

Improving Two-Stage Revision Arthroplasty Utilizing 3-D Scanning

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Abstract

It is estimated that 7,000 total hip arthroplasty (THA) revision procedures due to infection will occur in the year 2015, with this number expected to increase substantially by 2030 (Kurtz et al., 2007). Due to a lack of surgeon accessibility to the necessary equipment needed to perform these procedures, it is becoming increasingly essential to develop devices that increase surgeon accessibility and usability of revision materials. Therefore, the goal for our project was to design a readily-available, cost-effective, universal, and disposable kit, comprised of a set of femoral molds, to facilitate the treatment of THAs by a two-stage revision hip arthroplasty. Our method utilizes a Konica Minolta Range 7 3-D scanner and 3-D printing technologies to manufacture a set of silicone molds, used to create the temporary antibiotic-loaded cement spacers used in this procedure. These molds are considered universal as they can be tailored to the primary hip prostheses and surgical broaches that the orthopedic surgeon might regularly stock in the hospital. Our product addresses the main goal of increasing accessibility by providing hospitals with a full set of disposable silicone molds, which can be stored on shelf and used as needed in the operating room. Our results conclude that this method can be used to produce a temporary spacer that is cost-effective, non-cytotoxic, and is dimensionally comparable to the originally scanned implant, thus ensuring an accurate and reliable press-fit component.

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Chapter 1: Introduction

In 2010, 332,000 total hip arthroplasties (THA) were performed in the United States, alone (CDC, 2010). Further, due to the United States' aging population and increasing life expectancy, the annual incidence of THAs is expected to increase (Cheng, 2012). As the number of THAs continues to increase, so too will the number of hip revision arthroplasties. The three most common reasons for implant failure after THA surgeries are instability/dislocation (22.5%), mechanical loosening (19.7%), and infection (14.8%) (Boettner et al., 2011). The incidence of revision surgeries for infected THAs alone is widely debated among researchers but could affect well over 7,000 individuals in the United States (Kurtz et al. 2009; Boettner et al., 2011).

Depending on the time taken to detect the infection and its severity, there are a variety of viable treatment options. If the infection is detected after three weeks post-onset, an orthopedic surgeon may choose to perform a two-stage revision arthroplasty to manage the septic failure of THAs (Ellenrieder et al., 2011); this procedure is considered the gold standard for treating infected hip implants. During a two-stage revision arthroplasty, the surgeon removes the infected hip implant; upon removal, a broach is inserted into the femoral canal to create space in which the temporary component will be inserted. The temporary component is molded with antibiotic-loaded bone cement and inserted in place of the primary hip prosthesis, which allows the infection to be treated prior to the surgeon performing the second stage of the two-stage revision arthroplasty (Senthil et al., 2011).

The DePuy Prostalac Hip System (Prostalac, 2010), is perhaps the most widely utilized system for two-stage hip revision arthroplasties. Previous studies deem this system highly efficacious in two-stage revision hip arthroplasties; however, there remains substantial room for improvement. Perhaps of the greatest concern lies in the fact that there is only a single kit available to orthopedic surgeons in New England, which is delivered to New England's regional hospitals upon request by a

medical device sales representative (J. Wixted, personal communication, Sept. 17, 2014).

Furthermore, although the DePuy Prostalac Hip System has been deemed effective, further limitations remain regarding brand specificity, price, disposability, and accessibility. Based on the fact that the Prostalac Hip System was manufactured by DePuy Orthopaedics Inc., a Johnson & Johnson company, its components were designed such that DePuy products are most compatible with the system's equipment. Because the kit is reusable following a postoperative sterilization process, the financial model is such that physicians do not have to pay money to rent the kit for use; instead, they are required to purchase the components within the kit that are not reusable, which include a stabilizing hip stem, acetabular cup, and bone cement. However, because this is the only kit available to New England physicians, DePuy is able to charge exorbitant prices for these components, even if the cost of these components separate from the Prostalac Hip System are available at a greatly reduced price. Additionally, as previously stated, the Prostalac Hip System is non-disposable; therefore, the kit's components must be sterilized post-operation before it can be used again on another patient. If sterilization guidelines were not strictly followed, microbial contamination could result in person-to-person disease transmission via contaminated devices (Rutala & Weber, 2004).

Lastly, since there is only one Prostalac Hip System in the New England region, if two surgeons were to need the kit on the same day, one of them would need to tell their patient that they must wait up to several days in order to have surgery. This also poses a concern since many infections are detected when a surgeon is treating a patient for what he/she thinks is a mechanical failure. However, after opening the patient up, in many cases the patient's pain was actually a result of an infection at the site of the implant. Unfortunately, surgeons do not have the necessary equipment on shelf to perform a two-stage arthroplasty at the onsite of detection. Therefore, the surgeon must close the patient up and wait until the Prostalac kit is ordered and perform the procedure at a later date. The lack of accessibility that surgeons have to this device therefore could

lead to additional co-morbidities associated with the infection, ultimately leading to patient dissatisfaction and discomfort.

The goal of this project, therefore, is to design a medical kit comprised of components to perform a revision hip arthroplasty that accommodates the wide variety of hip implant brands and models on the market, and is cost-effective, disposable, and accessible. For the equipment to be disposable and accessible, the materials chosen for the design coupled with the manufacturing of the equipment must be more inexpensive than the current system. Additionally, the manufacturability and sterilizability of the equipment will be considered to ensure reproducibility and patient safety, respectively. Further, the components must be sized such that they are capable of accommodating for the variety of prosthesis brands in stock.

To achieve such, we propose a medical device that will simplify the process of performing a two-stage, hip revision arthroplasty. We suggest that by utilizing 3-D scanning technologies, various disposable molds, which may form the temporary antibiotic-loaded cement spacers, can be produced to allow surgeons to use surgical broaches and hip stems that are already stocked in the hospital, regardless of what brand or model of hip implant they may use. This will allow surgeons to perform this procedure at a reduced cost compared to existing techniques, while furthermore, increasing their accessibility to the tools necessary to perform two-stage revision hip arthroplasties.

Chapter 2: Literature Review

2.1 Clinical Need for Revision Hip Replacements

In 2010, 332,000 total hip arthroplasties (THA) were performed in the United States, alone (CDC, 2010). However, due to the United States' aging population and increasing life expectancy, the annual incidence of THAs is expected to increase (Cheng, C. 2012). On account of the aging population and its increasing life expectancy, Kurtz et al. (2009) projected that the number of THAs in the United States would exceed 800,000 by 2030.

Several risk factors, which may predispose a patient to a primary THA, include osteoarthritis, rheumatoid arthritis, osteonecrosis, injury, fracture, and bone tumors. These conditions can lead to the breakdown of the hip joint, thus leading to decreased mobility and increased joint pain (NIAMS, 2013). To increase mobility and alleviate joint pain, patients rely heavily on hip replacement surgeries. *Figure 1* depicts a typical hip replacement surgery whereby the surgeon first removes the compromised or diseased tissue and cartilage from the hip joint and replaces the head of the femur and the acetabulum with artificial components to promote natural articulation of the hip.

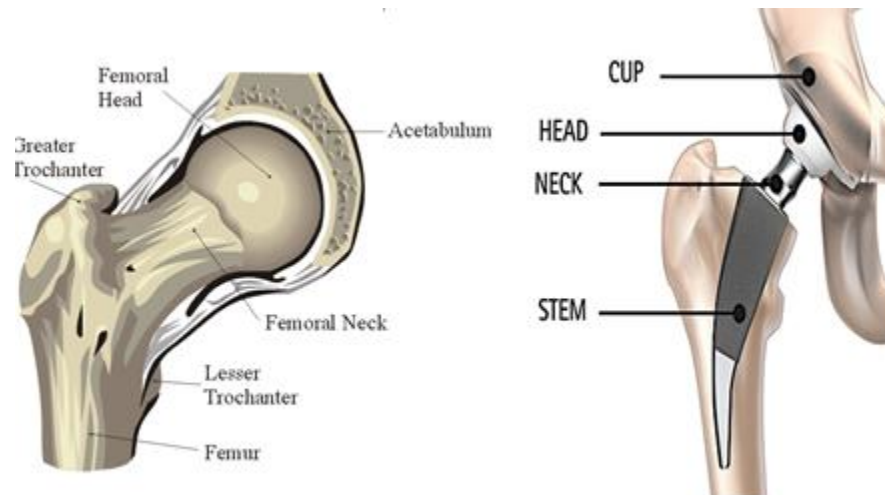


Figure 1: Hip Replacement; (Anterior Femur, 2000; Takano, Junji 2014. Retrieved from, <http://www.pyroenergen.com/articles12/hip-joint-pain.htm>)

Because human femora vary dimensionally, it is difficult to achieve a proper fit utilizing current implants, and they may therefore be subject to early revision. While the primary arthroplasty

has proven to be highly successful, many of these replacements will require premature revision surgeries as a result of both aseptic and septic failure (Boettner et al., 2011). Nearly 6.5% of all primary THAs will require revision surgery within five years of the procedure, which nearly doubles after ten years (Labek et al., 2011).

Provided the increase in the number of THAs performed annually in the United States, the number of complications necessitating revision surgery also increases (Aggarwal, Rasouli & Parvizi, 2013). The three most common reasons for implant failure after THA are instability or dislocation (22.5%), mechanical loosening (19.7%), and infection (14.8%) (Boettner et al., 2011). Unfortunately, with the increased need for hip replacement surgeries, researchers estimate that by 2030, the rate of revision THAs will exceed 90,000 annual procedures (Kurtz et al., 2009). This indicates that in the near future, over 13,000 revision procedures may be performed to counteract the presence of septic, infected hip implants, thereby necessitating the availability of viable treatment options.

2.2 Septic Hip Revision Surgery

2.2.1 Causes and Risk Factors of Hip Implant Failure Due to Infection

Kurtz et al. (2009) report that at the time of the study, it could be projected that by 2010, over 45,000 revision THAs would have been performed in the United States. In accordance with Kurtz et al. (2009) and Boettner et al. (2011), it is estimated that nearly 7,000 revision hip arthroplasties are performed annually as a result of implant infection. Deep prosthetic infections following THA are often difficult to treat because they may occur at the superficial incision or deep around the joint prosthesis (AAOS, 2011). Even a minute quantity of bacteria can create a permanent device-associated biofilm, which would prevent the body's immune system from fighting the infection at the implant site (Zimmerli, 2006). As a result of such, a patient could experience many adverse effects related to implant infection, which include serious morbidity, indicating severe

pain, loss of joint function, and implant failure, and sometimes even mortality (Berendt & McLardy-Smith, 1999).

2.2.2 Treatment Methods

Upon detection of an infected implant, it is vital to intervene. If an infected implant is left untreated the bacteria can proliferate and become a systemic problem in the body. When bacteria attach to an implant, the immune system can no longer fight it, which is why the implant must be removed (Cluett, 2014). At the tissue-implant interface, the body's immune response is inefficient at clearing the infection due to the biological environment created at the implant surface. Depending on the time taken to detect the infection and its severity, there are a variety of viable treatment options available, including debridement with retention of the implant, one-stage arthroplasty, and two-stage arthroplasty.

Debridement with Retention of the Implant

Debridement with retention of the implant is a surgical procedure for the treatment of infected THAs when the infection has been detected within three weeks of onset (Zimmerli, 2006). As a result, the surgeon will remove the infected tissue surrounding the implant while retaining the prosthesis in the patient's body. The patient is subsequently administered oral antibiotics to aid in treating the infection. Infections that are detected early are more easily treated due to the fact that the bacteria at the implant site have not yet penetrated deep within the tissue, nor have they formed a biofilm layer, whereby the infection would worsen. Although this method is simple and affordable, its success rates are inconsistent depending on how efficiently the surgeon cleans the infected areas (Tintle et al., 2009).

One-Stage Revision Arthroplasty

If a patient presents with an infection existing for more than three weeks, but the surrounding soft tissue is still intact or only slightly compromised, a one-stage revision surgery may be the most viable treatment option. This procedure entails the removal of the prosthesis and the

implantation of the same one in the same surgical procedure (Zimmerli, 2006). An advantage of one-stage arthroplasties is that the patient is exposed to a lower perioperative risk. Additionally, one-stage revision arthroplasties incur less of a financial burden, in that resources are preserved and a new prosthesis is not necessary. However, this treatment method is not frequently utilized because there is often an associated fear of recurring infections due to re-implantation (Senthi et al., 2011). Despite this fear, the success rate of this procedure has been reported to range from as 81.9%-100% (Zimmerli, 2006; Aggarwal, Rosouli & Parvizi, 2013).

Two-Stage Revision Arthroplasty

If the infection is detected after three weeks post-onset, a surgeon may choose to perform a two-stage revision arthroplasty to treat the infection (Ellenrieder et al., 2011). This procedure is preferred by surgeons among the various treatment methods and is considered the gold standard for the surgical management of infected THAs (Senthi et al., 2011) since surgeons have utilized it for more than four decades (Aggarwal, Rasouli & Parivizi, 2013).

Unlike the one-stage arthroplasty whereby the primary implant is removed and a new implant is inserted into the body in the same procedure, a two-stage arthroplasty requires that the primary implant is removed and an antibiotic-loaded cement spacer is inserted into the femoral canal in the first stage of the procedure. If the implant were to be removed without reinserting a temporary spacer, the presence of the opposing muscular tensions would act to pull the femur superiorly to its normal position in the body. The spacer simply acts to maintain limb position and length; the antibiotic loaded cement mantle surrounding the temporary spacer acts primarily to ensure the temporary component does not introduce new infection to the implant site, which would further compound the problem. The patient will be administered intravenous antibiotics once the primary implant is removed to clear the primary infection. A second procedure is performed at a later date, during which the spacer is removed and a new prosthesis is implanted.

The first stage of the procedure entails removing all foreign material. A surgical instrument, referred to as a broach, illustrated in *Figure 2a*, is used to debride the infected tissue and clear the medullary canal of any residual material from the primary implant, while also creating space for the temporary component to be inserted (Aggarwal, Rasouli & Parivizi, 2013). The temporary component, referred to as a spacer, seen in *Figure 2d*, is formed by injecting antibiotic-loaded bone cement into a mold and allowing it to cure (*Figure 2b & c*) before being implanted into the femoral canal. On average, the cement spacer will remain in the body for 4-8 weeks; during this time, the patient also receives intravenous and oral antibiotics to treat the residual infection. As described earlier, due to the high variability of human femora and the importance of prosthesis fit to effectively retain the component, it is vital that both the broaches and the temporary components are available in a variety of sizes to best accommodate the differing dimensions (Noble et al., 1988).

