Dead Blow Hammer for Orthopedic Surgery

Product Design Specifications

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Client: Dr. John Wollaeger

Team:

Connor Link	ctlink@wisc.edu
Samuel Ferris	sjferris2@wisc.edu
William Brown	wbrown23@wisc.edu
Isaac Krause	ikrause@wisc.edu

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.

References

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