Dead Blow Hammer in Orthopedics

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Abstract

Hundreds of thousands of knee and hip surgeries take place every year. These procedures give patients back control over their life because they are able to move more freely and enjoy the activities they once enjoyed. These major joint replacements are able to last 10 to 20 years inside of the patient, allowing them to live a close to normal lifestyle during those years. However, the surgery itself can be physically tough on both the patient and the surgeon. Large amounts of force provided by mallet striking from the surgeon is required to complete the surgery. This can cause a lot of wear and tear on the surgeon's joints. An orthopedic surgeon will perform these surgeries several times a week. After many years, they can begin to develop wrist, elbow, and shoulder problems. Therefore, our team is tasked with developing an orthopedic hammer that can increase the force generated with each swing and limit the rebound of the hammer. This could potentially decrease the amount of wear and tear on the surgeon's own wrist, elbow, and shoulder joints. Our main reference device to base our design off is a construction dead blow hammer. This device minimizes damage to the struck surface, allows one to help control their striking force, and produces a minimal rebound compared to other hammers, all traits we are looking for in an orthopedic hammer. The team came up with three preliminary designs based off of a dead blow hammer: the Fully Replaceable design, The Piston, and the Replaceable Caps design. Upon completing our design matrix, the team decided we will be moving forward with the Replaceable Caps design. A low-fidelity prototype was manufactured with PLA via 3-D printing. This prototype underwent initial testing by striking force plates with a control PLA mallet and our dead blow PLA mallet to check for differences in the force over time curves. A two-tailed statistical analysis test was performed which brought significant results of a difference in length of the strike on the force plate. Next, our team must make minor adjustments to our initial design to bring down the price of a high-fidelity metal prototype. Tests can then be performed comparing this prototype to the current orthopedic mallets that are being used in orthopedic surgeries today.

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I. Introduction

A. Motivation

In the US alone, more than 600,000 knee replacements, and about 330,000 hip replacements occur every year. These operations can provide a major improvement in quality of life and function for those in need of the replacement[1]. Therefore, there is a large demand for those who can perform the surgery efficiently and effectively. Each surgeon has a limited window of age where they can perform these surgeries due to its rigorous requirements[2,3]. Our team wants to increase this window of age by decreasing the amount of wear and tear on the surgeon generated by the surgery. In a study done in 2013, 44% of surgeon respondents reported one or more injuries during their career with a significant association between years performing surgery and prevalence of injury. Surgeons that had been working 21-30 years having the most occurring injuries [3]. We also want to give surgeons the ability to better perform these replacements by eliminating key factors that will often cause them issues or be a nuisance during the surgery. Thus, we have made a concerted effort to create an orthopedic dead blow hammer.

B. Competing Dead-Blow Devices

“Novel Bone Hammer”

There are not many well known “dead-blow hammer" devices for surgical purposes, but there are some interesting international devices that have a purpose similar to our objective. *Figure 1* below shows a Chinese patented device called the “Novel Bone Hammer". According to the patent claims, the cap of the hammer is screwed into the rod and is therefore replaceable after a certain amount of use. This would add to the long-term durability of the product. Whenever the head of the hammer would wear out to a certain degree, it can be replaced to extend its long-term life. Also, this allows different sized and weighted hammer heads to be connected to the hammer rod. This would be useful if different parts of a surgery require different sized hammer heads. However, this could be problematic if the cap were to unscrew mid strike while in a surgery [4].

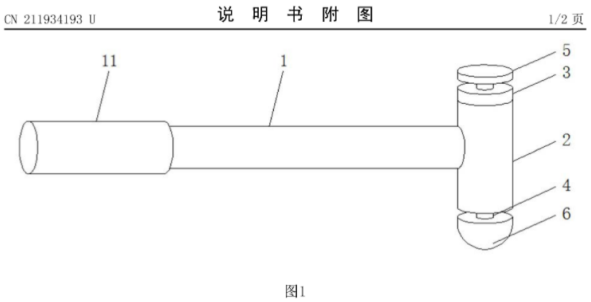


Figure 1: Novel Bone Hammer [4]

“Low Inertia Hammer”

Another device that has a paper written about it is called the “Low Inertia Hammer”, as seen in *Figure 2*. In the paper, there is not much about the configurement of the hammer. The image provided in the paper shows a casing with beads inside of the hammer head to produce the general effect of a dead blow hammer. The head is welded to the shaft. This could lead to a major issue for the hammer because beads could leak out of the weld points. This would cause complications during the surgery [5].

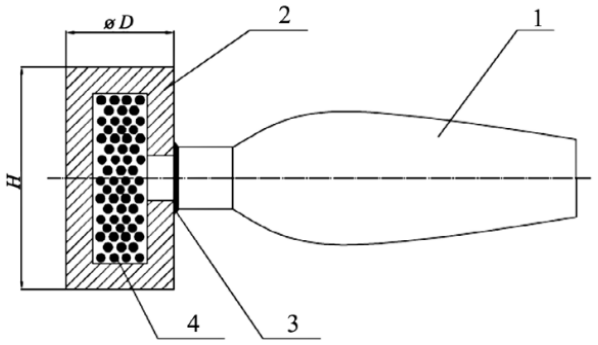


Figure 2: Low Inertia Hammer [5]

C. Problem Statement

Mallets are often used in orthopedics to insert metallic items into the medullary canal of bones. Examples of this are total joint replacements and intramedullary rods for fracture care. These surgeries require several forceful strikes that can create fatigue or injury in the surgeon. A dead blow hammer is a device that limits blow back and concentrates force upon striking a material. The goal is to develop a hammer with a dead blow like effect that can be sterilized, while also providing advantageous results compared to orthopedic mallets currently in use during surgeries that require several forceful blows.

II. Background

A. Design Research

Total Knee Replacement

A brief summary of a total knee replacement surgery must be understood to get insight on why a new orthopedic hammer would be beneficial to surgeons. Total knee replacement surgeries typically last about one to two hours in duration [6]. The orthopedic mallet is used during many steps of this hour long surgical procedure. The surgery begins by making incisions on the anterior side of the knee to gain access to the patella. The patella is rotated outside of the knee area so that the surgeon has access to the area needed to perform the procedure. Next, the femur is cut and resurfaced using surgical instruments, including the mallet. A metal component is then attached to the end of the femur by bone cement and the orthopedic mallet. These two steps are then repeated for the tibia side of the knee. A polyethylene buffer is many times included at this time onto the tibia or patella, depending on patient to patient variability. The knee is then bandaged up and the patient is sent to recover [7]. Obviously, not all surgeries are completely identical because not all knees needing replacement have the exact same problems. Refer to Appendix B to see images of total knee replacements and a link to a total knee replacement surgery.

Autoclaving

In between these total knee replacement surgeries, all surgical tools must be sterilized. The autoclaving process provides a physical protocol to disinfect lab equipment. Surgical equipment must be able to withstand the autoclave conditions because of the high exposure that these instruments have with a patient's body. As a result, most orthopedic mallets currently on the market are autoclavable. According to Princeton.edu, "the autoclave must reach 121 degrees Celsius in temperature for at least 30 minutes by using saturated steam under at least 15 psi of pressure. Increased cycle time may be necessary depending upon the make-up and volume of the load" in order to be effective [8]. The autoclave conditions mentioned must be kept in mind when choosing the materials that will be used to fabricate the hammer. Additionally, the thread size on the ends of our parts should be taken into consideration because of the ability for bacteria to grow if the insides of the threads are unable to be reached during autoclaving.

