Spring 2019

# Development and Exploration of a Z-Shaped Foot and Ankle Internal Fixation Plate

Rhaz Shaghaghi Paul
rjs165@zips.uakron.edu

Ian Hames
ijh11@zips.uakron.edu

Sean Rich
spr24@zips.uakron.edu

# Development and Exploration of a Z-Shaped Foot and Ankle Internal Fixation Plate

The University of Akron
4800:492 Biomedical Engineering Design 2

April 29, 2019

Group #6: Plates for the Sole

Heather Gibson
Ian Hames
Matt Ludwig
Sean Rich
Rhaz Shaghaghi Paul

Table of Contents


| | |
|---|---|
| Abstract: | 3 |
| Description of Project: | 3 |
| Background: | 3 |
| Design Requirements / Project Specifications: | 4 |
| Testing: | 5 |
| Business Aspects: | 6 |
| Final Implementation: | 7 |
| Deliverables: | 8 |
| Scope of Work Excluded: | 8 |
| Performance Test Results: | 8 |
| Progress: | 11 |
| Individual Contributions: | 12 |
| Financial Considerations: | 12 |
| Summary Feasibility Discussion: | 12 |
| Future Work: | 13 |
| Discussion, Conclusions, Lessons Learned, Recommendations: | 13 |
| References: | 15 |
| Appendix A: Specifications and Customer Requirements | 16 |
| Appendix B: Statistical Analysis | 17 |
| Appendix C: Additional Finite Element Analysis Figures | 19 |

**Abstract:**

This paper will detail the design process of developing a Z-shaped foot and ankle internal fixation plating system. Group 6: Plates for the Sole was made up of 5 team members, who worked together to accommodate their client's request to complete a biomechanical analysis of a Z-Plate design and a construct a prototype. The Z-Plate's purpose is to provide podiatrists with a new solution that can fit nicely on the small, irregular bones of the foot, while also remaining strong enough to withstand the forces and torques of the foot.

**Description of Project:**

There are many injuries or conditions of the foot that require internal fixation surgery to repair; and as with any medical device, these fixations should be optimized for patient care and usability. Dr. Mark Mendeszoon of Precision Orthopaedics in Chardon, Ohio expressed concerns to Group 6 that the current internal fixation systems used in podiatric surgeries are not always the best fit. It is not uncommon for operations to require corrections and repeat surgeries. Dr. Mendeszoon introduced an idea of utilizing a "Z-plate" design for internal ankle and foot fixation. He believes that such a design could be very beneficial for surgeons as well as patients when working with the bones of the foot. The main goal for Group 6 was to study the biomechanics of a Z-Plate design and determine whether or not it is a feasible design option and if it should be pursued further.

**Background:**

The bones of the foot are small and irregularly shaped, so the geometries of internal fixation systems used on larger bones might not always be the best fit when applied to the foot. According to our client, the current plates used tend to have the same plate shape and just change the sizes; therefore, there is very little variation in plate geometry. This limits surgeons' options when operating, but introducing a z-shaped plate will offer surgeons another possible solution, especially when dealing with smaller, nonuniform bones.

A hallux valgus, more commonly known as a bunion, is a nontraumatic deformity that occurs in 23% of adults ages 18-65, and 35.7% of elderly ages 65 and up [1]. They are most commonly found in women. A bunion forms when the first tarsometatarsal (TMT) joint becomes hypermobile, causing the toe to move too far in the medial direction. One procedure that is performed to correct a severe hallux valgus is called the Lapidus Bunionectomy, frequently called the Lapidus procedure. In the Lapidus procedure, the TMT joint is fused in order to reduce hypermobility and correct the deformation [2]. This fusion is commonly achieved using screws or small plates. Dr. Mendeszoon believes that the application of a Z-shaped plate could be especially useful in this procedure, securing the medial cuneiform and the first metatarsal in fusion.

**Design Requirements / Project Specifications:**

Customer requirements were prioritized and identified through questionnaires sent to the client, as well as an in person interview. In regards to the design of the Z-Plates, Dr. Mendeszoon made clear that the following requirements were paramount: the plate must be able to withstand normal loading of the foot, utilize various screw sizes, consist of one solid piece with no moving components, and be made of an inert, biocompatible material that can be sterilized using an autoclave. It was also requested that the plates be easily constructed with a low unit price. From these requirements, a list of specifications with measurable metrics were created in order to gauge the success of designs and aid in developing a testing procedure. A comprehensive list of the customer requirements along with the specifications and metrics can be found in Appendix A.

Stemming from these requirements and specifications, a total of four designs were created. A first design being the basic Z-shaped plate that Dr. Mendeszoon described, which can be seen in Figure 1a. Two other designs created were also based around the shape of the Z, one having an increased angle giving it more of a square shape, Figure 1b, and the other consisting of less material in attempts to save on cost and weight, Figure 1c. A fourth design was implemented to be used as a comparison. This plate was shaped like an H rather than Dr. Mendeszoon's proposed Z. The H design is more in line with plates provided in foot and ankle fixation kits manufactured by competitors, Stryker and Zimmer Biomet, and is pictured in Figure 1d. All of the designs discussed in this report were solely developed by Plates for the Sole team.

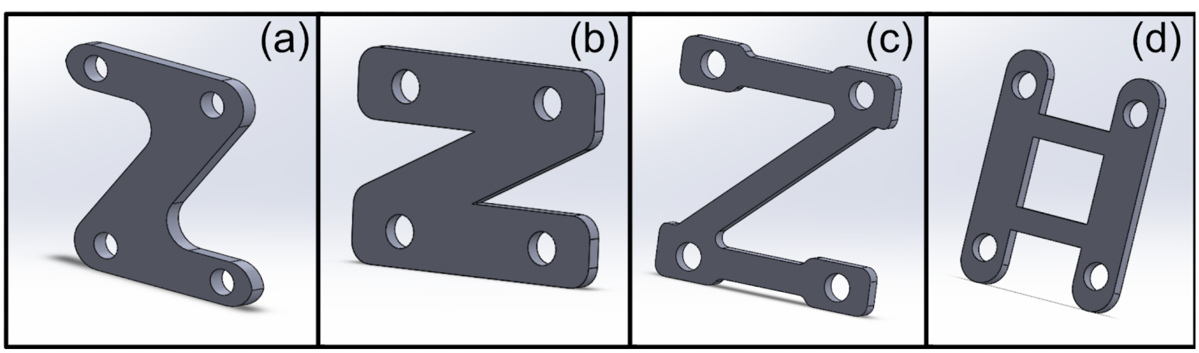


Figure 1: Four varying designs. (a) design closest to client's requirements. (b) Z-plate at increased angle. (c) Plate designed for less material use. (d) H-plate used for comparison.

**Testing:**

The primary focus of testing the various designs was to determine whether or not they could withstand the various loads exerted on the foot during a normal gait cycle. From the results of the initial Alpha tests, adjustments could be made to improve design function. Beta testing would the be performed on an updated design to determine whether or not changes had a significant impact on plate strength. There were two main phases of testing. Phase 1 was a mechanical test to obtain the stiffness property of the sampled designs using steel prototypes, as stiffness is a property based on geometry [7]. The machined prototypes would also be evaluated by the by the specifications to ensure that the client's requirements were met. Phase 2 testing involved using computer generated models in SolidWorks and testing them in the ANSYS Finite Element Modeling (FEM) software. A similar test to the mechanical test was performed in ANSYS, and stiffness values were obtained for each design. The stiffness values obtained from mechanical testing were then compared to the stiffness values obtained in ANSYS. The purpose for this comparison was to validate the results obtained in ANSYS, so that additional tests conducted through ANSYS could be confidently pursued. The stiffness values and overall performance in both tests also allowed the team to observe how the different designs reacted to load, giving an insight to possible improvements. Following the validation of ANSYS results, further testing was pursued using various methods to compare the load reactions of the different plate designs.

**Testing- Phase 1:**

Mechanical testing consisted of a uniaxial tension test of samples. The Alpha plates, consisting of the three "Z" designs and the "H" design, each had 6 samples machined and tested. 3 Beta plates were machined and tested later using the same procedure. All testing was performed on an Instron 3343 mechanical testing system equipped with a 1 kilonewton load cell. Testing was performed on-site by team members and the testing equipment was located at the University of Akron Biomedical Engineering Department. Each sample was stretched at a rate of 0.1 millimeters per minute (mm/min), to a maximum extension of 0.05 mm. The load cell recorded the force exerted from the plate at a sample rate of 10 Hertz. Data was collected using the Instron Bluehill 3 software, then exported to a .csv file containing time, load, and displacement values, which were then loaded into a MATLAB script for calculations and graphing. Stiffness values were calculated for each trial by using a MATLAB function to fit a line to the slope of the force versus displacement graph. Trials for each design had their respective stiffness values averaged. In addition to stiffness testing, measurements were obtained from the physical prototypes to ensure that the designs followed the outlined specifications located in Appendix A. A simple checklist was printed with metrics to determine if the designs passed or failed in any given criteria. The first two criteria were omitted, as the purpose of FEM testing is to identify the effectiveness of designs and fulfill these specifications. Plates were screwed into wood blocks to evaluate the metrics involving implementation of screws or the securing of the plates. Angle and dimension measurements were conducted with a protractor. A triple beam balance was used to determine the mass of the plates. Specifications involving material metrics were omitted, as a final marketable design would implement an acceptable material. The “H” plate design was not included in this testing.