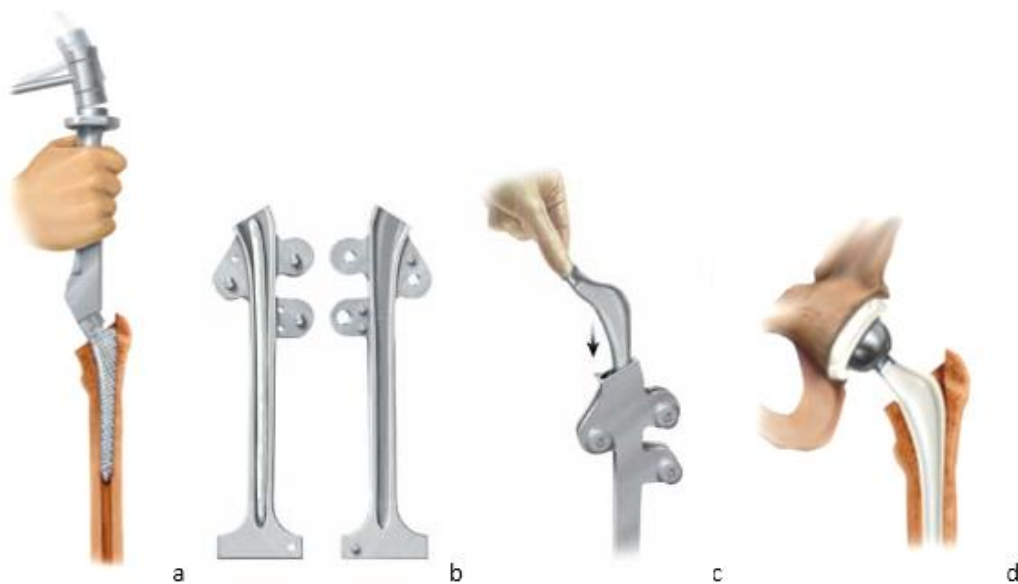


Figure 2: Broach (a), Mold (b), Stem insertion into mold (c), Temporary antibiotic loaded cement spacer (d); (Prostalac Hip System – Surgical Technique, 2010. Retrieved from, <http://gsortho.org/>)

In the second stage of a two-stage arthroplasty, the cement spacer is removed and a new prosthesis is inserted into the femoral canal (Aggarwal, Rasouli & Parivizi, 2013). Although a two-stage arthroplasty is considered the gold standard for treating infected THAs, discrepancies remain

regarding the correct timing for administering antibiotics, the appropriate use of the articulating spacers, and the correct time period prior to re-implantation (Senthil, Munro & Pitto, 2011; Aggarwal, Rosouli & Parivizi, 2013). Despite this, two-stage revision arthroplasties generally have a success rate that exceeds 90% (Zimmerli, 2006; Senthil, Munro & Pitto, 2011).

2.2.3 Current Products

There are several products currently on the market for the treatment of infected THAs. The two main categories of the current revision products are articulating and static temporary spacers. An articulating spacer is comprised of a separate head and stem component, while a static spacer is a single module that incorporates both the head and stem into the same component. Studies have shown that the use of articulating spacers in the first stage of a two-stage arthroplasty is more suited for maintaining soft tissue tension, meaning that the tissues surrounding the spacer are more able to maintain their structural and physiologic integrity (Bloomfield, M. R., Klika, A. K., & Barsoum, W. K., 2010). Articulating spacers have also been shown to allow an increase in the joint's range of motion when compared with static spacers, which allows for faster recovery times following the re-implantation of the new prosthesis. Depending on the patient's needs however, a static spacer may be preferred; due to the fewer number of components needed with static spacers, the increased ease-of-use and decreased time spent in surgery may be preferred (Chalmers, 2011).

TECRES Temporary Spacer

There are a variety of static revision systems available for surgeons to use in the treatment of infected hip implants. The TECRES Temporary Spacer, seen in *Figure 3*, is a static spacer, created for partial load bearing by the patient following implantation. The spacer is composed of a stainless steel core stem coated in PMMA bone cement that has been loaded with gentamicin or vancomycin. This system has three varying head sizes and two stem lengths in an effort to accommodate multiple existing, primary hip stem sizes. Like the other spacers discussed, the TECRES Temporary Spacer also maintains joint space and mobilization of the patient after surgery and has an effective release of

antibiotics to fight infection. However, because it is a static spacer, it only allows for deambulated, partial weight bearing because the spacer itself is not approved for the mechanical stresses of full load-bearing activities. This kit also does not provide specific broaches to match the dimensions of the spacer given. This could cause difficulties during surgery because if the stem does not match the broach size then the hip implant may fail as a result of improper fit, or not being long enough to attach to healthy, uninfected bone. The limited number of sizes available for the spacers also prompts concern since it is important that the spacer be an appropriate size for the patient's anatomical dimensions to ensure proper implant fit (TECRES, 2007).



Figure 3: TECRES Temporary Spacer is a good option due to the stainless steel core being pre-coated in PMMA bone cement; (TECRES, 2007. Retrieved from, <http://www.tecres.it/>)

InterSpace Hip

Like the TECRES Temporary Spacer, the InterSpace Hip, illustrated in *Figure 4*, is a partial load bearing, static spacer. It too, is composed of a stainless steel reinforcing core and coated in PMMA bone cement that has been loaded with gentamicin or vancomycin. Unlike the TECRES spacer though, the InterSpace Hip has six different stem sizes, which allow for greater

customizability and fit within a wider range of patient demographics. One additional advantage is that the InterSpace Hip is designed to have an increased surface area, and therefore a greater biological interface, allowing for greater antimicrobial activity than other treatment options (InterSpace Hip Operative Technique, 2011).



Figure 4: InterSpace Hip is very similar to the TECRES Temporary Spacer but offers a greater surface area for implant to tissue interaction; (InterSpace Hip Operative Technique, 2011. Retrieved from, <http://www.exac.com/>)

Biomet StageOne Select

Another product currently being used in two-stage revision arthroplasties is the Biomet StageOne Select, seen in *Figure 5*, which uses multiple components to create an articulating temporary implant. It consists of four different stem sizes that coincide with the variety of broaches that Biomet already produces. These broaches are not specific to the revision procedure, and they are not provided with the revision kit. The absence of the broaches could add difficulties when aiming to ensure that all components are available at the time of surgery. The kit does, however, provide a variety of medical grade silicone molds already equipped with reinforced stainless steel stems. PMMA bone cement is injected into the medical grade silicone mold and allowed to cure before the silicone is removed, and the cured spacer is implanted into the body. Upon injection of

the bone cement into the mold, the surgeon must take profound care to ensure that air pockets or other imperfections are not introduced into the spacer as this could severely compromise the structural integrity of the spacer. Unfortunately, the StageOne Select is also brand-specific, in that the molds are only fit to accommodate specific Biomet reinforcing, revision stems, and therefore, this kit may not be useful to a surgeon using another company's products. Despite these shortcomings though, the Biomet StageOne Select system is a single-use device and is disposed of following each revision procedure, thereby reducing the risk of cross contamination and decreasing operating costs of using the device (StageOne Select – Hip Cement Spacer Molds, 2013).



Figure 5: Biomet StageOne Select offers a unique mold system which PMMA is injected to perfectly fit the stem; (StageOne Select – Hip Cement Spacer Molds, 2013. Retrieved from, <http://www.biomet.fi/>)

DePuy Prostalac Hip System

The DePuy Prostalac Hip System (*Figure 6*) is a surgical kit used for creating an articulating hip spacer and is considered the gold standard for two-stage revision arthroplasties. This system consists of both broaches and molds, which are used to clear and prepare the femoral canal and to form the antibiotic-loaded bone cement spacer, respectively. The Prostalac Hip System contains a set of broaches, constructed from a medical grade metallic alloy, that are available in four sizes to ensure a more appropriate fit for the temporary component. This size is determined based on the size of the patient's previous hip implant. Molds are also provided in the kit and are made of a reusable, sterilizable, metal alloy. Inserts are additionally provided for the mold to allow for the temporary implant to be formed into four different sizes so the spacer created fits the dimensions

broached into the femoral canal. Antibiotic-loaded, PMMA bone cement is then loaded into the mold, and a pre-fabricated, custom DePuy revision femoral stem is inserted into the bone cement and allowed to cure before being placed into the body. The use of the Prostalac Hip System has proven advantageous in that it allows for early weight bearing, and because it provides an articulating system, the functional movement of the hip is retained (Scharfenberger, Clark, Lavoie, O'Connor, Masson & Beaupre, 2007). Researchers have further estimated that the Prostalac Hip System has an 89-96% success rate assuming that the surgeon follows protocol (Biring et al., 2009). While the Prostalac Hip System is known to be highly successful, it also bears a variety of disadvantages and places in which improvements can be made. As previously stated, the Prostalac Hip System is manufactured by DePuy, and therefore, it is only compatible with the other DePuy products and the reinforcing stems provided in the kit. The Prostalac Hip System is produced to be a reusable medical device, meaning that in between subsequent procedures, each component within the kit must be sterilized. If sterilization procedures are not then properly executed, contamination and introduction of foreign tissues between patients may occur and could impart detrimental health complications (Rutala & Weber, 2004). Additionally, the kit is expensive, meaning that most hospitals are not able to actively stock this kit as a readily available medical device. Because of this, hospitals often times have limited access to the kit, meaning that if a patient presents with an infected implant and requires revision surgery, they may need to wait for the hospital to acquire the kit, leading to pain and discomfort for the patient (Prostalac Hip System – Surgical Technique, 2010).

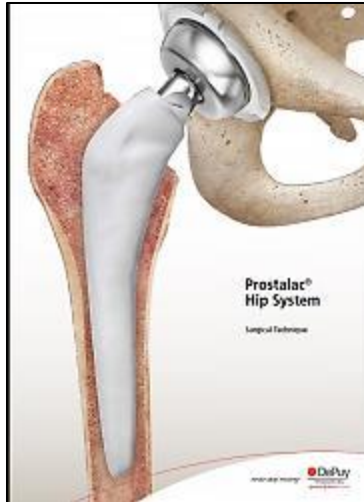



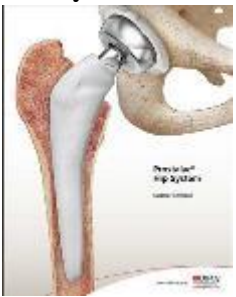


Figure 6: DePuy Prostalac Hip System is one of the most effective revision hip replacement surgeries with a success rate of 89-96%; (Prostalac Hip System – Surgical Technique, 2010. Retrieved from, <http://gsortho.org/>)

Table 1: Comparison of current products for treatment of infected hip arthroplasties and the pros and cons of each

Current Procedures	Pros	Cons
<p>Tecres Temporary Spacer</p> 	<ol style="list-style-type: none"> 1. Ease-of-use 2. Efficient 	<ol style="list-style-type: none"> 1. Partial Weight Bearing 2. Number of sizes limited 3. Non-specific broaches
<p>InterSpace Hip</p> 	<ol style="list-style-type: none"> 1. Six different stem sizes 2. Designed for greater surface area 	<ol style="list-style-type: none"> 1. Partial weight bearing 2. Non-specific broaches
<p>Biomet StageOne Select</p> 	<ol style="list-style-type: none"> 1. Provided silicone mold system 2. Single use/disposable 	<ol style="list-style-type: none"> 1. Absence of broaches in kit 2. Brand specific (Only Biomet products)
<p>DePuy Prostalac</p> 	<ol style="list-style-type: none"> 1. Six specific broaches 2. Early weight bearing 3. 89-96% success rate 	<ol style="list-style-type: none"> 1. Only usable with DePuy Products 2. Reusable (Sterilization needed before and after each use) 3. Not easily accessible

2.2.4 Project Need

Based on our research, we identified that there is a need to create a novel surgical system to address the shortcomings of the revision products already available on the market. During personal conversations with Dr. John Wixted, we learned that there exists only one kit to treat infected hip implants in New England. This leads to further pain endured by the patient if two hospitals need to perform a two-stage arthroplasty on the same date, or if the surgeon detects the infection while performing surgery for what he/she thinks is a mechanical failure. Additionally, this kit contains materials and components that are specific to the DePuy brand of hip replacements. Since the kit contains components such as hip stems that are only compatible with the Prostalac Hip System, the price of the kit is driven up. Although the surgeon may only lease the kit for 1-2 days at a time, the hospital must pay a total of \$5,400+ in order to use the hip stem, acetabular cup, and head included in the kit for the revision surgery. Further, before each use, this kit must be sterilized which can lead to a variety of shortcomings previously outlined. Due to these shortcomings, we aim to produce a kit that will increase the accessibility of septic revision kits to surgeons, will be adaptable to various companies' components which are already available to surgeons in-house, and will be comprised of disposable components to eliminate the need for subsequent sterilization processes.

Chapter 3: Project Strategy

The primary goal of our project is to produce a kit to facilitate orthopedic surgeons in performing two-stage revision hip arthroplasties. The purpose of this chapter is to explain the process by which our objectives and constraints were devised and the initial client statement was revised to meet our objectives and constraints.

3.1 Initial Client Statement

The initial client statement that was provided by Dr. John Wixted is summarized below. Based on this statement and the information provided, we devised a list of objectives and constraints to guide the direction of our project.

“When joint replacements become infected, the standard of care is to use an antibiotic impregnated cement coated implant. We envision a kit for broaching the femoral canal and molding the cement around any existing implant. This will provide an off the shelf, disposable solution to an increasingly common problem.

Joint replacement surgeries and revision arthroplasty are increasingly common. At least 1 in 200 of these becomes infected, requiring removal and treatment with antibiotics. Temporary components, covered with antibiotic impregnated cement, are used as spacers prior to reimplanting a new component.

However, most hospitals do not stock the equipment to easily mold the cement around a prosthesis, nor do they have broaches to match the molds. This generally requires making arrangement with a manufacturer to bring this equipment to the hospital, and can result in delays in care and difficulty scheduling surgery for what are frequently unanticipated infections.

Providing a disposable, one time use kit which contains the necessary equipment to make such a temporary component would greatly simplify this process. The kit should contain disposable broaches and a simple mold system for creating these temporary prostheses. Most hospitals readily stock standard prostheses, and any implant small enough to fit into the mold would work for this purpose. In addition, matching plastic liners are also readily stocked by hospitals, making the process of dealing with infected joint replacement patients far easier.

A simple, one time use, disposable kit would facilitate surgical management of infected joint arthroplasties.

Any hospital which performs joint arthroplasty must be prepared to deal with prosthetic infections. An off the shelf solution is much more preferable for the surgeon and the hospital than having to make arrangement for specialized instrumentation to be brought into the hospital for infrequent use.”

3.2 Objectives and Constraints

3.2.1 Objectives

Having analyzed the initial client statement, our team generated an objectives tree, shown in *Figure 7*, as a means to illustrate our project goals and objectives. We concluded that the components

of the kits must be accessible, accurate, reliable, universal, user-friendly, disposable, marketable, and manufacturable.

Our project must be accessible to the orthopedic surgeon for immediate use in the operating room. Since there is only one kit for the surgical management of a two-stage revision arthroplasty in New England, it is oftentimes double-booked, in which case one of the surgeon's patients must wait and resultantly endure further physical and mental pain. Also, if the surgeon had begun to perform a revision arthroplasty due to possible mechanical failure and he realized that the implant site had become infected, then it is crucial that he have the necessary equipment accessible to him almost immediately in order to perform the two-stage revision arthroplasty.

The surgical instruments comprising the kit must be accurate and reliable. Regarding the project scope, the accuracy of the system refers to how closely the space broached in the femoral canal matches its predefined dimensions; additionally, it refers to how effectively the mold system forms the antibiotic-loaded cement spacer and accounts for a press fit into the femoral canal. With respect to the reliability of the broach and mold system, we must consider the strength and durability of the kit's components. The mold system, for example, must retain its structural integrity and shape upon injection of the bone cement and therefore must be strong and durable. To ensure the broach can withstand the force exerted by the orthopedic surgeon without deforming or fracturing following several strikes of the mallet, its durability must remain constant for the length of the procedure.

The kit must also be universal, meaning that the broaches and mold system must accommodate the variety of hip stems that are on the market. Currently, the kits that are used in two-stage revision hip arthroplasties are brand-specific. The kit by DePuy, for example, only accommodates the reinforcing stem manufactured by DePuy. For the purpose of our project, we

would like our kit to be compatible with BioMet, DePuy, Stryker, and Zimmer stems since these stems are the most readily used and stocked by UMMC.