Previous FDA Recall

The strength of the hammer is also very important. If any hole were to be created, beads or shot could be leaked onto the surgical area. The effects of this happening can be seen in an FDA recall in 2016 for a dead blow mallet. The firm that manufactured this dead blow mallet were receiving "complaints of cracks in the weld on the head of the mallet. In the reported cases, some of the lead beads and particles escaped from the mallet into the surgical wound" [9]. This would create a huge issue if this were to happen with our device. As a result, most of our designs that will be discussed later make use of an inner

casing to hold these beads/shot. Additionally, the designs incorporate removable parts that may be replaced if they get damaged over time.

Physics of Dead Blow Hammer

Dead blow hammers use metal shot inside of a hollow cavity to change or limit the momentum of the hammer away from the target. In a scholarly article, Brian Y Lim goes through the testing of different bounce-back limiting devices and how they counteract the momentum.The mechanics of this is that each ball in the hollow cavity has a small momentum directed at the target immediately after striking the target. This counter momentum opposes the momentum of the hammer away from the target which limits the bounce effect. The kinetic energy of the hammer is counteracted by the sum of the momentum of each individual ball. Lim's hammer was filled with 0.76 mm balls that filled the hollow cavity 85 % full. Although Lim's hammer is slightly different from the team's model, the same idea can be applied [10].

Biomechanics of Hammer Swing

Many muscles and tendons allow a surgeon to swing an orthopedic mallet. The deltoid and supraspinatus muscles run superiorly between the humerus and scapula, allowing abduction, flexion, and extension of the arm. Together, these muscles allow for the surgeon to raise his/her arm. Rotation of the humerus is caused by the rotator muscles: the subscapularis, infraspinatus, and teres minor. These muscles run from the scapula to the humerus. These rotator muscles and the supraspinatus muscle end in tendons that surround the humerus head to form a structure called the rotator cuff. In addition to preventing dislocation, the rotator cuff also enables rotation of the humerus. This is what is in use when throwing a ball overhand or swinging a hammer/mallet [11]. Refer to *Figure 3* to see a visual of the rotator cuff muscles.

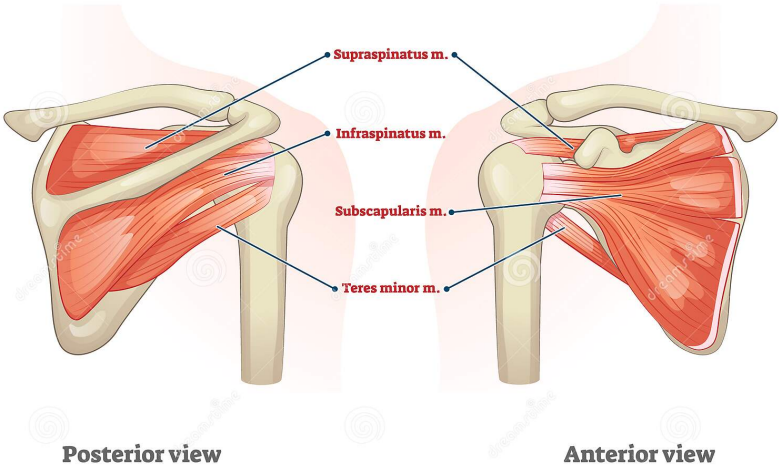


Figure 3: Illustration of the Anatomy of the Rotator Cuff [12]

B. Client Information

Dr. John Wollaeger is an orthopedic surgeon at UW Health. He performs a variety of surgeries including total joint replacements. Dr. Wollaeger has an interest in this project because he experiences first hand the strains on the surgeons associated with total joint replacements.

C. Product Design Specifications

The hammer must be lightweight, about 0.45 to 1.35 kg (1-3 lbs) [13], so it is not to put physical stress on the surgeon while swinging. The hammer must be able to exert 30 kN [14] so it is able to carry out the intended surgeries, while being able to withstand 40 kN of force without breaking [14]. This will give the instrument a factor of safety when comparing the force able to be exerted and the force it is able to withstand. The hammer must limit the recoil upon impact when comparing it to currently used orthopedic mallets. With safety being a major concern, the hammer must not leak any beads or shot onto the surgical area. The hammer must not interfere with a patient's biological systems if the material of the hammer were to come into contact. Also, the hammer must be able to withstand the autoclave process, which at basic levels means a temperature of 121 degrees celsius and 15 psi for about 30 minutes [8]. Because the hammer is considered a medical device, it must comply with the FDA rule set by Code of Federal Regulations Title 21, Sec. 878.4800 [15]. Lastly, the device must be able to be manufactured for less than $300 [16,17]. The full PDS can be viewed in Appendix A.

III. Preliminary Designs

A. Fully Replaceable Design

The fully replaceable design, as seen in *Figure 4*, consists of two caps, a metal head, a flexible inner casing filled with metal beads, and a removable handle. The two caps are screwed into the head of the hammer using large threads. Fabrication of this device will need to be done piece by piece, and then the prototype will need to be assembled. Each cap would be made out of either a metal or strong polymer that is FDA approved for surgical instruments. The outer shell and inner beads would be metal (likely stainless steel). The inner casing would be manufactured with a flexible polymer, giving it a different failure point to add another level of protection. Metal beads that lie inside of the flexible inner casing will lead to a limit in the rebound after striking with the hammer. With the fully replaceable design, the idea is that each piece would be easily replaced if damaged, but there will be more places for weak points in the mallet. The external threads on the caps and the internal threads of the mallet's head will need to be checked frequently for rust and bacteria growth.

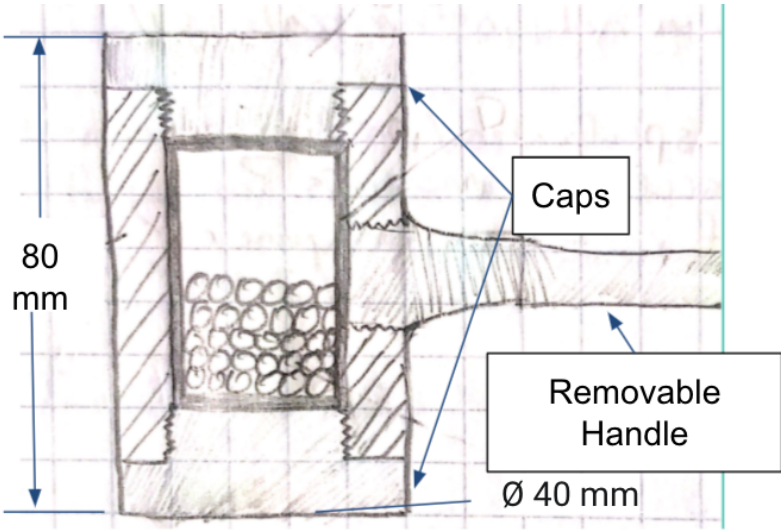


Figure 4: Fully Replaceable Design

B. The Piston

The Piston prototype, as seen in *Figure 5*, is composed of one singular welded piece. A piston-like device will be welded into the head, with the head of the hammer welded into the handle. A rod and metal ring compose the piston inside of the head. Upon striking, the ring will travel up and down the rod to provide the dead-blow aspect of the hammer. The device will not need to be taken apart before sterilization leading to a simple sterilization process when compared to the other multi-piece prototypes. The hammer would be made out of a similar metal that is used in currently available surgical mallets (stainless steel). The only piece that would not be metal would be the inner ring which could be made out of a strong polymer. A major drawback in this prototype is the need for a direct blow to the center of the hammer in order for the ring to move correctly. This could lead to more difficulty in using the device.

