Dead Blow Hammer in Orthopedics

University of Wisconsin - Madison
Biomedical Engineering Design 400
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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. Next, we will look to find the best suited material for our device and a vendor to complete the manufacturing of the hammer. Lastly, the hammer will undergo testing to see if the Replaceable Caps design fulfills our project's objectives.

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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]. Our team wants to increase this window of age by decreasing the amount of wear and tear on the surgeon generated by the surgery. 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 looked to create an orthopaedic dead blow hammer.

B. Current Devices

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. Also, the patent claims speak of a hollow inside of the hammer head, with a spring inside. Our group is not exactly sure of the purpose of the spring because of the translation from chinese to english. One can assume it has something to do with limiting the hammer’s recoil or affecting the force generated by the blow[3].

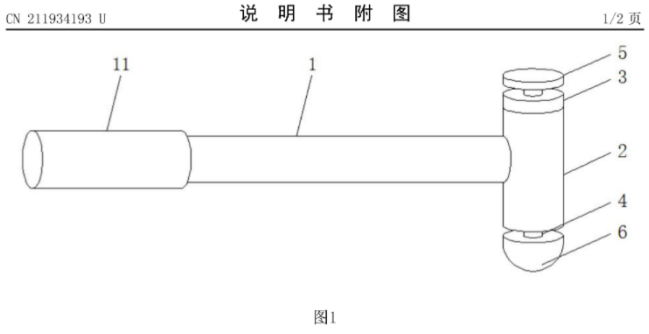


Figure 1: Novel Bone Hammer [3]

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 configurment 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 [4].

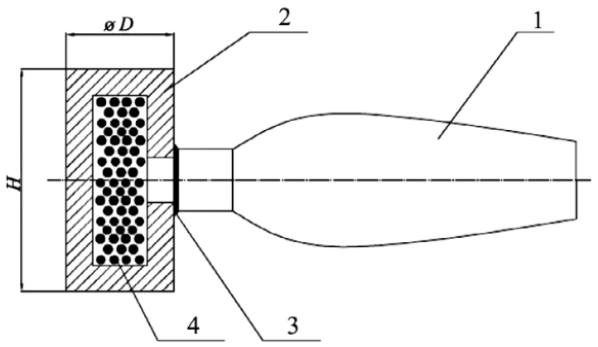


Figure 2: Low Inertia Hammer [4]

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

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 [5]. 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 [6]. Obviously, not all surgeries are completely identical because not all knees needing replacement have the exact same problems.

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 [7]. 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.

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 something like this actually 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" [8]. 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.

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 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 4 to 13 N (1-3 lbs) [9], so it is not to put physical stress on the surgeon while swinging. The hammer must be able to exert 30 kN [10] so it is able to carry out the intended surgeries, while being able to withstand 40 kN of force without breaking [10]. 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 [7]. 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 [11]. Lastly, the device must be able to be manufactured for less than $300 [12,13]. 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.

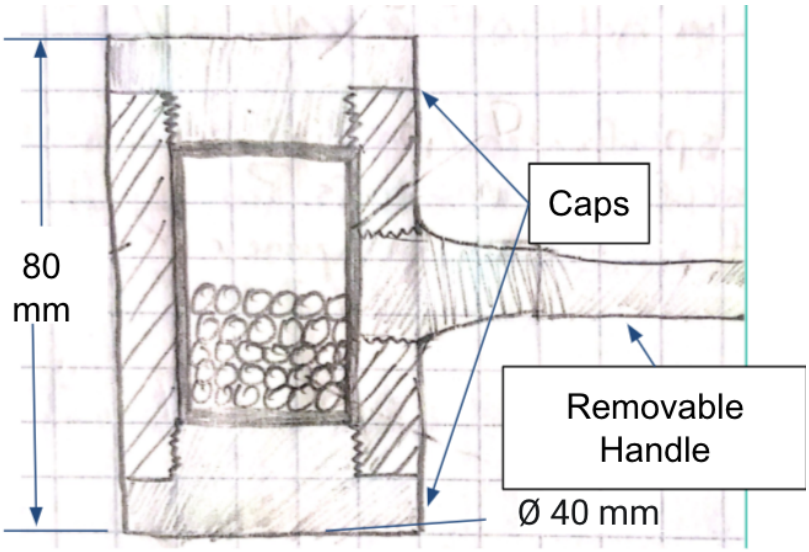


Figure 4: Fully Replaceable Design

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.

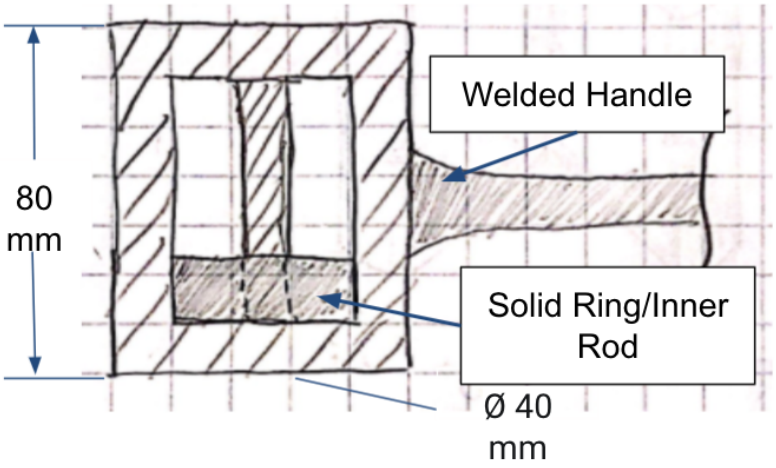


Figure 5: The Piston Design

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.