Further, we aim for our kit to be composed of disposable components. Currently, the kit used by UMMC is the DePuy Prostalac Hip System, which consists of non-disposable broaches and molds. Therefore, the components of the Prostalac Hip System must undergo sterilization following each revision procedure. Unfortunately, if sterilization procedures are not performed properly, foreign material left behind from the prior procedure could be introduced to a patient receiving a revision when performing a subsequent procedure. This could lead to detrimental health complications for the patient undergoing the revision procedure. Additionally, the need for sterilization imparts an additional expense to the cost of use for the kit, further necessitating the disposability of our kit. By ensuring that our kit is disposable, its ease of use is enhanced and the overall cost of the procedure can be decreased. In order for our kit to be disposable, the materials chosen for the surgical instruments and their manufacturing processes must be inexpensive relative to the current cost of using the Prostalac Hip System.

The marketability of our kit is an important factor to consider in order to distinguish our product from the kits already on the market to convince consumers of the advantages of our product. Key components that separate our kit from those currently on the market are that it is, accessible, disposable, inexpensive, and universal. The current gold standard, the Prostalac Hip System, is expensive to manufacture and use. Because UMMC is required to bring in the system upon scheduling a septic revision procedure and then sterilize the kit after each use, it can impart a significant financial burden on the hospital. Currently, there is only one Prostalac Hip System in New England, which makes the increased accessibility of our kit appealing to the consumer. The goal of our project is to design a kit that is both disposable and inexpensive such that it can be readily stocked in hospitals for immediate use. Since our kit will be disposable, the materials that

comprise the broaches and molds must be inexpensive to ensure our kit costs less than the current cost of bringing in the Prostalac Hip System. Lastly, the universality of the kit will appeal to a number of orthopedic surgeons because they can use the variety of stem brands stocked on their shelves as opposed to purchasing the higher cost reinforcing stem provided in the kit by DePuy.

Depending on the materials we choose for the broaches and molds, the manufacturing method of the kit may vary. For example, a certain material may be better suited for 3-D printing whereas another may be more easily manufactured by means of injection molding. We would like for our kit to consist of fewer components than the Prostalac Hip System, meaning that there are fewer detachable or moving parts, to increase its ease of use, simplify its manufacturing, and augment its reproducibility. Additionally, to identify which objectives were most important to our client, Dr. Wixted, we provided him with a pairwise comparison chart, and he ranked the objectives by importance. This chart can be seen in *Table 2*. *Table 3* shows the order of importance our client assigned to each objective. Further, *Tables 4-7* illustrate rankings of our sub-objectives to assist us in assessing the success of our final product.

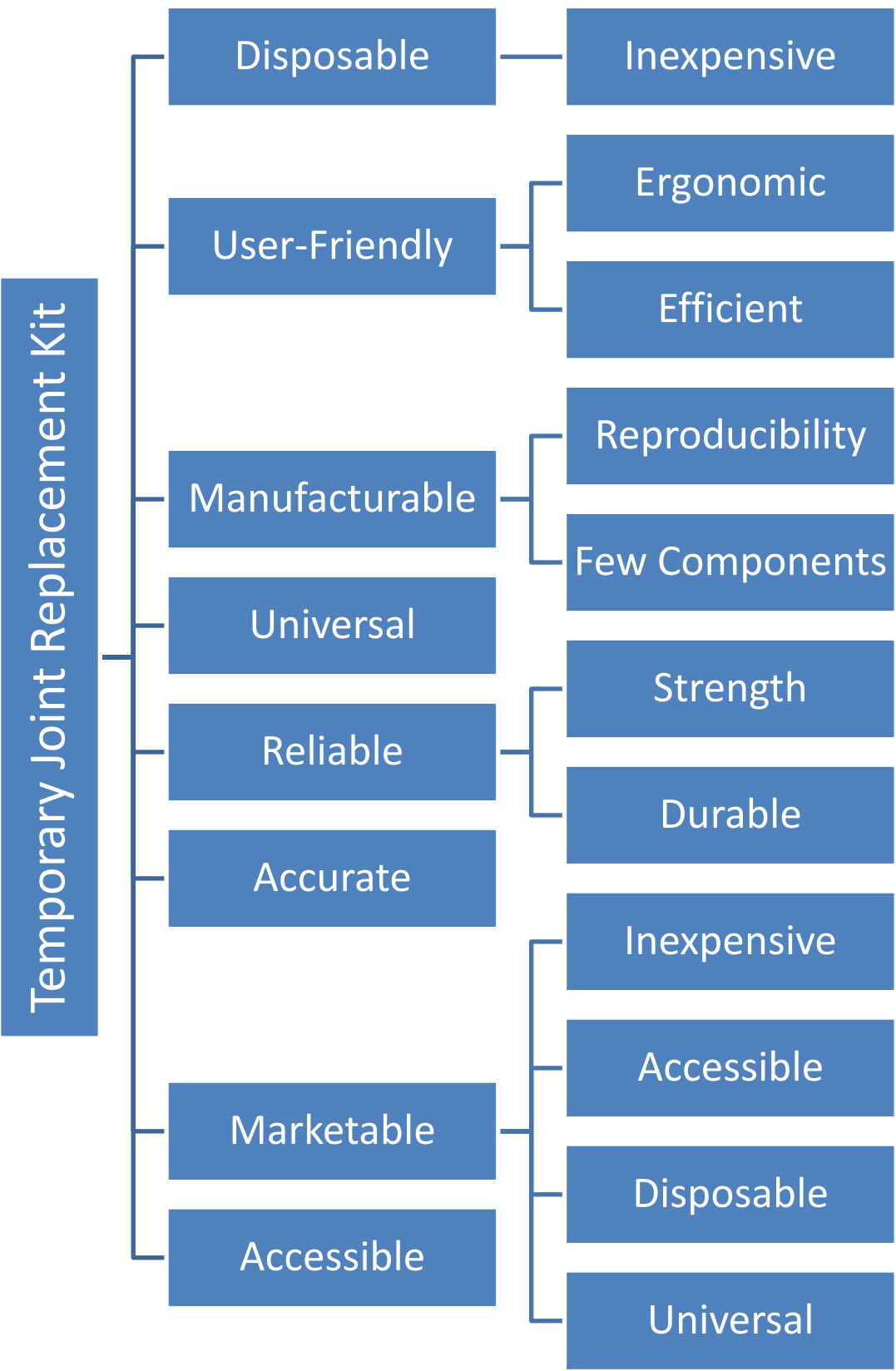


Figure 7: Objectives Tree

Table 2: Pairwise Comparison Chart

Objectives	Disposable	User-Friendly	Manufacturability	Universal	Reliability	Accuracy	Marketability	Accessible	Scores
Disposable	0.5	0	0	0	0	0	0	0	2.5
User-Friendly	0.5	1	0	0	0	0	0	1	2.5
Manufacturability	0	0	1	0	0	0	0	0	0
Universal	0.5	1	1	1	0	0	1	0.5	4
Reliability	1	1	1	1	0.5	0.5	0.5	1	6
Accuracy	1	1	1	1	0.5	1	1	1	6.5
Marketability	0.5	0	1	0	0.5	0	0	0	2
Accessible	1	1	1	0.5	0	0	1	1	4.5

Table 3: Ranked Objectives

Objective	Scores
1. Accuracy	6.5
2. Reliability	6
3. Accessible	4.5
4. Universal	4
5. User-Friendly	2.5
6. Disposable	2.5
7. Marketability	2
8. Manufacturability	0

Ranked Secondary Objectives

Table 4: Ranked Secondary Objectives for Reliability

Reliability	Durable	Strength	Scores
Durable	1	0	1
Strength	0	1	0

Table 5: Ranked Secondary Objectives for User-Friendly

User - Friendly	Ergonomics	Efficient	Scores
Ergonomics	1	0	1
Efficient	0	1	0

Table 6: Ranked Secondary Objectives for Marketability

Marketability					
	Inexpensive	Accessible	Disposable	Universal	Scores
Inexpensive		1	0	0	1
Accessible	0		0	0	0
Disposable	1	1		0	2
Universal	1	1	1		3

Table 7: Ranked Secondary Objectives for Manufacturability

Manufacturability			
	Reproducibility	Few Components	Scores
Reproducibility			1
Few Components	0		0

3.2.2 Constraints

The following constraints limit the design space in that we are required to abide by them for our project to be deemed successful. Our kit therefore:

- Must be biocompatible for implantation in the human body
- Must be sterilizable over time without negatively affecting its initial mechanical and chemical properties
- Must cost less than the DePuy Prostalac Hip System
- Must be completed within one academic year
- Must remain within the allotted MQP budget (\$1,624)

Because of the health risks associated with materials for implantation, we must ensure that our kit does not elicit a biological response within the body to guarantee patient safety. With this in mind, we must also be cognizant of the sterilizability of the materials in question. Just prior to use in the operating room, all components of the kit will have to be sterilized; for this reason, we must

ensure that the method of sterilization does not induce an adverse mechanical or chemical response in the materials we choose for the broaches and molds. If we were to utilize steam sterilization for the purpose of sterilizing the kit, for example, we would carefully select highly heat resistant materials for the broaches and molds.

Having devised our objectives and constraints, we revised the initial client statement such that it consolidated our project aims and goals.

3.3 Revised Client Statement

After further analyzing the initial client statement and speaking with Dr. Wixted, a revised client statement was devised to accurately depict his needs and wants and to explicitly state his expectations for the project:

“Design a low-cost, easy-to-use kit to facilitate the surgical management of infected joint replacement surgeries and revision arthroplasties. The kit must be accessible to the surgeon for immediate use in the operating room, appropriate for single-use applications, and capable of accommodating a variety of commonly used brands and sizes of hip implants. The kit must be designed such that either the equipment necessary for broaching the femoral canal is provided, or the molding system must allow surgeons to use broaches already in stock in the hospital to form the temporary antibiotic-loaded cement spacer.”

3.4 Project Approach

We devised a list of specific aims in order to direct our efforts in accordance with the objectives set forth by our revised client statement. Our preliminary aims were:

- To select a material for the broach that can cut through the cancellous bone of the femur without failure.
- To select a material for the mold that would not adhere to the bone cement or leave behind a residue on the mold-PMMA interface.
- To devise a set of dimensions for a variety of sizes of matching broaches and molds such that their dimensions could accommodate for the aforementioned prosthesis brands.

To achieve these specific aims, we propose a method in which we will perform extensive material research to determine, for the purpose of producing a broach, what materials exist that have the capacity to cut through cancellous bone, and offer a reduced material cost when compared to stainless steel. Utilizing mechanical testing such as Instron impact tests, we can determine the efficacy of this design and failure mechanisms to address.

Further, we must research materials that display non-adhesive properties to be used for the construction of a mold system. Following document research, we can then test adhesive properties through visual analysis of a cement component formed within the given mold material.

We can then obtain information relating to the dimensions of existing hip stems to ensure that our kit can accommodate for a variety of different hip stem dimensions that exist on the current market.

A variety of mechanical testing to prove structural integrity and safety, such as the aforementioned Instron impact testing, will be performed to illustrate the safety of this product. Further biocompatibility testing will be performed such as direct contact cell culture and live/dead staining to prove the materials being used will not elicit any unwanted biological response. Lastly, financial analysis will be done to show this system is more cost effective than current systems as well.

Chapter 4: Alternative Designs

Based off of our objectives and constraints, several design alternatives were created to meet our client's need. The first design alternative included creating a full set of disposable broaches and molds that had dimensions to accommodate for a number of prostheses brands. Our second design alternative included making a set of molds that had dimensions to accommodate for a number of prostheses brands, allowing the surgeon to use the broaches he/she has on shelf. Our third design alternative included making customizable molds by utilizing 3-D scanning technologies to create molds with the exact dimensions of those hip stems and broaches already on a surgeon's shelf.

4.1 Disposable Broaches and Molds

4.1.1 Design 1: Broach with Detachable Handle

First, we considered a design, shown in *Figure 8*, for which the handle was detachable and interchangeable between a set of varying size femoral broaches.

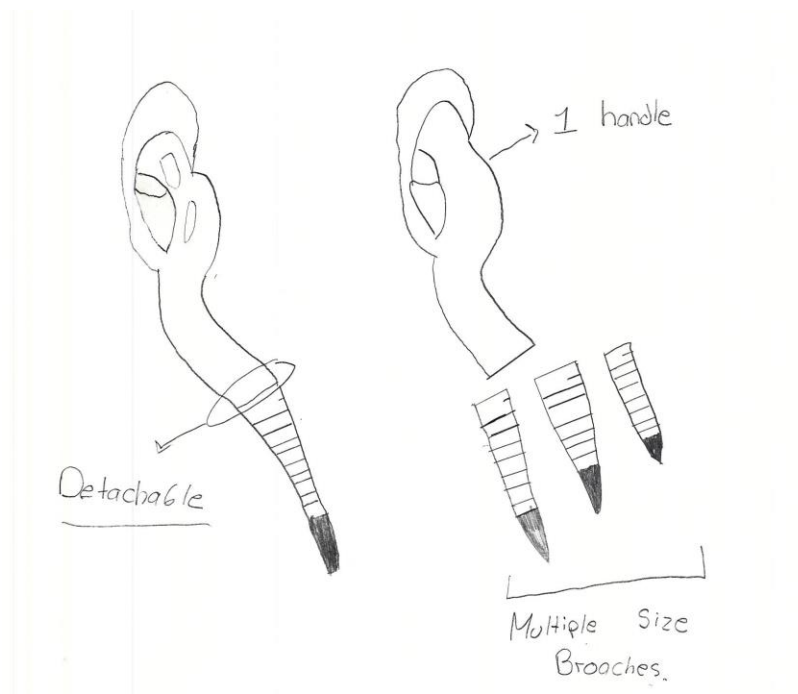


Figure 8: Surgical broach with detachable handle

This design could be advantageous provided that the reusable handle and assorted femoral broach components could significantly reduce the cost of the material of choice since it is less

massive. However, this design would nearly double the number of components that we would include in the kit, which may increase its manufacturing cost and decrease its simplicity and ease of use.

4.1.2 Design 2: Single Component Broach

With respect to the femoral broaching component of our project, our second alternative design entailed a single component, which we had intended to be disposed of postoperatively. Our preliminary broach design was based on the simplest broach design that we had concluded was the most commonly utilized broach by orthopedic surgeons for the purpose of a total hip arthroplasty. Our goal was to reverse engineer the design, shown in *Figure 9*, which entails a single component consisting of a handle welded to the femoral broach.

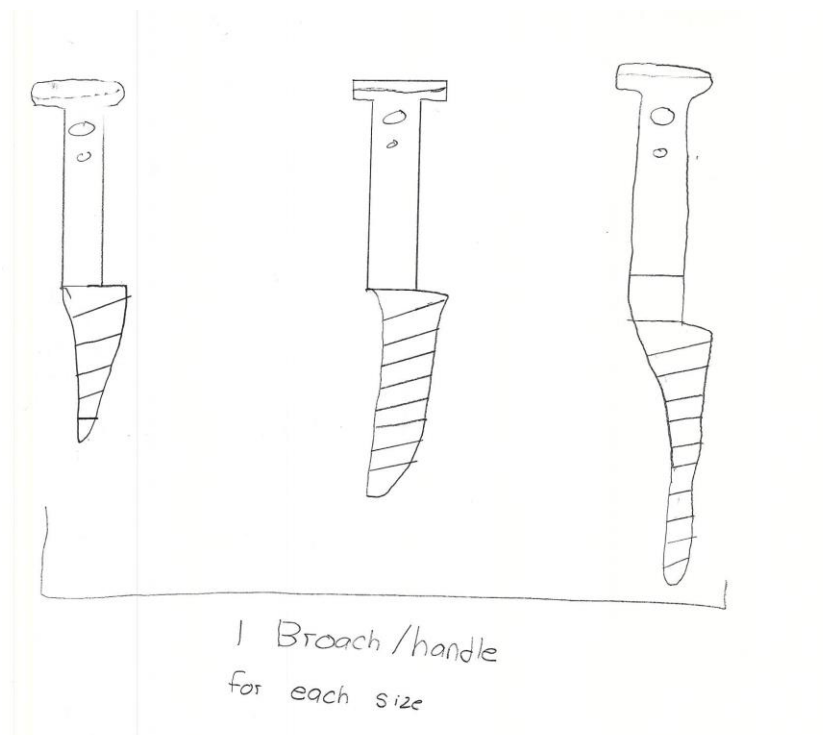


Figure 9: Single component surgical broach

By choosing a plastic that has mechanical properties (i.e., hardness, Young's modulus, compressive strength, and fracture toughness) greater than those of cancellous bone, we intended to produce a set of broaches that were significantly less expensive than the set of broaches

accompanying the DePuy Prostalac Hip System. The aforementioned design is particularly advantageous in that it comprises a single component and is prepared for immediate use by the orthopedic surgeon upon removal from its packaging. Additionally, the set of broaches would be inexpensive such that the surgeon could dispose of them following a two-stage revision arthroplasty. Upon completion of the SolidWorks model of the broach, a model of the mold could then be drafted to ensure that the temporary component formed from the mold would press fit into the broached femoral canal.