**Testing- Phase 2:**

Tests were then performed using ANSYS Workbench 17.2. Finite element analysis allowed the team to recreate an abundance of testing parameters and situations that displayed relevant visual results at a fast pace. These results have the potential for displaying how the Z-Plate would respond to similar loading experienced in use and will be used to determine the effectiveness of design. It should be noted that only the main Z-Plate designs, including the Alpha Z-1 plate and the Beta Z-Plate, were modeled in ANSYS for comparison. The other plates were omitted from this testing, as it was determined that the Beta design be based heavily on the Alpha Z-1 plate. Initial FEM tests were conducted to determine the stiffness of the Alpha Z-1, again for comparison with mechanical data for model validation. Attempts at recreating the mechanical test, by introducing a displacement of 0.05 mm to the design and measuring the force exerted from the plate using a force probe feature, yielded unrealistic results. Force data exerted form the plates using this method read as factor of $10^{10}$ Newtons, so these results were neglected and another method was developed. Stiffness being the direct result of force divided by displacement meant that simply loading the plates in tension and measuring the resulting displacement in the same direction as the load would yield the needed data. Using this method in ANSYS gave more accurate data that could be compared to the mechanical data that was obtained in Phase 1. Although the mechanical test and FEM test were not identical, stiffness is a geometry related property of the design, which allows for accurate comparisons despite different testing methods. Following stiffness testing, other loading tests were conducted to evaluate the Alpha design. These results were utilized to make adjustments for a Beta Z-Plate that improves on load bearing capacity without using much more material. Once the Beta Z-Plate was developed, multiple simulations were run in ANSYS to determine design viability and compare the results of the Alpha plate versus the Beta plate. These tests are all detailed further in the Performance Test Results section of the report.

**Business Aspects:**

Currently on the market are plates of varying geometries to satisfy the need of repairing various types of fractures. However, there is no true "Z" shaped plate designed solely for the foot and ankle. Osteomed, Stryker, and Zimmer all carry their own version of a plating system designed specifically for use in the foot and ankle. Zimmer's A.L.P.S. Total Foot System and Stryker's VariAx2 plating system both have smaller plates in similar geometries. However, neither of them have a specific "Z" shaped plate. Surgeons are not just using these internal fixation systems on fractures anymore, but they are also being used to correct deformities and bunions. James Jastifer, MD expressed that in the past 10 years, he's noticed a significant increase in the use of internal foot and ankle fixation systems for a variety of procedures. The increased use and need for plates in different procedures opens an opportunity for our Z-shaped plate as a viable option for surgeons operating on the smaller, irregular shaped bones of the foot.

**Final Implementation:**

The final Beta Z-Plate prototype was modeled using Solidworks and was shown with two curvatures representing the option to be produced in either direction. They are shown in figures 2 and 3.

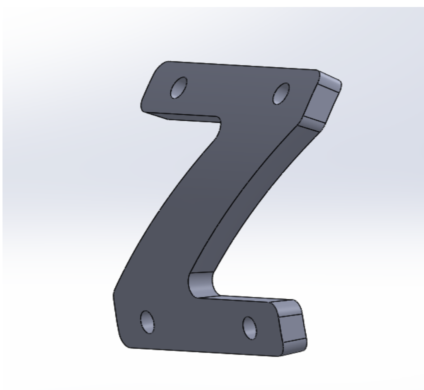

Figure 2: Beta Z-Plate with first curvature

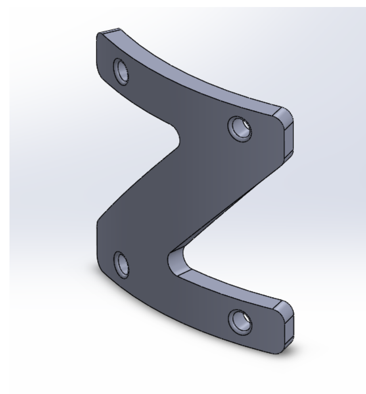

Figure 3: Beta Z-Plate with second curvature

Adjustments from the initial alpha designs were made to simplify the overall design. The angle of the main diagonal was reduced to 45 degrees and the holes are aligned horizontally at the center of the top and bottom pieces. The design could potentially be implemented into many foot and ankle correction procedures, such as the Lapidus Bunionectomy. The location of the Beta Z-Plate is shown on an open source foot model as shown in Figure 4.

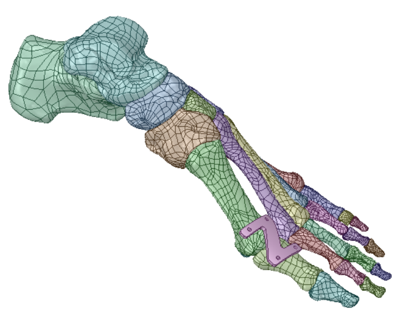

Figure 4: Beta Z-Plate shown on a foot model representing a realignment of a metatarsal and a proximal phalanges bone would be performed [6]

**Deliverables:**

Final deliverables to Dr. Mendeszoon include all test data and designs of all prototypes. A final marketable design was not expected given the time frame of this project. What was expected is a thorough evaluation of the pertinent forces placed on the device. From the data obtained in this report, he will decide whether or not the Z-plate idea is one that should be pursued further.

**Scope of Work Excluded:**

Designing a completed medical device was not in the scope of this project, as extensive research within the body and potential cadaver studies must be done to achieve a fixation plate that is ready to enter the market. Due to this, there were aspects of the project that needed to be either simplified or completely excluded in order to realistically complete the tasks. For example, at the start of the project, our solution included not only one set size of plates to be designed and tested, but other sets of designs specifically contoured to various bone structures, including larger bones like the tibia and fibula near the ankle. These contoured and large Z-Plates were omitted from the project's scope, as the team would have likely been unable to accurately model all of the designs in time, and would run into difficulty with larger prototype manufacturing and testing. Additionally, it would have been preferred to conduct mechanical fatigue testing on prototypes that were composed of the standard titanium material that the Z-Plate would ideally be made of. Time availability of team members and mechanical testing equipment was lacking for fatigue testing, and valuable design properties were able to be obtained in other means with steel prototypes, of which were easier and cheaper to produce. Also, the sample size of prototypes used for testing were limited to the availability of team members involved in prototype manufacturing and testing. Alpha prototyping consisted of a minimum of five samples per prototype and beta prototyping was limited to three samples completed for testing.

**Performance Test Results:**

**Phase 1:**

From the tensile mechanical tests, the stiffness for each plate was obtained by fitting a sloped line to the force and displacement graph using a developed MATLAB script. Stiffness is the material property obtained in this slope and has units of newton (N) per millimeter (mm). The first three Alpha Z-plates had stiffness values of 1479.8 N/mm, 1490.7 N/mm, and 356.8 N/mm, respectively. The third plate, the one with less material to save on cost, was significantly less stiff than the other two designs, which was an expected outcome. There was not a very big difference between the Z-1 and Z-2 plates. In addition, all plates, excluding the "H" plate, passed all checklisted specification metrics detailed in Testing.

After conducting tests on all initial designs, adjustments were made to the first Alpha Z-1 plate, pictured in Figure 1a. The Beta design can be seen in Figure 2. This design was subjected to an identical mechanical test as before, and a stiffness value of 1537.2 N/mm was obtained as the average of three trials. After conducting a two-sample t-test in Microsoft Excel, it was found that the difference between the stiffness values of the initial Alpha Z-1, and the Beta plate were statistically significant. The two-tailed p-value was $2.79*10^{-71}$, which is significantly less than 0.05. If this were to be greater than 0.05, the difference between the stiffness values would not be considered statistically significant. Comprehensive data for the statistical analysis can be found in Appendix B.

