-eng

Streubel, P. N., Ricci, W. M., Wong, A., & Gardner, M. J. (2011). Mortality after distal femur fractures in elderly patients. Clinical Orthopaedics and Related Research®, 469(4), 1188-1196.

Viano, D., Helfenstein, U., Anliker, M., & Rüegsegger, P. (1976). Elastic properties of cortical bone in female human femurs. *Journal of Biomechanics*, *9*(11), 703–710. https://doi.org/10.1016/0021-9290(76)90172-x

Wirtz, D. C., Schiffers, N., Pandorf, T., Radermacher, K., Weichert, D., & Forst, R. (2000). Critical evaluation of known bone material properties to realize anisotropic FE-simulation of the proximal femur. *Journal of Biomechanics*, *33*(10), 1325–1330. https://doi.org/10.1016/s0021-9290(00)00069-5

Appendix A

Needs and Requirements

Table A1. Need Statements and Justifications.

ID	Need statement	Justification
1	**The implant is strong enough and securely held in place to allow full weight bearing before the bone heals.**	“a surgical procedure needs to be performed which allows them full weight bearing” (“BMEG 230 Project”, 2022).
2	**The procedure is minimally invasive due to the patient’s age.**	“because of older individuals’ frailty, the proposed surgical treatment should result in minimal bleeding and should not require a long time under anesthetic” (“BMEG 230 Project”, 2022).
3	**The width of the implant is small enough to comfortably fit between the patient’s femur and the soft tissue of their thigh without causing any problems.**	“Prominent / Thick Hardware on the side of the knee is not well tolerated” (Guy, 2022).
4	**Implant is lightweight and promotes the natural bone healing process. The design minimizes contact area with the femur.**	“Local vascularity at the site of the fracture has been identified as one of the most significant parameters influencing the (bone) healing procedure” (Keramaris et al., 2008).
5	**The implant is made out of biocompatible material and will not be rejected by the body.**	“It is very important that materials to be used in implant applications must be biocompatible and behave in harmony with the bone tissue.” (Cakir et al., 2022).
6	**The implant is cost-efficient.**	“For the last two decades Canada’s health-care system has been characterized by unsustainable increases in health-care spending” (Barua, 2019).
7	**The implant minimizes stress shielding while still being able to bear the pre-designated stress.**	“Researchers have known for decades that stress shielding, as a long-term effect, may interfere with normal bone healing and potentially cause considerable bone loss underneath metal fracture plates”(Bagheri, 2014).

Table A2. Design Requirements and Justifications.

ID (category)	Design Requirement	Justification
1 (functional)	**The implant must be able to bear an axial force of 773.98N without experiencing plastic deformation.**	An axial force of 119% of body weight (D'Angeli et al., 2013) is likely the maximum load acting along the femur shaft during daily activities (walking, climbing stairs, etc.). The average weight of females over 80 is 66.3kg (Fryar et al., 2021, Table 3). Assumptions: - Data of young people apply to old people - Patient doesn't run, speed walk, jump, etc. - Forces in other directions are negligible. The force in the distal/proximal direction is assumed to be parallel to the shaft of the femur.
2 (physical/ constraint)	**Any inserted implant should not increase the knee thickness by more than 5.6 mm** (Liang et al., 2012)**. The implant should not exceed the length and width of the shaft of the patient's femur (328.3 mm and 32.5 mm respectively)** (Polguj et al., 2013)**.**	The industry standard for lateral, femoral plates is ~6mm (therefore no implant should exceed this amount of additional thickness). If the implant is too big it may cause discomfort.
3 (standard)	**The material used for the implant must become biologically inert and should not shed, or metabolize in the body** (Tapscott & Wottowa, 2022).	If the material used reacts inside the body it could trigger an adverse biological response in the patient, or impact other biological processes.
4 (standard)	**The implant must have a lifetime of at least twelve years.**	The life expectancy of an 88-year-old woman in Canada is around six years (Statistics Canada, 2022). This is doubled to increase the resilience of the design. Early failure of the implant requires additional surgeries and damages the patient's health.
5 (constraint)	**The implant should have a smooth surface with no sharp protrusions.**	Sharp protrusions may damage tissue surrounding the implant and restrict muscle movements.

