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Pediatrics Bone Fixation Device of the Femur

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Abstract - Bone fractures are one of the most common injuries that surgeons deal with which result in plates, rods, screws, etc. being put inside the human body. Bone fractures and breaks are even more common among children due to their hyperactivity on a daily basis. However, the added complication for children is not the severity or frequency injuries but accelerated growth humans have as children. Children in their younger puberty stage can grow about 2 inches a year which means their bones will grow as well. This project aims to rectify that complication. The goal is to design, manufacture, and test a fixation device for pediatrics that will adjust as the child grows. This will allow for the child to heal faster and prevent them from needed multiple surgeries so frequently. The design illustrated and evaluated here supported about twice a child's bodyweight. This shows that the adjustability design is strong enough to support the load of the body however, exaggerated, or high impact movements can damage the device and therefore cause damage to the bone. This concluded is supported by the fact that the average human exerts 1.5 to 2 times their body weight when walking. In addition, due university equipment, the material used for this design is not suggested for industry use because aluminium was used. Aluminium is highly corrosive in the human body. The iron and salt that runs through the bloodstream makes the aluminium rust and corrode over time and that corrosion can cause imbalance chemical complications in the human body especially for a human body that is in the process of development. A clamping fixture is tested using the Instron machine. The resulting compression test yielding a result of 223.235 lbs. that was the highest high the plates could handle before deforming. Using FEA to test the max. load which is placed on the top surface area of the plate and the fixed geometry is on the bolts to simulate the screws being inside the bone. The screws designed in Solid Work are 304 stainless steel resulting a yield strength of 31200 psi and the plates with the exerted force acting upon them are 6061 aluminium which resulting a yield strength of 42000 psi..

***Keywords*:** fracture, design, aluminium, FEA

1. Introduction

Femur fractures account for about 33% of stress fractures of which 7% of those occur in the distal fractures in adults and are extremely difficult to treat [1]. These stress fractures have bimodal effects on elderly patients as well as high energy trauma accidents in younger patients such as children. These traumas in children typically involve automobiles and can cause severe open wound fractures. The treatments that are implants can be traced back into two distinct 2 periods. The first period can be traced back to the 1960s it was advised and treated with traction and cast immobilization to allow foe the bone to heal and less damage to occur. during this time period surgical intervention was still discouraged because of the high-risk complications during that time period. Due to reports of good results from the arbeitsgemeinschaft fur Ostheosynthesefragen group (AO group) surgical treatment was implemented in the early 1970s [1]. these surgical treatments include the launch of locking plates that have been associated with new possibilities in fracture treatment. Numerous techniques have been describing for surgical treatment and are aided with plates and screws. Factors that play a part of this is fracture pattern, bone quality, bone quantity, functional demands of the patient, and the type of trauma associated with the fracture. Depending on the type of femur fracture, internal fixation devices will be used in older adults with non-displaced or minimal displaced trochanteric fracture. On the other hand internal fixation devices are typically used in young adults in all fractures. While, in the modern times surgical internal fixation devices are recommended more than fixed immobilization casting, there are still complications[2]. These complications can vary from incorrect fixation, fixation failure, to infections. Materials used for internal bone fixation devices need to be strong enough to support the load and stress that the body puts on its bones. However, a crucial factor other than strength is the type of material used for the devices and their ability to safely be put inside the human body. the material needs to be anti-corrosive so over time the human body doesn't experience chemical reactions. In addition, corrosion can cause the material to weaken and become brittle and that is dangerous if it needs to support hundreds of pounds. The main biocompatible materials used in the industry today is stainless steel, cobalt based alloys, titanium alloys, composite materials, and certain polymers. The material needs to fall into these categories bioinert, porous, bioactive, and bioresorbable [3]. In most cases bioinert materials are uses for plates because its less likely to attach to softer tissues. This lack of serious attachment is crucial for the removal process when the patient no longer needs the plates. Stainless steel is one of the most preferred biomaterials for bone plates because its ideal mechanical properties. Stainless steel has an elastic modulus of 200 GPa. It is also corrosion resistant, bioinert, and cost effective. On the other hand, for bone screws titanium is preferred because of its extra corrosiveness and its ductility.