**Phase 2:**

ANSYS Workbench 17.2 was used for this phase of testing. The alpha prototypes were given a curvature in their design to better simulate their response to forces once implemented in the body. The alpha prototypes seen above in Figure 1b, 1c, and 1d were analyzed to compare the results of mechanical testing on them; however, those models have been omitted as the prototype seen in figure 1a was further modeled and used in the development of the final beta prototype. Stiffness values were obtained for Alpha Z-1 and the Beta designs as 1490.12 N/mm and 1642.58 N/mm respectively. Comparing these results with the mechanical tested data shows a 0.7% increase in stiffness values from mechanical to FEM data in Alpha Z-1 and a 6.7% increase for the Beta Z-Plate. Seeing these low values when comparing the differences between the mechanically tested prototypes and FEM tests bodes well for the validity of the other FEM tests conducted in this report. A bar graph depicting these stiffness data is located in Appendix B.

Upon FEM validation, various tests were performed and evaluated. In all models, the mesh structure has been suppressed to allow for the difference in stress, strain, and deformation to be easily seen. The plates were modeled as Titanium with 6 percent Aluminum and 4 percent Vanadium (Ti-6Al-4V). Total deformation and equivalent stress are shown in Figures 5 and 6 for one curvature of the alpha Z-plate-1 and the beta plate. The equivalent strain figures are located in Appendix C along with figures for the second curvature of each plate.

To begin gaining an understanding of the plates, the inside faces of each screw hole were fixed to simulate the plate being screwed into the surface of a bone. Simulating an impact, such as a blow to the location of the plate, a force of 500 Newtons (N) was applied to the center of the plate. The total deformation at the center location reached a maximum of approximately 0.014 millimeters (mm). The stress reached a maximum of approximately 147 MegaPascals (MPa) near the edges of the screw holes, but remained much lower throughout the rest of the plate. The same plate was also modeled under a force of 300 N pulling from the top and bottom faces with the screw holes fixed in place. This was done to simulate the action of the two portions of bone being pulled apart as a patient is walking. This action produced less than 0.01 mm of deformation and a maximum equivalent stress of approximately 43 MPa. These results indicate a strong resistance to these forces and support advancement of this plate. Finally, the plate was modeled by fixing the two screw holes along the main diagonal while applying a 300 N force to the other two holes, simulating a torsional force due to misalignment or failure of those screws. It can be noted that due to the lack of stability, a much larger displacement was seen in the plate. The plate experienced a maximum deformation of 0.6 mm and a maximum equivalent stress of almost 700 MPa.

The beta prototype was adjusted in dimension slightly from the Alpha prototype A. The outside dimensions are 1 inch by 1 inch, with the holes being in line with each other, rather than offset. The angle of the main diagonal was reduced to 45 degrees. This allowed for simplification of manufacturing as well as reduced deformation and stress due to the same forces applied. It can be noted in the first model with the centered force of 500 N that the maximum deformation and stress were slightly reduced, showing a minor improvement of this design. It is considered a major improvement that the beta design saw an average stress of 14.7 MPa, while the alpha prototype saw an average stress of 19.7 MPa, a reduction of approximately 25 percent. Using the same 300 N force at each end as in the alpha modelling, Beta Z-Plate performed similarly. The Beta Z-Plate did experience a greater stress near the holes; however, the stress across the rest of the plate was lower. For the Beta Z-Plate, the maximum deformation and the maximum stress were both decreased when a force was applied to the corners that were not fixed. This indicates that the plate is stronger and would perform better if a screw were to malfunction. This is important in the reduction of failure and repeated surgeries. In another finite element model, bone was approximated to have a Young's Modulus of 29 Gigapascals, Poisson's ratio of 0.3, and density of 3.8 kilograms per meter cubed [5]. The left first metatarsal, medial cuneiform, and our Beta Z-Plate were modeled to understand how the movement of those bones when a patient is walking would impact the plate. These results can be seen in Appendix C, Figures C10 and C11.

A final model designed to understand the usability of this plate was modeled as a fatigue test. The average adult in the United States walks approximately 6,000 steps in a single day [3]. The hardware was modeled to be removed at 40 weeks to exceed the typical removal time period [4]. The amount of steps were increased to 10,000 and the cycles were calculated at 2,800,000 to determine if there is potential for this plate to withstand the forces seen in a patient walking in the weeks following surgery. Steel was used for this model due to the readily available data on fatigue testing already present in the finite element software. A finite element model of a fatigue test on both Alpha Z-1 and the Beta plates can be found in Appendix C. Comprehensive figures for finite element analysis for all plates can also be found in Appendix C.

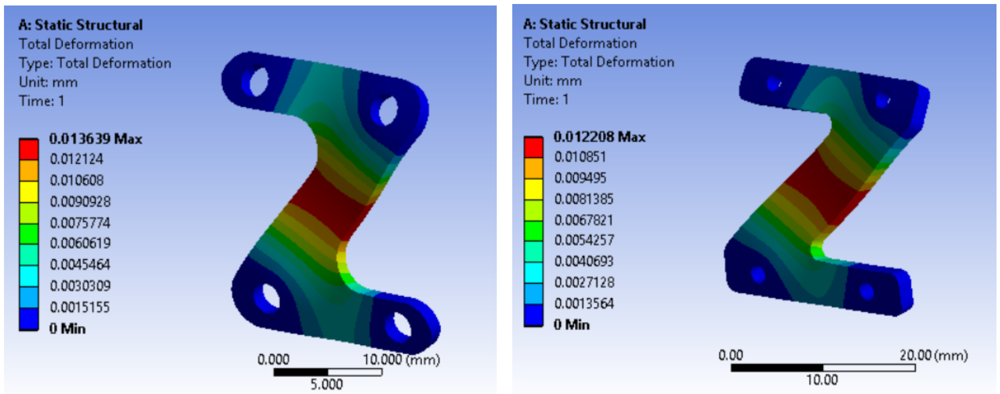


Figure 5: Total Deformation in Alpha (left) and Beta (right) Z-Plate from a centralized force of 500 N, simulating any sort of displacement of the plate during use. Beta plate can be seen to deform slightly less.

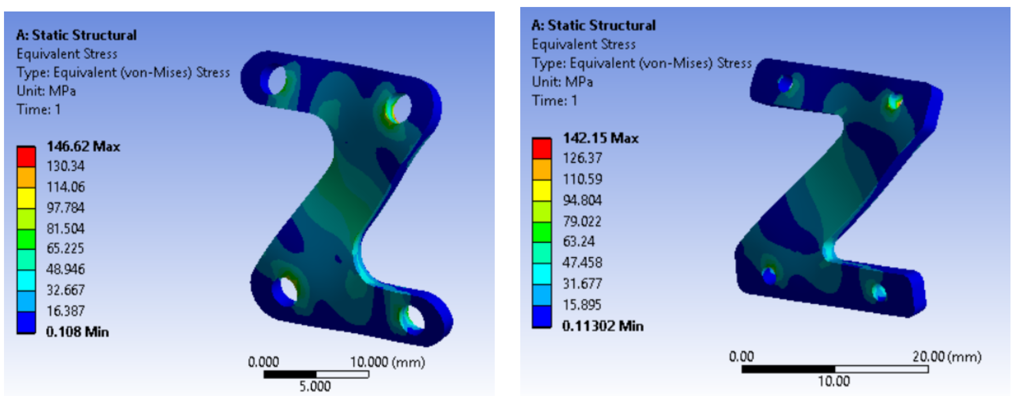


Figure 6: Equivalent Stress in Alpha (left) and Beta (right) Z-Plate from centralized force of 500 N, identifying any areas of potential failure. Alpha plate can be seen to take more stress in the center of the plate.

**Progress:**

No specifications need to be explicitly excluded from the design of the Z-Plate. All of the client's requirements were reasonable for implementation. The only specification that was not satisfied was that the plates be made of an inert, biocompatible material. Steel was used for all prototypes, however it was not medical grade and would not be acceptable to use in the human body. While physical prototypes were made of steel to reduce machining costs, advanced modelling was completed using titanium to better understand how the Z-Plate would function and its feasibility of use in foot and ankle fixation. Designs and results will be relayed to our client, upon which additional testing may be requested. Following these deliveries, our client will assess the potential of the Z-Plate and if further design iterations and evaluations should be pursued.

**Individual Contributions:**

Throughout the project, all members contributed in one way or another. Ian was mainly in charge of Solidworks and ANSYS modeling. Matt, Sean, and Ian were in charge of mechanical testing, machining, and overall design. Rhaz was in charge of data analysis, and Heather and Rhaz were in charge of documentation and business aspects. All five members were a part of design implementation. Finally, Matt conducted all communication between the team and the client, Dr. Mark Mendeszoon. Team coordination beyond team roles was common and aided in overall project efficiency and progress.

**Financial Considerations:**

Most orthopedic medical device companies sell their plates in kits, rather than individually. This causes difficulty in getting our single plate on the market by itself. In order for our plate to viable on the market, it will likely need to be included in a plating system. Ideally, the plate would be patented and sold to companies allowing for the plate to be included in many complex plating systems. This would optimize the Z-Plate, allowing for surgeons to have it as another option when completing complex foot and ankle correction surgeries. Our plate would not excel on the market on its own, and would be eclipsed by the competitor's kits.

