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Medical Device for Loading of Knee at Differing Angles

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Medical Device for Loading of Knee at Differing Angles

Honors Project

Alex Dragota

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Abstract

This was a design report for a device that would be used in patellar instability research. The device would be used inside an MRI machine and allow the patient to adjust the angle of their knee to the desired position.

Methods: Solidworks was used in the design process to model and to simulate the strength of the components used. The Solidworks simulation software allowed for a better understanding of the strength of individual components and the strength of the full device. Complexity of operating the device while inside an MRI machine were taken into account by using animations of the moving parts. The complexities of manufacturing were considered by designing parts with ease of manufacturing in mind.

Findings: The device design allows patients to adjust the angles of their knee to the required positions. The results of the strength simulation analysis indicate that some parts needed to be made of brass as opposed to polycarbonate.

1. Project Need

Background

More than 10% of office visits to musculoskeletal specialists are due to patellar instability [7]. Recurrent patellar instability usually requires surgical stabilization, especially in young, active patients. One of the most common surgical approaches is medial patellofemoral ligament (MPFL) reconstruction. However, up to two-thirds of patients treated with MPFL reconstruction may be unable to return to their previous level of sports activity [8]. The data guiding physicians on optimal surgical approaches with considerations on patient-specific anatomy are lacking. To collect data for research in patellar instability, a device that applies loading conditions at specific angles of the knee is required.

Problem Statement

Develop a device that positions a patient's knee at angles of 3°,18°, and 33° while inside an MRI machine. The angles are measured from an extension distal of the femur to the anterior of the tibia as shown in Figure 1. There is a need for the patient's quadriceps muscle to be engaged while testing. To accomplish this, the device needs to allow the patient to press the plantar side of their foot against a resistive force.

The device is to be used inside an MRI machine, and thus can only be made of compatible materials. The materials, as instructed by Dr. Elias, are limited to non-metals (plastics) or brass (only metal allowed). The device must be able to fit inside an open bore MRI machine, which has a bore diameter of 70cm [3]. The device must also be adjustable to fit large or small patients alike. The goal of this device is to noticeably reduce the time required to change the angle of the patient's knee, from 3° to 18° and from 18° to 33°. A noticeable improvement for this device would be a 95% reduction in time required to move between the angles.

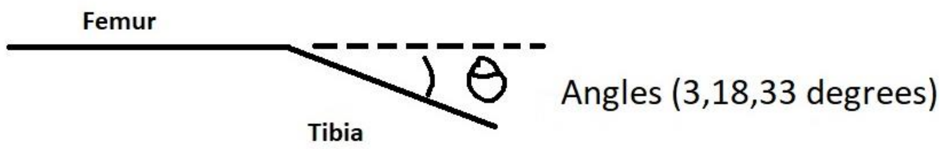


Figure 1

Current Device

Figure 2 shows the current device that is used for studying patellar instability and MPFL surgical reconstruction. This design does not allow for easy adjustment after the patient is in the MRI machine. The design uses blocks to place behind the foot holder and the back wall of the machine. This is done to adjust between the different angles as well as the different heights of patients. This design takes approximately 3-5 minutes to change between the required angles as the researcher must stop the MRI machine, walk into the testing room and estimate which blocks to use to change the patient's knee angle. The average cost for Dr. Elias to use an MRI machine is approximately $500 an hour. If the new device can reduce the time required by 95% this would result in a total time savings of 5.7-9.5 minutes and total monetary savings of $47-$80 per patient tested. Among monetary benefits, the new device should be more precise in terms of actual knee angles. With the current device, there is no measuring apparatus used to exactly identify the actual angle the patient's knee is located. An increase in angle precision would be beneficial to the research being conducted.

Figure 2

2. Design Process

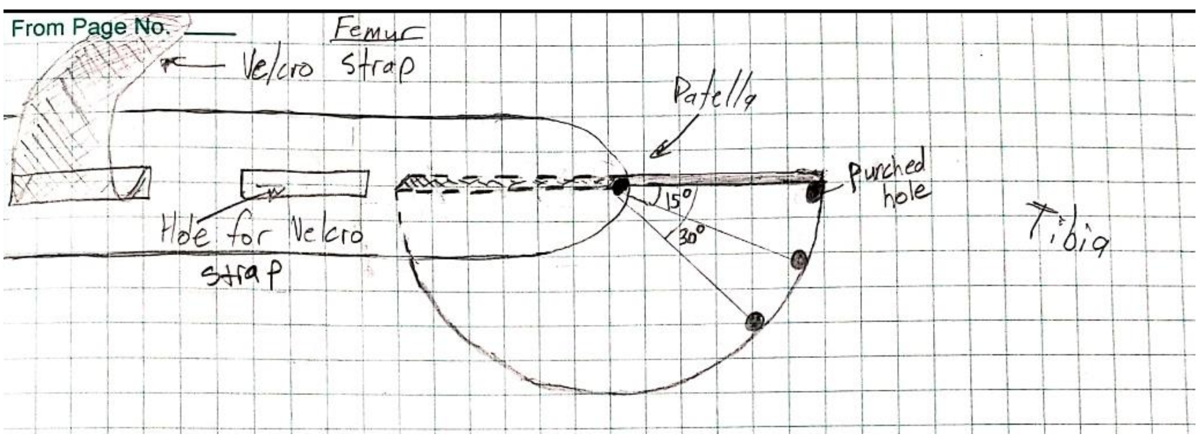


Figure 3

Femur Locking Tibia

Figure 3 shows a preliminary design for the mechanism that holds the upper portion of the leg (femur bone) and the mechanism that aligns the knee to particular angles. The portion that holds the upper leg will be 3D printed from polycarbonate filament. This is because polycarbonate filament is the strongest 3D printable plastic I have access to, with a tensile yield strength of 4300 psi. The cutouts will be used to loop Velcro straps to wrap around the patient's leg. The semi-circular portion will have drilled through holes where a pin could be inserted to lock in place. The femur bar will be mechanically attached to the half circle via screws with Loctite to ensure a secure contact. Loctite (red) has a breakaway torque of up to 230 in-lbs for a ⅜-16 size bolt. The load bearing portion of the femur bar is 6 inches from the 2 (⅜-16) bolts. This means that an individual femur portion of a patient's leg can be up to 77 lbs. If the assumption that this portion of the leg (thigh) is approximately 11% of a patient's body mass, then the patients could weigh up to 700lbs [1].

Figure 5 shows an exploded view of the mechanism, which includes a brass pin that is threaded to match the threads on the semi-circular plate. The roller has a high strength plastic bearing (up to 180lbs axially) which allows smooth rotation of the tibia bar. This design will have a second assembly of the one shown in figure 4, however it will be the inverse of figure 4. A patient's leg would fit between the two assemblies and would be held by 2-inch-wide Velcro straps.