2 Design and Manufacturing

The materials used and design implemented here is for pediatric use. children grow at a rapid pace and to prevent constant adjustment surgery, the plates need to be able to lengthen as the bone lengthens. Therefore, the assembly made is an adjustable design comprised of 2 parts, an inner shell, and an outer shell as shown in figures 1 and 2. Due to university restrictions, a stainless or titanium model was not cost effective or allowable in this study's timeframe. This design prototype was manufactured and assessed using 6061 aluminium, stainless steel screws and magnets.

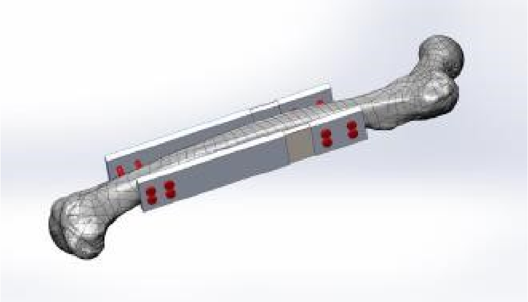

Fig. 1: Full assembly design

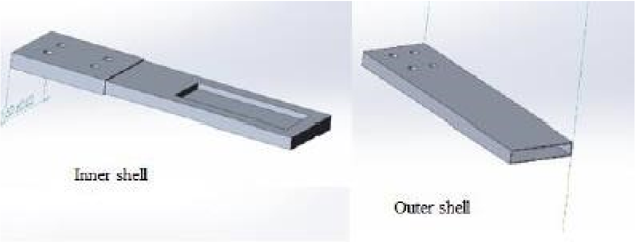

Fig. 2: Inner shell and outer shell

2.1. Manufacturing Process

The main objective of this work is to evaluate the conceptual design by using inner shell – 6061 aluminium, outer shell – 60601 aluminium and screws – 304 stainless steel and testing femur bone (3D printed) – Polymer Vero white photopolymer. The dimensions of the model are length – 7.6 in (unstretched), 10.6 in (stretched), thickness – 5/16 inches and width – 1.5 inches. Two plates get screws into the bone using 8 stainless screws with no screws in the middle section. The middle section does not have screws to allow for the adjustability. The plates have a max extension of 3 inches each. In addition to the screws and shells, there are 2 pieces of galvanized stainless-steel sheets to allows for magnets to be places inside the shells. These steel sheets and magnets allow for the assembly to extend from 7.7 inches in length to 10.7 inches. The plates are designed to be places between the hip and knee joints as shown in figure 3. The magnets inside the shells are rated for a pull force of 15 lbs. each for a total of 60 lbs.

According to the body's proportional ratio, the femur is ¼ the size of the height of the person. Due to this ratio, whatever length the child grows in height will also be true for the femur on a ¼ scale. For dimensional purposes, I used the average heigh of a male boy and carried those dimensions for 6 years' worth of growth. On average, a male boy will have a height of 58.7 inches and through the years to 18 years old they will have an average height of 69.3 inches. In relation, which makes the femur length of a 12-year-old boy 14.675 inches and an 18-year-old boy 17.325 inches. That lengthening results in 2.65 inches.

Fig. 3: The plates are designed to be places between the hip and knee joints.

The design listed in Figure 4 for the basis to the adjustable plate design. The goal is for the planes to be adjustable but still able to be removed if the patients no longer want metal inside their body. Using the adjustability which is like the rod design but the ease of removal of the plate design. For the proposed design, it combines both. However proposed design, the plates don't need to be inside the bone marrow therefore it will have a less risky surgery and the healing process will be shorter.