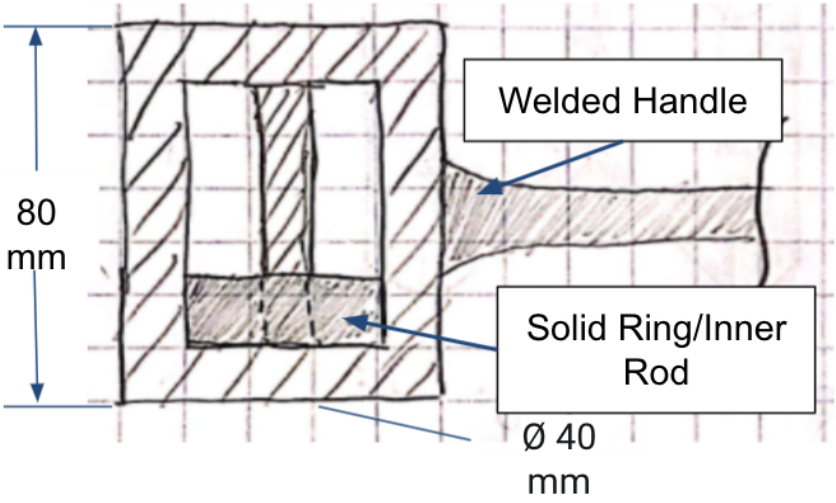


Figure 5: The Piston Design

C. Replaceable Caps Design

This orthopedic mallet design with replaceable caps, a welded handle, and a flexible inner casing with metal bead media was designed in Solidworks and can be seen in *Figure 6*. This prototype is very similar to the fully replaceable design with the exception of the welded handle. This change to the handle being a part of the outer head will lead to the device having fewer issues with failure at the handle-head joint. These prototypes share the same materials that would be used. The metal beads will limit rebounding for the hammer when it is struck. Similar to the fully replaceable device, the threads of the replaceable cap will need to be inspected regularly to check for damage and bacteria build-up. This prototype was designed in order to prevent the inner media from spilling. If either cap is damaged it can be replaced before the inner casing needs to be replaced.

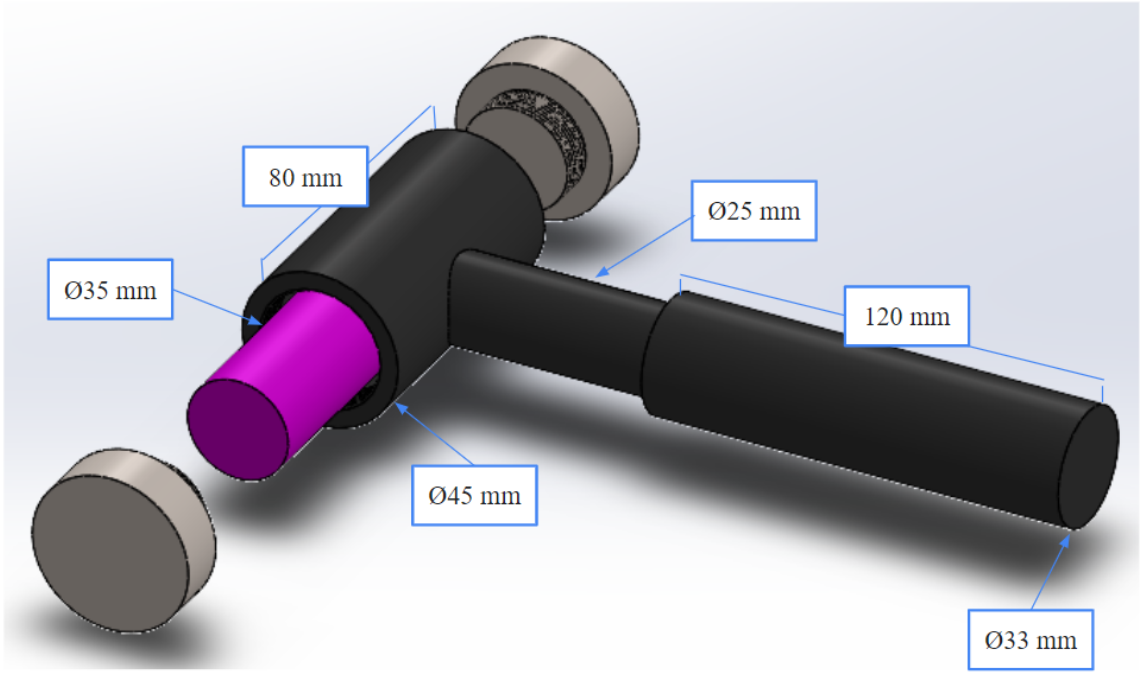


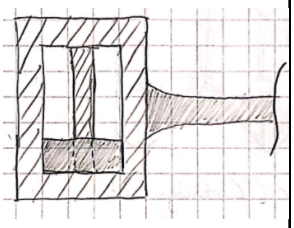
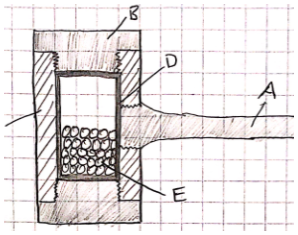
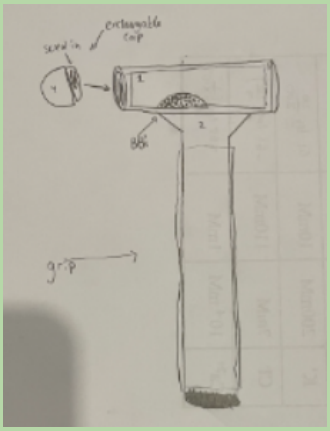
Figure 6: Replaceable Cap Design. The handle is optimized for ergonomic comfort of the user.

IV. Preliminary Design Evaluation

A. Design Matrix

A design matrix was used to analyze three different design ideas according to seven important criteria. Each criteria was weighted to represent the importance in the project. The design matrix and criteria are shown in *Table 1*.

Table 1: Preliminary Design Matrix for the dead blow hammer in orthopedics. Design 3 (highlighted in green) scored highest.

Criteria (Weight)	**Design 1: The Piston** 		**Design 2: Fully Replaceable (with Inner Casing)** 		**Design 3: Replaceable Caps (with Inner Casing)** 	
Durability (25)	2/5	10	5/5	25	4/5	
Effectiveness (20)	2/5	8	5/5	20	5/5	
Safety (15)	5/5	15	3/5	9	4/5	
Ergonomics (10)	2/5	4	4/5	8	4/5	
Cost (10)	4/5	8	2/5	4	3/5	
Ability to be sterilized (10)	5/5	10	2/5	4	3/5	
Ease of fabrication (5)	4/5	4	3/5	3	4/5	
Total 100	59		73		76	

B. Justification of Criteria

Durability

The first category evaluated was the durability of the hammer. This category ranked how long a hammer would last with repeated use without the need to be fully replaced. Since Design 2 had completely replaceable parts, it ranked highest in this category. However, Design 3 was ranked closely because the caps, which would take a majority of the damage, were replaceable.

