Hip Implant Femoral Stem
Loosening Device
Volume I

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1.1 – Executive Summary

Approximately 285,000 hip replacement surgeries are performed every year in the United States. Of these, roughly 10% of the implants will fail due to excessive wear, dislocation, infection, loosening, or patient-related factors [1]. In these cases, the patient must undergo a revision surgery where the failed implant is replaced with a new one. The most commonly reported complication that occurs in the revision surgery is difficulty in extracting the femoral stem implant from the surrounding bone [2]. Current loosening techniques include using slap hammers and osteotomes to pry the implant from bone. These methods are often time consuming, ineffective, straining on the surgeon, and harmful to the patients. In difficult cases, it is often necessary to cut or further fracture the bone surrounding the failed implant. After the implant is removed, the remaining bone fragments need to be reconstructed. The goal of this project was to design a device that simplifies the femoral stem loosening process by reducing implant extraction time and patient trauma.

The designed device uses vibrations to loosen the femoral stem of an orthopedic hip implant from the femoral bone. A motor driven camshaft will create a 1 mm displacement of two clamps attached to a parallelogram driving linkage. The clamps secure the device to the implant and the femur. As a result of the parallelogram driving linkage, the clamp attached to the implant vibrates out-of-phase from the clamp attached to the femur. This out-of-phase apparatus will amplify the vibrations and assist in the stabilization of the implant and the bone. The motor and driving linkage are secured to an outer housing which enables the surgeon to easily operate and manipulate the device settings. The device is powered by a rechargeable battery that is attached in a stainless steel casing on the outside of the housing.

SolidWorks model simulations, ANSYS simulations, and a rough physical prototype were used to assess the validity of the design. These techniques were used to assess the top five design requirements established for this device. The results of these tests were desirable. SolidWorks simulations of the virtual device prototype verified that the Hip Implant Femoral Stem Loosening Device’s ability to fit within the incision and to be operated by one person. The stresses present in the ANSYS simulation were large enough to fracture the inner trabecular bone of the femur but were not large enough to fracture the outer cortical bone of the femur. From this analysis, it was determined that a vibration with a 1 mm displacement at a natural frequency of 15,503 Hz will successfully loosen a femoral stem implant from the surrounding femur in 53.88 seconds. By using the Hip Implant Femoral Stem Loosening Device and thus decreasing the removal time of the femoral stem implant, hospitals could save approximately $3,348 per surgery.
1.2 - Project Contributions

Contributions of Maggie Goshert:
- Project Manager
- Researched total joint revision surgeries and corresponding complications
- Researched thermal damage to the surrounding bone and tissue caused by current loosening procedures of implants
- Co-interviewed orthopedic surgeons: Dr. Braman and Dr. Cheng. Sole interviewer of Dr. Meyer
- Created Gantt Chart
- Obtained Cobalt-Chromium material properties needed for ANSYS simulations of the femoral stem implant
- Aided in planning of presentation and documentation for Site Visit 1 by defining the current problem and the need for the device
- Aided in concept generation and selection process
- Co-observer of total shoulder joint replacement surgery with Dr. Braman
- Co-author and presenter of the mid-project review presentation. Focused on the technical plan for completing our project including virtual prototype and a physical prototype.
- Observer of total hip joint revision surgery with Dr. Marston
- Co-author of Site Visit II handout
- Co-author of design show poster
- Author of following Volume I sections of design report: Executive Summary, Additional Uses, Number of Operators Evaluation and Abstract
- Author of following Volume II sections of design report: Customer Needs (includes overview, interview notes, and shadowing in the O.R), Bill of Materials (co-author), Manufacturing Procedure, Number of Operators Evaluation Report, Environmental Impact Statement, and Regulatory and Safety Considerations
- Compiled drafts and final report
- Edited final report

Contributions of Ben Moyer:
- Co-Author of Design Requirements and Customer Needs Matrices
- Author of following Volume I sections of design report: Design Requirements, Device Size Evaluation and Abstract, Discussion (includes strengths, weaknesses, next steps
- Author of following Volume II sections of design report: Design Description (including detailed description, functional block diagram, description of functions/mechanisms – co-author), Part Drawings, and Device Size Report
- Co-Interviewed orthopedic surgeon, Dr. Braman
- Research competitors and their products and current methods
- Co-observer of total shoulder joint replacement surgery with Dr. Braman
- Research material and viscoelastic properties of trabecular and cortical bone, and bone cement
- Aided in concept generation and selection process
- Aided in planning of presentation and documentation for site visit 1 by refining the design requirement and customer needs matrices
• Researched and obtained solid models of human femur, hip implant, and femoral muscle properties. Also modified models to create a solid model of a hip implant embedded in a femur
• Conducted experimental and analytical analysis of device dimensions and weight using software tools provided within SolidWorks
• Co-author of Site Visit II handout
• Revised 3D solid model of the original design to include external battery, on/off switch, and potentiometer
• Modified original design to fit within 3D printer, coordinated efforts with ME student shop to have the device printed, responsible for delivering a prototype that illustrates the mechanism of the device
• Co-author and presenter of the mid-project review presentation, focusing on addressing customer needs and how they evolved into device constraints, which arrived at the top five design requirements
• Co-author of design show poster
• Edited final report

Contributions of Ben Pitzen:
• Creator of Website and Google Drive Assignment Folder
• Co-interviewed orthopedic surgeons: Dr. Braman and Dr. Marston
• Aided in concept generation and selection process
• Compiled Interview notes
• Existing patent, vibration technology, and implant revision research
• Record and upload meeting minutes
• Author of following Volume I sections of design report: Problem Scope, Loosening Time Evaluation and Abstract (co-author),
• Author of following Volume II sections of design report: Manufacturing Overview, Part Drawings (co-author), Bill of Materials (co-author), Loosening Time Analysis Report, Cost Analysis Evaluation Report (co-author)
• Aided in ANSYS meshing and test plan creation
• Co-author and presenter of the mid-project review presentation. Wrote and presented on problem statement, need, and identifying customers.
• Observer of total hip joint revision surgery with Dr. Marston
• Reviewed/Edited design show poster
• Co-Interviewed John Gorman for ANSYS testing help
• Author of Statement of Work
• Edited final report