Figure 4

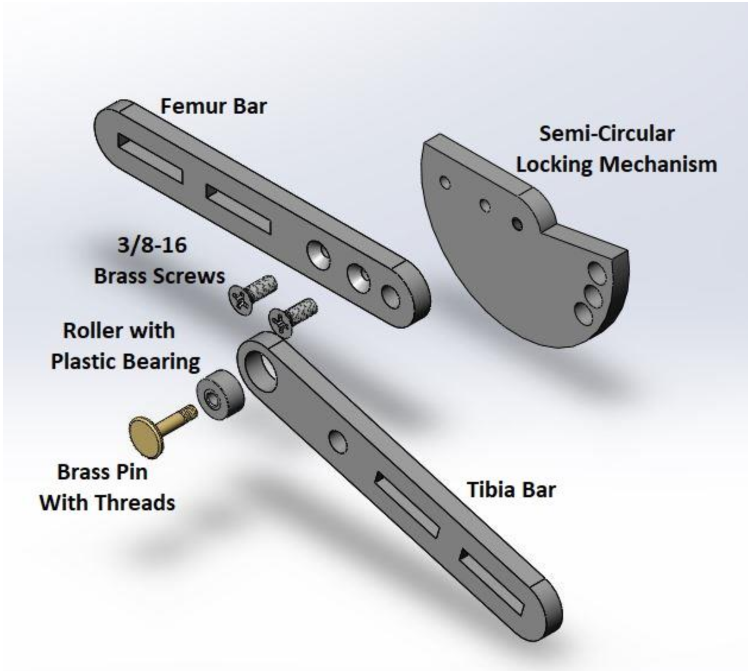


Figure 5

Pop-Pin

This design assumes that there will need to be a pin the patient could trigger to lock the device at a set angle. In order to accomplish this, a pop-pin style design will be incorporated. This is similar to a workout bench where a spring-loaded pin can be pulled to release the mechanism and the pin could be triggered at the appropriate position to lock the mechanism.

The entire device has limitations to the materials that could be used due to the magnetic fields that are used inside an MRI machine. It was strongly recommended, by Dr. Elias, to design this device with minimal metal, the only metal allowed being brass. Searches for a pop-pin that could be purchased with the given criteria were conducted on McMaster-Carr, Grainger, and eBay. A pop-pin device entirely made from plastic and brass was not available for purchase and thus needed to be designed. Figure 6 shows the pop-pin mechanism in the compressed view (spring extended). In this position, the pin will insert into the hole at the specific angle for locking the device.

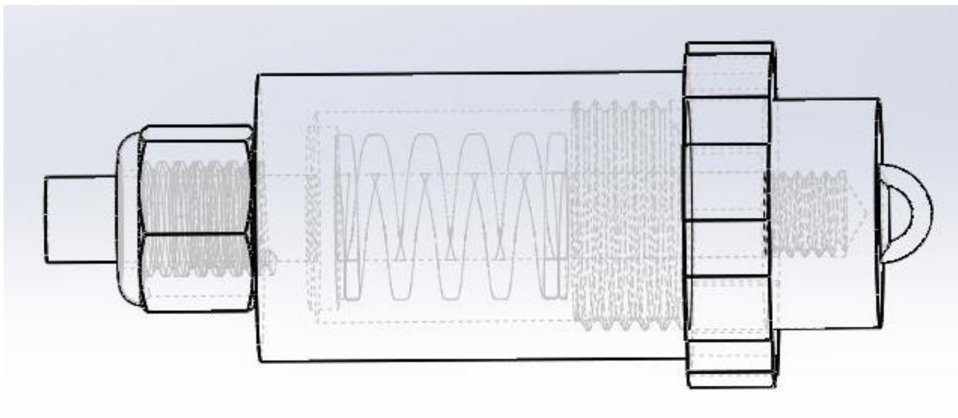


Figure 6

Figure 7 shows the pop-pin mechanism in the extended view (spring compressed). In this position, the pin will be pulled out of the hole from the semicircular mechanism and will allow the mechanism to freely move.

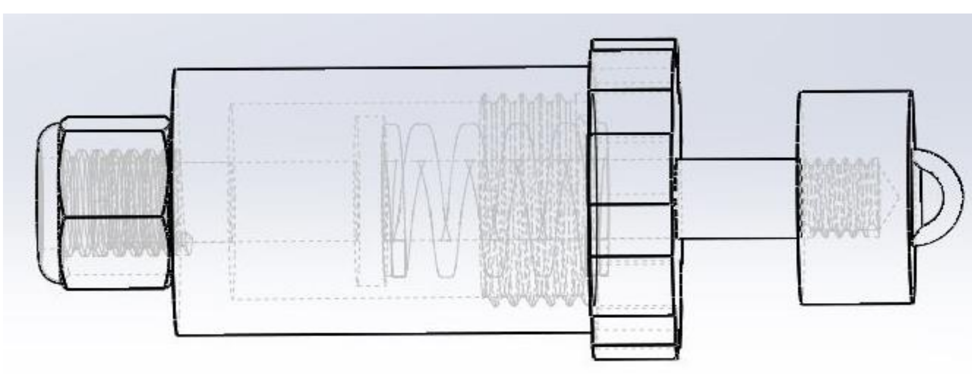


Figure 7

The above pop-pin consists of a body, body cap, brass pin, pin cap, and a nut, (refer to figure 8). The body of the assembly is threaded on the top end to match the threads of the body cap. The body also has a threaded flange with matching threads to the nut to clamp it in place when mounted to the rest of the device assembly. The pin is made of brass to ensure high strength when an axial load is applied when in the locked position. The pin also has a soldered or tig welded brass washer which the plastic spring rests upon. The body cap is threaded to match the body and has a clearance hole which allows the brass pin to move freely through to attach to the pin cap. The pin cap is threaded to match the threads in the top portion of the pin.