Effectiveness

The second category was that of the effectiveness of the hammer to the ability to increase force and limit recoil of the hammer during surgery. This is largely due to the media used in the inner chamber of the hammers to achieve a dead-blow effect. Since Design 1 contained a solid ring that must travel along a rod, it ranked lowest. This is because to allow the ring to best absorb the energy, the line of action of the strike would have to be parallel with the guiding rod.

Safety

The safety of the hammer was also a very important consideration. Because the device would be used in invasive surgery, this criteria largely evaluated the chance of contamination. Designs 2 and 3 ranked lowest due to the use of small, metal beads as the dead-blow media. In previous designs, this media has led to the metal balls escaping from the weld points, and ultimately, an FDA recall [9]. The size of the ring and rod of Design 1 mitigates this risk.

Ergonomics

Ergonomics of the design refers to the feeling of the hammer in the surgeon's hand upon striking during surgery. Designs 2 and 3 ranked the highest because of the addition of metal shot as the media should allow for an increase in the dead-blow effect. They could also be made with polymeric caps that would help limit the shock to the surgeon.

Cost

The cost was also a factor because in order to compete with current designs on the market, the hammer should not exceed $300. The use of many different parts would increase this category, thus Designs 2 and 3 were ranked lower than Design 1.

Ability to be sterilized

A key safety feature of this device is its ability to be sterilized after each use. Design 1 would be the best in this category because it would have few places where organic material could exist other than the outer surface. The threads in Design 2 and 3 lead to surfaces that are harder to clean. Also, containing several pieces complicates the sterilization process.

Ease of Fabrication

The least important evaluated criteria was the ease of fabrication. This was largely due to the fact that we will be outsourcing the fabrication. However, it was still considered in order to complete this project within the semester. The pieces of Designs 2 and 3 make these the easiest to fabricate relative to the complex inner media of Design 1.

C. Proposed Final Design

The proposed final design for the dead-blow hammer in orthopedics is listed as Design 3, “Replaceable Caps (with Inner Casing)” in Table 1. This design consists of four distinct parts, which are as follows: two replaceable caps, an outer shell with handle, an inner casing, and small metal beads. The caps will be either a metal or strong polymer that is already FDA approved for surgical instruments. The outer shell will also be metal. The inner casing will be a flexible polymer with the intended purpose to keep the metal beads from leaking by having a different failure than the outer shell. The final piece is the small, metal beads that will be used for the dead-blow effect when struck. A Solidworks model of this design is depicted in *Figure 6*.

V. Fabrication

A. Materials

The final prototype as presented in this report was made using a PLA in a 3D printer. PLA is a common plastic that is used in 3D printers. The yield strength can vary based on the true composition, however, some recent work has quantified the average yield strength of PLA as 49.23 +/- 1.18 MPa [18]. The theoretical maximum stresses for the head and the handle of the final prototype were found to be 15.92 MPa and 30.56 MPa, respectively. Thus, the PLA material will not break under the forces that will be applied for preliminary testing.

The end goal is to manufacture the caps, outer shell, and handle with a surgical metal that is already in use for current surgical mallets. These metals are of the AISI 420 class of stainless steel, which is a martensitic stainless steel [19]. Although the mechanical properties are variable depending on the exact chemical composition, the yield strength is about 1280 MPa, which is sufficient for our current proposed design [20]. The polymer that will hold the metal beads has not been fully researched at this time, but must hold up to the 40 kN repeated force as described in the product design specifications. The metal beads are currently 4.5 mm in diameter, but may be decreased in the future to test different conditions and effects. The mechanical properties in these balls are not as important as their structure does not have to be perfectly maintained to achieve the dead-blow effect.

B. Methods

The preparation for the testing procedure included gathering the following materials. Two 3D-printed mallets (PLA plastic) of the same design, steel beads (4.5 mm diameter), plastic epoxy, a ruler, a scale, sand paper, and force plates. The mallets were 3D printed at the University of Wisconsin-Madison Makerspace with PLA plastic. In order to assemble the dead blow mallet, the beads were first weighed using the scale. A total weight of 107 grams resulted in a filled volume of 50.6% in the inner chamber of the mallet. These beads were inserted into the chamber and the end caps were sealed with a plastic epoxy. No inner containment chamber was used at this time. The control mallet was then assembled by applying the plastic epoxy to the end caps. The mallets rested for 5 hours and then were sanded to remove any excess epoxy.

C. Final Prototype

Two prototypes were 3D printed with PLA plastic for testing. Figure 7 shows the assembled control mallet and Figure 8 shows the assembled dead blow mallet. These mallets were printed with the Solidworks model represented in Figure 6.

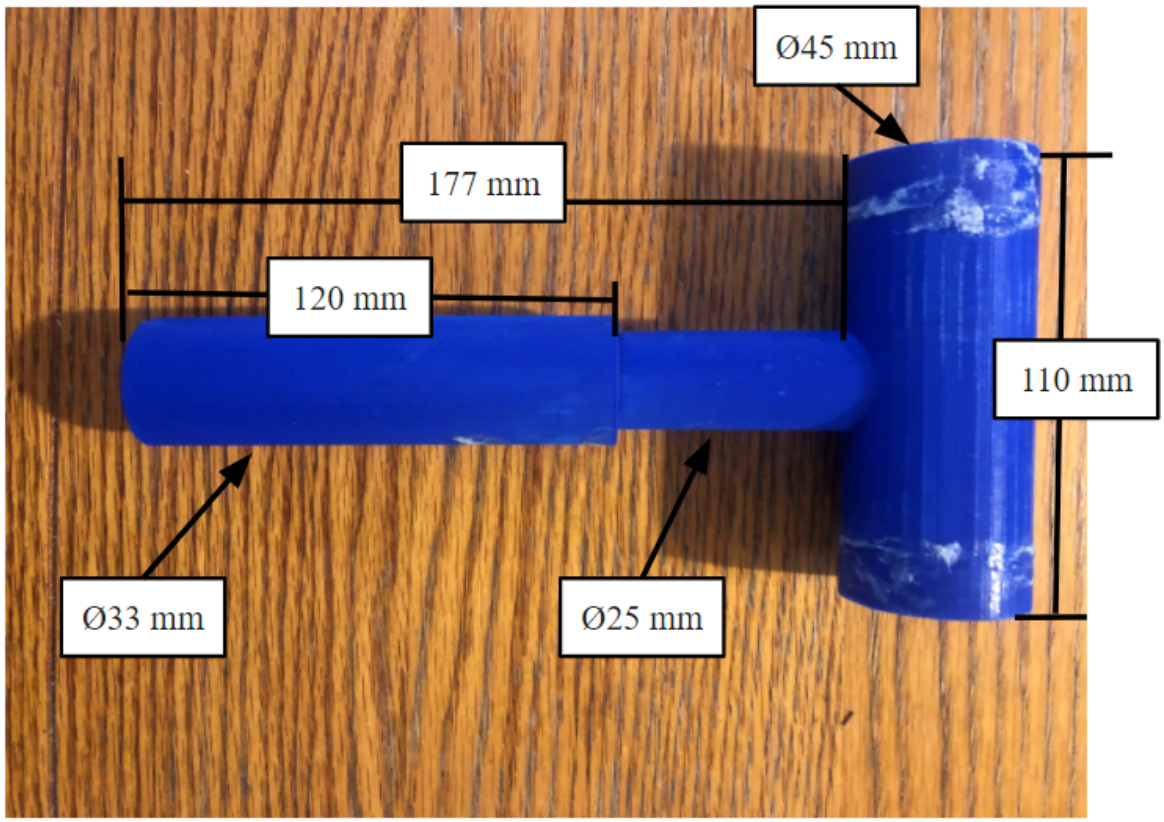


Figure 7: Assembled PLA control mallet from 3D printed Solidworks model. The measured mass of the mallet totalled 110 grams.