Contributions of John Van Drasek:
• Researched total joint revision surgeries and corresponding complications, existing patents, and vibration technologies
• Co-interviewer for orthopedic surgeons: Dr. Braman and Dr. Marston
• Created sketches of the different concepts
• Purchased motor and power supply for the prototype
• Aided in concept generation and selection process
• Observer of total knee and hip joint replacement surgery with Dr. Marston

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• Co-author and presenter of the mid-project review presentation. Focused on the concept selection process.
• Designed the basic idea of the device’s structure and the vibrating mechanism used in the device
• Created the 3D model of the device parts, assembly of the device, and the animation of the device
• Co-obtained material properties of trabecular bone, cortical bone, muscle, and implant used in ANSYS simulation.
• Co-assembled bone, implant, and muscle model for ANSYS simulation
• Co-created mesh used in ANSYS simulations
• Co-setup boundary conditions and solution settings for ANSYS simulations
• Ran modal analysis on ANSYS to find the natural frequency
• Ran transient structural analysis of a simple model on ANSYS to find the stress, force, deformation, and fatigue life for cortical and trabecular bone
• Ran transient structural analysis of actual model on ANSYS to find the stress, force, deformation, and fatigue life for cortical and trabecular bone
• Calculated torque and force to loosen trabecular and cortical bone
• Author of following Volume I sections of design report: Natural Frequency Evaluation and Abstract
• Author of following Volume II sections of design report: Concept Alternatives (includes concept scoring and screening matrices), Part Drawings (co-author), Natural Frequency Report, Loosening Time Report (co-author), and Cost Analysis Report (co-author)
• Edited final report

Contributions of Colin Zauner:
• Co-Author of Design Requirements and Customer Needs Matrices
• Co-Interviewed orthopedic surgeons: Dr. Braman and Dr. Marston
• Research competitors and their products and current methods
• Observer of total shoulder joint replacement surgery with Dr. Braman
• Assisted in ANSYS model development
• Author of following Volume I sections of design report: Technical Review (includes background, removal procedure, relevant technology and art), Design Requirements, Design Description (including detailed description, functional block diagram, description of functions/mechanisms – co-author), and Battery Power Evaluation and Abstract
• Author of following Volume II sections of design report: Battery Power Evaluation Report
• Researched relevant technology products and patents
• Aided in concept generation and selection process
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2 – Problem Definition

2.1 – Problem Scope

Of the 400,000 total joint replacement surgeries performed in the United States annually, nearly 10% will need revision [1]. This requires the implant to be removed and/or replaced. Difficulties arise during removal due to bone cement or a porous coating used to secure the bone to the implant. Surgeons typically have to hammer and chisel at the bone to free it from the cement during removal, causing bone fractures or the need for bone fragments to be attached back to the joint. The current methods can cause long operation times and excessive harm to the patient. There is a need to design a device that simplifies the total joint removal process. Focus will be given to the hip joint revision procedure, as this is currently a more difficult task to perform compared to knee revisions [2]. Hip revisions are also more commonly performed in comparison to shoulder revisions [1]. The designed implant loosening device will loosen the femoral stem implant from the surrounding bone through vibration technology. The key customers for this device are hospitals and the orthopedic surgeons practicing there.

2.2 – Technical Review

2.2.1 – General Background

Joint replacement surgery is needed when joints such as hip or shoulder become arthritic or unable to function as needed. This requires the joint to be replaced with an orthopedic prosthesis. Every year over 285,000 hip replacement surgeries are performed. Approximately 10% of the replacement joints will fail. In this case the failed joint is replaced with a new one in a revision surgery [1].

Revision surgeries are necessary when implants fail. Major causes of failed implants are infections, loosening of implant, or dislocation [1]. An implant can become loose due to the friction causing excessive wear on the joints, which may cause excessive pain to the patient. Infection can occur if implants are exposed to bacteria causing pain and swelling. Dislocation may occur if the ball comes out of socket on the implant.

Revision surgery requires replacing some or all of the components that make up the hip implant. Depending on the amount of damage that has been done to the bone surrounding the implant, the length of the surgery may be increased. In addition, complications often arise while removing the implant [3]. These complications may cause excessive bone loss or bleeding, which results in longer recovery times as well as increased cost to hospitals and patients.

2.2.2- Removal Procedure and Methods

The surgical procedure for total hip replacement surgery starts with an incision over the hip joint. This incision ranges from 20 cm to 30 cm [3]. The surgeon then uses a cautery pen to burn through the surrounding skin, soft tissue, and muscles which allows access to the hip joint. After the incision, the femoral head and acetabulum components are removed. The hip socket is then cleaned and new components are inserted. The next step is often the most complicated part of the revision surgery which deals with removing the femoral stem implant. The implant is typically fixed to the bone with either bone cement or a porous coating. Porous coating allows the implant to bind to the femur bone through bone formation into the implant. Another fixation method is bone cement. While in a liquid state, the bone cement fills the space between the bone and implant. The bone cement then undergoes an exothermic reaction and hardens, securing the implant to the surrounding bone [3]. Certain tools are used to assist in the implant removal process. Tools utilized in many surgeries include drills, chisels, hammers, reamers, and various ultrasonic devices. In difficult cases, it may be necessary to cut apart the bone surrounding the implant piece by piece and then remove the implant [4]. This procedure, along with many tools and techniques today result in excessive bone damage or blood loss. Complications result in a greater recovery period for patient and at a greater cost to patient [5]. The methods in which hip implants are loosened can be found in Table 1.
### Table 1: Summary of Removal Methods