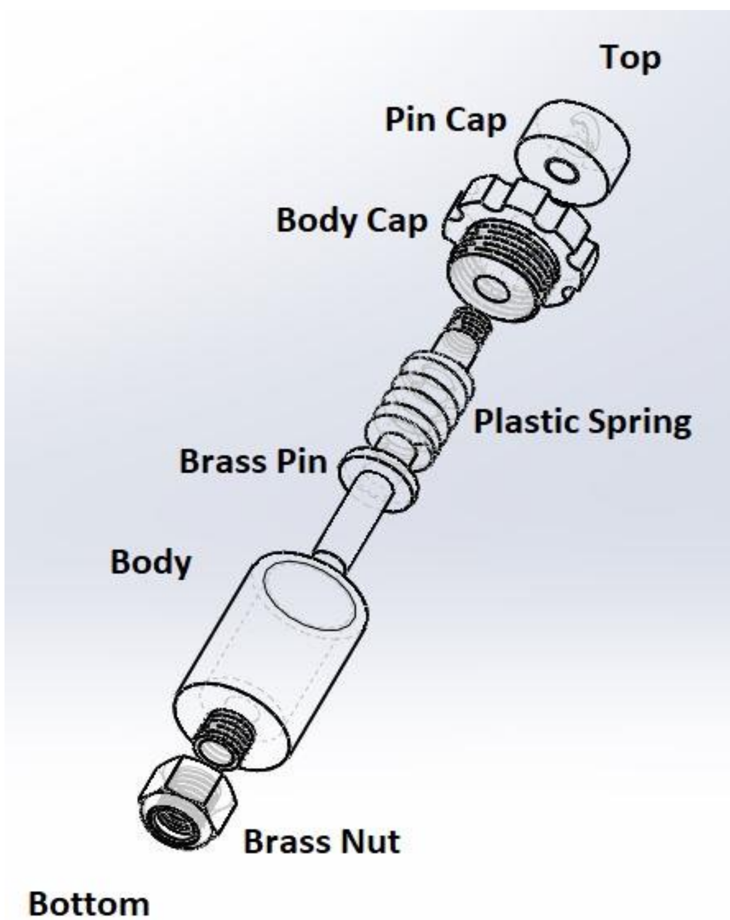


Figure 8

Designing the pop-pin assembly was an iterative process. The previous designs had a similar concept but had a few problems. Firstly, the nut was not attached to the bottom portion of the body's threaded flange. It was originally attached to threads at the bottom of the pin. This would not allow the pin to move freely, in fact the pin would not have moved at all. Secondly, the pin originally did not have a cap. The idea was to drill a clearance hole through the pin top and attach a future pulley mechanism to pull it. While the pulley mechanism is still a viable option, a cap was chosen instead because it would be a better attachment point. Thirdly, because there was no threaded pin cap there would have been no way to replace the plastic spring had it failed. With the threaded pin cap in place and a large body cap with grip cutouts the entire pop-pin mechanism can be taken apart as shown in the exploded view above.

All of the parts above would be 3d printed out of polycarbonate, except the plastic spring, the brass nut and the brass pin. The plastic spring and brass nut would be purchased through McMaster-Carr and Solidworks files of these parts were downloaded from McMaster's website. This was done to ensure proper sizing of the other parts as well as the fit when assembled. The brass pin would also be purchased and would be threaded with a tap die, of the matching thread type to the pin cap, upon delivery. The pin would also need to have the brass washer soldered or tig welded to it for the spring to rest on.

Base Design

This design would only work if there was a base that all the assemblies could mount to. It should be noted that only at this point in time a full device assembly was created in Solidworks. Up until now there have only been designs that were not attached to any base. This was done to ensure a working proof of concept with the pop-pin and semicircular locking mechanism before pursuing the idea further.

The idea was to create a flat rectangularly shaped base that the sub-assemblies could mount to. The sub-assemblies included the pop-pin and semicircular locking mechanism as well as future assemblies. Future assemblies would allow the patient to control the locking and unlocking of the device as well as to help the patient position their knee. There was an immediate problem with this design of permanently fixing the subassemblies to the base. The patient could only test one knee, either right or left, but only one. A new design had to incorporate attaching the subassemblies but allowing them to move to either the right side of the body or the left side of the body.

The new base has a carriage style system that can be used to shift the attached assemblies to one side or another. According to Dr. Elias, he only tests one knee at a time on patients, however the knee could be either the right or left knee. He agreed that having a base that could shift to the right or left side was needed in order to successfully test either knee.

According to dartmouth-hitchcock.org, a standard bore size for an MRI machine is 70 cm in diameter [6]. This means that the base must have a width that is only slightly less than 70cm. This is to accommodate larger patients while still being able to fit inside the MRI machine.

The base below (Figure 11), fits inside the MRI machine and has a carriage system (Figure 9 & 10) that can slide to either position. The carriage system has plain linear bearings made entirely of plastic. This helps reduce friction and allows the carriage to slide on the brass bars smoothly. The carriage system also has a locking mechanism that consists of 4 screws with rubber caps. These screws can be twisted to release or clamp the bar which either allows that carriage to slide or remain fixed respectively.