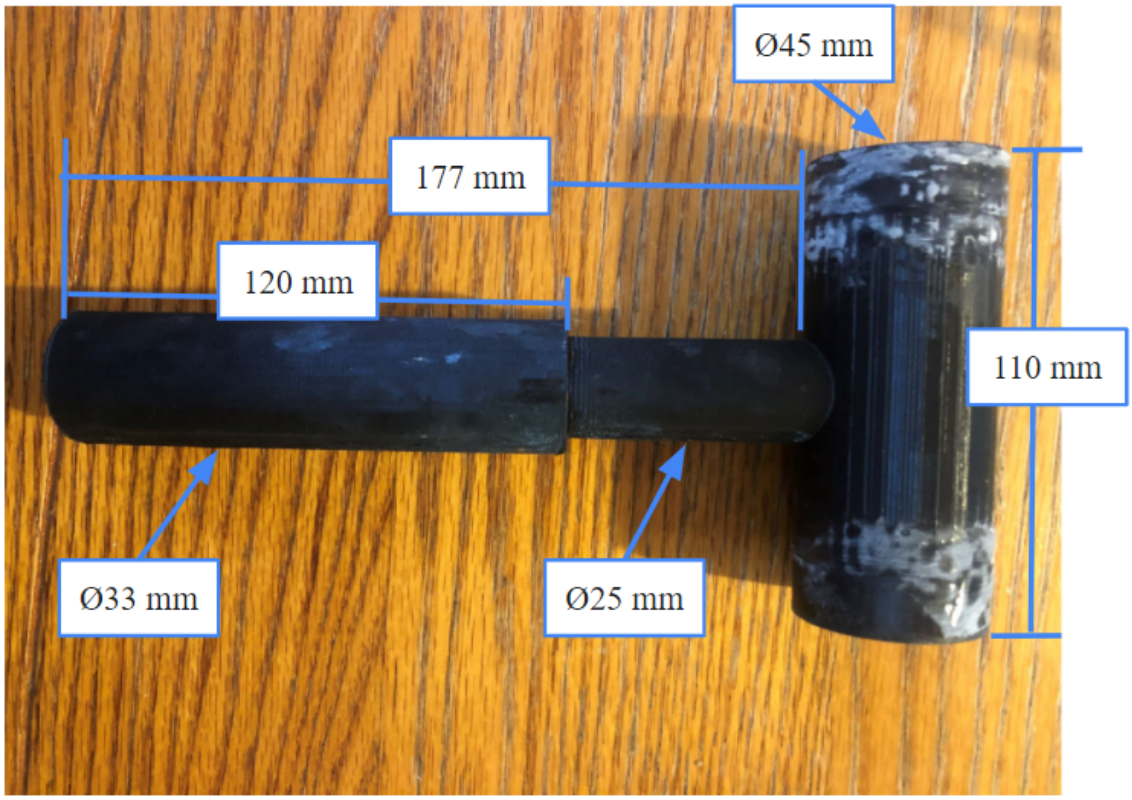


Figure 8: Assembled PLA dead blow mallet from 3D printed Solidworks model. The mass of the printed components was measured as 107 grams, and the mass of the beads was 107 grams. This resulted in a total mass of 214 grams for the dead blow mallet (nearly twice that of the control).

D. Testing Procedure

With a PLA plastic prototype, the focus of the testing was to determine the impact time that the dead blow mallet underwent as compared to the control mallet of the same design. This testing involved striking the force plates available in the BME Teaching Lab at the University of Wisconsin-Madison. A detailed procedure is attached in Appendix D of this report.

For testing, one team member conducted all strikes in order to minimize variability in the data. The force plate is on the ground, so the team member performing the tests kneeled next to the plate. The ruler was set up next to the mallet to provide a reference point for the beginning of the strike at 0.3 meters (1 foot) tall. The control mallet struck the force plate three consecutive times during each data collection period. This was then repeated five times for a total of fifteen strikes by the controls mallet. Refer to *Figure 9* to see a visual of one strike to the force plate. The individual striking the plate was instructed to swing at about 10% of their maximum speed in order to not cause damage to the plates. The whole procedure was then repeated with the dead blow mallet in order to gather fifteen total strikes. The collected data was placed in a CSV file and analyzed with Matlab.

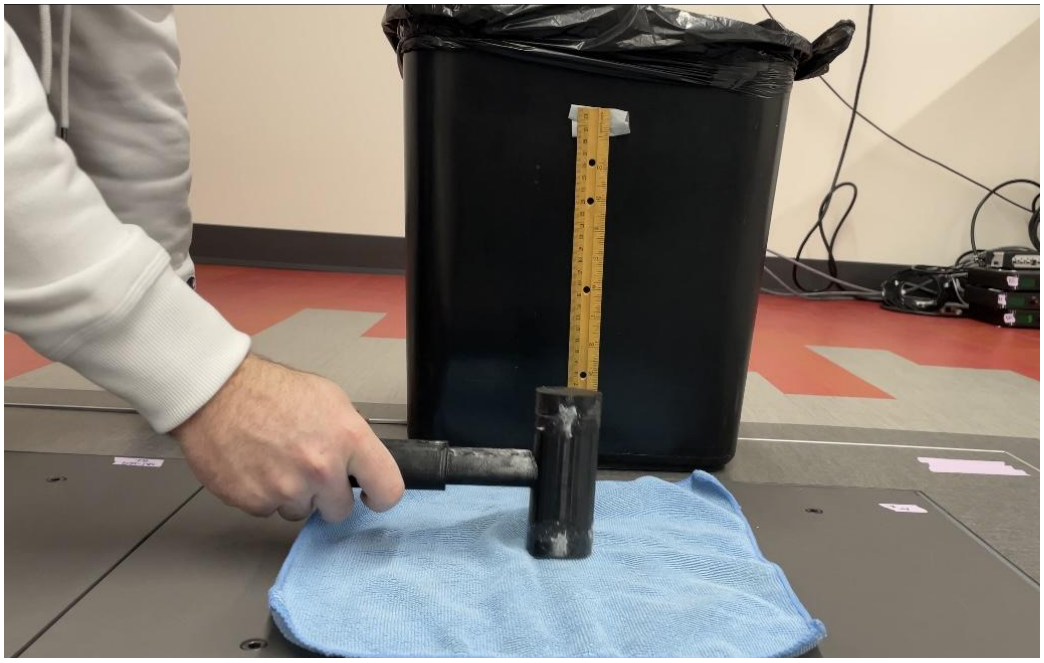


Figure 9:PLA prototype sticking the force plate in the Engineering Centers Building teaching lab. The light blue cloth is placed over the force plate in order to protect it from the hammer.

The value that was important to gather for prototype testing was that of the impact time. This was hypothesized to be significantly longer for the dead blow mallet compared to the control mallet due to the second impact of the beads inside the mallet. The significant difference in material characteristics of the PLA as compared to the stainless steel suggests that analyzing the maximum force will not lead to any significant conclusion about the intended final product. Thus, the focus of this round of testing was only on the impact time to ensure that a dead-blow effect can be reached at the size scale of the surgical mallet.