For the duration of the project, a total of $89.90 was spent on material and machining costs. The production of the alpha prototypes were outsourced and cost $80 for parts and labor. The beta prototypes were machined by the team with a total cost of $9.90, which was used on steel.

**Summary Feasibility Discussion:**

Dr. Mendeszoon requested for the team to design an internal fixation plate that was Z-shaped, small, and strong enough to handle the load a foot takes. He was interested in studying the biomechanics of the foot to evaluate the potential for a Z-shaped plate. This need was satisfied. After evaluating all data provided by mechanical testing and finite element modeling, a more refined design was produced. Initial testing and more advanced modelling through the use of finite element analysis indicates a potential for this plate design to support the loads of the foot; however, more advanced testing is recommended for implementation of this plate design into the medical field. Expert opinion should be sought out to identify the overall Z-Plate effectiveness and potential in the marketplace. Even so, the team is satisfied and encouraged by the results found during this project.

**Future Work:**

Further steps can be taken to prove the concept of the Z-shaped internal fixation plate. More testing could be conducted, including the use of a cadaver foot with more natural loading. Further comparisons to other designs, such as between the Z-Plate and other modeled plates by competitors, would be valuable assessment. Due to inconclusive fatigue modelling, a more extensive model is recommended with multiple forces included to better understand how many cycles of loading would impact the plates. Aspects of the plate that have yet to be developed are varying angles that specific screw designs that could be inserted, as well as the addition of compressive options to the plates. These are features that should be investigated in future research. Additional market research and an expert patent search would also be suggested, as well as research for potential applications outside of the foot and ankle region of the body. In order to reach the market, additional research is necessary for a competent final design to be achieved, and other options like scalability and design applications should be investigated in the future.

**Discussion, Conclusions, Lessons Learned, Recommendations:**

Throughout the course of the eight months provided for this project, a few issues arose. One of the most critical was a delay in manufacturing of alpha prototypes. The original plan was to have two members of our team utilize the machine shop in the Mechanical Engineering department to machine our own prototypes; however, when discussing options with the head of the machine shop, this was deemed impractical and the production of our samples was outsourced. This process was originally expected to take one week, but ended up taking approximately two. This in turn delayed the testing of these prototypes. Issues were encountered early in the finite element phase of testing as well. Initial attempts at recreating the exact same parameters of the mechanical test yielded unrealistic results, so the team had to spend extra time to redevelop a method that works. Along with that issue, the time it takes to model, load, and run analysis in ANSYS was underestimated, leading to delays in modeled results. Even so, the team is content with the various models and methods explored during testing.

Full team meetings were generally held weekly, with additional meetings planned as needed. Tasks were divided amongst the members of the team with respect to each member's personal strengths. Each member contributed to every aspect of development, but were put in charge of aspects they excelled at.

In reference to purchasing, there were no issues at hand. The $500 budget provided by the University of Akron proved to be plenty for the development of our project. Since each plate design was small, manufacturing costs were not extreme since the cost of steel was relatively low.

Dr. Mendeszoon has been an valuable asset to the team. In addition to being our client, he was a source of hands on information and resources. He responded well to interviews and questions for requirements and was quick to return messages to our team.

The capstone course was fairly well organized. The access of a "project manager" in the form of the course's TA was a resource that was appreciated in the first semester. That resource was greatly missed in the second semester of the course. During the first semester, being pushed to have an entire design completed helped to accelerate the manufacturing and testing portion in the second semester. A heavy focus on early scheduling should be encouraged for future classes, as it is easy to lose track of time and lead to difficulties later in the project.

Overall, this project taught hands on design skills and gave the opportunity to apply what had been learned in various engineering courses. In addition, valuable communication skills were developed in the form of knowing how to professionally communicate with a client, as well as how to work well in a group of five individuals over an 8 month time period.

**References:**


[1] Nix, S., Smith, M., & Vicenzino, B. (2010). Prevalence of hallux valgus in the general population: a systematic review and meta-analysis. Journal of foot and ankle research, 3, 21. doi:10.1186/1757-1146-3-21

[2] Lapidus Bunionectomy Surgery. (n.d.). Retrieved April 17, 2019, from https://www.orthoneuro.com/patients/patient-education/medical-procedures/foot-ankle-procedures/bunion-sx-lapidus-procedure/

[3] Tudor-Locke, C., Johnson, W. D., Katzmarzyk, P. T. (2009). Accelerometer-Determined Steps per Day in US Adults. Medicine & Science in Sports & Exercise, 41, 7. doi: 10.1249/MSS.0b013e318199885c

[4] Bednarz, P. A., Manoli, A. (2000) Modified Lapidus Procedure for the Treatment of Hypermobile Hallux Valgus. Foot & Ankle International, 21, 10, 816-821. Doi: 10.1177/107110070002101004

[5] Niu W. X., Wang L. J., Feng T. N., Jiang C. H., Fan Y. B., Zhang M. (2013). Effects of Bone Young's Modulus on Finite Element Analysis in the Lateral Ankle Biomechanics. Applied Bionics and Biomechanics, 10, 189-195. https://doi.org/10.3233/ABB-140085

[6] Hamer, S. Human Anatomy V3 - Male. Body Parts 3D Source. Retrieved from https://grabcad.com/library/human-anatomy-v3-male-life-sciences-japan-bodyparts3d-source-1/details?folder_id=4524680

[7] Amini, Rouzbeh. Experimental Techniques in Biomechanics Lecture 3/18/19. Experimental Techniques of Biomechanics Spring 2019. University of Akron. Akron, OH, 2019.

## Appendix A: Specifications and Customer Requirements

| Requirement | Specification | Metric |
|---|---|---|
| Withstand the loads of a foot | Can bear physical loading without failure | Plate design properties respond well to various loads experienced by the foot, with minimal stress concentration areas |
| Handle torque of a foot | Can bear torsional force without failure | Plate design properties respond well to various torsional loads experienced by the foot, with minimal stress concentration areas |
| Fit various screw sizes | Fit #4 and #5 screw sizes (2.845 and 3.175 mm respectively) | Can fixate plate with either screw size without failure of plate |
| No moving components | Plates must be rigid bodies when fixated with screws | Plates cannot be moved by hand (or wiggle) in any direction while screwed down |
| Material used is biocompatible and will remain inert for device lifespan | Metal used for plates is considered biocompatible by ISO standards | Material must be considered biocompatible by ISO 10993 standards |
| Able to fixate fracture without damage or failure to plate | Failure shall not occur while screwing in the plate for testing | No visible damage or plate failure upon screwing in plates |
| Compatible with autoclave sterilization (122 degree Celsius) | Alloy will be able to withstand 122 degree Celsius | Material must have a melting point greater than 244 degrees Celsius |
| Easily Constructed | Design must not require advanced machining | Plate design is flat and constructed by removal of material |
| Small device | Design is small | Device dimensions cannot exceed 2x2 inches |
| Z-Shape | Design structure must follow that of a “Z” shape | Design contains two parallel horizontal pieces connected by a diagonal piece not exceeding an angle of 60 degrees from either horizontal piece |
| Lightweight | Plates must be lightweight in design | Prototypes must not weigh more than 100g |
| Low unit price | Plate design is inexpensive to manufacture | Prototype machine costs less than 5$ a unit |
| No need to service plate | Plate design does not require maintenance or additional steps upon installation | Procedure for proper plate use includes only installation and removal of screws and device |
| Shelf life of product is not limited as long as the product is stored in a clean, dry environment at room temperature | Device will not degrade in quality or physical structure over time if stored properly | Plates are made of nonferrous metal |

## Appendix B: Statistical Analysis

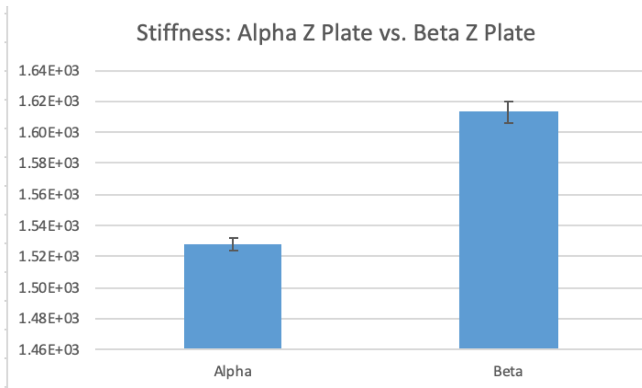


Figure B1- Average Stiffness value between Alpha and Beta plates, with error bars signifying a 95% confidence interval

| | *Variable 1* | *Variable 2* |
|---|---|---|
| Mean | 1528.478207 | 1613.257505 |
| Variance | 1250.900711 | 3347.025236 |
| Observations | 290 | 290 |
| Hypothesized Mean Difference | 0 | |
| df | 479 | |
| t Stat | -21.29157691 | |
| P(T<=t) one-tail | 1.39453E-71 | |
| t Critical one-tail | 1.648040972 | |
| P(T<=t) two-tail | 2.78905E-71 | |
| t Critical two-tail | 1.964928859 | |