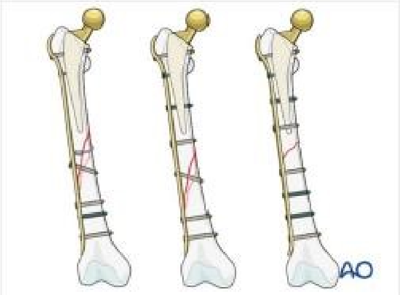

Fig. 4: Plate design

3. FEA and Testing

The load that was uploaded into SolidWorks was places on the top surface area of the plate and the fixed geometry was on the bolts to simulate the screws being inside the bone. The screws designed in SolidWork's were 304 stainless steel and the plates with the exerted force acting upon them were 6061 aluminium. 304 stainless steel has a yield strength of 31200 psi, and 6061 aluminium has a yield strength of 42000 psi. throughout all simulation runs, the max stress was experiences by the stainless-steel screws. Due to its high yield modulus, the stress experiences by the bolds don't cause a shear to occur in the screws. However, as the load increases the aluminium plates experienced crumble loads. Due to the stresses illustrated in figure 5, the aluminium plates and stainless-steel screws theoretical should be able to handle approximately 4 times the weight of a 115-pound boy.

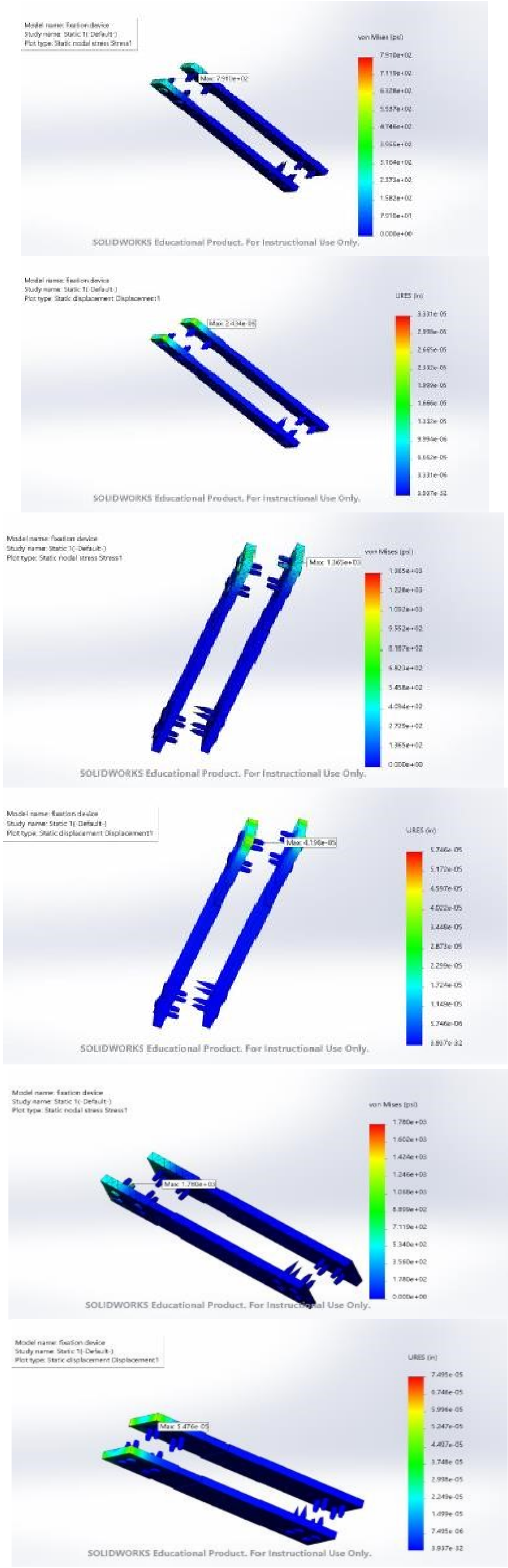

Fig.5: Illustrates different stresses.