Appendix B

Weighted Decision Matrices (WDM)

Table B1. WDM Analysis of Concepts Using Solid Steel

Solid Steel		Updated Intramedullary Nail	Rod-Plate Combination	Two Plates in Conjunction
Criteria	Weight			
Bear load > 773.98NN without significant strain	45%	0.14	0.00	0.72
Does NOT increase knee thickness by >5.6mm (implant thickness)	20%	0.55	0.02	0.38
Blood needs to circulate through the bone, (% of surface area of bone NOT covered)	25%	1.00	0.97	1.00
Price per kg	10%	1.00	1.00	1.00
Total satisfaction rating	100%	52.36%	34.41%	74.80%

Table B2. WDM Analysis of Concepts Using Aluminum (1060 Alloy)
* Note: Every static analysis using this material has failed, rendering this comparison invalid

Aluminum		Updated Intramedullary Nail	Rod-Plate Combination	Two Plates in Conjunction
Criteria	Weight			
Bear load > 773.98NN without significant strain	45%	0.00	0.00	0.00
Does NOT increase knee thickness by >5.6mm (implant thickness)	20%	0.55	0.02	0.38
Blood needs to circulate through the bone, (% of surface area of bone NOT covered)	25%	1.00	0.97	1.00
Price per kg	10%	1.00	1.00	1.00
Total satisfaction rating	100%	46.00%	34.46%	42.46%

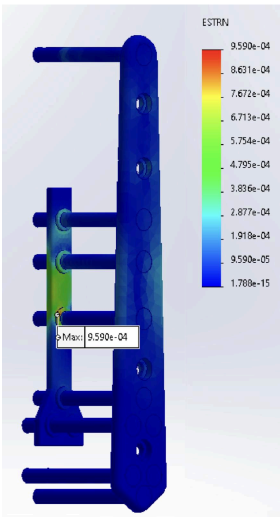
Table B3. WDM Analysis of Concepts Using Titanium

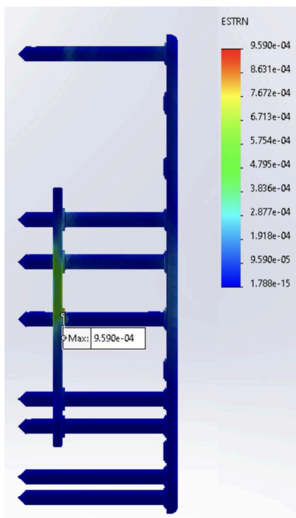
		Updated Intramedullary Nail	Rod-Plate Combination	Two Plates in Conjunction
Criteria	Weight			
Bear load > 773.98N without significant strain	45%	0.72	0.96	0.86
Does NOT increase knee thickness by >5.6mm (implant thickness)	20%	0.55	0.02	0.38
Blood needs to circulate through the bone, (% of surface area of bone NOT covered)	25%	1.00	0.97	1.00
Price per kg	10%	0.92	0.93	0.98
Total satisfaction rating	100%	77.57%	77.06%	80.77%

Appendix C

Stress/Strain Distribution Models

Table C1. Stress and Strain Distribution Models of Each Design.

<table>
<tr><td colspan="2">Two Plates in Conjunction</td></tr>
<tr><td>Strain</td><td>Stress</td></tr>
<tr><td>




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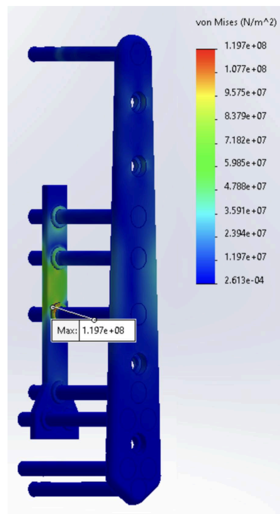