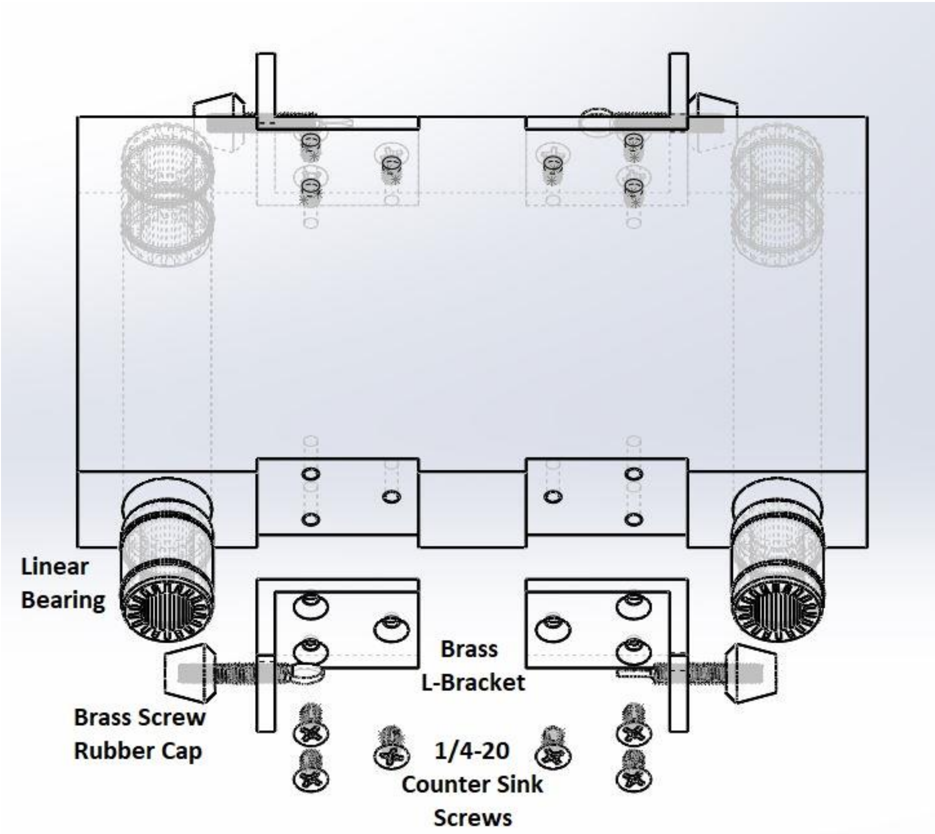


Figure 9: Carriage which ride on base rails to allow test of either knee

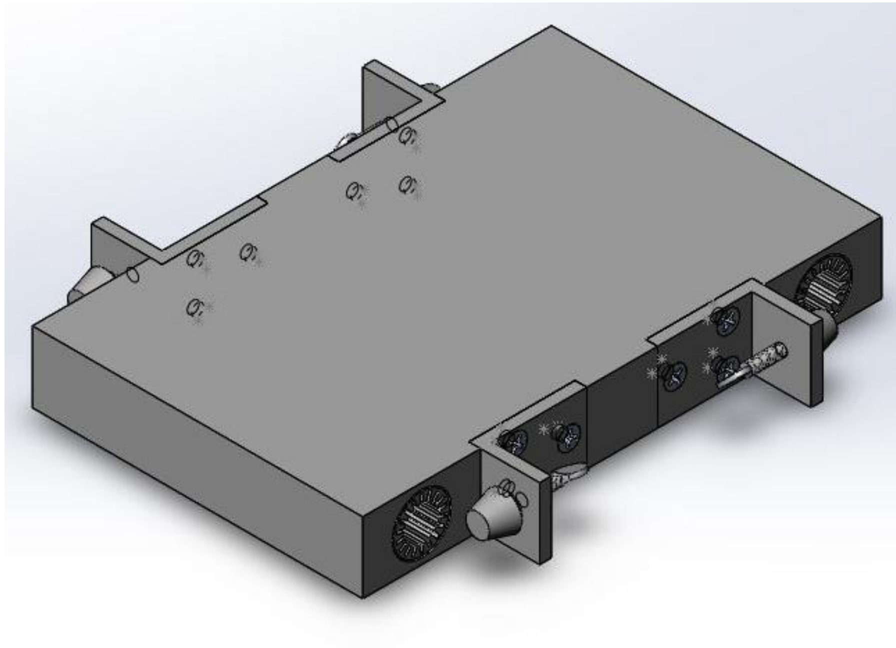


Figure 10: Carriage in solid model view

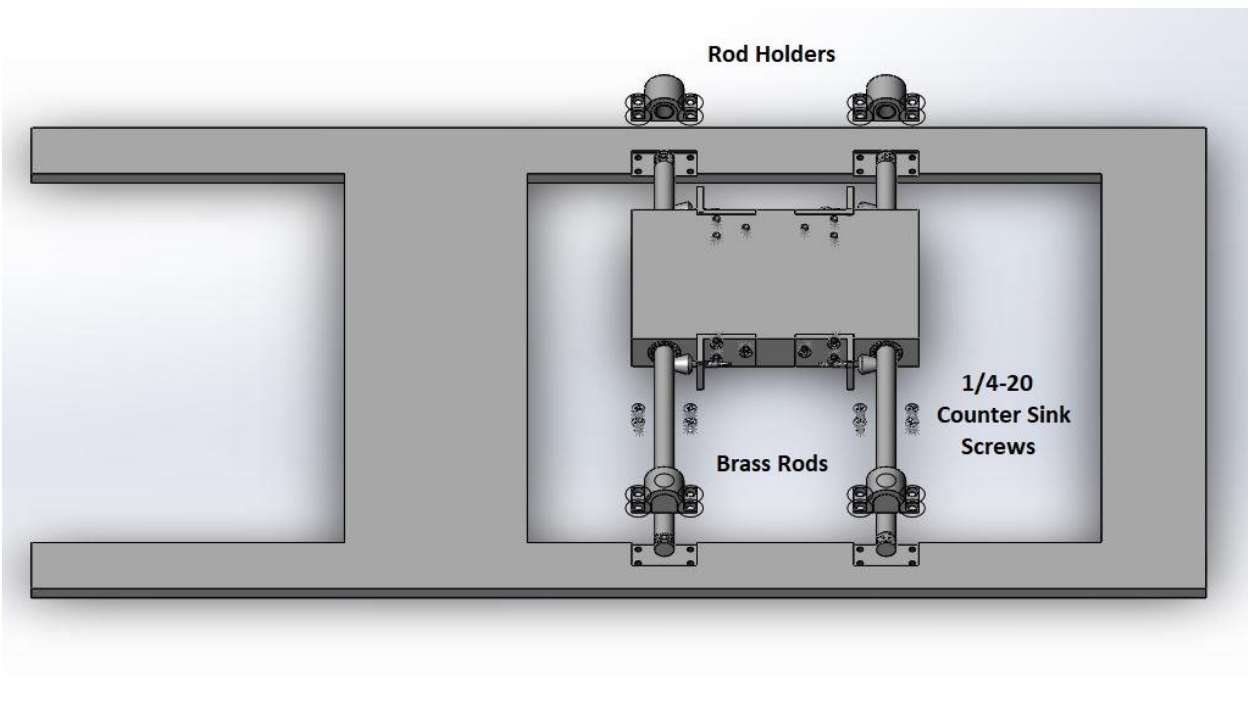


Figure 11: Full base top angle view

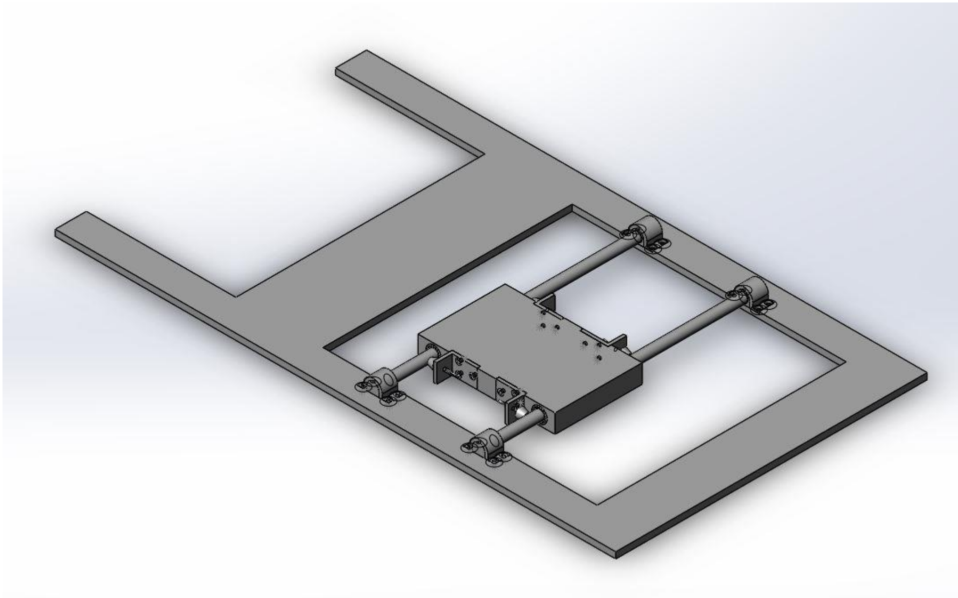


Figure 12: Full base orthographic view

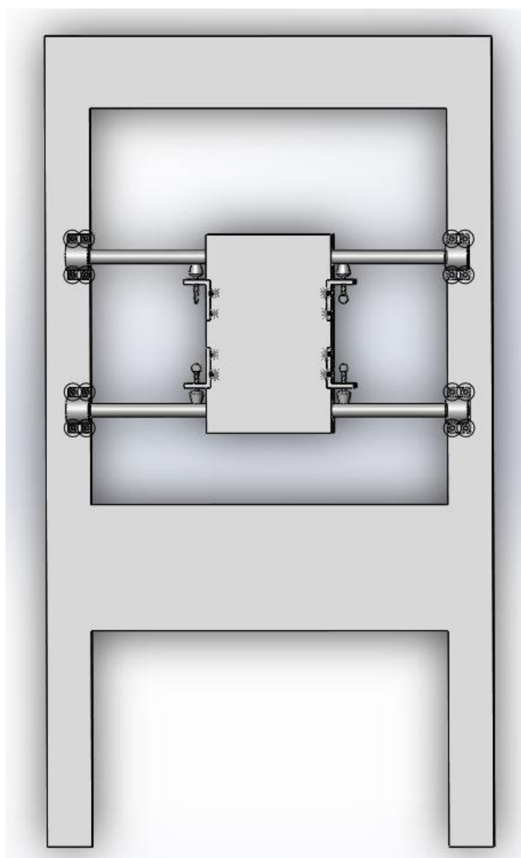


Figure 13: Full base top view

The base has rod holders that will be 3D printed out of polycarbonate. The rod holders have matching threads to the rods and will be screwed in with Loctite (red) to ensure a high strength bond of over 850 in-lbs. The carriage system can lock in place while being used. The carriage system can be moved to either side to test either the right or left knee. This design also allows for more adjustability in regards to the size of the patient. The carriage does not have to be moved all the way right or left and would be left up to the researcher and patient how far to move.