Table B1: t-Test: Two-Sample Assuming Unequal Variance

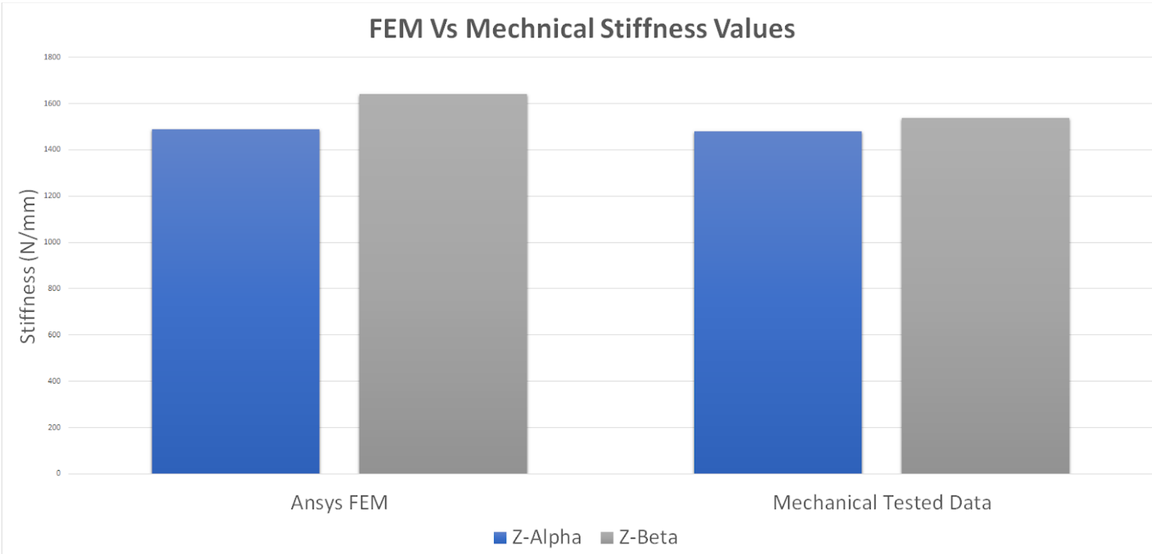


Figure B2- Comparison between ANSYS stiffness values and Mechanically tested values

## Appendix C: Additional Finite Element Analysis Figures

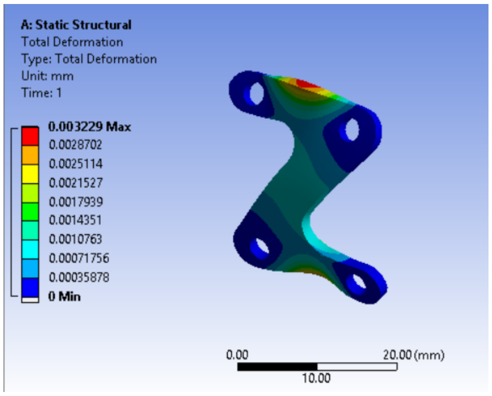


Figure C1: Total Deformation in Alpha Z-Plate from 300 N forces pulling at each end

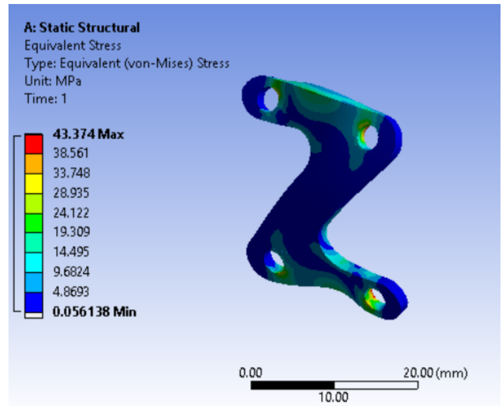


Figure C2: Equivalent Stress in Alpha Z-Plate from 300 N forces pulling at each end

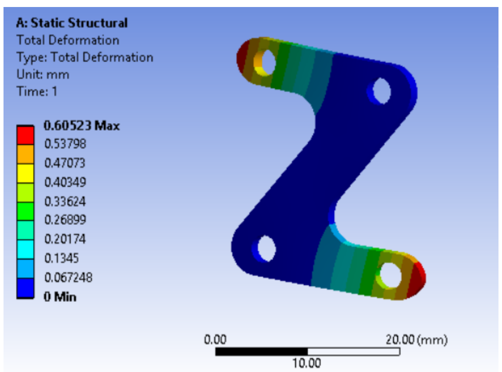


Figure C3: Total Deformation in Alpha Z-Plate from 300 N force placed on unfixed screw holes

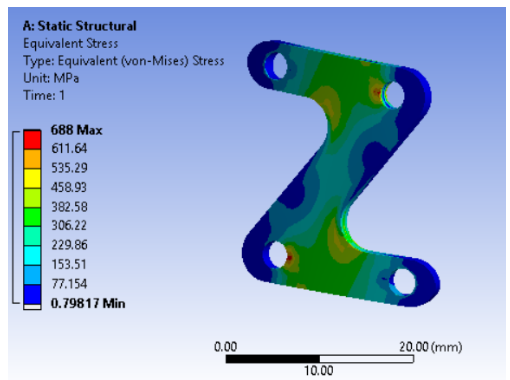


Figure C4: Equivalent stress in Alpha Z-Plate from 300 N force placed on unfixed screw holes

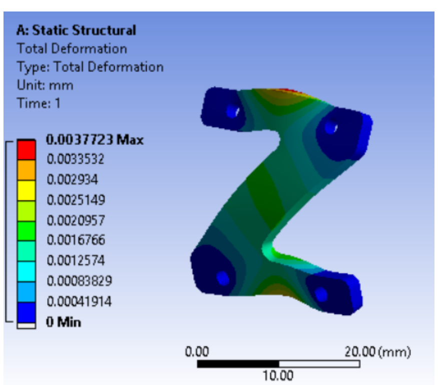


Figure C5: Total Deformation in Beta Z-Plate from 300 N force placed on unfixed screw hole

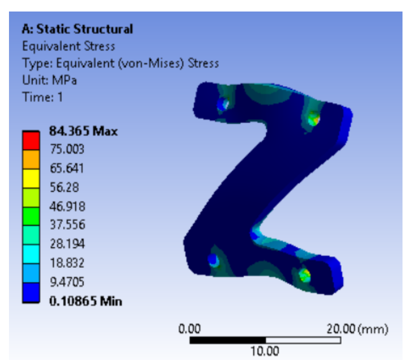


Figure C6: Equivalent Stress in Beta Z-Plate from 300 N force placed on unfixed screw hole

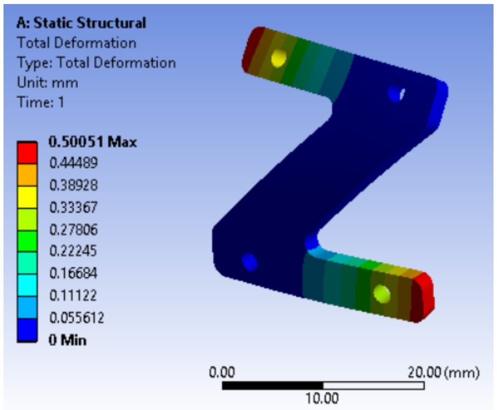


Figure C7: Total Deformation in Beta Z-Plate from 300 N force placed on unfixed screw holes

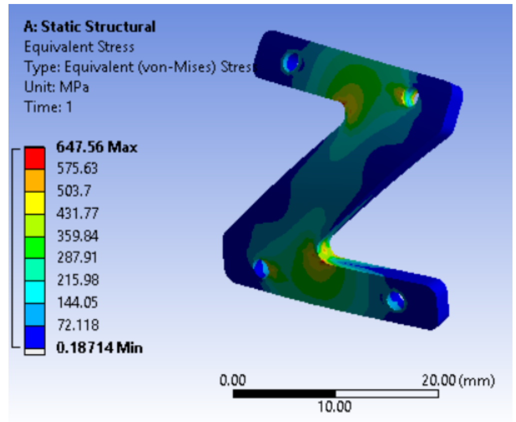


Figure C8: Equivalent Stress in Beta Z-Plate from 300 N force placed on unfixed screw holes