<table>
<thead>
<tr>
<th>Method or Tooling Used</th>
<th>What is It?</th>
<th>How it is used?</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
</table>
| Hand Extractors        | • Slap hammer  
                         • Chisel  
                         • Hip/Femoral component extractors | Uses force delivered by surgeon to remove implant | • Manual force  
                         • Wide variety of tools | • High Trauma  
                         • Low precision |
| Drills/Saws            | Specialized drill bits such as flexible osteotomes | Pieces of bone are removed so implant and bone cement can be easily accessible. | Short removal time | • Excessive bone damage  
                         • Extreme blood loss |
| Ultrasonic Revision Systems | Series of tool tips that vibrate at ultrasonic frequencies | Bone cement interface is heated via vibrations which melts bone cement and allows special tooling to remove implant | • Short removal time  
                         • Less traumatic  
                         • Tactical and audible feedback | May induce cell death to surrounding bone and tissue due to excessive heat |

### 2.2.3 – Relevant Technology and Products

Several products relating to removing hip implants currently exist. A wide variety of tools can be utilized in surgery. The most common include osteotomes, slap hammers, and ultrasonic systems. A review of current products is show in Table 2.

### Table 2: Summary of Relevant Products

<table>
<thead>
<tr>
<th>Product Name</th>
<th>How Does it Work?</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
</table>
| **Biomet Ultrasonic Revision System** [6]        | • Operates at stem interface by using ultrasonic vibrations to cut and melt bone cement around implant  
                         • Audible and tactile feedback | • Quickens cement removal  
                         • Feedback systems | • Thermal damage to surrounding tissues due to excessive heat  
                         • Unable to gain access to hard to reach areas |
| **Innomed Femoral Implant Extractor (Slaphammer)** [7] | • Clamps onto the taper of a femoral hip stem  
                         • A swivel block attached to a hammer provides excess force and moment to detach implant from bone | Generates large amounts of force which makes it easier for detachment of bone and implant | Force may be delivered in wrong direction, which leads to bone fracture and excessive bleeding |
| **Symmetry Medical Flexible Osteotome Blades** [8] | • Blades which couple to a drill or saw  
                         • Carves out cement | • Decreases cement removal time  
                         • Flexible | • Unable to reach curved surfaces of bone  
                         • Increases bone damage |

### 2.2.4 – Relevant Prior Art

In an effort to reduce the length of the procedure, lessen trauma to the patient, and increase ease of use in the operating environment, a design which utilizes vibration technology will be a special feature
that will help to assess the needs of the customers. Relevant prior art is reviewed in Table 3. This table also includes the differentiating features between the Hip Implant Femoral Stem Loosening Device and the corresponding patent.

Table 3: Relevant Prior Art

<table>
<thead>
<tr>
<th>Patent</th>
<th>Patent Number</th>
<th>Description</th>
<th>Differentiating Feature(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Removal of Prosthesis [9]</td>
<td>US 20100100139</td>
<td>This invention describes an apparatus that uses ultrasonic vibrations in torsional or longitudinal modes to remove prosthetic implants. The apparatus is composed of an adapter that attaches to the end of the implant which is clamped down by a screw. A generator is used to induce vibrations.</td>
<td>• Vibration frequency and modes • Clamping mechanisms</td>
</tr>
<tr>
<td>Implanting and Removal of Orthopedic Prostheses [10]</td>
<td>US 5019083</td>
<td>The apparatus described by this patent uses ultrasonic vibrations to dislocate implant and bone interface. The apparatus is composed of an osteotome which vibrates ultrasonically and can be inserted along bone and implant interface. In addition to the osteotome, a transducer is connected to the implant via self-holding taper. The transducer is also vibrated ultrasonically.</td>
<td>• Use of a vibrating osteotome • Self-holding taper mechanism</td>
</tr>
<tr>
<td>Apparatus for Removal of Osteal Prostheses [11]</td>
<td>EP 0617935 B1</td>
<td>This patent describes a device that uses ultrasonic vibrations to melt bone cement surrounding implant, and to break ingrowth bone from implant. There is also a coupling device which engages the implant with a selectable chucking device.</td>
<td>• Radial mode resonant oscillation • Coupling device.</td>
</tr>
<tr>
<td>Apparatus and Method for Removal of Cement from Bone [12]</td>
<td>US 5167619</td>
<td>This device uses vibration, suction, and cooling technology to remove implant from bone cavities. A vibrating hand piece is used to remove cement. In addition to vibrations, a suction tool is utilized to remove the cement being removed. In addition a cooling mechanism irrigates canal to prevent tissue death.</td>
<td>• Cooling mechanism • Suction tooling.</td>
</tr>
<tr>
<td>Orthopedic and Dental Implant System and Method [13]</td>
<td>US 8292895 B2</td>
<td>This device removes implants using vibration technology, and special control mechanisms. A special tool is mounted on a transducer which adapts to implant. The transducer sends vibrates implant which softens and breaks cement.</td>
<td>• Clamping technique • Microcontroller mechanisms utilized for vibration control</td>
</tr>
</tbody>
</table>

2.3 – Design Requirements

The design requirements for the Hip Implant Femoral Stem Loosening Device have come from a variety of sources such as interviews with numerous surgeons, surgical observations, medical journals, and online database research. Interviews and surgical observations have produced the most influential feedback, aiding in the ideation and confirmation of all design requirements. Five of the most important requirements are summarized in Table 4, and subsequently discussed in more depth.
### Table 4: Summary of Key Design Requirements