The design for the base did not always look like this. The base was originally just a rectangular sheet of plastic for which the sub-assemblies could mount on to. This would have been an issue as it would only allow for testing on the right or left knees but not both. If the locking mechanism was mounted to the previous base, then it would remain in a fixed position and therefore could only test one knee.

Femur Bar Mounts

The next steps for this device is to mount existing sub-assemblies and develop other sub-assemblies the patient can use to move their leg. Femur bar mounts were used to attach the femur bar to the sliding carriage system. Figure 14 shows the femur mounts (in blue) as well as both the medial and lateral locking plates with attached femur and tibia bars. This a culmination of the entire assembly thus far.

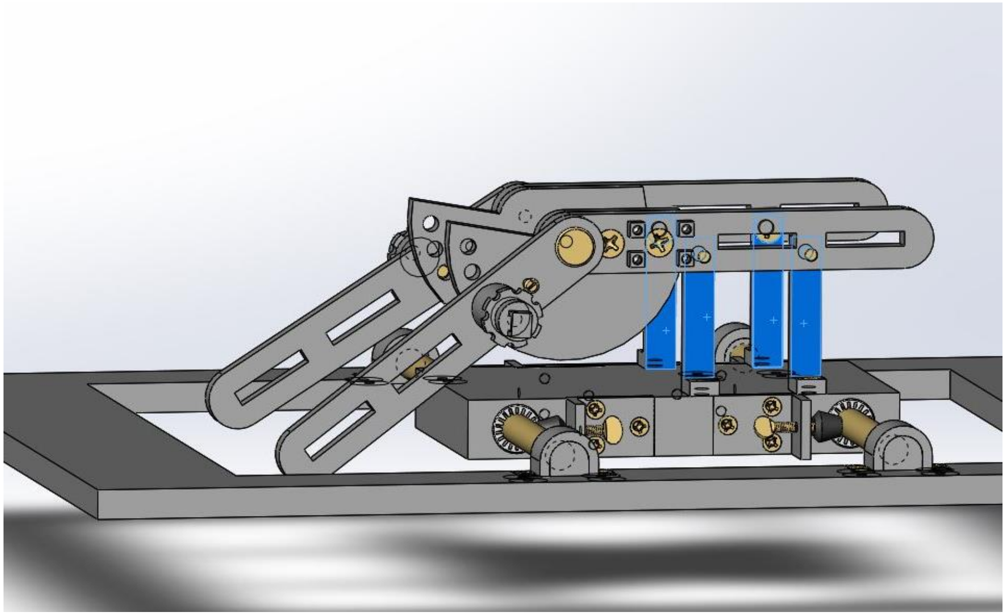


Figure 14: Femur Mounts

Rotation Mechanism and Lock Engagement

For leg movement at different angles the original idea was to use a pulley system. This system would allow the patient to pull a lever connected to a cylinder wrapped with a rubber belt on one end and on the other end have another cylinder that is connected to the locking mechanism. This design would work in theory however, it would be very bulky and crowded. This is especially true since the pop-pin locking assembly would also have a similar system controlling it. Two pulley systems on each side of the leg is heavy and very bulky. A better design is to have four bars connected in such a way that pulling a lever would rotate the end bar. A similar 4-bar linkage is shown below.

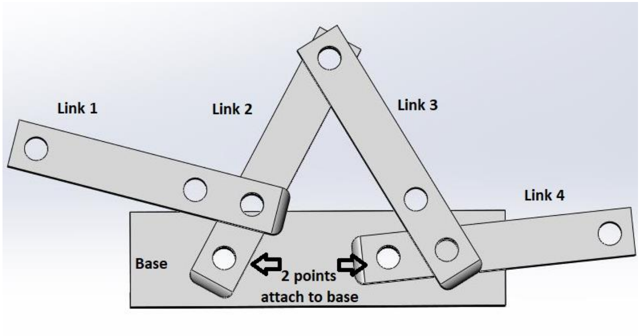


Figure 15

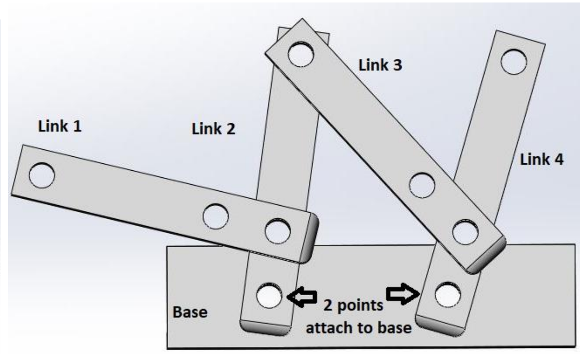


Figure 16

Figures 15 and 16 are only rough draft models to test the theory of operation. In this design if the patient pulls a lever connected to link 1 then it pulls link 1 which in turn rotates link 4 by some angle theta. This would allow for a design that has predetermined values for slots that the patient could pull a lever into.

A way to combine the motion required to pull the pop-pin and the motion required to move the knee to a required angle is to use a lever with a button. This design is very similar to an automatic transmission lever. The trigger/button is used to disengage the locking mechanism (pop-pin) and the lever can be pulled to a specific slot corresponding to a hole on the locking disk. A small pulley system can be used to attach a thin high strength plastic wire to the trigger/button and the cap of the pop-pin. When a patient wants to move their leg to a new location they simply pull the trigger and shift the lever into a predetermined slot.

The idea mentioned above, using the automatic transmission style design, does not work. Upon further thought it has become apparent that using a pulley mechanism to release and engage the pop-pin would only work if the sub-assemblies would be fixed in a single location. This is due to a pulley wire being of a fixed length. When the base carriage slides to a new position it would pull the pop-pin as the wire holding it is a fixed length. Figure 17 below shows this more clearly.

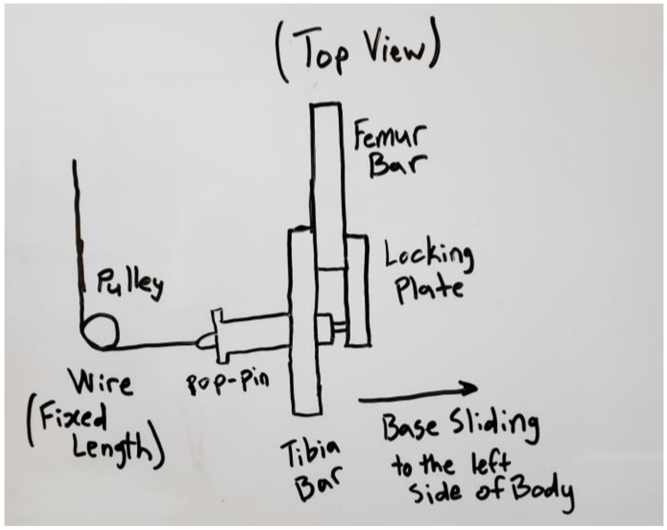


Figure 17

A better design would be to attach the 4-bar linkage, as shown in figures 15 and 16, to a lever the patient can control. This lever can slide freely forwards and backwards as well as right to left. If the 4-bar linkage has pins that allow side to side (right or left) motion, then another bar could be attached to the pop-pin cap to trigger its motion. From the patient's perspective, in order to move to a new angle, the patient must slide the lever out of a predetermined slot, and then move it to another slot. This design firstly would work compared to the old design. Secondly, the new design is less bulky compared to a pulley mechanism. Furthermore, the new design is simpler to use as there is no longer a need for a trigger to be pulled.