When a bone is fractured, the body will start to create new bone and fix whatever damage is done, however if the bone is not placed in the property place the bone will heal incorrectly to a person's anatomy. That is where the plate and screws come in. the plate allows for proper bracing and compression of the two fractured parts of the bone. It allows for bone to be placed like it was originally and allow for the bone to heal properly. However, the plates and screws need to be able to withstand the load of the body i.e. the body's weight.

The screws and plates are evaluated for the amount of shear force it can withstand. The plates are screwed into the bone with stainless steel screws and a load is applied to the top of the plates. The load is transmitted to the screws, and they will experience shear loads as shown in figure 6. Once the screws shear off or the plates start to deform or bend, that will show what the maximum weight the device can handle. This load data shows what limit needs to be for a patient's weight in order to use this device.

Fig. 6: shows the load applied to the top of the plates.

Fig. 7: shows the displacement and load.

For testing purposes, the kneecap and hip joint needed to be cut off to allow the machine to accurately fix the bone and plates. In addition of the kneecap and hip joint being removed, a fracture was places 3.9 inches proximal of the hip joint to allow for realistic testing data as shown in figure 7.

Fig. 8: fracture placement

The testing machine used was the Instron universal testing 6800 series compression/tensile machine as shown in figure 8. The clapping dimensions only allowed for a max of .5 inches in width. With this restriction. I needed to construct a clamping fixture that attaches to the Instron machine that then will push down on the bone plates. The resulting compression test yielding a result of 223.235 lbs. that was the highest high the plates could handle before deforming. The deforming occurred in the outer shell section. Due to the wrapping being so thin, .025 inches, the plates started to bend inwards while it was extended.

4. Real World Application

Based on this design a child of 115 lbs. to 223 pounds can use this plate with the dimensions listed however, the material would need to change, and the manufacturing process would ideally need to change as well. the aluminum material used in this process would be dangerous and possibly deadly inside a human body. aluminum is not anti-corrosive enough to handle the fluids processed in the human body. In addition, the manufacturing process in this project was not ideal. For the outer shell, a thin aluminum sheet needed to be wrapped around an aluminum block to allow for the shell design to take place due to the university milling equipment not being able to cut deep enough. In addition, the school equipment was not able to weld the thin plate together therefore JB welding glue needed to be used. The best manufacturing would be to using a milling machine to cut the aluminum so there wouldn't need to be weak joints due to welding or wrapping.

5. Conclusion

In conclusion, this design as it is will be able to handle the load of a child however it ideally it needs to be made of a titanium alloy. This will allow for stronger plates and in turn the plates can be thinner and still be strong enough to support the body's weight. In addition, the titanium will be less likely to bend and yield at 223 lbs. further testing needs to be done however because of the lack of adequate equipment at the university. Not only is titanium testing equipment advised but a mechanism that allows for bone lengthening similar to human bone is needed to test the effect on the magnets used. The magnets can support 60 lbs. therefore the growth force that the bone produces in puberty needs to be implemented in testing to see the magnets results. That being said, the design illustrated in this analysis does show that a shell design has adequate strength to be used in a child's femur while lengthen 1 inch.

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[3] panelMatthieuEhlingerabHenriFavreauaDavidEichleraPhilippeAdamabFrançoisBonnometa, A. links open overlay, MatthieuEhlingerab, a, b, HenriFavreaua, DavidEichlera, PhilippeAdamab, FrançoisBonnometa, & AbstractProximal femur fractures have significant functional repercussions in both older adults (sometimes life-threatening) and younger adults (socioeconomic). This study will review the early mechanical complications (EMC) associated with the fixation o. (2019, October 31). *Early mechanical complications following fixation of proximal femur fractures: From prevention to treatment*. Orthopaedics & Traumatology: Surgery & Research. Retrieved August 19, 2022.

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