4.2 Utilizing Stocked Surgical Broaches

Another design alternative would be to suggest that surgeons utilize the broaches that they already have in stock in their respective hospitals. This would be advantageous in that these broaches have already been approved for surgical procedures. In this iteration, we identified two options. It is important to note that these designs were not conceptualized until after the preliminary testing period when we determined the scope of our design needed to shift.

4.2.1 Design 3: Templates

The first option is to create one set of molds that accommodate for the varying dimensions of a number of prostheses brands. Through dimensional analysis and relation, we would then be able to provide a compatibility chart, carefully depicting which size of which brand of broach would be accommodated for by which mold. This document would be provided in the surgical kit for the orthopedic surgeon to refer to in the midst of the procedure.

4.2.2 Design 4: Customizable Molds

The second option is to create an entirely customizable kit, whereby each orthopedic surgeon could provide a set of the hip stems they utilize for a total hip arthroplasty for analysis. The stems would then undergo 3-D scanning to create a point cloud. This rendering would be converted to a SolidWorks model, and then a 3-D printed negative mold would be created. This negative mold would then be placed in PDMS for 24 hours until the PDMS had cured. The negative mold could

then be removed, and the PDMS mold could be sterilized to allow individualized, customizable molds to be provided, specific to the stems each surgeon uses, thus enabling the surgeon to use the broaches compatible with that given stem size. This option is particularly advantageous in that the orthopedic surgeons would be able to use the same broaches they use in a primary total hip arthroplasty, meaning that they would not have to become accustomed to relying on a new device.

4.3 Initial Chosen Design

Based on comparing the different design alternatives, our team initially decided to move forward with Design 1: Disposable Broaches and Molds, since this design iteration matched most closely with the desires outlined by our client. Since the single component broach was more feasible, we explored designing this iteration.

Because we wanted this design to be disposable, we investigated the option of forming both the broaches and molds out of a polymer material. A patent search was conducted to ensure the novelty of this design option. While existing patents proposed alternative broaching modalities, none were found that explored the use of polymers for the broach material.

Various preliminary testing procedures were carried out to create the broaches and molds, determine viable material selection, and determine whether or not this option could be a more cost effective method than that already put forth by the Prostalac system. We originally decided to pursue the option of generating SolidWorks models (*Figure 11*) for a set of customizable broaches because our initial client statement stated that our kit must contain a set of broaches and molds. Because we were unaware of other resources that existed at the time we chose this option, we continued the processes of dimensional rendering, and SolidWorks modeling. Using existing templates that outlined the dimensions of stems manufactured by Smith & Nephew, Biomet, and Stryker (shown in *Figure 10*), we were able to determine appropriate dimensions that would accommodate for a variety of different stems already available on the market. However, after using these dimensions and

spending several weeks drafting the model of the broach in SolidWorks that manually modeling the broach in SolidWorks may be unfeasible given our constraints. Of even greater concern was our discovery of the price it would cost to manufacture the broaches even with a viable SolidWorks model. We learned that our design would have to be outsourced to an external company to ensure the proper dimensions and details of our design which would ultimately make our design even more expensive than the use of the current kit.

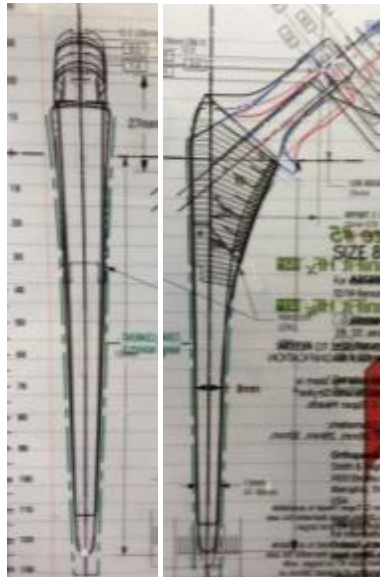


Figure 10: Surgical template overlays used for determination of dimensions

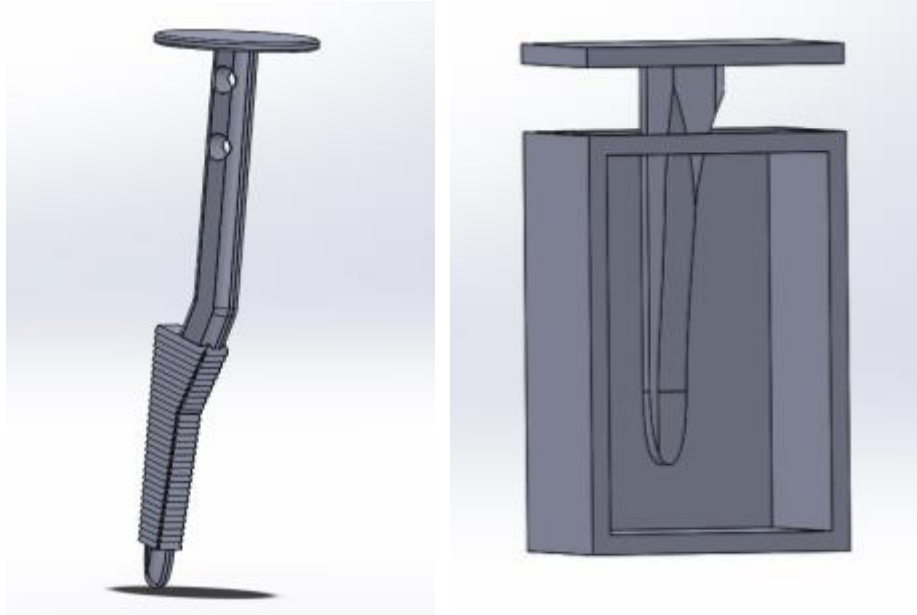


Figure 11: 3-D SolidWorks model of initial broach and mold design

Further validating that our device would be unfeasible to pursue in this manner, we obtained rods of various polymers into which we manually cut different teeth orientations. These test broaches were then used to attempt to cut through wooden dowels and both cancellous and cortical bone (shown in *Figures 12 and 13*). Although the mechanical properties of these polymers were higher than that of cancellous bone, we did not consider that the surgeon would have to cut through some cortical bone during the surgery. Therefore, it is logical that the rods tested could not cut through the porcine femur. We determined that the mechanical properties of the polymers that we had chosen for the broaches are not sufficient enough for the purpose of effectively broaching the femoral canal.



Figure 12: ABS teeth and result of sawing wooden dowel with this instrument



Figure 13: Porcine femur cut with ABS teeth (negligible damage to cortical bone)

Due to these shortcomings, new methods and considerations had to be devised. The procedure we followed to come to this conclusion can be found in *Appendix A*. We reconsidered our design alternatives, which would allow surgeons to utilize surgical instruments already in stock in the hospital, and compared this to this initial chosen design.

4.4 Conceptual Final Design

Our three design alternatives were evaluated primarily on surgical practicality, brand specificity, and cost to devise a conceptual final design as seen in *Tables 8-10*.

4.4.1 Surgical Practicality

Table 8: Ranked designs based on surgical practicality with 1 being the best option

Design	Rank
Injection Mold Broach	3
Compatibility Chart	2
Custom Molds	1

The kit that provides the compatibility chart and the entirely customizable kit are more surgically practical than the injection mold broach. Orthopedic surgeons are already accustomed to using specific instruments and may be apprehensive about utilizing an instrument that may perhaps be made of a material they have not previously worked with. Additionally, the broaches used for total hip arthroplasties have already been proven effective for broaching the femoral canal, thus making the implementation of either option more likely. Ultimately, the customizable kit was ranked with the highest surgical practicality because, having spoken with orthopedic surgeons at UMMC, we realized that many prefer a specific prosthesis brand and model; the customizable kit would allow the surgeons to continue to use their preferred broaches and hip stems that they have sworn by for years.

4.4.2 Brand Specificity

Table 9: Ranked designs based on brand specificity with 1 being the best option

Design	Rank
Injection Mold Broach	2.5
Compatibility Chart	2.5
Customizable Kit	1

The customizable kit is undoubtedly the most brand-specific in that a mold can be tailored to any brand and model of broach that a surgeon may wish to use. Both the injection mold broach and the kit that provides the compatibility chart are simply designs we based on a compilation of select broach or hip stem designs and dimensions. In doing so, we did not account for all brands and models of broaches and hip stems, which would likely result in a mismatch between the dimensions of the broach and those of the temporary component. A customizable kit would suggest that truly every prosthesis brand could be accommodated for to ensure that the temporary component that is formed matches the dimensions of the femoral canal into which it would be introduced shortly after broaching.

4.4.3 Cost

Table 10: Ranked designs based on cost with 1 being the best option

Design	Rank
Injection Mold Broach	3
Compatibility Chart	1
Customizable Kit	2

The kit providing the compatibility chart would undoubtedly cost the least to manufacture. The most predominant cost would be that of the 3-D printed molds and a laminated copy of the

compatibility document for surgeons to refer to during the procedure. The customizable kit would be more expensive because not only would the rendered hip stems have to be 3-D printed, but the hospital would also incur a cost for having their specific prostheses molds customized. The injection molded broach would likely be the most expensive on account of the costs associated with injection molding and the fact that the kit would comprise both broaches and molds. Since our kit is intended to be disposable, it is important to bear in mind all associated costs that may make an alternative design unfeasible.

4.5 Chosen Design

Based on careful analysis, we were able to choose our final design. On account of its high degree of surgical practicality, customizability, and relatively modest cost, the customizable kit design alternative was selected as our final design. Preliminary testing was conducted in order for us to realize a conceptual final design and to determine the material for the mold system and the accuracy with which the 3-D scanner collects a point cloud and renders a 3-D solid model of the hip stem.

A patent search was again conducted to validate that this design alternative was a novel approach to this problem. Based on a lack of patents addressing this methodology of reverse engineering, we determined that we could pursue this option as no current products were on the market.

4.5.1 Revised Project Approach:

Based on the new direction of our project, we found it vital to create a new list of specific aims more relevant to our new design alternative. We devised a list of specific aims in order to direct our efforts in accordance with the newly focused objectives of the new design alternative. Our revised aims are:

- To create a molding system that allows surgeons the use of their own, stocked surgical equipment.
- To create molds that can be customized to the shape and dimensions of any given hip implant on the market.

- To select a material for the mold that will not adhere to the bone cement or leave behind a residue on the mold-PMMA interface.

To achieve these specific aims, we propose utilizing 3-D scanning technologies to provide a rendering of a solid model that replicates the dimensions of any given implant stem, precisely. We then propose printing this rendering using a 3-D printer. The 3-D printed component would then be used to develop a mold, by curing a molding material around it, with the exact dimensions of the original stem. The space created in the mold material can then be filled with bone cement and a smaller primary stem to aid with structural integrity. As with the initial project approach, direct contact cell culture techniques and live/dead staining can help to prove that this device is as safe as existing products on the market.

Then, utilizing various analytical and statistical analyses, we can prove that our developed design is as efficacious as the existing Prostalac system, while also allowing for the benefits of customizability, greater surgeon accessibility, and a reduced cost.

4.6 Preliminary Experimentation

4.6.1 Efficacy of 3-D Scanning

To determine whether or not 3-D scanning would be an efficacious means of creating a model with the same dimensions of the original hip stem, we obtained a femoral stem from Dr. Wixted to perform some preliminary feasibility tests. The way in which the 3-D scanner works is by a method of laser triangulation measurements during which, a laser line is passed across an object. The laser reflected off of the object is then picked up by a sensor, located at a known angle and distance from the laser source. Based on the angle at which the laser is returned to the sensor, the specific distance between the object and camera can be discerned. Then, trigonometric triangulation allows the software to calculate distances and create a point cloud of data representing the point locations of the edges of the scanned object.

With this in mind, we utilized the 3-D scanning technologies (Konica Minolta Range 7) at the College of the Holy Cross in Worcester, MA, where we obtained several scans of the implant utilizing their Rapidform scanning software. With this software, we were able to roughly determine, using calipers and a measuring function in the Rapidform software, that it appeared that the 3-D rendering of the implant displayed the same dimensions as those of the original implant. We subsequently concluded that this method of rendering a 3-D model would be both feasible and seemingly efficacious while providing a means to produce results that would be able to be replicated for any given hip stem. We concluded that we could proceed with more in-depth testing and data acquisition based off of the preliminary successes of accurate data collection through the use of 3-D scanning.

4.6.2 Determination of Efficacious Mold Material: PDMS

We conducted preliminary adhesive tests to determine whether or not the chosen material for our mold would adhere to materials similar to bone cement. Based on previously conducted research, we determined that polydimethylsiloxane (PDMS); a silicone based elastomer that is used quite regularly in mold-making and known for its non-adhesive properties, can be steam sterilized and is biocompatible. We carried out some preliminary testing to conceptualize whether or not PMMA bone cement would in fact, not adhere to the mold surface if it were made out of PDMS. To do so, we made a solution of PDMS and allowed it to cure in a 60-degree oven overnight. We then mixed the components of an epoxy grout for use as a cost-effective alternative to PMMA bone cement. Small holes were cut out of the PDMS disk, which were subsequently filled with the epoxy grout. Grout was also placed directly on the flat surface of the PDMS and allowed to cure overnight. The following morning, the grout was removed from the PDMS mold; dust left behind by the grout was the only visible residue remaining on the PDMS disc, thus indicating the non-adhesive nature of PDMS. The results are portrayed in *Figure 14*.



Figure 14: PDMS visual adhesive testing proved to be a success since only dust particles remained on the surface

4.7 Moving Forward

With the success of our preliminary experimentation, we confirmed that our third design alternative, customizable molds, would be our final design.

Chapter 5: Final Design & Validation

After several design revisions, we went into the production and validation stage of our final design with the following specific aims:

- To create a molding system that allows surgeons the use of their own, stocked surgical equipment
- To create molds that can be customized to the shape and dimensions of any given hip implant on the market
- To select a material for the mold that will not adhere to the bone cement or leave behind a residue on the mold-PMMA interface

To achieve these specific aims, we propose a method with which 3-D scanning and printing technologies can be used to improve upon the current technologies available for two-stage revision hip arthroplasties. To do so, we utilized the following methods and procedure.