<table>
<thead>
<tr>
<th>Requirement Description</th>
<th>Units</th>
<th>Marginal Value</th>
<th>Ideal Value</th>
<th>Requirement Source</th>
<th>Requirement Test Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>The device must be able to fit within the incision to properly attach to the implant and existing bone.</td>
<td>Centimeters</td>
<td>&lt; 25</td>
<td>15</td>
<td>To perform an implant revision procedure in a contemporary manner, the device size must not inhibit its ability to enter the incision to remove the device.</td>
<td>Use SolidWorks to measure device dimensions, including device weight and clamp travel caused by camshaft.</td>
</tr>
<tr>
<td>The device must use a vibration frequency less than that of ultrasound.</td>
<td>Hertz</td>
<td>&lt; 20,000</td>
<td>15,000</td>
<td>Ultrasonic technology already exists and is protected by patents. Also, ultrasonic waves can heat up the surrounding bone and tissue which can cause additional patient trauma.</td>
<td>Use ANSYS to determine the natural frequency of the bone and implant assembly.</td>
</tr>
<tr>
<td>The device must be able to loosen the implant to ensure easy stem removal in a timely manner.</td>
<td>Minutes</td>
<td>&lt; 30</td>
<td>10</td>
<td>The device is designed to decrease implant loosening time, therefore the device must be able to loosen a femoral stem more quickly than contemporary methods</td>
<td>Use ANSYS to determine time required to fracture trabecular bone.</td>
</tr>
<tr>
<td>The device must use battery power.</td>
<td>Yes/No</td>
<td>Yes</td>
<td>Yes</td>
<td>Battery power would limit clutter and avoid unnecessary wiring or tubing that could contaminate the sterile environment</td>
<td>Use ANSYS to determine necessary force and duration of procedure to determine correct battery to power electric motor.</td>
</tr>
<tr>
<td>The device must be operable by 1 or 2 people</td>
<td>Number of People</td>
<td>2</td>
<td>1</td>
<td>Limited space around the incision in the operating room requires that the device must be operable by 1 or 2 people.</td>
<td>Use line drawings, device weight calculations, and rough prototype to determine how many people are necessary to operate device.</td>
</tr>
</tbody>
</table>

During invasive procedures, surgeons are required to make an incision to access the affected area. In the case of an orthopedic implant revision case, the surgeon must make an incision and move the muscle and other tissue out of the way to expose the joint. To reduce the amount of additional trauma caused to the patient and to increase likelihood of reduced recovery time, the surgeon will make an incision just large enough to access the joint. According to Dr. Braman, an orthopedic surgeon, the incision is usually around 20-30 cm and the device must fit into the incision easily [3].

There is also a limit on how much space is available around the patient and the operable area. The area around the incision is to remain as clutter free as possible and sterile. If anything around the patient touches something outside of the sterile field it is considered contaminated, and can therefore no longer come in contact with the patient or anything else in the sterile field. Utilizing battery power for the device eliminates the use of wires or tubing, thus reducing clutter and eliminating the risk of contamination.
Generally, two people are directly performing surgical actions such as cauterizing, sawing, and drilling, while the third person is responsible for holding the wound open wide enough for the others to work. Due to these limitations, the device needs to be operable by one or two people [4].

One of the current methods used for implant removal utilizes the properties of ultrasonic waves of 20,000 Hz and higher to heat the bone cement, weakening the cement allowing eased removal [11]. The use of ultrasonic waves is problematic to this design project as this technology is patented and can produce heat causing unsafe temperature rises in the body [12]. To avoid patent infringement and unsafe temperature rises in the body; the device uses an operable frequency range of less than 20,000 Hz.

The success of a revision procedure can be largely attributed to the actual removal of the original implant. To increase revision surgery success rates, the device will loosen a femoral stem implant, ideally in a manner requiring less time than the contemporary methods.

3 – Design Description

3.1 – Summary of the Design

The device uses vibrations to loosen the femoral stem of an orthopedic hip implant from the surrounding bone. For the device to be successful, two criterions must be considered: the vibration mechanism and the securement of the device to the implant and femoral bone.

The vibration force and frequency must be sufficient to loosen an implant from the bone cement or bone ingrowth used to secure the implant to the femur. A motor driven camshaft will create the vibration. Structural analysis on an implant in a femur determines the optimal frequency and amplitude. The device vibrates the femur using an out-of-phase vibration relevant to the vibration applied to the implant. We have designed a mechanism that achieves this out-of-phase vibration.

The device must be securely fastened to the implant and femur to ensure vibrations reach the intended area. Clamps that can be tightened to a range of implant and femur sizes are attached at the end of the vibrating arms. The clamps are secured so that slipping will not occur when the vibrations are applied. An overview line drawing of our device can be seen in Figure 1.

3.2 – Detailed Description

The Hip Implant Femoral Stem Loosening Device requires three elements to loosen the implant by breaking the bonds between the bone cement or new bone growth into the porous region of the implant: 1) securing, 2) loosening, 3) user interface. These functions operate in unison using clamps, a metal housing with attached handles, a spring, a drive assembly comprised of a motor, camshaft, steel linkage, battery, and a user interface made of a potentiometer. The device is shown in Figure 1 with a breakdown of each of the components.
Figure 1: Model of the Hip Implant Femoral Stem Loosening Device

Figure 2 and Figure 3 show different views of the Hip Implant Femoral Stem Loosening Device attached to both the implant and the bone.
3.2.1 - Functional Block Diagram

In order to successfully loosen the femoral stem from the bone, the device must utilize three mechanisms simultaneously. These three major mechanisms and their functional components can be seen below in Figure 4.

![Functional Block Diagram](image)

3.2.2 - Description of Functions/Mechanisms

The Hip Implant Femoral Stem Loosening Device uses sub-ultrasonic vibrations to loosen the femoral stem of a hip implant from the surrounding bone. The device is secured to the patient’s femur and the exposed implant using clamps, and then vibrated in a proximal and distal lateral motion using a 180° out of phase linkage, spring, and drive mechanism. The inner workings of the device are contained within a metal housing unit equipped with anchoring points for the internal mechanisms, as well as handles and a user friendly interface for control. Implementation of this device allows the surgeon to loosen the femoral stem for eased and timely removal of the old implant. The functions of the mechanisms described above are explored in more depth in the following sections.