The new design would involve a rail system as well as a new linkage system to move the tibia bar and the pop-pin. Figures 18,19 and 20 show this design.

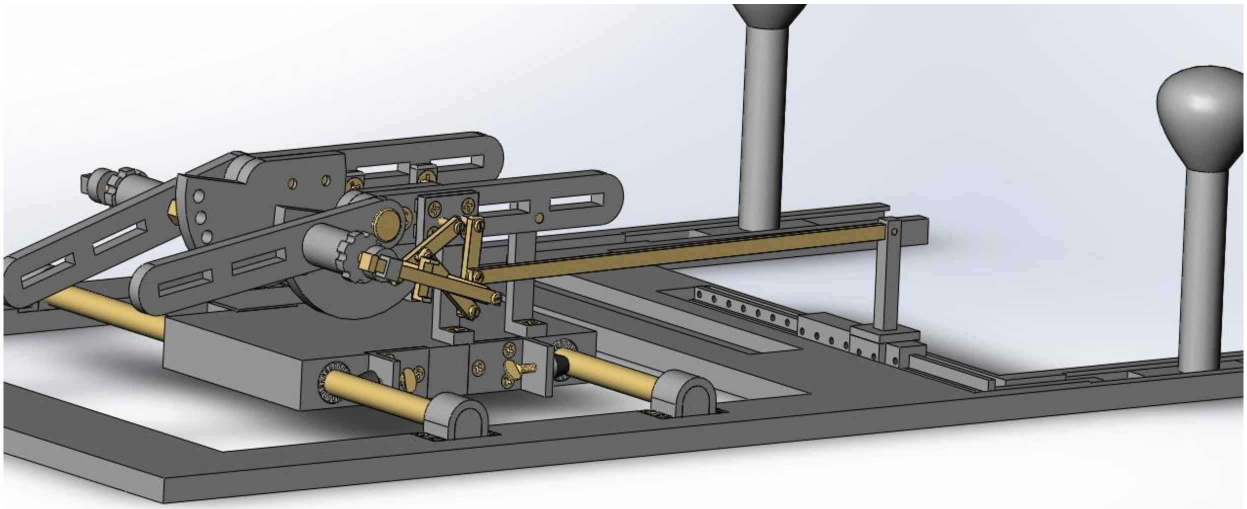


Figure 18

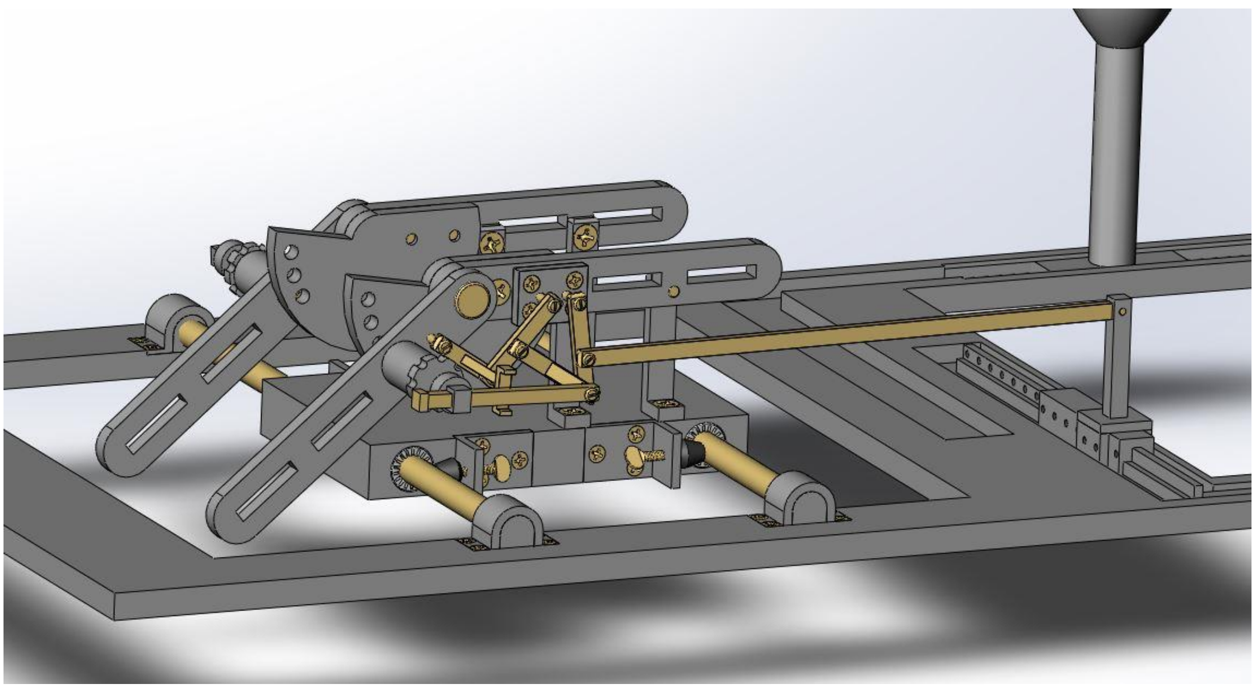


Figure 19

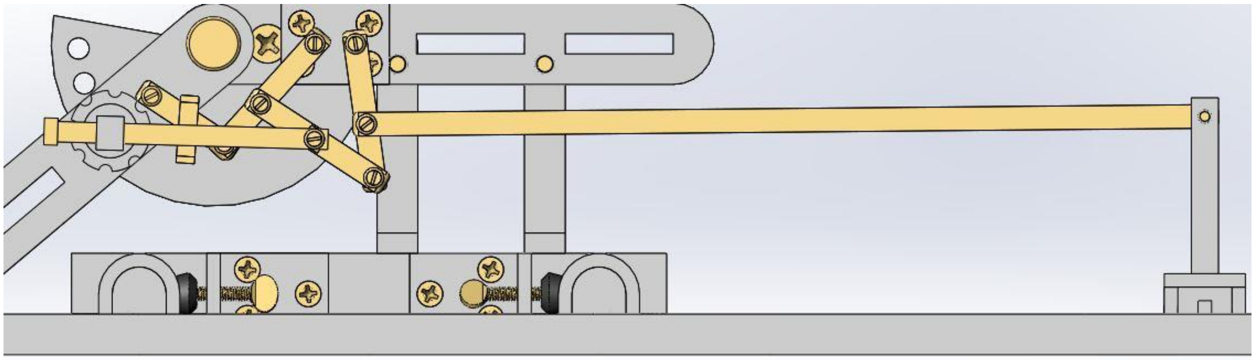


Figure 20

The new linkage is a 5-bar linkage, however it is very similar to the 4 bar linkage above (Figures 15 and 16). The new mechanism can rotate the tibia bar and engage or disengage the pop-pin by controlling the lever. The lever can slide forwards or backwards which also moves the rail system forward or backwards. The rail system is not fixed to the base and can move freely on the plane of the base. It will be supported by a slotted rail system so as to limit its motion to only the plane of the board. By looking at Figure 21, one can see that the linkages are free to move on the pins that hold them to the supporting mount. The linkage is also connected to the new pop-pin cap which allows the side-to-side linkage movement to be translated to the pop-pin. The levers are also free to move on the plane of the base, being limited from movement in the Z direction by a slotted rail system as shown in Figure 22. This means that the patient can move the lever to control the locking mechanism as well as the angle at which their knee is located.