5.1 Image Processing

A hip implant was obtained from Dr. Wixted to begin the testing procedure. Utilizing a Konica Minolta Range 7 3-D scanner, we obtained over fifteen scans of different angles and views of the hip implant in order to construct a viable solid model. Images for this process can be seen in *Figure 15*. The scans are processed as a point cloud, meaning that due to the laser triangulation that occurs in the system, various points in xyz coordinates could be obtained, indicating the surface topography of the implant. The more faces that can be obtained and meshed together, the more accurate the final model will be, as this will produce a greater number of points in the meshed point cloud, thus leading to a more accurate 3-D model. The individual face scans were then stitched together using Rapidform scanning software, assembled in conjunction with the laser camera. This created a complete point cloud representing the entirety of the solid hip implant. This file was then saved as a .rgv file for further processing.

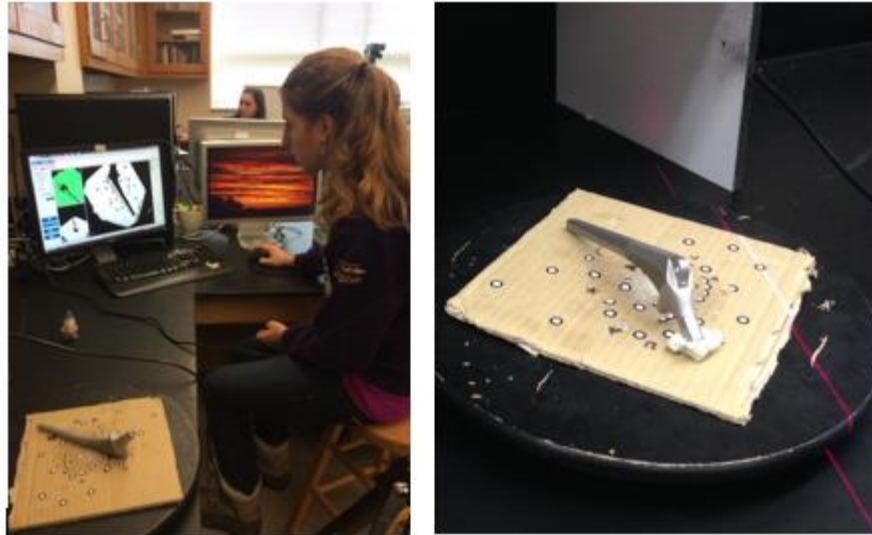


Figure 15: 3-D scanning of femoral stem

The faces comprising the complete point cloud were then uploaded into MeshLab software. Using this software, a variety of different image processing techniques had to be followed. First, the fifteen different point cloud faces were meshed together so that one solid point cloud now existed. Next, the point cloud was processed through a subsampling filter, known as Poisson-disk sampling. The sample number was input as the number of points in the point cloud. Normal reconstruction was then performed; the normals were then computed for the point set; the number of neighbors was set to 20. Next, a surface reconstruction was performed using a Poisson triangulation, in which the octree or recursion level was set to 11 to maintain high resolution. A remeshing, quadratic edge collapse was then used to simplify the component by removing unnecessary triangulations or faces. Next, the object was made manifold, such that the existing faces did not overlap one another. Finally, the hole filling function was used in order to ensure that a solid object was formed. This file was subsequently saved as a .stl file (*Figure 16*). This file could then be read and processed for 3-D printing.

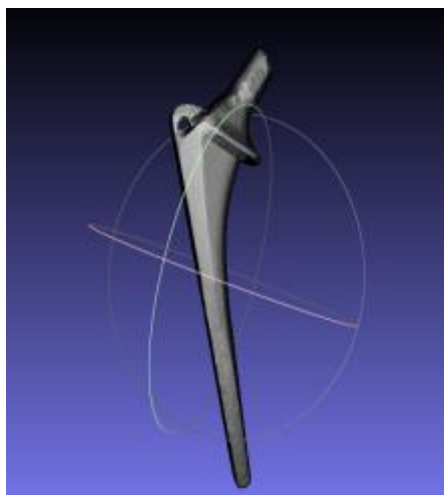


Figure 16: 3-D rendering of hip stem formed through meshing 3-D scans in MeshLab

5.2 3-D Printed Model

The .stl file was then used to 3-D print a negative mold to be used for the formation of the PDMS mold with dimensions exactly that of the original hip stem. This is seen below in *Figure 17*. It is important to note that 3-D printing the stem rather than simply curing a PDMS mold around a normal, metal hip implant is of vital importance to the overall cost effectiveness and potential surgeon satisfaction. Simply using a primary stem directly, around which to cure PDMS would incur much higher costs in that in order for the system to accommodate all existing hip stems, we would need to obtain a set of all the primary stems on the market, which is financially unfeasible; even if a surgeon were to provide the stems to be used to create a mold of those specific dimensions, this may be an inconvenience for surgeons. Additionally, following each procedure, whenever a mold would be used, the specific stem used to create that mold would have to be re-obtained in order to replace the mold used.

Using a 3-D scanned and 3-D printed model allows for a database of different implant brands and models to be created. Once a stem is in the database, its geometries can be accessed at any time, meaning that after a surgeon uses a mold, he may simply ask for a replacement, without again having to provide primary stems to be processed. Because of the creation of a database,

production time can be decreased while the ease of reproducibility increases. Furthermore, using a 3-D printed mold from a 3-D scan allows for changes in hip implant technologies for the future; as the field of orthopedics continues to expand and change, it is important that the technologies used to address the associated problems are capable of adapting, simultaneously.



Figure 17: 3-D printed component (right) compared to primary hip stem (left)

The full process for creating the 3-D printed component to use as a master template for the creation of the mold can be seen below in *Figure 18*.

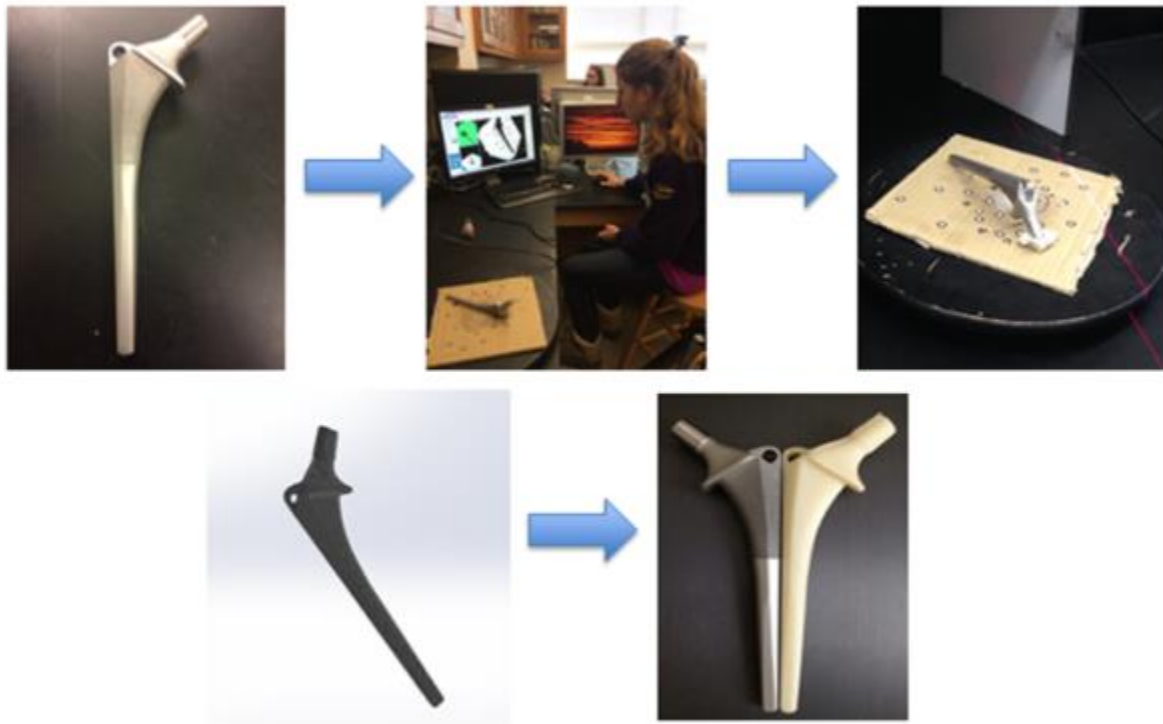


Figure 18: Full process for 3-D scanning the hip stem; Step 1: Obtain hip stem (of an existing broach/implant set) from orthopedic surgeon, Step 2: Obtain scan of the stem using 3-D scanner, Step 3: Rotate stem to obtain scans of various planes, Step 4: Mesh the point clouds and convert to .stl file, Step 5: Rapid prototype negative template

5.3 Mold System

After obtaining the 3-D printed component, the mold to form the PMMA bone cement component could be prepared. As the component is of a unique geometry and to ensure the integrity of the while the component was being removed, it was first coated. To coat the component so that PDMS did not stick to it and allow for easy removal, 50 uL of Trichloro (1H, 1H, 2H, 2H-perfluorooctyl) silane (Sigma Aldrich) was placed on a 35 mm petri dish inside a vacuum desiccator inside a laminar flow chemical hood. The component was coated for 24 hours before removing.

PDMS was created by mixing 585 grams of base and 65 grams of curing agent. The uncured PDMS was poured into a container and the 3-D printed component was then suspended in the PDMS, deep enough so the PDMS covered the parts of the stem that would otherwise be implanted into the femoral canal. The construct was degassed by placing it in a vacuum for 30 minutes. It was

then transferred into a 60 °C oven and allowed to cure for 24 hours. After PDMS had polymerized, the component and mold were placed in a -20 freezer for one hour and then allowed to come to room temperature for one hour. The mold was then submerged in 70% ethanol. Following submersion (for 20 minutes), the component was slowly removed. *Figure 19* shows the stem inserted in cured PDMS and the resulting mold after this process.



Figure 19: Process for making PDMS molds

5.4 Antibiotic-Loaded PMMA Bone Cement Component Construction

As the set of molds are what would be included in our kit, to emulate the process the surgeon would complete in the operating room, cement was mixed and loaded into the mold space of the cured PDMS. A wooden dowel, to replicate a primary implant that is smaller than the size to make the mold, was inserted into the cement and allowed to cure for 20 minutes (*Note bone cement would cure in ~4 minutes in the operating room). The PDMS was then cut away from the temporary spacer, and the component was then removed. *Figure 20* shows the cement curing around the wooden dowel to use as a proof of concept for forming the temporary spacer that would be implanted in the patient's body.

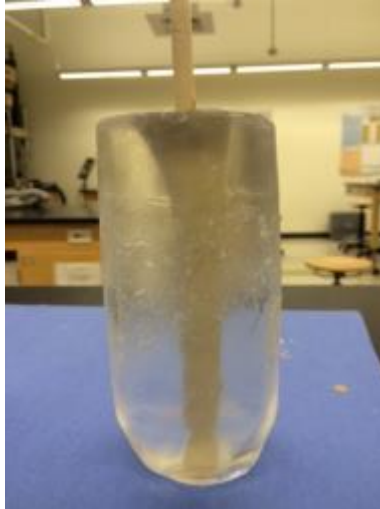


Figure 20: Proof of concept for forming the temporary spacer

The full process for creating the mold and temporary spacer can be seen below in Figure 21.

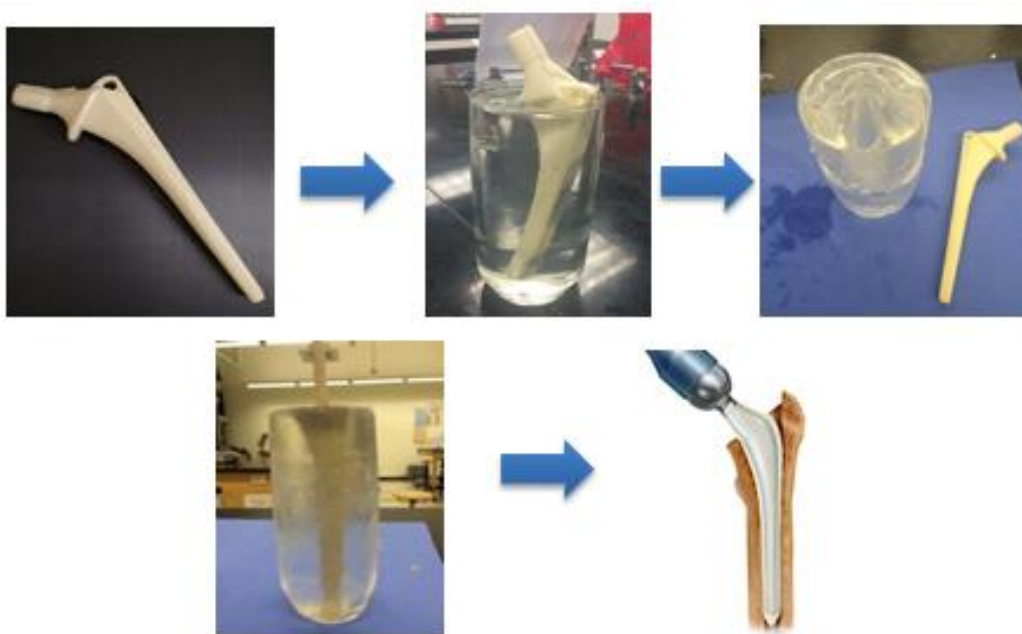


Figure 21: Full process for making the mold and temporary spacer; Step 1: Obtain negative template, Step 2: Fill container with PDMS, insert component, and allow it to cure, Step 3: Remove component from mold and place mold in respective kit, Step 4: In the operating room, fill mold with bone cement and insert smaller size stem allowing cement to cure around the stem, Step 5: Insert the temporary component into the body

5.5 Validation

Following antibiotic-loaded PMMA bone cement component construction, dimensional analysis was performed. Using precision calipers, dimensions of the bone cement component were taken and compared to dimensions taken at the same location on the metal primary implant. These dimensions were then analyzed via an ANOVA single variable test to prove whether or not the cured component had dimensions close to those of the primary implant.

A cytotoxicity test was also carried out to ensure that our process did not cause possible leaching of cytotoxic substances onto the bone cement implant. An elution cytotoxicity test was performed in accordance with ISO standards with a positive control, negative control, and an experimental group. A live/dead stain using propidium iodide and Hoechst was then used to determine proportion of live to dead cells in each culture dish, to determine if any cytotoxic effects may have been incurred during our process.

Lastly, a visual surface analysis was performed to determine whether or not the PDMS stuck to the PMMA component following removal from the mold. This was done using a specimen microscope to see if more macroscopic amounts of PDMS could be seen on the removed PMMA component.

Chapter 6 goes into our results for these tests and explains our methodology in greater detail.

Chapter 6: Design Verification

To verify the efficacy of our design for the use in two-stage revision hip arthroplasties, a variety of imaging and testing procedures were performed and analyzed. The results of these tests are discussed below.

6.1 Dimensional Analysis

As discussed in the previous chapter, 3-D scans were taken of the provided hip implant, rendered into a solid component using image processing software, and 3-D printed. This device was then used to create a PDMS mold with a space resembling the exact dimensions of the 3-D scanned component. For a proof of concept, cement was then used to fill the mold, and a supporting dowel was submerged in the bone cement until it cured as seen in *Figure 22*. This dowel was used to function like the smaller metal stem a surgeon would be placing in the mold during the procedure. Because it is vital to the success of our device that the temporary component exhibits dimensions precisely to that of the original hip stem, it was necessary to prove that this was in fact the case.