VI. Results

The force-time characteristics of the control and dead blow mallet testing was analyzed using Matlab. *Figure 9* and *Figure 10* show a plot of the impact of each strike for the control mallet and dead blow mallet, respectively.

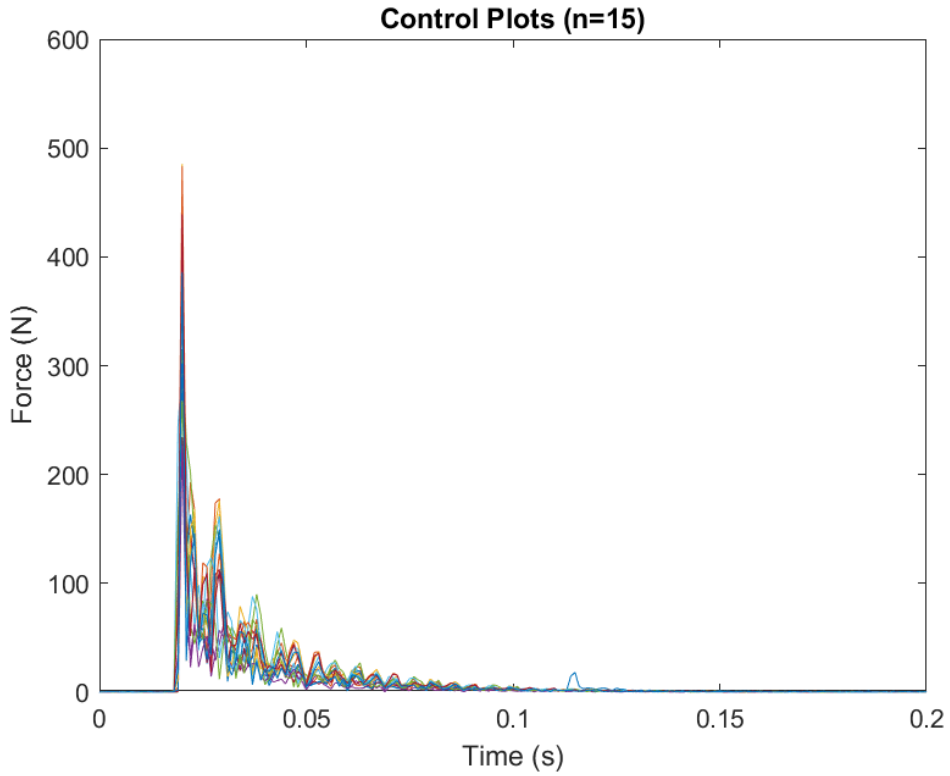


Figure 10: Impact plot for the control mallet. This contains an overlay of all 15 strikes that were conducted for this mallet.

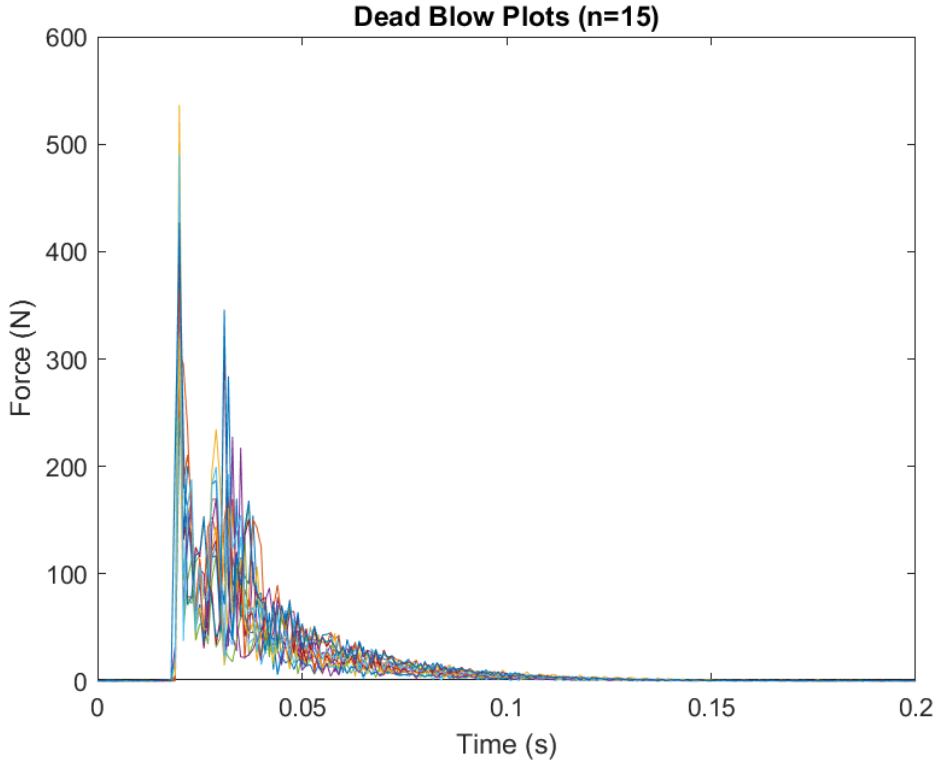


Figure 11: Impact plot for the control mallet. This contains an overlay of all 15 strikes that were conducted for this mallet.

Visual inspection of the two plots aligns with the expected differences. As seen in the plots, the dead blow mallet contains a more prominent second impact peak that is likely a result of the beads striking the bottom surface of the inner chamber. This would be the cause of an increase in the impact time for the dead blow mallet. *Figure 11* contains the average impact of both the control and dead blow mallet tests for further visual inspection. This was found by calculating the average force value at every time point of the data collection.

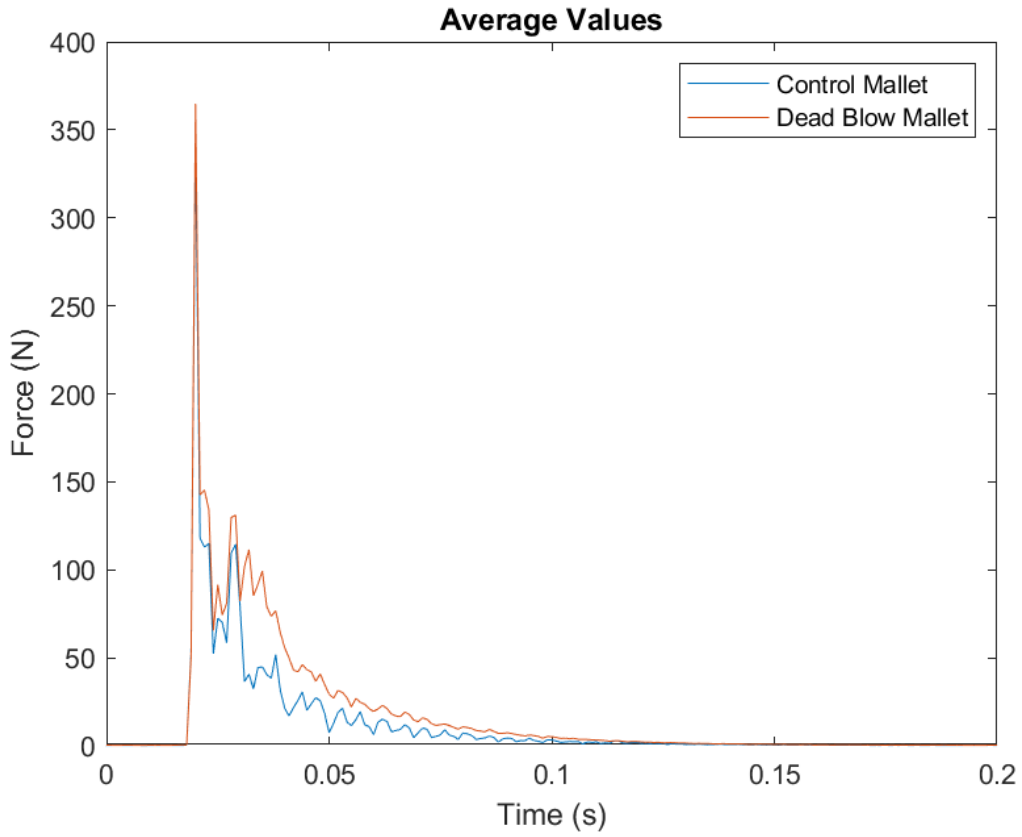


Figure 12: Average impact plot for the control mallet (blue) and dead blow mallet (orange). These peaks were calculated by finding the average force value at each time point of the data collection.