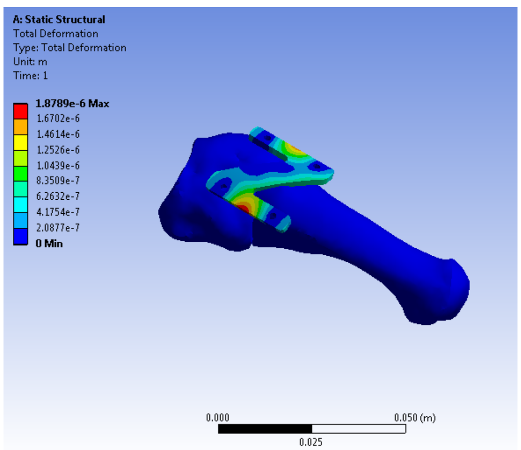


Figure C9: Total Deformation of Beta Z-plate connected to the first metatarsal and medial cuneiform

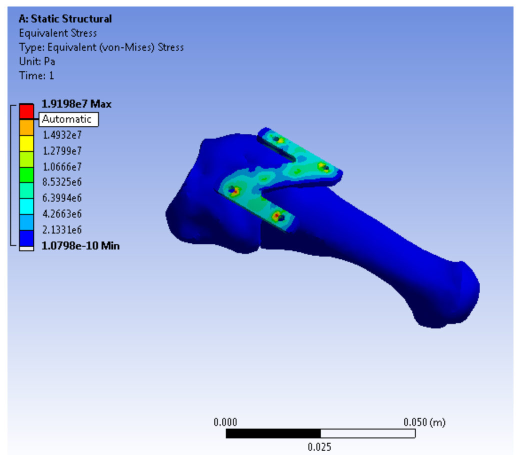


Figure C10: Equivalent Stress of Beta Z-plate connected to the first metatarsal and medial cuneiform

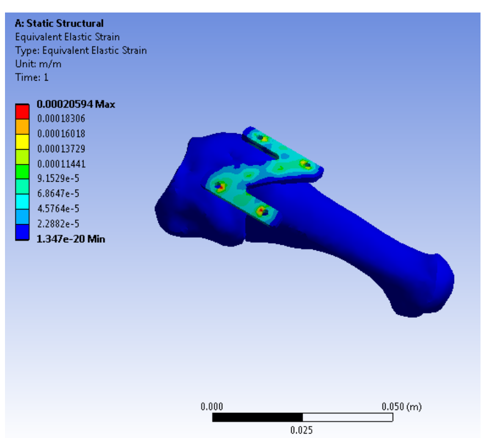


Figure C11: Equivalent Strain of Beta Z-plate connected to the first metatarsal and medial cuneiform

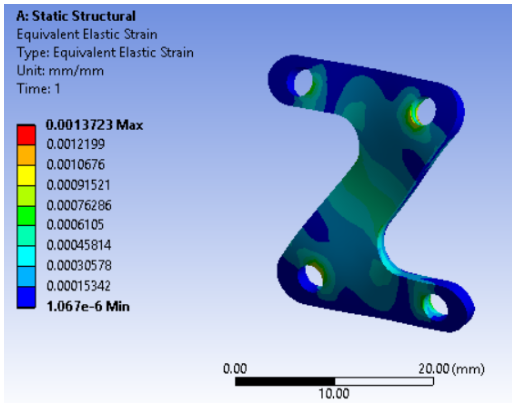


Figure C12: Equivalent Strain in Alpha Z-Plate from centralized force of 500 N

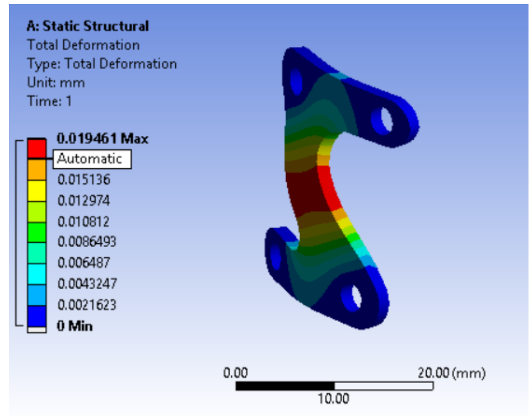


Figure C13: Total Deformation in Alpha Z-Plate Second Curvature from centralized force of 500 N

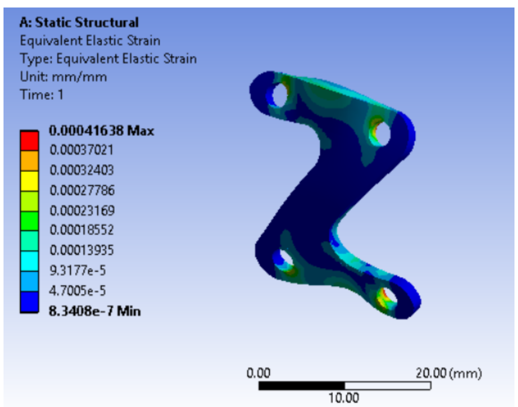


Figure C14: Equivalent Strain in Alpha Z-Plate from 300 N forces pulling at each end

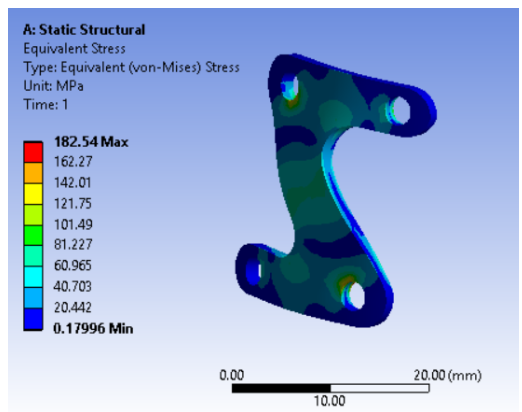


Figure C15: Equivalent Stress in Alpha Z-Plate Second Curvature from centralized force of 500 N

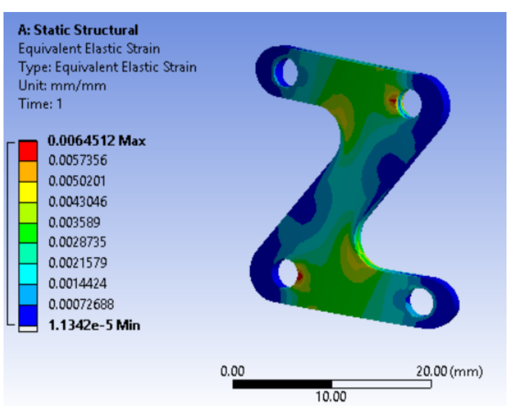


Figure C16: Equivalent Strain in Alpha Z-Plate from 300 N force placed on unfixed screw holes

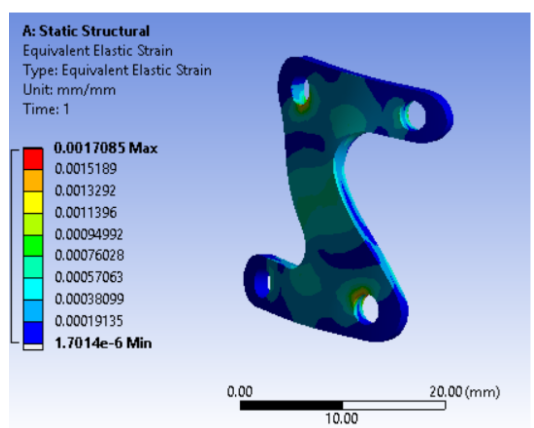


Figure C17: Equivalent Strain in Alpha Z-Plate Second Curvature from centralized force of 500 N

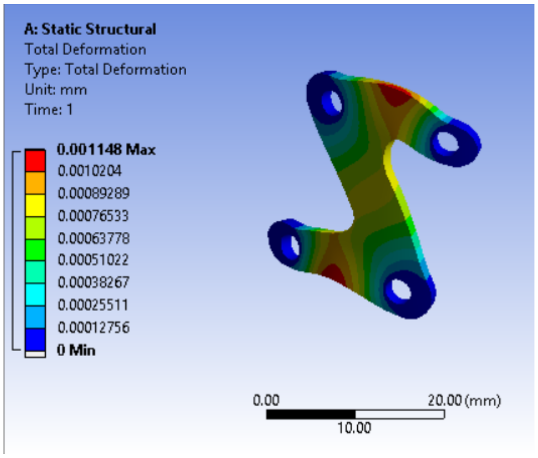

Figure C18: Total Deformation in Alpha Z-Plate Second Curvature from 300 N force pulling at each end