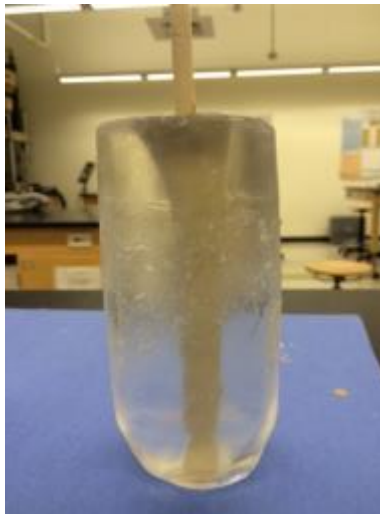


Figure 22: Mold filled with cement and a supporting wooden dowel, as a proof of concept for the process to form a temporary spacer in the operating room

To do so, we obtained comparative measurements of the original hip stem and the temporary spacer formed from the mold. We took several measurements along the hip implant in 1cm increments for the back, side, and front faces using precision calipers. The raw data for these

dimensions can be found in *Appendix B*. This information was then analyzed, and the results can be seen below in a side-by-side comparative bar graph comparing the measurements obtained for the original implant dimensions versus the dimensions of the formed PMMA temporary component in *Figure 23, 24, and 25* respectively.

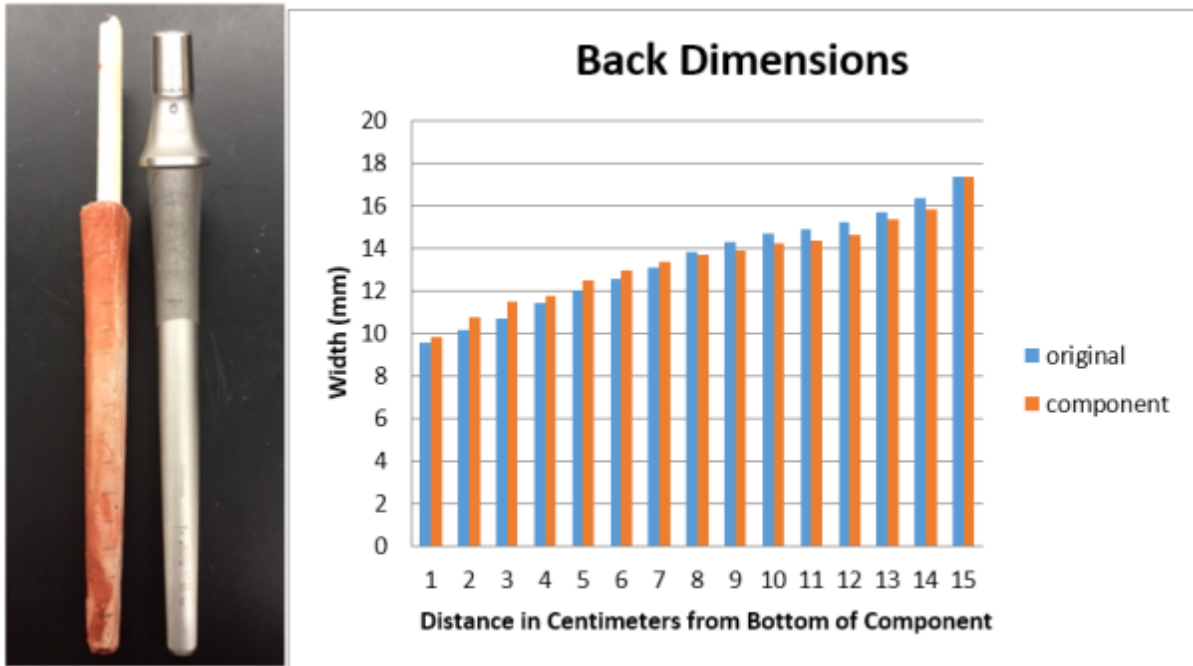


Figure 23: Dimensions obtained for the Back Face comparing the temporary spacer and original hip stem

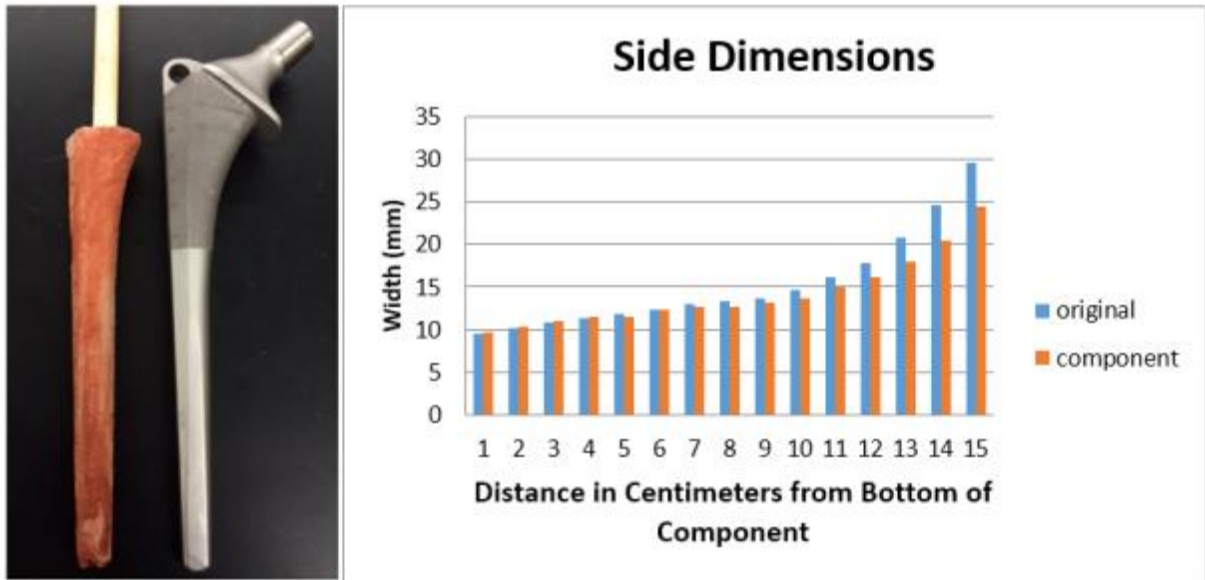


Figure 24: Dimensions obtained for the Side Face comparing the temporary spacer and original hip stem

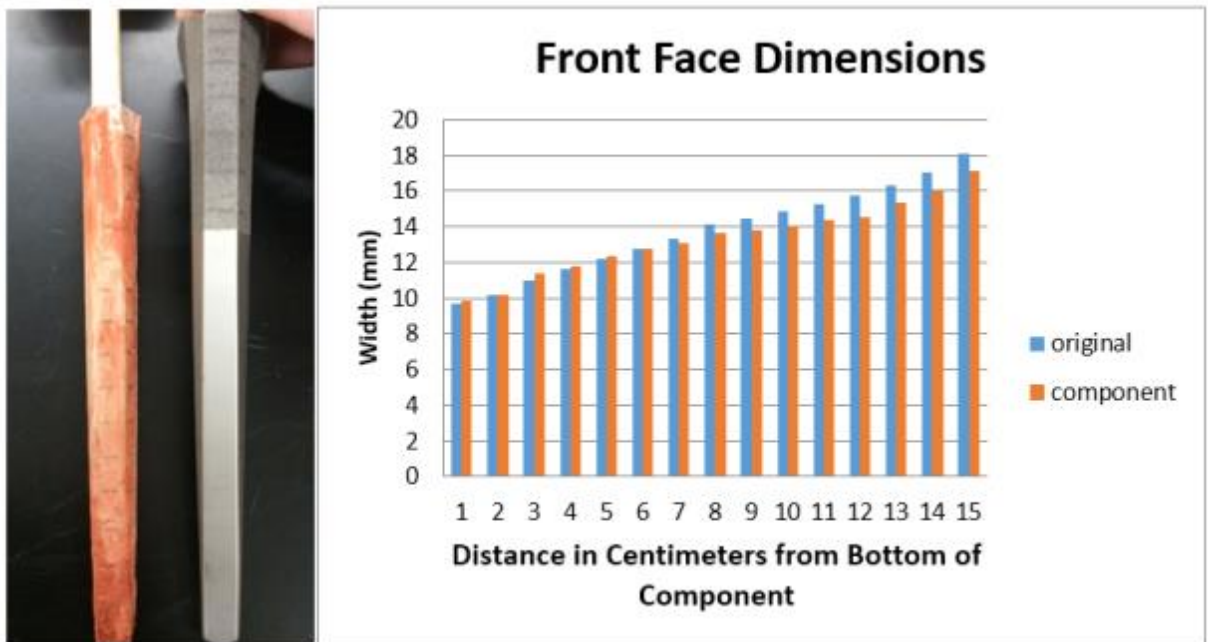


Figure 25: Dimensions obtained for the Side Face comparing the temporary spacer and original hip stem

A single-variable ANOVA test was carried out to determine if there was a statistical significance between the resulting temporary spacer and the original hip stem. After taking several measurements along the front, back, and side faces of the components, the data was compared and for each face a p-value of greater than 5% was obtained. These values can be seen in *Table 11*. This

proves that there is no significant difference between the original hip stem that was used to 3-D scan, and the cement spacer formed from the mold.

Table 11: Calculated p-values after running an ANOVA test on the back, side, and front faces of the temporary spacer vs. the original hip stem

Back Face	Side Face	Front Face
0.985	0.537	0.617

6.2 Microscopy Analysis

We wanted to ensure that a significant amount of PDMS from the mold would not be left behind as residue on the temporary component once that component was removed from the mold. To ensure this, we performed a visual analysis of the cured component using a specimen scope. *Figure 26* shows the cement spacer under the specimen scope. No PDMS was visibly seen on the surface of the component. It could be concluded that the spacer would be safe to implant inside the body after being formed from the PDMS mold.

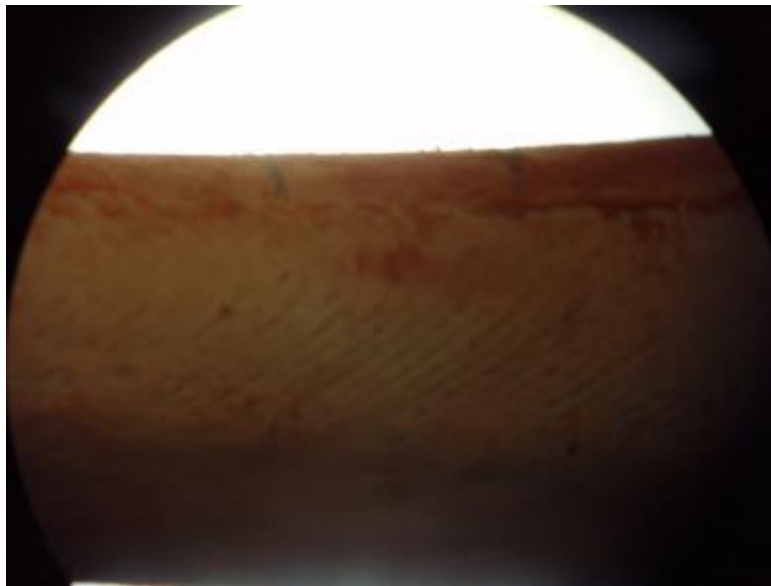


Figure 26: Temporary spacer under a specimen microscope, proving that no PDMS adhered to the component

6.3 Sterility & Cytotoxicity Testing

In order to ensure that our device was safe for use in the operating room, it was necessary that we test that the PDMS mold created through our proposed process would not impart any sort

of cytotoxic residue onto the PMMA spacer before the temporary component's implantation into the human body. Sterility tests in accordance with ISO 10993-5: Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity were performed (ISO, 2009).

Several modifications were made to this test modality based on the availability of materials; specifically, instead of L-929 mouse fibroblast cells, NIH/3T3 mouse fibroblasts were propagated and maintained in a 6cm dish until the time of experimentation. The cells were maintained and subcultured every three to four days when the cells had reached about 80% confluence. Cells were fed and cultured in single strength Minimum Essential Medium was supplemented with 5% fetal bovine serum (FBS) and 2% penicillin/streptomycin supplements (1X MEM), and were stored in a gaseous environment of 5% carbon dioxide (CO₂) at 37C (ISO, 2009).

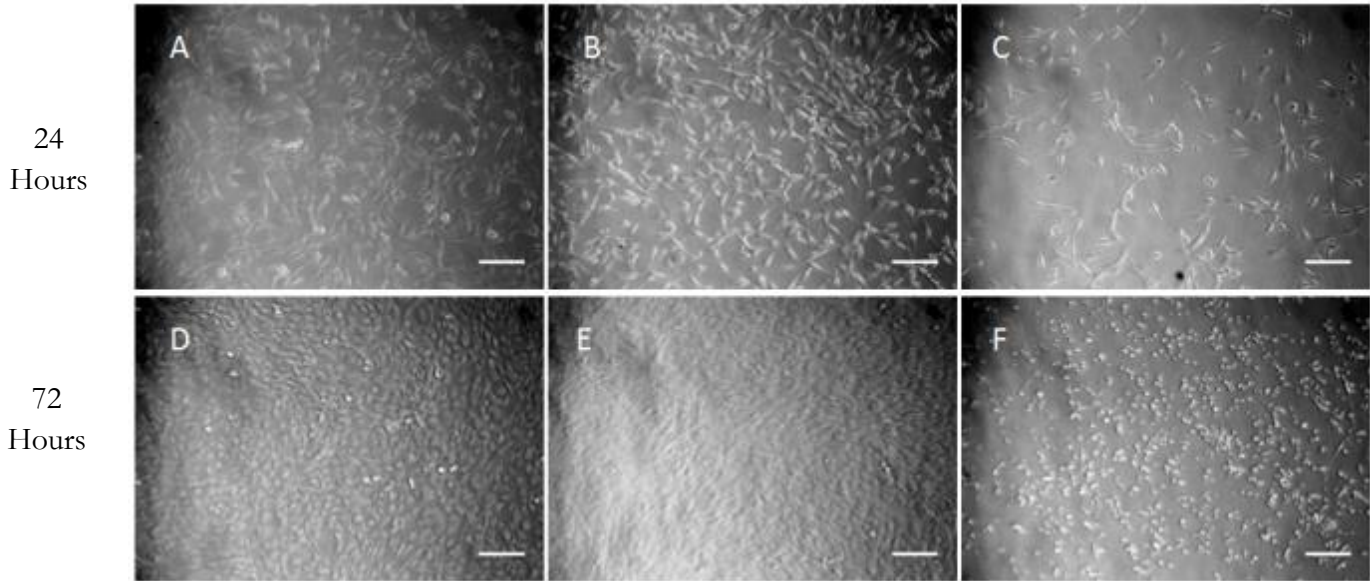
An *in vitro* elution cytotoxicity experiment was developed to show whether or not the final product manufactured by our device would incur cytotoxic effects to the environment. The positive control for this experiment was latex, the negative control was unmodified PDMS, and the experimental group was antibiotic loaded bone cement (Simplex P, Stryker Orthopedics) that had been cured on PDMS that had been prior cured around a 3-D printed, ABS plus component, the same as is used in the negative mold of our device. These materials, including the latex, unmodified PDMS, and experimental PDMS were then either removed from sterile packaging, or sterilized using an autoclave.

In a laminar flow biosafety hood, gentamycin-loaded bone cement was cured on the PDMS in the location where the plastic component had been, prior. The PMMA bone cement was allowed to cure for about ten minutes to emulate the time it would take to cure during surgery. The resulting piece of PMMA was then removed from the PDMS construct and was used as our experimental group in the cytotoxicity test.

The test materials were then placed in a sterile 6cm dish, and 1X MEM was added to each in accordance with the U.S. Pharmacopoeia (USP) standards for the ratio of necessary eluding surface area to media. This ratio is defined as 60cm²:20mL; an eluding surface area of 60cm² was obtained of each group and cultured in 20mL of single strength MEM, which will be referred to as elution media (Baker, 2007). The elusion media was allowed to incubate overnight.

On the same day, a 12 well plate was seeded with 30,000 cells per well, to achieve appropriate confluence for this test, in 2mL of 1X MEM. Each well was seeded with cells because the procedure was run in triplicate. These cells were allowed to incubate overnight.