3.2.2.1 - Loosening Mechanism

The loosening mechanism describes the dynamic components of the device. In order to apply the required force at the required frequency to the bone and the implant, the clamps need to move the same distance with equal force and frequency. To accomplish this, a four bar linkage was designed to be driven by a motor and cam shaft on one linkage and counteracted by a stiff spring on another. By utilizing a linkage, a 180° out-of-phase motion is more easily attained on a consistent basis than by using two...
motors. The linkage also eliminated the need for a second motor to power the device. The motor spins the cam shaft, which propels the drive shaft. As the drive shaft travels downwards, the reaction link travels upwards against the force applied by the spring. This occurs until the drive shaft begins its upward motion and the reaction link is then forced downwards due to the force counteraction caused by the spring. A motion diagram can be seen in Figure 5.

![Figure 5: Motion Diagram of Loosening Mechanism](image)

### 3.2.2.1.1 - Drive Mechanism

In order to loosen the implant, the implant device needs to apply waves of force with constant and equal frequency and amplitude to the bone and the implant 180° out-of-phase from each other. These waves are created by a small DC motor weighing 25.3 g to keep the device small, lightweight, and easy to handle, while still creating the force necessary to loosen the femoral stem. This motor provides the rotational speeds and torque necessary to vibrate the bone and device. To translate the motion of the motor to the linkage, a cam shaft has been designed to displace the drive linkage 1.0 mm downwards. The camshaft achieves the maximum displacement at the point shown in Figure 6, and returns to its highest position when the shaft has traveled an additional 90°. The shaft is welded onto the motor shaft to ensure a secure connection to avoid mechanical failure due to the high levels of torque required to loosen the implant. Figure 6 displays the assembly of the motor and the cam shaft.

![Figure 6: Drive Mechanism](image)

### 3.2.2.1.2 - Linkage

The force translated from the cam after being converted from the torque of the motor is then transferred to the bone and implant through the use of a parallelogram linkage. The linkage consists of two long rods about 19.5 inches and two shorter cross rods about 6 inches. The two shorter rods are anchored to the housing of the unit and act as a pivot point for the longer two rods. The two longer links move upward and downward 180° out-of-phase with one another. In order to loosen the implant using only one motor, the driving link must be out of phase with the other to cut down on the distance the links must travel for easier control. The further the arm travel downwards the greater the lateral displacement,
which adds vibrations in the transverse direction. This aids in the loosening process. The linkage assembly is displayed in Figure 5.

3.2.2.1.3 - Spring

The reaction link does not have a motor to drive it. Therefore a spring is used to counteract the force of the motor and to keep the drive link pressed against the camshaft. The spring needs to be stiff to make effective use of the potential energy created by the drive link at its lowest displacement.

3.2.2.2 - User Interface Mechanism

In order for surgeons to loosen the implant, frequency control must be implemented into the design as well as controls to power the device on and off. In addition, the user interface must be simple to understand. To accomplish frequency and power control the user interface was designed to consist of one component which can carry out both functions. The device will be powered by a battery pack attached to the housing unit. The battery will be rechargeable and designed to last the entire duration of the surgery and will meet all sterility requirements determined by the FDA.

3.2.2.2.1 - Switch

Power control is achieved through an on/off button. To obtain power, the button is pushed down and is locked until the device needs to be powered off. When the device is no longer powered the button will pop out. The push button is selected to ensure that the device is not unintentionally turned off when getting caught on foreign objects.

3.2.2.2.2 - Variable Resistance

The second function of the component is a potentiometer. A potentiometer is used to control resistance and vary the frequency of vibrations subjected to the implant. Varying the frequency is achieved by twisting the push button. Figure 7 displays the user interface mechanism.

3.2.2.3 - Battery

A rechargeable battery unit is used to power the device. The battery will be placed in a stainless steel compartment attached to the housing. This will prevent the battery from being exposed to the operating environment and will meet all sterility needs set by the FDA. Battery selection is designed according to motor properties and the length of operation. Figure 8 displays the battery attached to the housing unit.
3.2.2.3 - Securing Mechanism

The securing mechanism is composed of securing the device to the implant as well as securing the motor, linkages, and spring to anchor points within the housing. The motor, linkages, and spring are anchored to a metal housing that encompasses the entire linkage system. In addition to allowing the loosening mechanism to achieve its function, the housing also protects the inner mechanisms from being disturbed.

3.2.2.3.1 - Clamping

Anchoring the device to the implant is achieved through the use of two Fischer clamps. One Fischer clamp is secured to the bone, and the other is secured to the stem implant. Both clamps are attached to the arms of the linkages. This mechanism allows the loosening mechanism to transfer the lateral and axial vibrations to the implant and bone. The attachment of the clamps to the bone and the implant can be seen in Figure 3.

3.2.2.3.2 - Housing

Anchoring the motor, linkages, and spring to anchor points is achieved through the use of a metal housing compartment composed of two handles. The motor is anchored to the housing and is connected to the camshaft. The camshaft is used to propel linkages which transmit the vibrations to the bone and implant. In addition the linkages are anchored to the housing to maintain the linkage geometry which is crucial for providing the out of phase vibrations. To enhance ease of use the housing also has two handles attached to it. These handles maximize ease of use by providing multiple grip locations. Figure 1 shows the housing in detail.

3.3 – Additional Uses

The implant loosening device described above was designed to successfully loosen the stem component of the total hip implant from the femur. However, this device can also be used on the stem component of a total shoulder implant that is lodged in the humerus. After interviews with upper extremity orthopedic surgeons, it was noted that the removal process for a stem in a humerus is also very difficult and timely in most cases. Therefore, this device could be used to improve this process and could make the stem removal process more manageable and simple.
4 – Design Evaluation

The following test plans and evaluations were performed in an attempt to ensure that the top five design requirements for the femoral stem implant loosening device, as described in Table 4, are met. This is done by using two types of prototypes: a virtual prototype and a physical prototype. The test evaluation plan and results are described in the sections below.