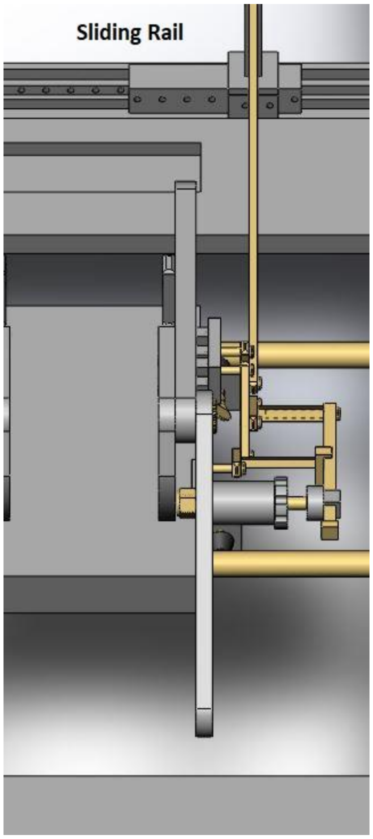


Figure 21

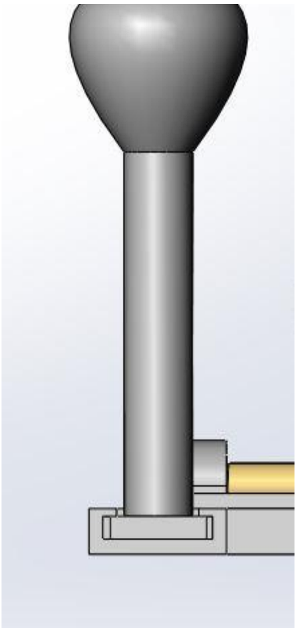
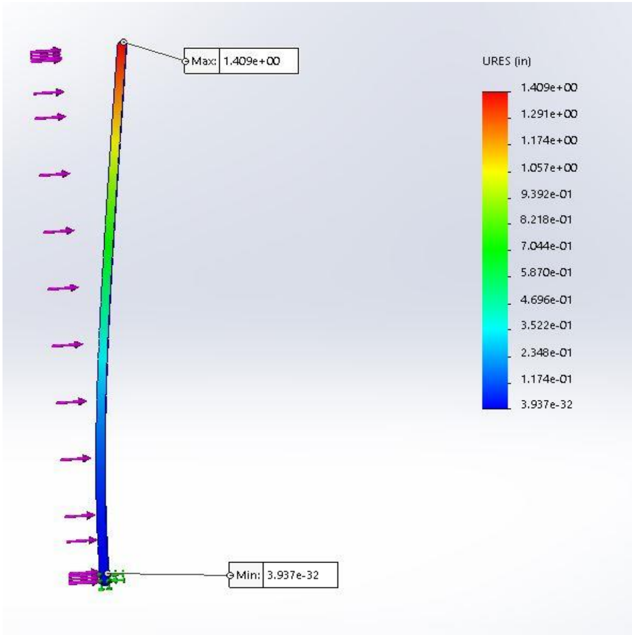


Figure 22

The next steps are to work out the exact dimensions for the lever mechanism, design a slotted rail system for the current rail system, and begin another linkage assembly for the other side of the knee. However, due to time constraints these portions of the device will not be created in Solidworks. It should be noted that due to these time constraints either the aforementioned portions or a Solidworks strength simulation for individual components would be sacrificed. It was determined that strength simulations would be a higher priority as the unfinished portions of the model are essentially mirror images of already existing portions of the model. The Solidworks strength simulations would allow me to discover if there are any problems with material or design selection based on strength.

3. Analysis

For the Solidworks strength simulation a selected load was placed on the part at the point the force would be generated. From this a Von Mises stress and displacement test was outputted, from these tests I could see if the part failed or was close to failure.



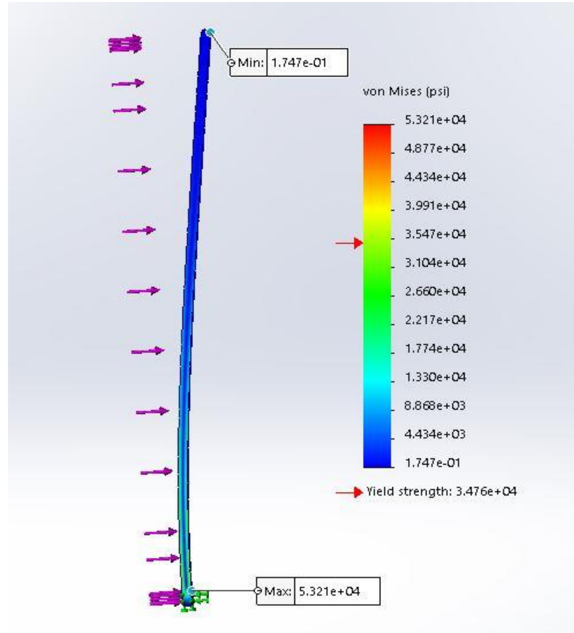


Figure 23: Displacement Test using Polycarbonate   Figure 24: Von Mises using Polycarbonate

Figures 23 and 24 show link 1 of the sliding and rotation mechanism, deforming under a loading condition of 35 lbs axially. Link 1 is used to transmit the pulling and pushing motions from the lever to the rotation and sliding mechanism, due to its length it was of high concern. The 35lb force was determined as a high end value a patient may apply to the lever if the system was jammed. If the system was jammed and the patient was not aware or familiar with the device mechanisms then 35 lbs of force was assumed to be large enough for the patient to realize something was wrong, and they should stop pushing. From the results, however, there is about a maximum of 1.409 inches of displacement. This is too large and it was determined that link 1 should be made of brass instead. While not shown, a simulation was done for brass and maximum displacement was less than 0.25 in.