After 24 hours of incubation, the elution media was harvested from the test materials. Media in the 12-well plate was removed, and 2mL of respective elusion media was added to each well. 3 wells were also cultured with unmodified 1X MEM to add as an additional control to the experiment. The cells were observed and imaged every 24 hours for 3 days, as outlined in the ISO standards (ISO 2009). These images are seen below in *Figure 27*.



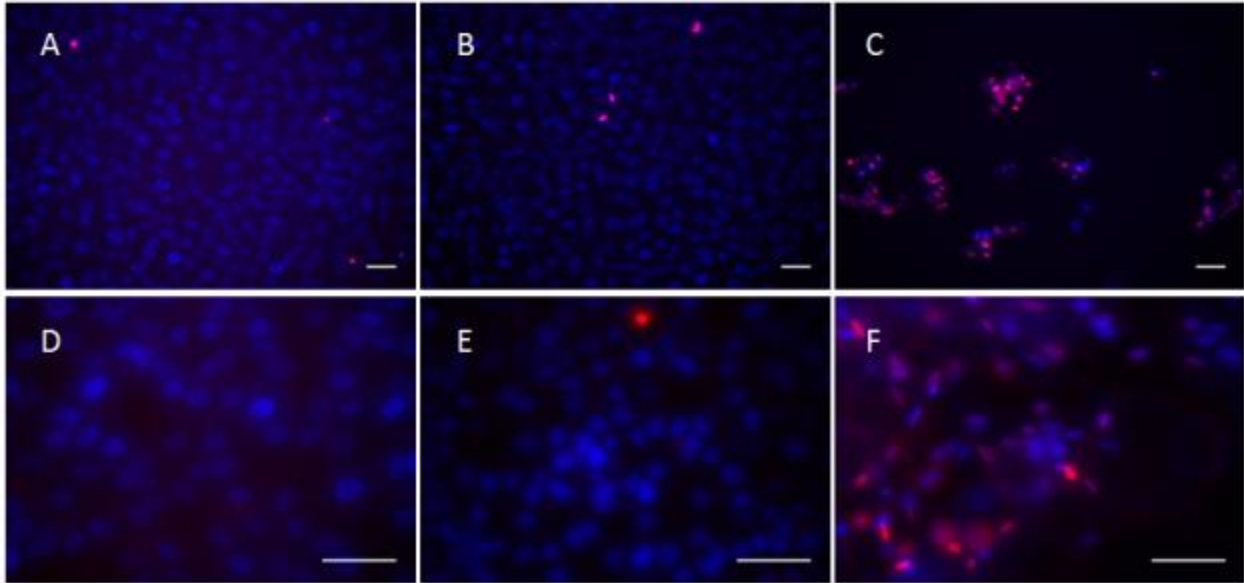
PDMS (Negative Control)

Bone Cement (Experimental)

Latex (Positive Control)

Figure 27: Visual analysis of cells after 24 hours (A-C) and after 72 hours (D-F), culturing in extraction media. A and D are culturing in media extracted from the negative control (unmodified PDMS). B and E are cultured in media extracted from the experimental group (modified PDMS). C and F are cultured in media extracted from the positive control (latex). All images taken at 20X with a 100um scale.

After three days, a live-dead stain was additionally performed on the cells to test viability. Hoechst was used to stain for viable cells, which would appear blue, whereas propidium iodide was counterstained to identify dead cells, which would appear red or purple. This is an additional test not necessitated by ISO cytotoxicity standards, but we thought it would provide stronger visual evidence. The images from this procedure can be seen below in *Figure28*.



PDMS (Negative Control)

Bone Cement (Experimental)

Latex (Positive Control)

Figure 28: Live-dead stain of cells after 72 hours. Blue nuclear stain (Hoechst) indicates live cells, and red or purple nuclear stain (propidium iodide) stains dead cells. A and D were cultured in media extracted from the negative control (unmodified PDMS). B and E were cultured in media extracted from the experimental group (modified PDMS). C and F were cultured in media extracted from the positive control (latex). A-C are imaged at 20X and D-F are imaged at 40X. The scale in all images is 50um.

It is evident by these images that there is a much higher density of dead cells in the latex wells than in the experimental wells or the controls, as was anticipated. Based on *Table 12* below, used in evaluating cytotoxic response, a reactivity score of 0 was assigned to the negative control, 0 for the experimental group, and a 4 for the latex.

Table 12: Cytotoxicity reactivity chart (ISO, 2009)

Grade	Reactivity	Condition of all Cultures
0	None	No cell lysis
1	Slight	Not more than 20% of cells are round, loosely attached; occasional lysed cells are present
2	Mild	Not more than 50% of cells are round; no extensive cell lysis and empty area between cells
3	Moderate	Not more than 70% of the cell layers contain rounded cells or are lysed
4	Severe	Nearly complete destruction of the cell layers

Based on the results of this test it was determined that the experimental group did not incur any undue cytotoxic effects when compared to the results from the negative control. Because of this, we concluded that the methodology used to create our mold would also not induce cytotoxic effects

if it were used to produce a temporary spacer in the operating room, and thus, our device would be safe to use in this application.

6.4 Cost Analysis

A cost analysis was performed to determine how our proposed device compares in cost to the existing Prostalac Hip System by DePuy. *Table 13*, which can be seen below, outlines a comparison of the cost of the different components that are necessary when performing a single procedure for a two-stage revision hip arthroplasty. Because UMMC performs about four of these procedures per year, we also provided a cost analysis projection of eight uses comparing our kit to the current gold standard; this can be seen below with the annual data expressed numerically in *Table 14*, and graphically in *Figure 29*.

Table 13: Cost Comparison of Prostalac Kit vs. Our Kit

	Bone Cement	Stem	Cup	Head	Molds	Total
Prostalac	\$622	\$3687*	\$1130*	\$597*	\$0	\$6036
Our Kit	\$622	\$960**	\$1130**	\$597**	\$147	\$3,456

*Cost of stem, cup, and head provided by DePuy

**Cost of standard hip stem, cup, and head stocked by hospital

Table 14: Cost Comparison of the Prostalac Kit vs. Our system after Eight Uses

Use Number	Prostalac	Our System
1	\$6,036	\$3,456
2	\$12,072	\$6,912
3	\$18,108	\$10,368
4	\$24,144	\$13,824
5	\$30,180	\$17,280
6	\$36,216	\$20,736
7	\$42,252	\$24,192
8	\$48,288	\$27,648

***Total Saved = \$20,640**

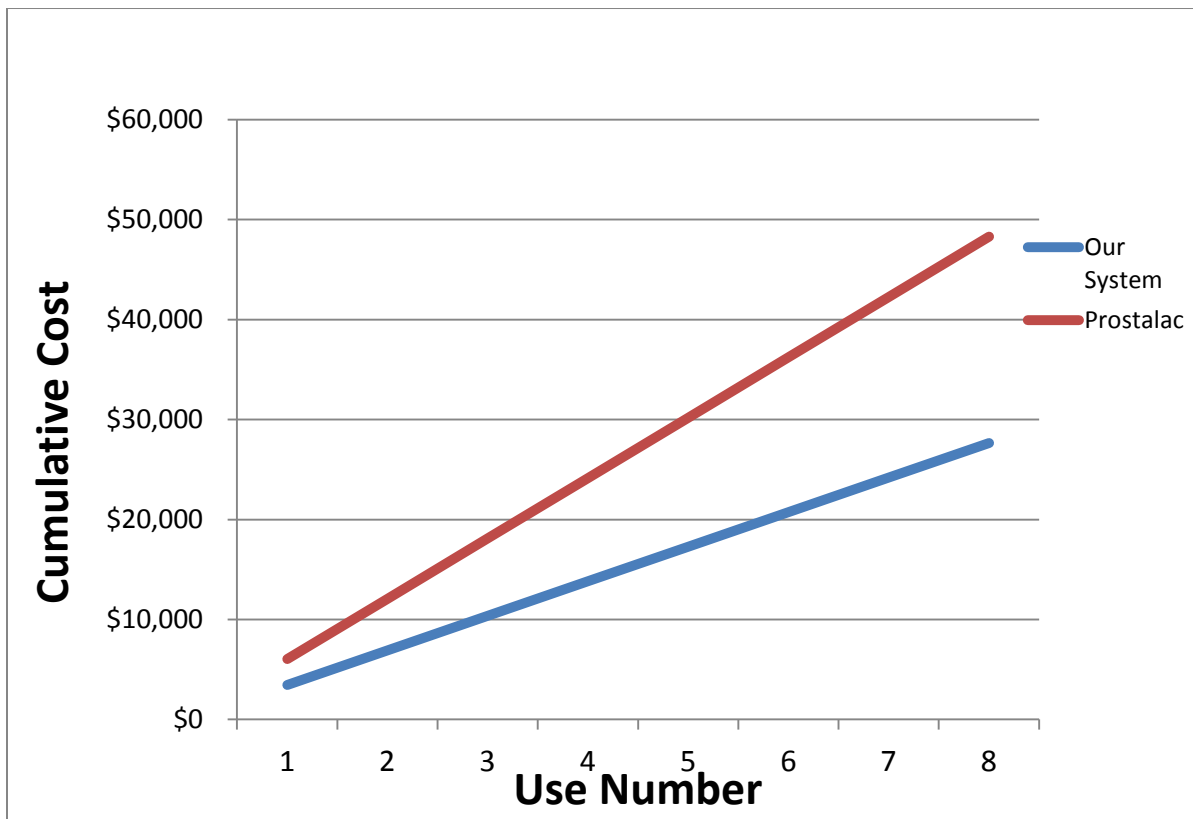


Figure 29: Comparison of cumulative cost over time for the Prostalac kit and our system

Chapter 7: Discussion

7.1 Validation of Met Constraints

To evaluate the success of our device we needed to ensure that our device was able to overcome all of the constraints that were initially presented to us. This was done by analyzing the results of the dimensional analysis, microscopy analysis, cytotoxicity testing, and cost analysis.

7.1.1 Dimensional Analysis

The measurement values obtained for the original hip prosthesis and the PMMA component yielded a p-value greater than 0.05. This indicates that the numbers are not significantly different and that the newly formed component is comparable in size to the original implant.

7.1.2 Microscopy Analysis

Visible deposits of PDMS on the device could not be distinguished, indicating that unwanted deposition of PDMS from our mold onto the component was not an issue that needed further consideration.

7.1.3 Sterility & Cytotoxicity Testing

The percentage of live to dead cells in the negative control was found to not be statistically different from the percentage of live to dead cells in the experimental group. Both the negative control and the experimental group were found to have statistically significantly different percentages of live to dead cells. This indicates that we can assume our experimental group to not impart cytotoxic effects onto tissue when implanted into the body.

7.1.4 Cost Analysis

Because the Prostalac Hip System requires a given expense that must be paid for each procedure when needed, the cost over time of this system increases in a linear fashion beginning with the first procedure. Our proposed system requires that a preliminary investment be put in to receive an initial, full set of molds, customized to the surgeons preferences; however, following this preliminary expense, which in and of itself still does not surpass the cost of a single use of the Prostalac Hip System, our device only requires that surgeons restock the single mold that is used

during a given procedure. The cost of a single mold is only \$147 and with all necessary equipment our kit costs \$3,456, whereas the Prostalac Hip System costs \$6,036 for a single use. This means that while the initial cost of our system is comparable to a single use of the Prostalac Hip System, the annual cost over eight uses will be 43% less than that of the Prostalac Hip System, indicating that our proposed system is a cost effective alternative to the Prostalac Hip System.

Through this testing, we have proved that our method and device provide an efficacious, safe, and cost-effective alternative to be used to create the antibiotic-loaded bone cement spacer used in two-stage revision hip arthroplasties. These test results indicate that our method and device created for approaching this problem is successful in overcoming the pre-prescribed constraints of safety, efficacy, and cost effectiveness.

7.2 Analysis of Met Objectives

Because our device was successful in overcoming all of our preliminary constraints, we looked to validate where our device was successful in meeting our objectives.

7.2.1 Customizable

Through our dimensional analysis, we have proved that our method is efficacious in producing components that match the dimensions of an existing implant. We conclude that this method can be used with any brand or model of hip implant and the same results can be achieved. We thus believe we can say that success was achieved in creating a customizable system.

Additionally, we believe that because our device is entirely customizable, it will also be able to accommodate for the needs for the constantly changing marketplace for orthopedic implants. With new models of hip implants coming out each year, it is important that our technology is able to adapt to the ever-changing market. We believe our device achieves such, making it applicable and viable to perform this procedure for many years to come.

7.2.2 Accessible

Because there currently only exists a single Prostalac Hip System in all of New England that must be shared amongst the regional hospitals and because of the exorbitant cost of purchasing another system specifically for each hospital, the Prostalac Hip System is, overall, highly inaccessible. However, because our system is so cost-effective, each hospital can easily stock its own kit to have available for use whenever a septic revision surgery is necessitated. Surgeons can have the system available at all times and therefore do not have to wait to receive the device from an external vendor, while they additionally will not have to run into conflicts should the device be needed by two surgeons on the same day. Having our system available in stock in the hospital could therefore reduce the rate of co-morbidities associated with an infected implant.

7.2.3 Disposable

Because our device was manufactured in such a way that it is resultantly so much more cost-effective than existing methods, we propose that this can be used as a disposable device. This means that if the surgeon would like to simply cut the PDMS mold to dislodge the PMMA component after curing, they are free to do so because the mold will simply get discarded anyway following the surgery. This eliminates the need for sterilization; the surgeon may simply order a new mold to replace the one that was used during the procedure.

7.3 Project Impact

It is important to take into account the impacts that a product will have on several factors including: economics, the environmental impact, societal influence, political ramifications, ethical concern, health and safety issues, manufacturability, and sustainability.

7.3.1 Economics

The results of this project would suggest that the kit of customized molds would be economically advantageous to both hospitals and patients undergoing the surgery. By using our product, hospitals would save over \$2,000 per surgery for the instrumentation used in a two-stage arthroplasty. Based on the calculated cost of renting the Prostalac kit vs. buying our kit, over \$20,000

could be saved with just eight uses of our kit. Additionally, if the product is less expensive for the hospitals to purchase, the cost of the surgery may also decrease for the patient. Especially when considering the case where a patient has to wait to receive the kit for this procedure to be performed, the expense incurred by the increased time spent in the hospital would also decrease.

7.3.2 Environmental Impact

Low molecular weight PDMS polymers are used in household care products, while high weight PDMS polymers are used as antifoams and lubricants. Also PDMS-based rubbers or sealants are used as textile coatings, electronics, silicone moldings and rubber gaskets. Since silicone and PDMS is used so commonly in everyday products, the customizable molds should have no greater negative effects on the natural environment than these current products. Solid silicones that enter the environment will be land filled or incinerated. Therefore, they are converted back to inorganic ingredients such as amorphous silica, carbon dioxide, and water vapor (Stevens, n.d.) Since the material can be recycled and reused in other applications, the reuse reduces its environmental impact.

7.3.3 Societal Influence

Because there is just one kit in the New England region, if multiple hospitals need to perform a two-stage arthroplasty on the same date, one patient will suffer and endure further pain. Also, if an infection is detected when the surgeon believes there is a mechanical failure, the necessary components are not available on the shelf to perform the emergency surgery. Therefore, our product has a positive societal influence since patients can be treated right away and will not have to endure further physical and emotional pain while waiting for the kit. Our kit thus allows the overall quality of patient care to increase.

7.3.4 Political Ramifications

The main goal of our project was to create a more accessible way to conduct a two-stage revision arthroplasty. We hope our system can be used in the future to help surgeons and patients

accomplish these surgeries much faster, so there is less pain endured by the patient. This system will have an impact on the health care system but with relation to political ramifications, the impact is minimal.