Figure 11 shows that, on average, the dead blow mallet maintained a larger time of impact. Another feature of the plot that is interesting occurs at approximately 0.04 seconds. While the control and dead blow plots largely resemble the same shape everywhere else, at this point the dead blow plot does not drop in force like the control. This point of interest corresponds with the second peak seen in Figure 10. Thus, it is most likely a result of the beads colliding with the inner at this time, causing the increase in impact time.

Statistical analysis methods were used to determine the true significance of the experiment. The amount of time that the impact was above 5 N was calculated for each of the trials and used as the metric for impact time. It was found that the mean (+/- the standard deviation) impact time of the control mallet

was 0.061 +/- 0.007 seconds and 0.077 +/- 0.009 seconds for the dead blow mallet. A two-tailed t-test was run in Matlab to determine the statistical significance of these results. A p-value of 0.00001 was calculated, thus it can be concluded that the impact time of the dead blow mallet was significantly greater than that of the control mallet.

VII. Discussion

The results from the testing of the plastic prototype suggest promise for the efficacy of this product. The main concern that was addressed was if there would be a significant dead blow effect at the scale of the surgical mallet. Although significant results were found with the testing, caution should be taken in drawing any final conclusions without further testing. One major source of error that could have contributed to the results include the weight differences of the two mallets. When fully assembled, the dead blow mallet had a mass of 214 grams, which is nearly twice that of the 110 gram control mallet. Another source of caution for confirming conclusions in this experiment is the significant difference between the materials of the prototype (PLA plastic) and the final intended design (stainless steel).

However, the results do suggest that the dead blow effect can be scaled to the size of a surgical mallet. There was a clear difference in qualitative and quantitative measurements of impact between the two tested mallets. Also, this protocol can be used for further testing with future prototypes made of materials with characteristics more similar to that of stainless steel. The immediate next steps involve fabrication of a metal prototype that can be tested. This would then be tested against surgical mallets that are currently in use in surgical operations.

Another major focus of the future will be to integrate the inner casing into the design of the dead blow mallet. Due to a recall of a previous surgical dead blow mallet in 2016 [8], this is an important ethical design feature that would mitigate the risk to the patient from leaking of the beads. This feature must eliminate the risk without reducing the effectiveness of the mallet.

VIII. Conclusion

Current orthopedic mallets used by surgeons during total knee replacement surgeries are not ergonomically favorable. The mallets fatigue the surgeon quickly because of the force needed to be put into each strike and the recoil that occurs when striking metal on metal. The surgeon may even experience an injury from overuse of the shoulder during high intensity surgeries, like a total hip or knee replacement. A hammer must be designed that will allow the surgeon to use less force per swing and limit the bounce back of the hammer upon striking.

Our solution to this problem is a dead blow hammer. These types of hammers are currently being used in construction settings. The heads of the hammer contain beads or shot that move inside the hammer during the striking action. When swinging, the dead blow hammer better concentrates the force applied into the material that is being struck. In theory, this idea could be used to design an orthopedic hammer that does the same for a surgeon. However, there has yet to be an effective dead blow hammer on

the market to be used during surgeries because of the sterilization and durability hurdles limiting potential designs.

Our ultimate design goal makes use of an inner casing to house the metal beads or shot located in the head of the outer shell. This inner casing adds an additional level of safety. There are caps that can be screwed on and off both ends of the hammer head. The caps allow access to the inner casing if that component needs to be replaced. The caps can also be easily replaced if either end were to be damaged. We believe these features increase the durability and safety needed to be met for surgical tools when compared to the current dead blow hammers used in construction. Once manufactured, our orthopedic dead blow hammer must be tested and compared to current orthopedic mallets.

Initial validation of this design was conducted throughout the course of this semester using a PLA prototype. Results are promising that the dead blow effect can be scaled to the size of a surgical mallet. However, further testing with a higher fidelity prototype made of steel is required before any significant efficacy claims can be made.

Keeping the overall goal in mind, the stresses put on the surgeon's own body during intense orthopedic surgeries needs to be limited by creating a mallet that reduces rebound force and recoil. With safety and durability as main concerns, we have taken the steps in initial validation for a solution. Future experiments with a metal prototype are of immediate concern for the continuation of this project.

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X. Appendix

A. Product Design Specifications

Dead Blow Hammer for Orthopedic Surgery

Product Design Specifications
September 21, 2021

Client: Dr. John Wollaeger

Team:

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Function:
Mallets are often used in orthopedics to insert metallic items into the medullary canal of bones. Examples of this are total joint replacements and intramedullary rods for fracture care. These surgeries require several forceful strikes that can create fatigue or injury in the surgeon. A dead blow hammer is a device that limits blow back and concentrates force upon striking a material. The goal is to develop a hammer with a dead blow like effect that can be sterilized while also providing advantageous results compared to orthopedic mallets currently in use during the surgeries that require several forceful blows.

Client Requirements:

- The device must be lightweight enough to limit physical stress for the surgeon.
- The device must limit recoil upon impact.
- The device must not leak beads unto the surgical area.
- The device must be able to be sterilized with currently used protocols.
- The device must be able to exert the proper amount of force for the intended surgeries.
- The device must not interfere with the patient's biological systems.
- The device must be produced for less than $300.