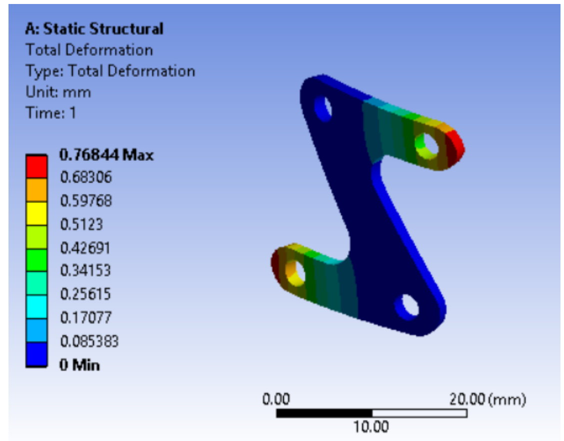

Figure C19: Total Deformation in Alpha Z-Plate Second Curvature from 300 N force placed on unfixed screw holes

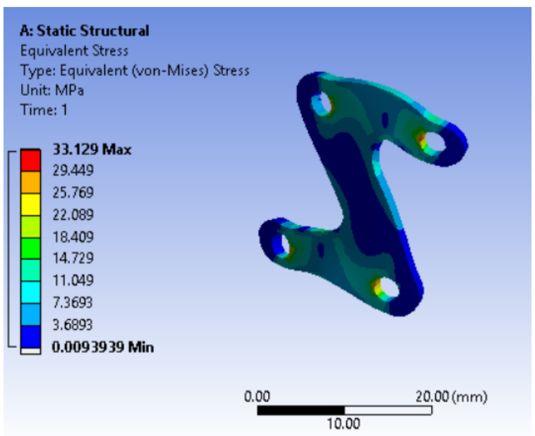

Figure C20: Equivalent Stress in Alpha Z-Plate Second Curvature from 300 N force pulling at each end

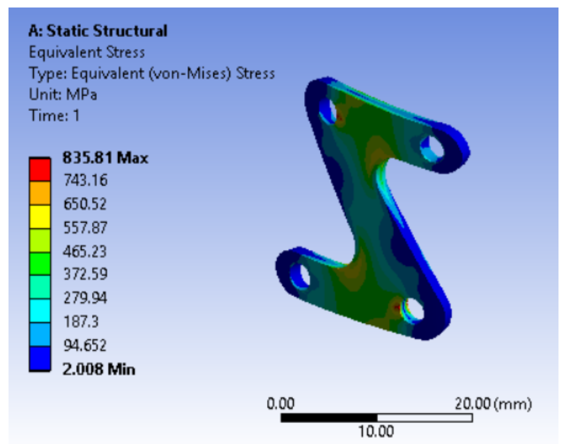

Figure C21: Equivalent Stress in Alpha Z-Plate Second Curvature from 300 N force placed on unfixed screw holes

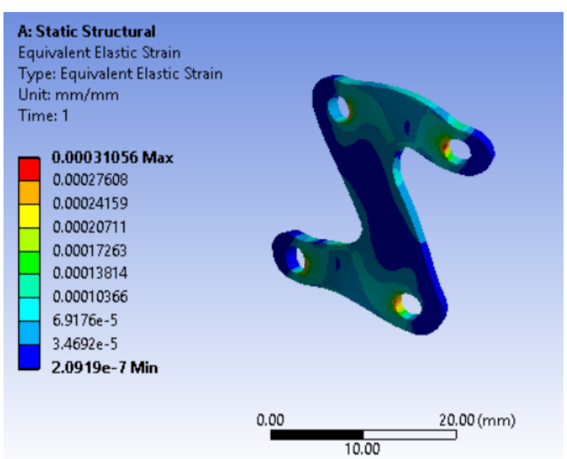

Figure C22: Equivalent Strain in Alpha Z-Plate Second Curvature from 300 N force pulling at each end

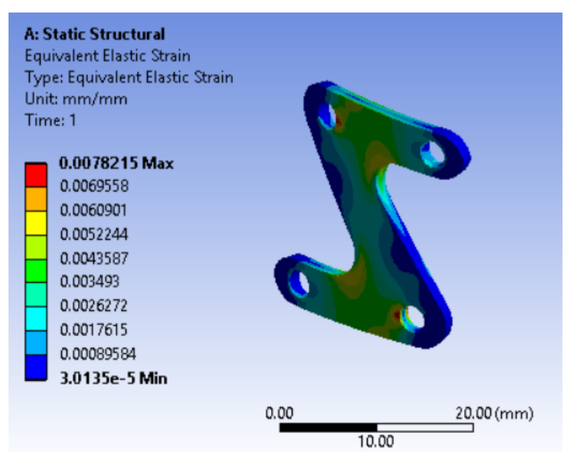

Figure C23: Equivalent Strain in Alpha Z-Plate Second Curvature from 300 N force placed on unfixed screw holes

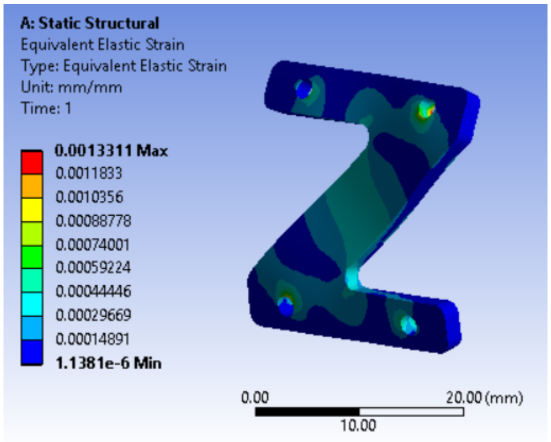


Figure C24: Equivalent Strain in Beta Z-Plate from centralized force of 500 N

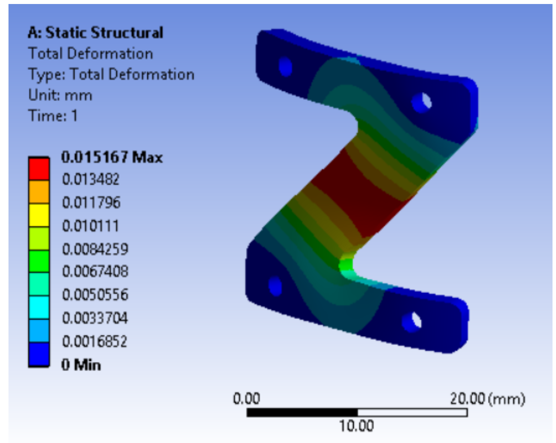


Figure C25: Total Deformation in Beta Z-Plate Second Curvature from centralized force of 500 N

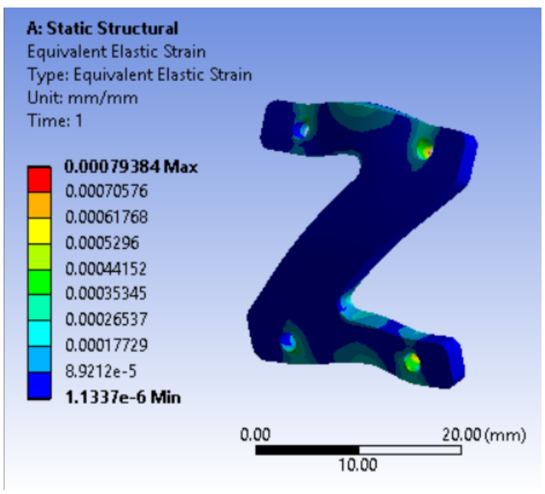


Figure C26: Equivalent Strain in Beta Z-Plate from 300 N force placed on unfixed screw hole

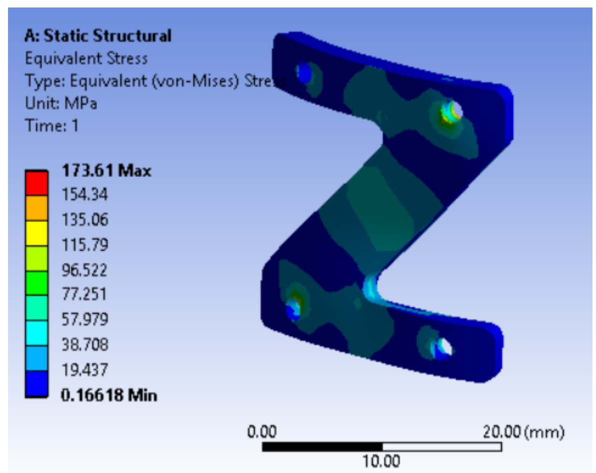


Figure C27: Equivalent Stress in Beta Z-Plate Second Curvature from centralized force of 500 N