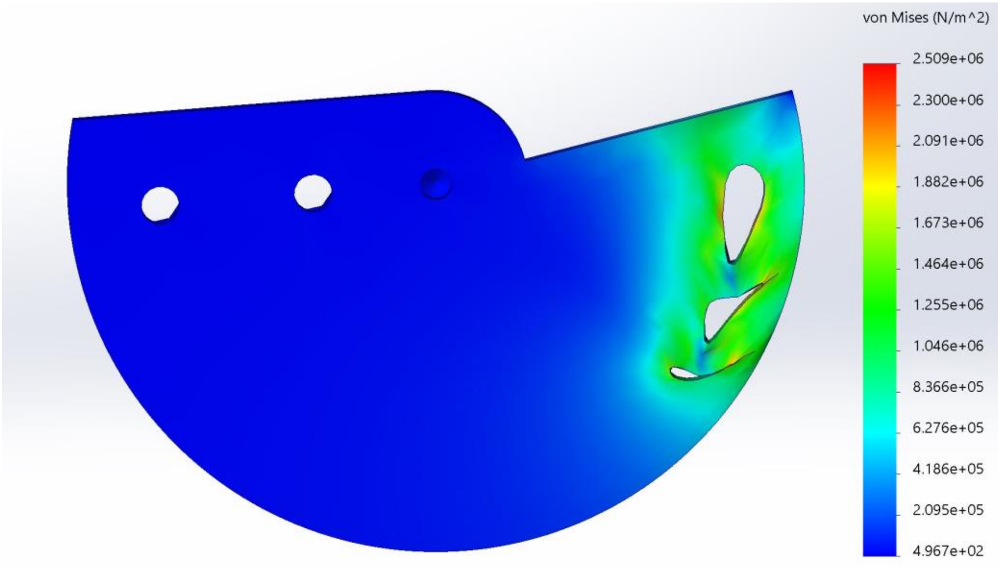


Figure 25: Von Mises test using Brass

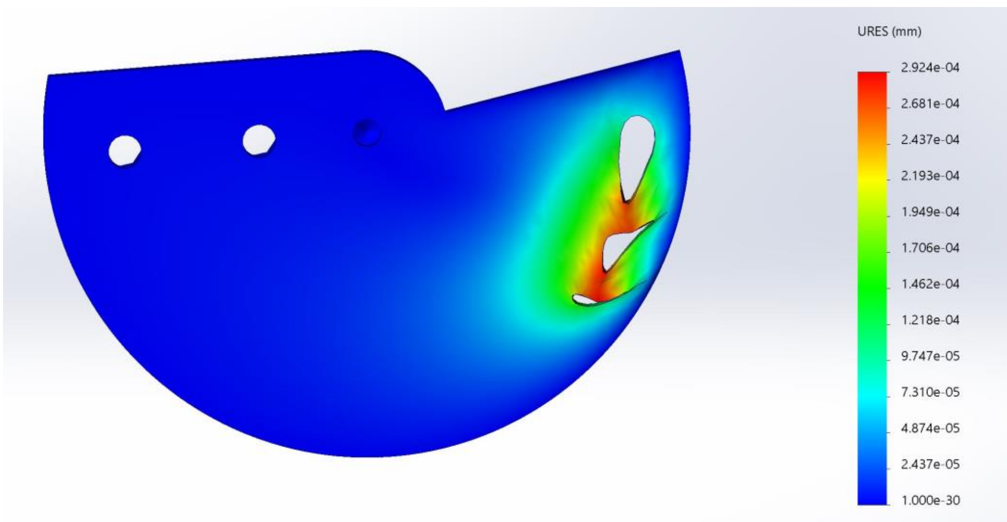


Figure 26: Displacement Test using Brass

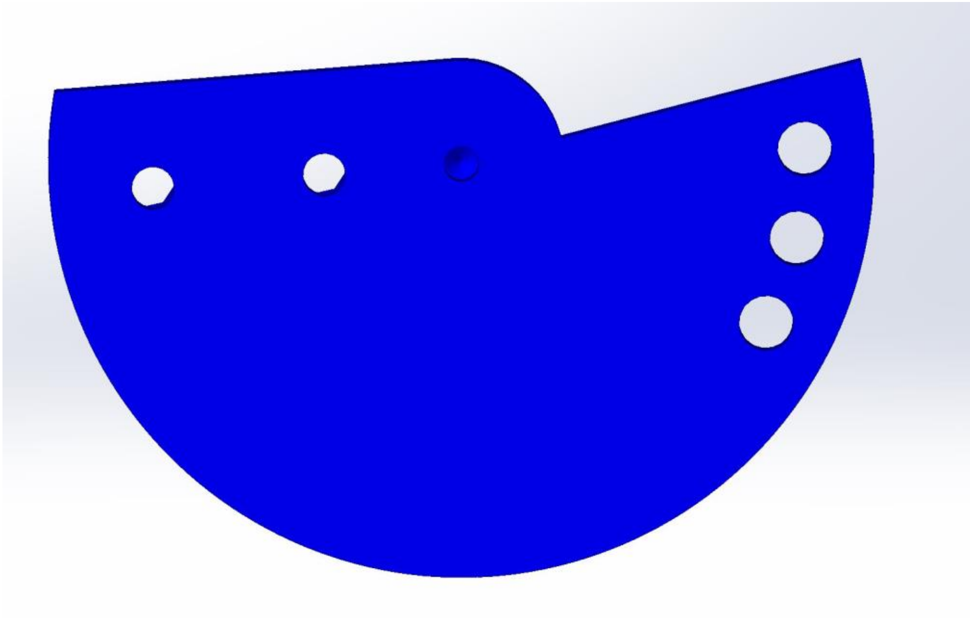


Figure 27: Factor of Safety Test using Brass

Figure 25 and 26 represent the Von Mises and displacement tests respectively of the angle marked disk. This part is used as the locking mechanism that the pop-pin inserts into. It was a large area of concern as this portion of the device needs to be able to support up to 75 lbs. The tests above show that using brass the maximum deformation is only 0.00029mm. The images of the displacement are purposefully exaggerated as a means of visualization, however 0.00029mm is a very low deformation. The factor of safety test (figure 27) showed that there was a factor of safety of 95.3 for the 75 lbs load.

When trying to do the simulation for a polycarbonate version the simulation failed due to material failing. It was determined that this piece would have to be made of brass instead of polycarbonate. This part is not complex to manufacture therefore machining it from brass should not be an issue. The threads of the now brass piece would also allow for longer longevity as plastic 3D printed threads are known for stripping.

4. Parts List

Parts Number	Parts Type	Number Required	Price per Unit ($)	Total Price ($)	
3955T291	Velcro Strap	4	4.41	17.64	
1568T65	No-Stick Idler Roller	2	25	50	
2017N119	Plastic Compression Spring	2	16.38	32.76	
2570K13	Linear Sleeve Bearing	4	7.31	29.24	
9968K26	External Retatining Ring For Linear Bearing	4	0.92	3.68	
5147A34	Toggle Clamp Holding Screw Tip	4	2.06	8.24	
92092A033	Brass Nylon-Insert Locknut	2	2.88	5.76	This is for holding the pop-pin
92427A546	Brass Spade-Head Thumb Screw	1	13.66	13.66	This comes in a 5 pack
92480A537	Brass Philips Flat Head Screw	1	7.05	7.05	Comes in 25 pack (Counter Sunk) 1/4-20
92480A853	Brass Philips Flat Head Screw	2	7.86	15.72	Comes in 5 pack (Counter Sunk) 3/8-16
94070A537	Brass Philips Pan Head Screw	1	10	10	Comes in 25 pack 1/4-20
	Total			193.75	

Figure 28

Figure 28 shows the excel sheet used for a parts list. The list only shows parts that are pre-made and would need to be bought. All the parts shown are from McMaster-Carr.

5. Future Work

Future work for this device would be finishing up the remaining Solidworks parts, more stress testing, and building the full device. With more stress testing one can be more sure if the device would fail under any given conditions. Some other areas of improvement could be to the rotation and sliding mechanism. This system is bulky and could potentially be made better using alternative designs.

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