Design Requirements:

1. **Physical and Operational Characteristics**
    a. *Performance Requirements:*

i. The device must be able to exert 40 kN (calculated with factor of safety of 1.5) onto the body which it is striking [1].
    1. The device also must withstand this same amount of impact force (40 kN) repeatedly, without failure.
ii. The device must decrease the amount of recoil upon strike compared to the currently used orthopedic mallet.
iii. The device must not damage the body which it is striking

b. Safety:

i. If the device fails during a procedure, there must be a way to contain the inside components of the device, so the patient does not become infected by said inside components.
ii. The device must be able to be sterilized between surgeries through the currently used sterilization procedures.
iii. The device must not interfere, if it comes into contact, with the patient's biological systems.

c. Accuracy and Reliability:

i. The device must be reliable in regards that it should not decrease significantly the amount of force that it is able to exert.
ii. There is some allowed tolerance in the overall dimensions of the hammer, but it should be proportioned well and feel comfortable to use.

d. Life in Service:

i. The device must be able to be used for no less than 100 surgeries without failure.

e. *Shelf Life:*

i. The device must be able to be stored at a standard atmospheric temperature of 10-30℃ [2].

f. Operating Environment:

i. The product should be able to operate in one specific environment, and its performance should not be altered by standard temperature humidity or pressure changes.
    1. Surgery operation rooms
ii. The device should operate within standard atmospheric temperatures, from 10-30℃ [2].
iii. The device should be able to withstand autoclave temperatures of up to 1R [3].

g. *Ergonomics:*
    i. The hammer should fit nicely inside of the hand. The handle of the device should not be sharp or cause discomfort for the surgeon. (grip will likely be used)
    ii. The device should be lightweight, so as to not strain the user.

h. *Size:*
    i. The hammer's handle should be able to fit into the average person's hand.
    ii. Based on other similar mallets, the device should be around 7-10 inches in length [4].
    iii. The head of the hammer should range from ¾" to 1 ¾" [4].

i. *Weight:*
    i. The finished product should weigh no more than 1-3 pounds for easy sterilization and use. This is specifically important for the surgeon to not have to swing too heavy a hammer.

j. *Materials:*
    i. The material must fulfill the weight requirements for easy use but must also be sturdy enough to withstand a large amount of force when the hammer is being used. The material must be user-friendly so it does not cause irritation of the skin, yet must be able to withstand sterilization after use in an autoclave.

k. *Aesthetics, Appearance, and Finish:*
    i. This device will have a small head similar to that of a regular hammer.
    ii. The grip will either be a metal of some sort or a leather grip for better traction when swinging the hammer.
    iii. Creative freedom was granted to the group in terms of aesthetics and color, however, the colors will most likely be neutral because of the components that will be used.

2. Production Characteristics

a. *Quantity:*
    i. One finalized prototype should be created.
    ii. Many devices, at least 100 to start, would be needed if brought to market.

b. *Target Product Cost:*

i. Ideally, the finished product should cost around $300.

3. Miscellaneous

a. Standards and Specifications:

i. The FDA's Center for Devices and Radiological Health is responsible for regulating all medical devices sold, imported, repackaged, etc. in the United States. According to the FDA, this device is a Class I medical device. The rules and regulations for this product are set forth by the Code of Federal Regulations Title 21, Sec. 878.4800 [5]. This code is specific to a manual surgical instrument, under which a hammer is listed [5].

b. Customer:

i. This device is directed for use by the trained orthopedic surgeon.
ii. The mallet must also be easily cleaned by a trained member of the hospital staff.
iii. The handle should be designed in a way that maximizes comfort and control for the surgeon.

c. Patient Related Concerns:

i. The hammer must be sterilized by autoclave after every use.
ii. The hammer must have safety measures as to not break and leak any components onto an open surgical field.
    1. This has been a problem for orthopedic dead-blow hammers in the past as described by an FDA recall in 2017 from Smith & Nephew, Inc. [6].
iii. The material must be safe for brief contact with exposed tissue and bone.
iv. The ability to control the hammer is important as to minimize impulse forces away from the intended line of action of the hammer strike.

d. Competition:

i. Several designs exist for orthopedic mallets that do not have force-distribution (shock-absorbing) characteristics.
    1. These are commonly used in current total joint replacements and are often made of surgical stainless steel or hard polymeric materials [7].
ii. A few instances of orthopedic shock-absorbing hammers are on the market as well.
    1. These mallets are "filled with a shock-absorbing media and [have] a flat striking surface to keep the mallet centered on the instrument." [8].

2. The specifications for what they are filled with are not listed, but several improvements could be made that ensure the safety of using steel balls for shock absorbance.

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B. Total Knee Replacement Images and Link to Video

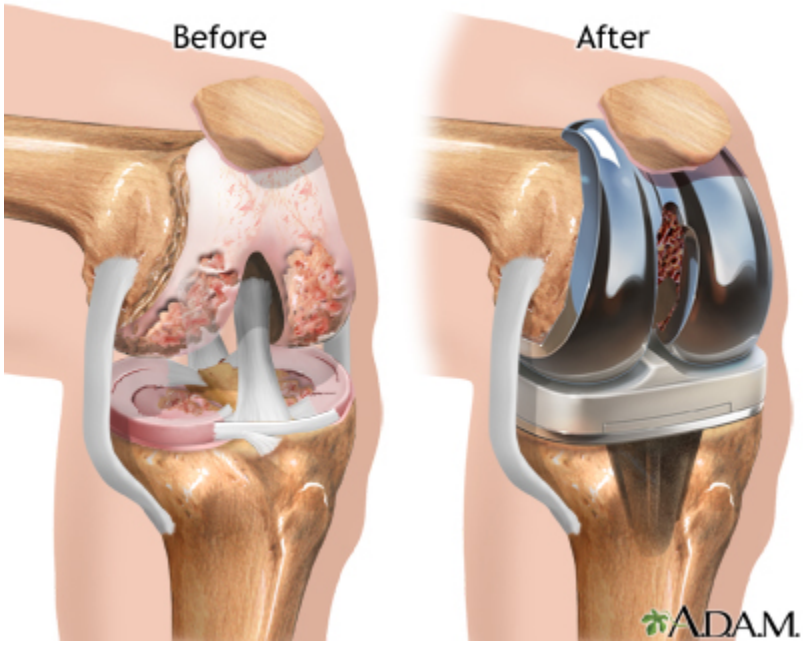

Figure 12: Before and after images of a total knee replacement surgery

The following link can be viewed to get a sense of the force needed to be applied during a total knee replacement surgery:
https://www.youtube.com/watch?v=vJL8n_82ITM

Although not a total knee or hip replacement, this video also shows an orthopedic mallet in use:
https://www.youtube.com/watch?v=Fn3aby0GWo4

C. Expense Table

Table 2: List of expenses from the Fall 2021 semester

Item	Description	Manufacturer	Part #	Date	QTY	Cost Each	Total
3D print of Design 1	Makerspace PLA	N/A	N/A	11/18/2021 & 12/01/2021	2	$10.96	$21.92
Steel Beads for Interior	3mm bearing balls (non-magnetic) x 200	PGN Bearing	N/A	11/29/2021	1	$6.75	$6.75
Total:	**$28.67**						

D. Testing Protocol

Materials Needed:

- Dead blow mallet with steel beads (test)
- Regular mallet w/o dead blow media (control)
- Force plate
- Ruler

Procedure:

1. Assemble the dead blow mallet by placing the steel beads in the open space. Seal the end caps of both the dead blow mallet and the control mallet.
2. Set up a ruler for consistent striking. The mallet will be brought up to 0.3 meters (1 foot) before each strike.
3. Prepare the force plate for data collection. Ensure that the force reads zero when no loads are applied.
4. Begin data collection on (Bertec Force plate).
5. Strike the surface of the force plate with the control mallet three consecutive times without stopping in between. Ensure that the mallet is brought back up to the height of the ruler before every strike.
6. Stop data collection.
7. Repeat steps 3-6 for a total of five separate times. Attempt to keep the striking force consistent with each test. This should be at approximately 10% of maximum striking force (for a force of approximately 3-4 kN).
8. Repeat steps 3-7 with the dead blow mallet.
9. Collect all tests and analyze in Matlab

Notes:

- A total of 10 tests will be performed with 3 strikes each.
- This should not take more than 15 minutes once all items are prepared
- The striking force will be below 4 kN as the mallets in this test are PLA plastic prototypes
    - The goal is to keep the strikes consistent. One individual will perform all the tests.