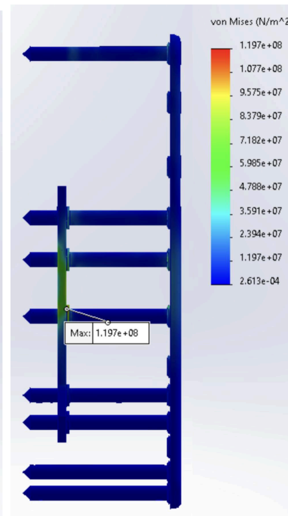

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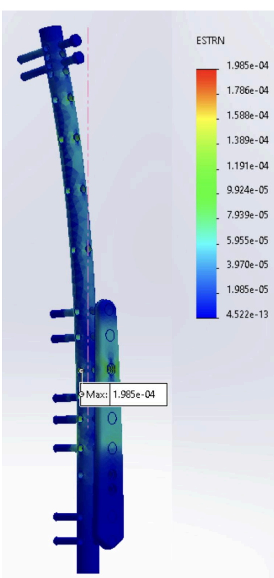
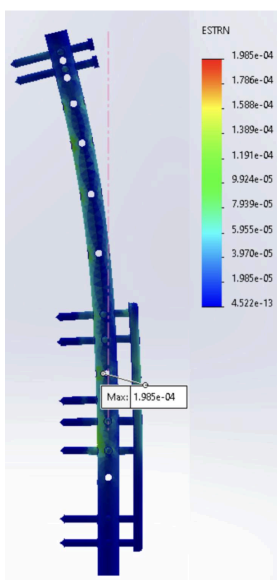
<tr><td colspan="2">Rod-Plate Combination</td></tr>
<tr><td>Strain</td><td>Stress</td></tr>
<tr><td>




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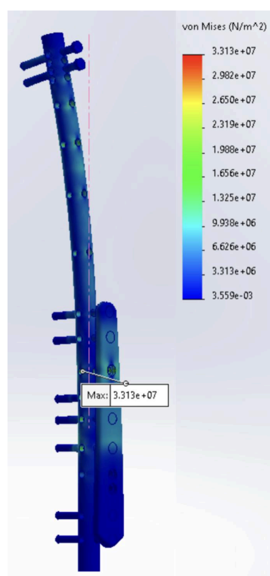

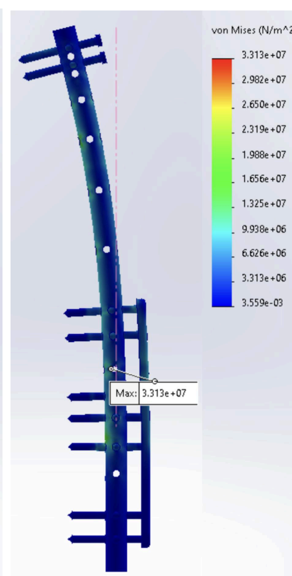

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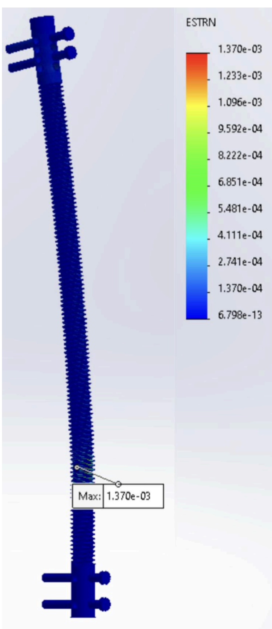
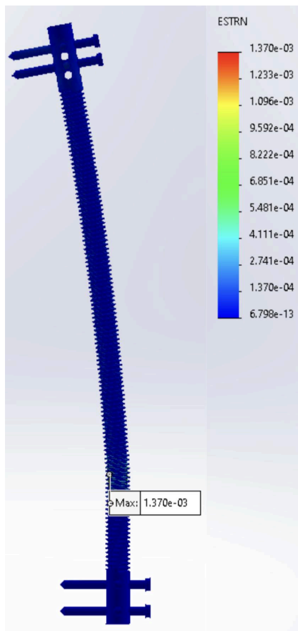
<table>
<tr><td colspan="2">Updated Intramedullary Nail</td></tr>
<tr><td>Strain</td><td>Stress</td></tr>
<tr><td>




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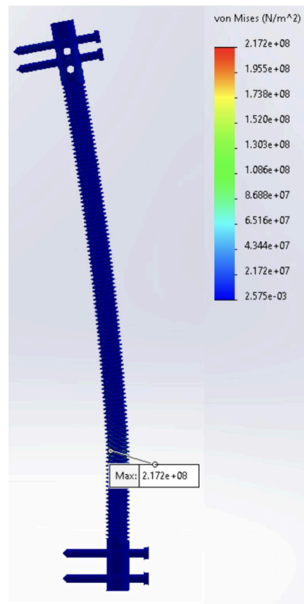