4.1 – Evaluation Plan

Table 5 summarizes the top five design requirements and their verification methods. The various evaluation methods used will be described in more detail in sections below.

<table>
<thead>
<tr>
<th>Design Requirement</th>
<th>Evaluation Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>The device must fit within the incision and properly attach to the implant and existing bone.</td>
<td>Use SolidWorks to measure device dimensions, including device weight and clamp travel caused by camshaft.</td>
</tr>
<tr>
<td>The device must use a vibration frequency less than that of ultrasound.</td>
<td>Use ANSYS to determine the natural frequency of the bone and implant assembly.</td>
</tr>
<tr>
<td>The device must be able to loosen the implant to ensure easy stem removal in a timely manner.</td>
<td>Use ANSYS to determine time required to fracture trabecular bone.</td>
</tr>
<tr>
<td>The device must use battery power to minimize the amount of clutter/equipment in and around the patient.</td>
<td>Use ANSYS to determine if it is feasible to power the device by a battery.</td>
</tr>
<tr>
<td>The device must be operable by one or two people.</td>
<td>Use line drawings, device weight calculations, and rough prototype to determine how many people are needed to operate device.</td>
</tr>
</tbody>
</table>

4.1.1 – Device Size Analysis

This test sought to evaluate three main objectives all relating to the size and weight of the device; the maximum spacing of the clamps, the size and weight of the device for co-evaluation with the Number of Operators Evaluation described in Section 4.1.5, and the verification of the ability of the camshaft to deliver a 1 mm displacement. The ability of the clamps to fit into the current incision size used for a total hip revision case was essential for the function of the device. Research revealed that the average incision size ranges from about 25-30 cm [14]. With procedures today becoming more minimally invasive, our team determined it would be wise to set the maximum acceptable width to 15 cm to accommodate to the smaller incisions. It is essential that the device is operable by one or two people, ideally one. The size and weight measurements from this were evaluated in unison with the Number of Operators Evaluation to examine the feasibility of this being a single operator device. Finally, the ANSYS simulations yielded that the most favorable results were obtained from using a 1 mm displacement. This test sought to verify that the camshaft was designed in a manner to deliver this 1 mm displacement.

Using the 3D model of the device in SolidWorks, the “Measure” and “Mass Properties” tools were utilized to obtain the length and weight measurements of the device. By assigning different material properties to the components, SolidWorks was able to calculate an expected weight of the device. This test is explained in more detail in Section 3.1.1 of Volume II.

4.1.2 – Natural Frequency Analysis

To determine at which frequency we want to vibrate the implant and bone of our device, we first established the natural frequency of the implant and bone assembly. If we use the natural frequency as our
target to vibrate the implant and bone, we will have the maximum vibration transmissibility. This way we will have the optimal amplitude that our cam and motor can provide.

We ran a modal analysis using ANSYS finite element software. A model of the femur with an orthopedic implant surrounded by muscle was meshed and tested to find the natural frequency. This model ran until the results converged with low residuals. This test is explained in more detail in Section 3.1.2 of Volume II.

4.1.3 – Loosening Time Analysis

The purpose of the loosening time evaluation was to verify that a displacement of 1 mm from our loosening device would produce a stress greater than the yield stress of the bone. This evaluation was performed using the transient structural package in ANSYS. The 1 mm displacement was applied to the bone and implant in an out of phase behavior using sine functions that incorporated the natural frequency results yielded in the natural frequency experiment. The fatigue tool in ANSYS was also implemented in this test to calculate the number of cycles needed to create a force greater than the yield stress of the bone. The attained results for the stress value and number of cycles could then be used to determine the time required to loosen the implant. It will also be used in the Battery Power evaluation report. This test is explained in more detail in Section 3.1.3 of Volume II.

4.1.4 – Battery Power Analysis

A crucial design requirement is that the device must be battery powered to eliminate clutter in the operating room. In addition, the power supply must meet sterilization standards thus a battery powered device is essential in meeting these customer needs. The objective of this test will be to evaluate the feasibility of using a battery to power the loosening device.

This objective will be completed by determining the size of battery that will power the device using estimated time of loosening and various motor parameters. The time required to loosen the implant will contribute to the motor selection as it will provide an estimate as to how fast the motor will draw power from the battery. In addition, motor parameters such as operating torque, power rating of motor, and rpm at which motor operates will be utilized. Battery power analysis will include desired motor properties that will be required to loosen the implant from the surrounding bone, and most importantly the size of the battery that will be needed to power the device for the duration of the operation. This test is explained in more detail in Section 3.1.4 of Volume II.

4.1.5 – Number of Operators Evaluation

The fifth design requirement is that the device must be operable by one or two people. This evaluation contains two components: the weight of the device and how the device is handled while in use. The weight of the device was determined by using the mass properties simulation on the CAD model in SolidWorks. The ergonomics of how the device is handled while in use was validated by a line drawing in addition to operating the rough physical prototype. Input from members of team who operated the rough prototype was used to demonstrate the optimization of one operator rather than multiple operators. This evaluation is explained in more detail in Section 3.1.5 of Volume II.

4.1.6 – Cost Analysis Evaluation

Cost effectiveness is one of the most influencing factors for the need of this device. Current orthopedic hip implant revision surgeries, may last 3 to 4 hours. Our goal is to significantly reduce the time in the operating room, thus reducing the cost of the procedure. This evaluation is explained in more detail in Section 3.1.6 of Volume II.

4.2 – Evaluation Results

The abstract and results for each of the five test evaluations described in Section 4.1 are shown below. The full evaluation reports for each design requirement can be found in Section 3.1 of Volume II.
4.2.1 – Device Size Analysis Abstract

The maximum width from outside of the left clamp to the outside of the right clamp was measured to be 14.47 cm. With the maximum acceptable width being 15 cm and the average incision size for a total hip revision being 25-30 cm, the device was found to be satisfactory and in no need for immediate revision to this design requirement.