7.3.5 Ethical Concern

Our project has minimal ethical concerns. However, one ethical concern could arise when considering that we would be scanning other companies' hip stems. While we do not believe we are infringing on existing patents, if this were to be a concern, we could simply obtain the existing CAD files from these companies with their approval to create the mold, rather than scanning the hip stems obtained from a surgeon.

7.3.6 Health and Safety Issue

The main materials used in our design, PDMS and ABS plus, are both biocompatible materials that can be autoclaved to ensure the safest environment for our device. Our group performed a cytotoxicity test to help ensure that our device was non-toxic and will not cause a harmful response. However, all of testing was done on our proof of concept so going forward further testing must be done for a potential final design that surgeons will be using. Due to the testing we have already accomplished and the use of biocompatible materials, the health risks associated with this device is minimal.

7.3.7 Manufacturability

Regarding the manufacturability of our project, one could easily reproduce the temporary spacer by following the aforementioned protocol for utilizing our molding system to form the temporary spacer. So long as a rendering of the hip stem is rapid prototyped, then the temporary spacer could easily be reproduced simply by injecting the negative PDMS mold with antibiotic-loaded PMMA bone cement, inserting the hip stem into the mold, and allowing the bone cement to cure. Since the surgeon would be provided PDMS molds for each size of hip stem that he regularly stocks on his shelves, he would only need to concern himself with forming the temporary spacer

and not the PDMS mold. That being said, the manufacturability of our project is dependent upon the ease with which the PDMS mold could be reproduced.

7.3.8 Sustainability

Since the PDMS molds are disposable, there is concern for how the disposal of the molds might affect the environment. As stated earlier, releases to the environment from the manufacturing of PDMS will either be landfilled or incinerated; in the case of incineration, PDMS degrades and is converted to inorganic constituents, amorphous silica, carbon dioxide, and water vapor. If the disposed PDMS is landfilled, there are no adverse effects because PDMS is too large to pass through the biological membranes of plants and animals (Stevens, n.d.).

Also notable to mention regarding sustainability is that our methodology allows the devices used for this procedure to evolve and change with changing hip technologies. Even if the geometry of hip stems evolves over time, our system will not have to be modified to produce the necessary molds to fit the new implant technologies. In this sense, our methodology is sustainable for this application.

Chapter 8: Conclusions & Recommendations

In this study, we produced a medical device, which through cytotoxicity testing, we deem is safe to use for a two-stage hip revision arthroplasty. Through dimensional analysis, we were able to determine that our device can create a temporary PMMA component that is effectively the same size as the surgeons' original permanent, metal hip implant. This means that our device can allow surgeons to utilize broaches and other equipment they already have in stock while still being able to produce an efficacious, temporary component. We determined through cost analysis that our device will allow surgeons to perform a two-stage revision arthroplasty procedure at a cost much less than that of the current Prostalac system. Because of the cost effectiveness of our device, it can be disposable, increasing ease-of-use for the surgeon because they do not need to worry about damaging the mold during the procedure. The low cost of the system furthermore makes the device highly accessible because all surgeons can stock this device for an affordable cost compared to existing technologies.

Additionally, our device is entirely customizable to surgeon needs and preferences. No matter what implant model a surgeon keeps regularly stocked, our system for creating molds allows for any model of hip implant to be accommodated for. As the technology continues to change and new models of implants continue to come out, our system for creating these molds will continue to be adaptable to accommodate for whatever geometry of hip implant needs to be accommodated for.

Regarding continued work to be done, we would like to create kits with full sets of molds corresponding to the broaches and hip stems that the surgeon prefers. Some work still needs to be done if we are to pursue 510K FDA approval for our device. To establish 510K approval for our medical device, we identified predicate devices to support our claims. However, other testing may still be necessary; we propose that a shelf-life test be performed on our device to determine how long a surgeon may keep a kit stocked before he or she may have to purchase new molds if they

have gone unused for too long. Also, we would like to manufacture a smaller container to make the mold as the amount of PDMS used could be reduced significantly with this modification. Lastly, we would like to expand our market by applying this methodology to both knee and shoulder infection surgeries as well. For infected hip and knee revision surgeries alone, the market value could be expanded to \$1.6 billion (Kurtz, 2007). Therefore, there is ample opportunity for our system to have a great influence in the medical device industry.

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Appendix A:

Dimensional Rendering Using Templates of Commonly used Hip Implants

Utilizing surgical templates of hip stems from Stryker, Biomet, and Smith & Nephew, overlays, shown in *Figure 30* could be drafted to determine the dimensions necessary to design a broach that could accommodate for the slight variations that exist between prostheses brands.

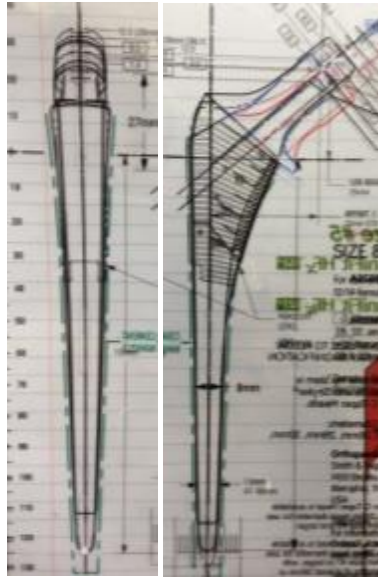


Figure 30: Surgical template overlays used for determination of dimensions

We first overlaid the smallest and largest hip stems from each company and took photographs of the side and front views. To determine accurate dimensions from these overlays, measurements were taken, using ImageJ software, of the smallest size stems and the largest size stems, to determine what range of dimensions our broach would have to accommodate for.

Once we were able to determine the upper and lower limits for the broach sizes, we developed intermediate sizes by creating a standard curve. Dimensional analysis of the prostheses used by UMMC could be converted to a SolidWorks model that would then be used to manufacture the broaches. The molds could then be modeled in SolidWorks with the same dimensions as the

broaches, but with a 0.5 mm. shell to be manufactured as well. The SolidWorks models for both the broaches and molds can be seen in *Figure 31*.

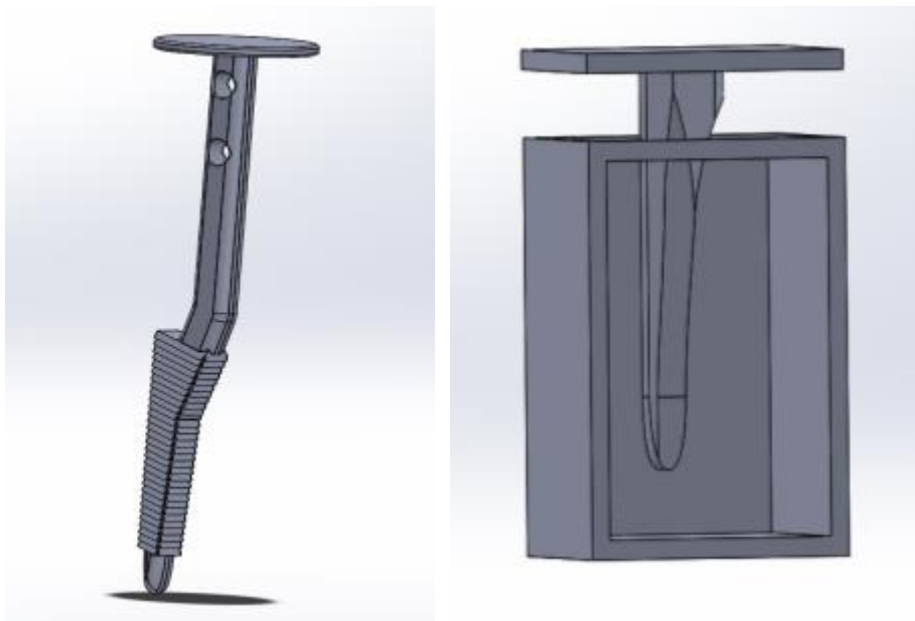


Figure 31: 3-D SolidWorks model of initial broach and mold design

Material Selection for Broaches and Molds

It was necessary to determine a variety of material options to consider for the design of an effective broach and mold. For the broaches, we assembled a table of the relevant material properties including hardness, Young's modulus, compressive strength, fracture toughness, and price of various polymers, including: ABS plastic, polycarbonate, ultra-high molecular weight polyethylene (UHMWPE), and nylon. Similarly, we tabulated the previously stated material properties of 316L stainless steel and aluminum to compare their properties to those of polymers. The mechanical properties of the polymers and metals were subsequently compared to those of cancellous bone to assess whether or not the broaches manufactured from these materials could cut through the cancellous bone of the femur, as is necessary when broaching the femoral canal. The material for the mold would ideally be non-adhesive and able to be cut away from the temporary component once the prosthesis had cured. We researched silicone for this purpose. Also for the

box, or outermost encasing of the mold, we would use an inexpensive polymer or metal. This table of values is shown in *Table 15*.

Table 15: Material properties including price, hardness, elastic modulus, compressive strength, and fracture toughness

Material	Price (USD/lb)	Hardness (HV)	E (MSI)	Compressive strength (KSI)	Fracture toughness (MPa*m ^{1/2})
Broach					
ABS	1.29 – 1.42	5.6 – 15.3	0.16 – 0.421	4.5 – 12.5	1.19 – 4.29
Polycarbonate	1.86 – 2.05	17.7 – 21.7	0.29 – 0.354	10 – 12.6	2.1 – 4.6
UHMWPE	0.798 – 0.88	6.4 – 8.3	0.135 – 0.136	3.77 – 4.79	1.7 – 5.2
Nylon	2.06-2.26	25.8-28.4	0.38-0.464	7.98-15.1	2.22-5.62
Mold					
316L Stainless Steel	2.62 - 2.88	170 - 220	28.3 - 29.7	27.6 – 31.9	90 – 100
Aluminum	1.07 – 1.17	60 – 150	10.4 – 12.9	7.25 – 47.9	18 – 35
Mold					
Silicone	4.77 - 5.67		0.0016 - 0.00435		
Inexpensive Plastic					
Cancellous Bone					
		0.3 – 1.5	0.0102 – 0.218	0.29 – 2.18	0.11 – 0.8

Testing Various Polymers by Cutting through Wooden Dowels and Porcine Femurs

Regarding the broach, preliminary testing was carried out to determine the feasibility of using a polymer versus a metal as the material chosen for the broach. To perform these tests, we acquired samples of a variety of materials including ultra-high molecular weight polyethylene (UHMWPE), polycarbonate, nylon, and ABS plastic, the specifications of which can be seen in *Table 15*. These materials were chosen based on their mechanical properties and how they compared to those of cancellous bone.

We then acquired a fresh frozen bovine femur that had been sawed laterally, down the diaphysis of the bone to expose the medullary canal and cancellous bone. The yellow marrow plug of the bone was removed, and they were then thawed in a 0.9% saline solution for 90 minutes (Ipsen B. J. et al., 2003).

We first tested the UHMWPE because teeth could be manually cut into the rods using a box cutter (*Figure 32*). Before testing the device on the bovine femur, preliminary tests were carried out on pine wooden dowels (*Figure 33*); based on hardness values, it appeared that UHMWPE would be able to cut through the dowel, as well as the cancellous bone. While the device was initially sharp to the touch, the teeth were found to dull within the first one to two sawing motions. While the recorded mechanical values for this material appeared as if they may be able to cut through the dowel and bone, it became clear that the teeth carved into the UHMWPE rod were unable to retain their structural integrity when subjected to the shear forces imparted by a sawing motion. We repeated the test on the bovine femur as well to be certain, and again came to the same conclusion that this material would not retain its structural integrity and would be incapable of clearing the femoral canal if made into a broach.



Figure 32: Teeth cut into UHMWPE rod to test on wooded dowels and bovine femur for a proof of concept



Figure 33: Result of cutting wood with UHMWPE formed teeth

Similarly, tests were conducted on the ABS plastic that were carried out on UHMWPE. Initially, the ABS plastic was able to saw right through the wooden dowel as seen in *Figure 34*. Next, we used the ABS plastic rod and attempted to saw through the bovine femur. The ABS plastic failed to cut the bone and the plastic teeth either chipped away or became dull after attempting to saw through the bone (*Figure 35*). From these results, we determined that ABS plastic would not retain its structural integrity and would be incapable of clearing the femoral canal if manufactured into a broach.



Figure 34: ABS teeth and result of sawing wooden dowel with this instrument



Figure 35: Porcine femur cut with ABS teeth (negligible damage to cortical bone)

Although the mechanical properties of these polymers were higher than that of cancellous bone, we did not consider that the surgeon would have to cut through some cortical bone during the surgery. Therefore, it is logical that the rods tested could not cut through the porcine femur. We determined that the mechanical properties of the polymers that we had chosen for the broaches are not sufficient enough for the purpose of effectively broaching the femoral canal. Of even greater concern was our discovery of the price it would cost to manufacture the broaches. We learned that our design would have to be outsourced to an external company to ensure the proper dimensions and details of our design.

Manufacturing

3-D Printed Broach

Although we had doubts regarding manufacturing the broaches out of polymers, we decided to research various manufacturing techniques and the associated cost to do so. Having the broach design already in SolidWorks, our first thought was to research 3-D printing the set of broaches. Specifically, we researched printing the device in ABS plastic or nylon. However, the quote we received was \$232 per broach for ABS plastic and \$324 per broach for nylon. If we were to produce

a kit of at least five broaches, the kit itself would have been too expensive for it to be considered disposable.

Injection Mold Broach

In this iteration of the design, we proposed fabricating a mold of a rendered broach for injection molding purposes. The broach mold could then be injected with our material of choice, allowed to cure, and peeled away from the shell, leaving behind a plastic broach component.

Traditional injection molding projects, for which a metal mold is produced and then injected with the client's material of choice, usually cost over \$2,000 for small, simple parts. If we were to pursue this more traditional option, the cost alone for producing five molds of different sizes would likely cost well over \$10,000. 3-D printing our broach molds could significantly decrease that cost. The main drawback, however, to 3-D printing a broach mold, lies in the fact that 3-D printed injection molding systems are only meant for short injection molding runs of about 10 to 100 parts. Having to repeat the process of manufacturing these molds could then lead to even greater costs in the end. Due to these realizations, we determined this would not be a feasible option to pursue either.

Due to the results from testing the costs associated with the manufacturing techniques our device would necessitate, we decided to look back to our other design alternatives of Universal and Customizable Molds.

Appendix B:

Results from dimensional analysis for the temporary spacer (component) compared to the original hip stem provided to us by Doctor Wixted.

Table 16: Dimensions obtained from measuring every cm along both the temporary spacer and original hip stem at the front, side, and back faces (mm)

Front Face (mm)		Side Face (mm)			Back Face (mm)	
Original	Component	Original	Component	Original	Component	
9.66	9.87	9.52	9.69	9.57	9.86	
10.2	10.17	10.25	10.39	10.14	10.77	
10.97	11.36	10.85	10.98	10.71	11.48	
11.61	11.82	11.37	11.49	11.43	11.77	
12.21	12.36	11.81	11.59	12.02	12.46	
12.78	12.75	12.35	12.28	12.57	12.95	
13.34	13.11	12.94	12.67	13.06	13.34	
14.14	13.63	13.34	12.75	13.82	13.69	
14.45	13.82	13.62	13.17	14.28	13.89	
14.88	14.08	14.7	13.7	14.68	14.25	
15.26	14.35	16.15	14.92	14.92	14.37	
15.73	14.54	17.86	16.23	15.23	14.61	
16.28	15.34	20.72	17.95	15.67	15.38	
17.02	15.96	24.63	20.46	16.35	15.85	
18.1	17.12	29.55	24.44	17.33	17.33	