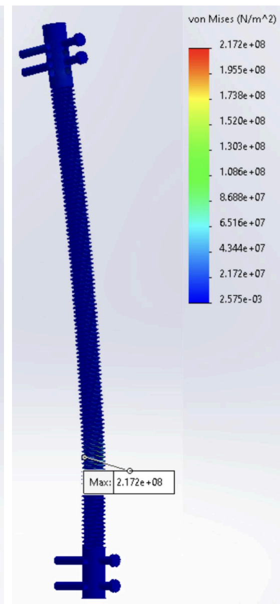

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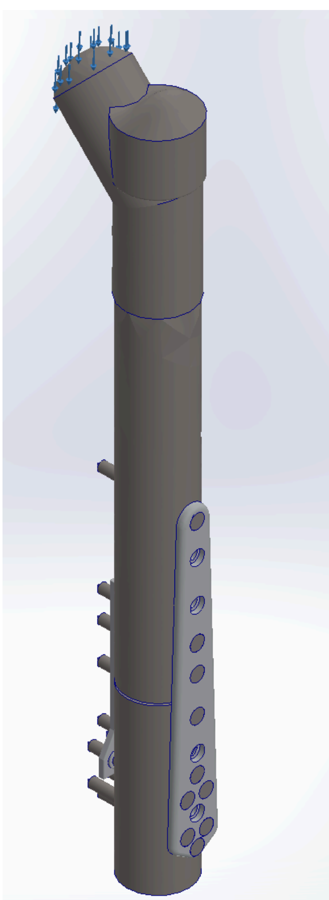


Figure C1: Image of force simulation (before simulation is ran)

Appendix D

Bone material properties used in simulation (Elderly female)

Table D1. Physical Properties of Bone for Elderly Female

Spec	Cortical	Trabecular
Young's modulus (GPa)	15.4 (Reilly et al., 1974)	11.38 (Carretta et al., 2013)
Shear modulus (GPa)	5.28 (Viano et al., 1976)	0.04 (Wirtz et al., 2000)
Poisson ratio	0.3 (Wirtz et al., 2000)	0.12 (Wirtz et al., 2000)
Mass density (kg/m^3)	1011.5 (Ito et al., 2011)	210 (Høiseth et al., 1990)
Tensile strength (MPa)	92.95 (Mirzaali et al., 2016)	8 (Hart et al., 2017)
Compressive strength (MPa)	153.59 (Mirzaali et al., 2016)	50 (Hart et al., 2017)
Yield strength (MPa)	115.06 (Mirzaali et al., 2016)	7.88 (Nikodem, A. (2011)
Thickness (mm)	2.68 (Endo et al., 2020)	32.5/2 - 14.1/2 - 2.68

Femoral canal diameter: 14.1 mm (Milligan et al., 2013)

Diameter: 32.5 (Polguj et al., 2013)

Shaft length: 328.3 mm (Polguj et al., 2013)

Price of each material

Titanium: 20.85 USD/kg (*Orthopedic Implants Price List at Best Rates*, 2022)

Aluminum: 3.07 USD/ kg (*1060 Grade Aluminium Alloy Plate*, n.d.)

Alloy steel: 1.98 USD/kg (*Prime Quality ASTM F138 304L Stainless Steel Round Bar for Surgical Implant*, n.d.)