The second portion verified that the size of the handles of 2.5 cm diameter and length of 10 cm for the side handle and 2.5 cm thick and 12 cm wide for the top handle, were adequate in size for use by persons of all hand sizes ranging from grip size of < 3-4 cm and width of ≤ 12 cm [15].

Also, in the second part of this test, the 3D model was used to obtain a calculated weight estimate of the design given the material properties assigned to the different device components. SolidWorks “Mass Properties” yielded a weight of 12.34 lbs. This value was analyzed in further detail in the Number of Operators Evaluation. Ideally, the device will weigh less than 10 lbs, however this weight will be dependent upon design revision necessary based upon further analysis of failure modes of the device which will be further analyzed upon completion of concept feasibility testing. Refer to Section 4.2.5 in Volume II for a more detailed analysis of the weight of the device.

The final portion of this test measured the camshaft dimensions to ensure it delivered the required 1mm displacement of the clamps. The dimensions of the camshaft were measured to be 2.0 cm x 2.2 cm. Using Equation 1 it was possible to verify that the clamp travel displacement was equivalent to 1 mm.

\[ dy = \frac{(2.2 - 2.0)}{2} = 1 \text{ mm} \]

Equation 1

4.2.2 – Natural Frequency Analysis Abstract

The natural frequency of our system was found using a modal analysis with ANSYS finite element analysis software. We searched for frequencies between 5,000 Hz and 19,000 Hz in order to find a frequency that was high enough to remove the implant in a timely manner and not infringe on existing patents. The ANSYS results came up with 25 harmonics of the natural frequency in that range. We ended up choosing 15,503 Hz as our target frequency. This was chosen because we thought it was well enough below an ultrasonic frequency so it would not infringe on another patent, but it was high enough to remove the implant under our target time of operation.

4.2.3 – Loosening Time Analysis Abstract

Four ANSYS simulations were performed on the implant in bone model. A simple model and full model simulation were performed for both cortical and trabecular bone. There are two main types of osseous tissue that make up bone: trabecular and cortical. Trabecular bone is found near the center of the femur, while cortical bone is found near the outside of the femur. A 1 mm displacement force was applied out-of-phase to the bone and implant and results yielded a stress map so we could observe where the highest stresses were located. Then we were able to verify that the experimental stress was higher than the yield stress for trabecular and lower than yield stress for cortical. This ensured that the implant would loosen but no damage would be caused to the rest of the femur. The ANSYS simulations yielded a max experimental stress of 12.735 MPa for trabecular and 119.76 MPa for cortical. The yield stresses for trabecular and cortical are 3.31 MPa and 221 MPa, respectively. Therefore, our simulations were successful. Once the ANSYS simulations were complete, we were able to determine the time it takes to loosen the implant. Using fatigue analysis we determined that the number of cycles to failure in the bond between the implant and trabecular bone was 835339.3 cycles, which we converted into a time of 53.88 seconds. This time value was then used to determine the battery power needed to last the duration of a revision procedure, as explained in the Battery Power Analysis Evaluation.
4.2.4 – Battery Power Analysis Abstract

Due to sterility restriction and limited space in the operating room, it is important that the loosening device can be operated by a cordless battery. We found that the loosening device can be operated with a standard rechargeable battery. A 90 V DC motor that operates at 1.4 Amps can be powered by a battery with a capacity of 2 Ah and a minimum of 0.94815 V. Many viable options are available for rechargeable batteries. Many surgical drills in the orthopedic industry use battery packs ranging from 9 V to 20 V, thus our device will be able to use a small and lightweight battery. The device does meet the requirement that it must be powered by a battery, and will also meet sterility requirements.

4.2.5 – Number of Operators Evaluation Abstract

Due to limited space around the patient and incision site, it is essential that the Femoral Stem Implant Loosening Device can be operated by one or two people. To meet this requirement, the team decided to set a hard constraint to only pursue designs that can be operable by one person. There are two components in analyzing the number of operators needed: the weight of the device and how the device is handled while in use. Using SolidWorks software, the weight of the device was determined to be 12.33 lbs. This is a reasonable weight and is comparable to the weight of current hand-held orthopedic surgical power instruments. Line drawings and operating the rough prototype validated the ability to operate the device with only one person. Comments from the operators (Team Removal members) using the rough prototype also confirmed the optimization of one operator rather than multiple operators. More details about this experiment can be found in Section 3.1.5 of Volume II.

4.2.6 – Cost Analysis Abstract

One of the motivations for creating an orthopedic hip implant removal device is to reduce the time in the operating room. This is especially significant because the number of orthopedic implant replacement surgeries performed each year is continuously rising. There is a significant amount of wasted time spent in the operating room with the current revision process, causing higher costs to hospitals and patients. A device that removes implants faster as well as less traumatically can save hospitals a significant amount of money. By running ANSYS simulations, we found that our device takes about one minute to loosen the implant. Including 5 minutes to setup and physically remove the implant, a total time of removal for our device is about 6 minutes. This is significantly improved when compared to the 60 minutes average it currently takes. The time difference equates to a savings of about $3,348 per surgery.

4.3 – Discussion

4.3.1 – Strengths

The hip implant femoral stem loosening device has many strengths, including the design, cost, and usability of the device. The device utilizes a relatively simple design consisting of a four bar linkage, powered by an electrically driven camshaft all anchored to a metal housing. The motor is powered by an externally attached battery, making it relatively easy to remove an exhausted power source and attach a new one during the procedure. A 2 cm x 2.2 cm elliptical camshaft delivers a consistent 1 mm displacement, which was used as a basic assumption for the ANSYS simulations and results, which are important to the function of the design. Lastly, the first evaluation test confirmed that the clamps that attach to the bone and the implant fit within the average total hip revision procedure incision size by about 10 cm, with a maximum spacing between them of about 14.5 cm. The clamps ability to fit within the current incision sizes is crucial to the successful operation of the device.