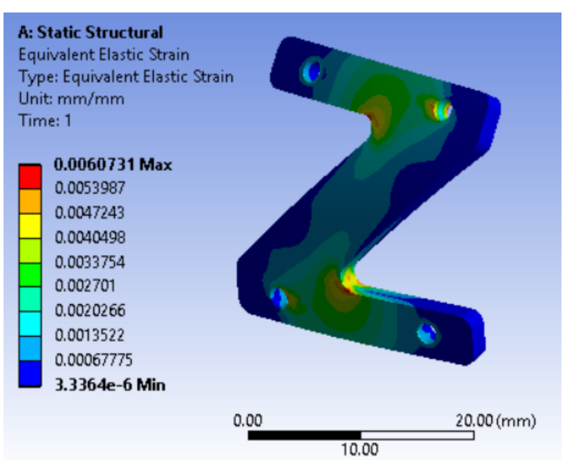


Figure C28: Equivalent Strain in Beta Z-Plate from 300 N force placed on unfixed screw holes

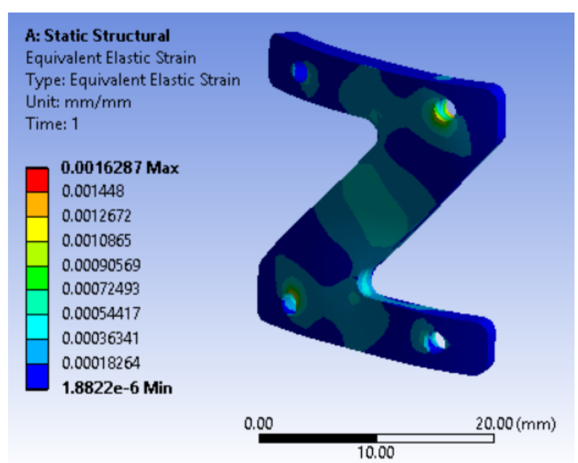


Figure C29: Equivalent Strain in Beta Z-Plate Second Curvature centralized force of 500 N

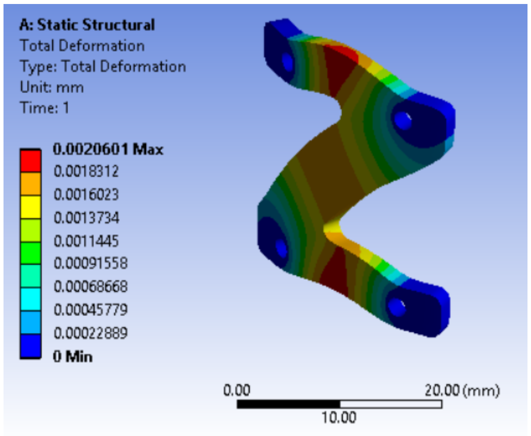


Figure C30: Total Deformation in Beta Z-Plate Second Curvature from 300 N force pulling at each end

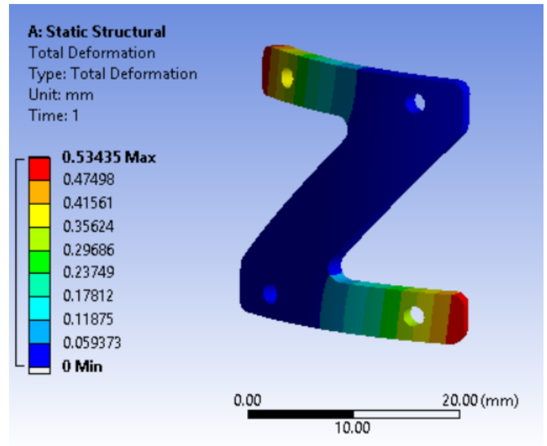


Figure C31: Total Deformation in Beta Z-Plate Second Curvature from 300 N force placed on unfixed screw holes

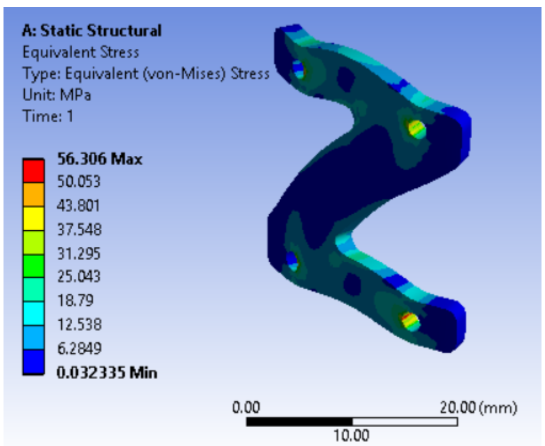


Figure C32: Equivalent Stress in Beta Z-Plate Second Curvature from 300 N force pulling at each end

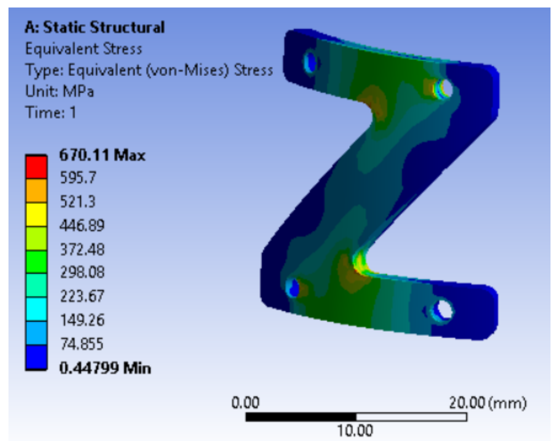


Figure C33: Equivalent Stress in Beta Z-Plate Second Curvature from 300 N force placed on unfixed screw holes

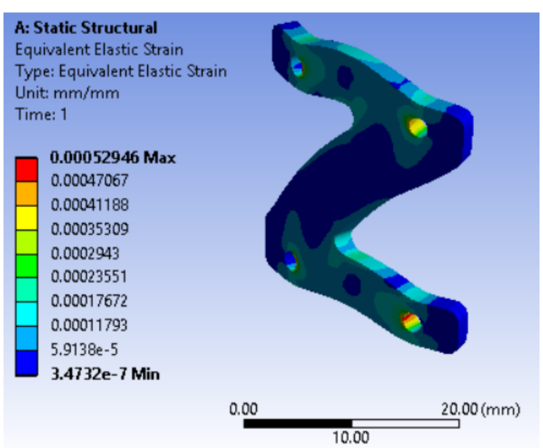


Figure C34: Equivalent Strain in Beta Z-Plate Second Curvature from 300 N force pulling at each end

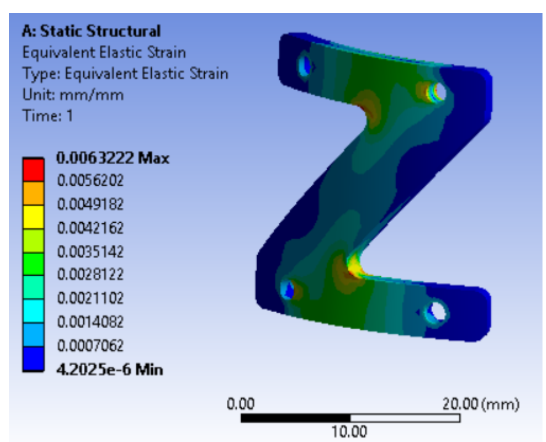


Figure C35: Equivalent Strain in Beta Z-Plate Second Curvature from 300 N force placed on unfixed screw holes

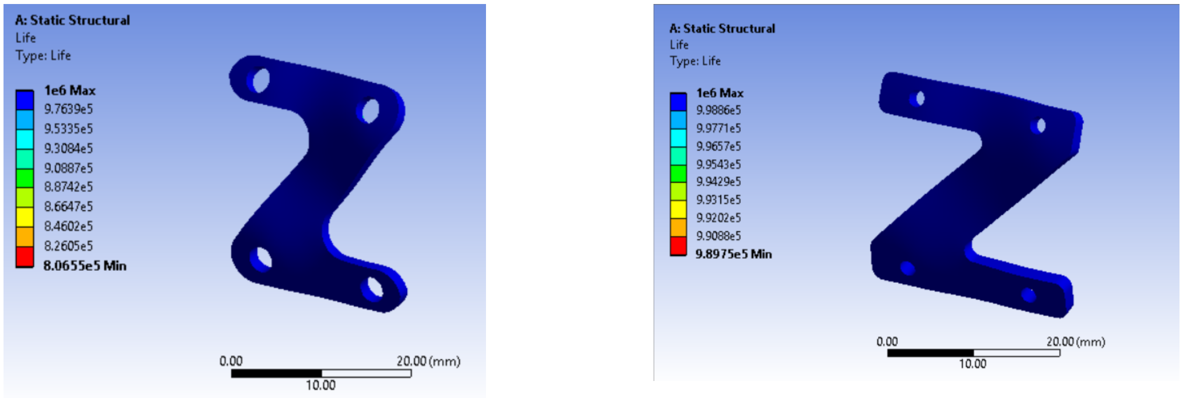


Figure C36: Approximate life in Alpha (left) and Beta (right) Z-Plate from centralized force of 300 N due to fatigue testing.