<u>**Appendix E**</u>

Final Design Dimension Drawings

Figure E1. Lateral Plate Dimension Drawing

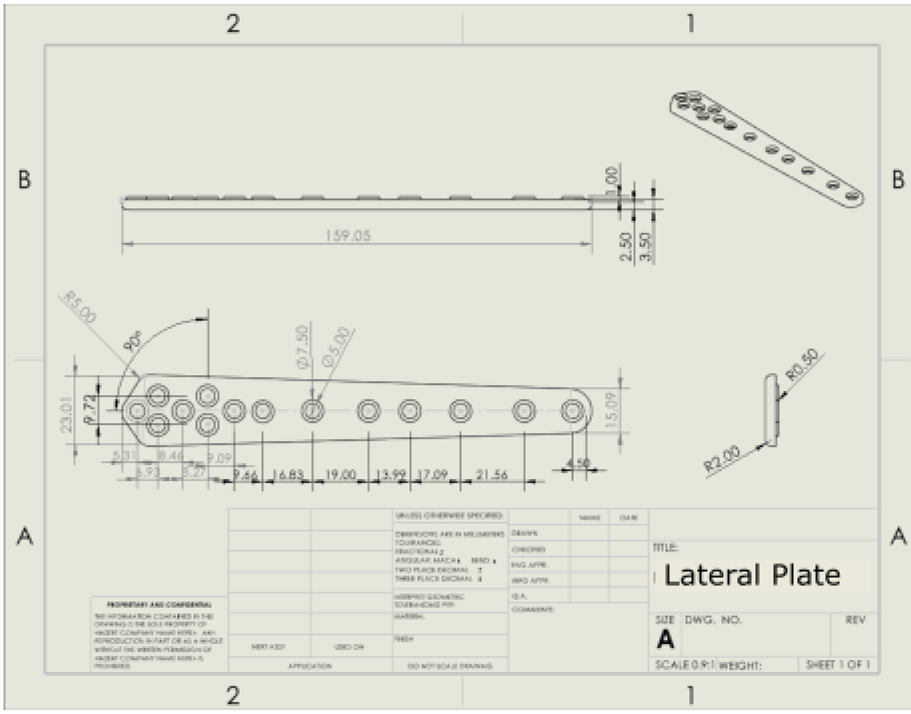
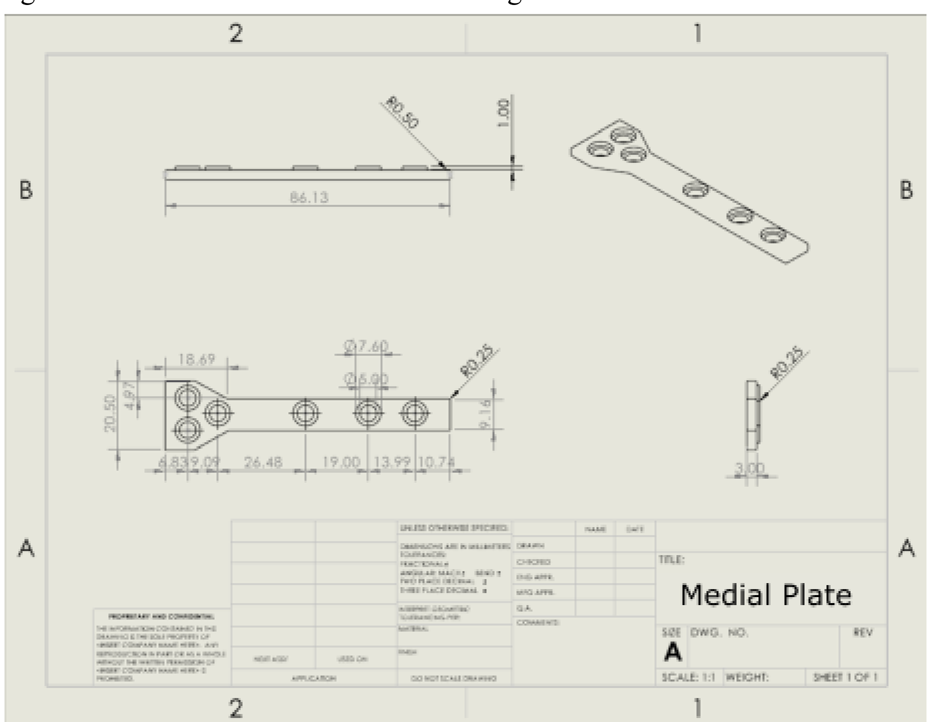


Figure E2. Medial Plate Dimension Drawing



Group Contributions

Arnaz: Worked on background information for the project, contributed to the needs and requirements for the concept generation. Created the "Internal Spiral Cast" initial design concept and worked along with the team to create a weighted decision matrix for the concept selection. Worked on the design features and advantages components of the brochure.

Amelie: Created "Intermedullary rod and lateral plate combination" concept idea and produced a sketch of the model. Helped come up with initial needs and requirements, and was involved in the decision making process. Also worked on the background section of the report, writing about the current solution, and client, as well as contributing to the future work section. In the brochure, wrote the problem and solution sections, and formatted the second page.

Alexandra: Generated an initial design concept producing a sketch and description for a double plated model, assisted in concept screening and selection process, contributed to needs and requirements section as well as future work section, helped with design features section in brochure as well as general report and brochure formatting.

Nick: Created "Updated intramedullary nail" concept. Created CAD models of all three designs in solidworks for testing. Created CAD model of cortical and trabecular femoral bones. Researched material properties of female, elderly cortical and trabecular bone. Ran loading simulations on every model. Contributed to formatting the brochure.

Nicola: Created "Two Plates in Conjunction" initial concept. Contributed to needs and requirements. Wrote Concept Generation, Needs and Requirements, and Concept Selection sections of report. Drew fully rendered design mock-ups for brochure, helped with design and editing of brochure and report formatting and editing. Put together Appendix.

Rex: Created "Grooved Plate" concept. Contributed to and edited needs and requirements. Wrote a potential surgical procedure for the final design. Assisted in screening and ranking (WDM). Suggested changes to the WDM and improvements for the final design. Contributed to the design features portion of the brochure.