The simple design also aids in the ability of the device to be used by a single operator. The Number of Operators Evaluation confirmed through the use of ergonomic stick drawings that the device may be operated by a single person. Also, the Device Size Evaluation confirmed that the dimensions of the device were all within the acceptable ranges for use by a single person. The most important measurements included the handle dimensions, height and width of the device, and the device weight. All
but the weight of the device were found to be favorable for single person use. Lastly, the manual and electronic controls for the loosening device are simple. By pushing the on/off switch, a potentiometer rises up allowing the surgeon to make fine-tuned adjustments on a per case basis and the clamps are easily attached to the bone and the implant by positioning the fingers around the desired anchor point and securing them using the winged bolts.

The final strength of the loosening device is that it is inexpensive compared to other capital based surgical tools. Due to the simple design, the device will be easy to manufacture, which will aid in counteracting the cost of the strong, but lightweight materials necessary.

4.3.2 – Weaknesses

First, a large portion of this design project was based around ANSYS simulations seeking to identify some key design requirements that would have required intensive clinical testing and resources. In performing these simulations we assumed elastic properties of bone, when really each specimen of bone is different based on molecular composition and would require a range of values to be tested. Also, we were not able to take into consideration the dampening effects of surrounding bones and tissues, which we would assume to have some impact on the results of a real clinical test. Lastly, the bone interface was assumed to be linear, when in fact osteointegration of the bone and implant may have nonlinear deformation properties, meaning that the bone and the implant may have different moduli or coefficients as one travels from the outer diameter to the inner diameter (as with a tree).

The assumptions made in the ANSYS testing also leads to the question of how feasible is the concept of using sub-ultrasonic vibrations to loosen the femoral stem of an implant without causing the patient additional unnecessary trauma. A weakness of our device is since we made the assumptions we described earlier, and knowing that each patient is different, especially osteoporotic patients, the consistency of the outcome of the device is unknown. For instance, patients with osteoporosis possess more brittle and porous bones than an average person without the condition. This means they are at an increased risk for additional trauma caused during a revision case (not to mention they are also most likely for a revision procedure due to bone complications), and their bones may not be able to handle the intense vibrations from the device.

Although the design met the acceptable values for size, there is always room to make the device smaller and lighter. By cutting down on the size, the ease of manufacturing may decrease while the associated costs increase, but the cost of materials will be minimized by the ability to use materials of similar strength, but slightly heavier and less expensive while still maintaining a weight usable by a single operator. Also, there is no display on the device to tell the surgeon if he/she is within the optimal operating range nor is there any control that determines whether a consistent force is being applied to the implant and the bone other than the use of the 1mm displacement caused by the camshaft. Lastly, the device lacks the option of clamp removal. Ideally, this device would be marketed as a piece of capital with sterile, removable clamps, designed specifically for the device. The current clamps are Fisher chemistry lab clamps that are only able to obtain finger tightness using wing bolts, which may be able to wiggle loose if the vibrations from the device are strong enough.

4.3.3 – Next Steps

Addressing some of the weaknesses of the design, the next steps would be to redesign some specific aspects of the design including size and the clamps, building an actual prototype for testing in a clinical setting, and analyzing specific failure modes of the device.

As mentioned in the weaknesses section, the current device needs to be smaller, lighter, and possess a more user friendly electronic control interface. The current design uses steel, titanium, and aluminum, which can get expensive and heavy. The new design would ideally fit within a 10 cubic inch area, and weigh less than 10lbs. It would integrate a digital display onto the side of the device that displays the optimal frequency and current frequency. The frequency monitor would be an essential component because the required torque output from the motor may vary based upon the strengths of the
bonds securing the implant. Also, new clamps will need to be designed for this device. The clamps will be removable from the main component of the device and will be individually packaged and sterilized in accordance with FDA and CE standards. Lastly, the clamps will utilize a different tightening mechanism to ensure that they can be tightened beyond finger tight, and lockable into position to avoid being wiggled loose.

Once the redesign is complete in a 3D model, drawings of the separate components should be created for machining. The machined parts will then be assembled into a working prototype for use in a clinical setting to observe how the device performs in various settings including, but not limited to animal and cadaveric trials. The current prototype was printed in a rapid prototyping machine and cannot be used in clinical trials due to the strength of the materials used to print the device. The new prototype can be used to test the feasibility of the vibration loosening concept, performance of the new clamps, user feedback, and potential areas of device failure (high stress, dynamic failure modes, etc).

The animal and clinical trials will also be conducted to address the risk of the concept of the device and use on osteoporotic patients of varying levels of severity. Tests will be conducted to address how well the device loosens the implant as well as how much trauma is caused to the diseased bone.

The results obtained from the actual prototype can be compared with results from simulations dealing with device failure modes that used the 3D model. In this next step of the process, the 3D model will be subjected to ANSYS simulations to determine where the areas of high stress and strain are, how the device could fail, and why. These tests will allow the design team to make adjustments to the design and material selections to ensure that the device will not fail under normal operating conditions. After these steps have been completed, the device will need to be reevaluated before proceeding to more clinical trials required by the FDA and the additional steps required to bring a medical device to market.

One final item that will be addressed as a separate design project is the impact of thermal energy on the process of loosening the implant using vibrations. ANSYS simulations and clinical trials will be used to measure the temperature changes caused by the device. If the thermal impact is found to be significant, a cooling mechanism will be designed and implemented into the device. This cooling mechanism with calm the thermal impact of the device to reduce risk of device failure due to high temperatures and lessen the risk of additional trauma caused to surrounding tissue by increased heat energy caused by the vibrations.

5 – References


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