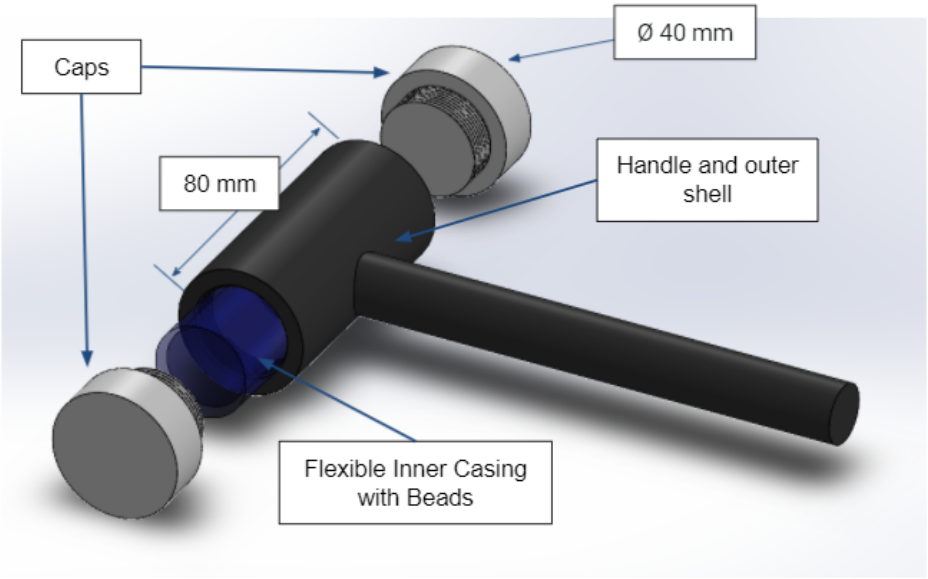
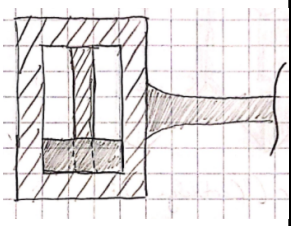
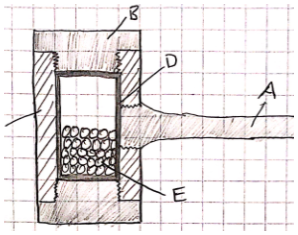
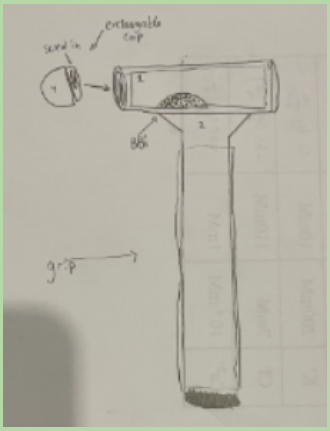


Figure 6: Replaceable Cap Design

IV. Preliminary Design Evaluation

A. Design Matrix

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

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.

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.

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 [8]. The size of the ring and rod of Design 1 mitigates this risk.

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.

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.

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.

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 caps and outer shell with handle will consist of 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 [14]. 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 [15]. 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 will be stainless steel balls that are nearly 0.5 mm in diameter. 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 final design will first be finalized in Solidworks with all of the intended dimensions. Then the different metal pieces (the caps and the outer shell) of the mallet will be outsourced to a local metal fabrication shop. A supplier will also be found that can provide the metals needed. It will be important to check with the supplier and the fabrication company to ensure that the items can be delivered at an appropriate price and lead time. The polymeric inner casing will likely be also outsourced with a prototyping company. The metal beads will be ordered separately and inserted into the inner casing. Once all of the pieces have been fabricated, the hammer will be assembled and tested.

C. Testing Procedure

The testing of the hammer will fall into two distinct categories, which are testing the force generated and the recoil after impact compared to a normal surgical mallet in current use. In order to test the force, each hammer will undergo 15 blows by each member of the design team. In order to capture the force, each blow will occur on a force plate with at least a 50 kN load cell. These data points will then be separately analyzed to account for any difference in force generated by each individual and compared to the normal mallet. Statistical analyses will be performed to determine any differences. Force time curves will also be generated for each of the blows.

The second category of testing is to test the recoil of the device. This will occur concurrently with the force test. This will include using a video camera to capture a video of each strike. Post-processing with ImageJ will then occur to determine the maximum recoil that occurred during each strike. The dead-blow hammer will be compared to the normal surgical mallet to determine any quantitative differences.

VI. 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 final design 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.

The stress put on surgeon's own bodies during intense orthopedic surgeries needs to be limited by creating a mallet that reduces striking force needed and recoil. With safety and durability as main concerns, we have created a solution. Our proposed final design of a dead blow hammer will hopefully solve this problem to allow surgeons to keep their own body healthy during surgeries.

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VIII. Appendix

A. Product Design Specifications

Dead Blow Hammer for Orthopedic Surgery

Product Design Specifications
September 21, 2021

Client: Dr. John Wollaeger

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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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