BMEN 411

CAD Design of an Artificial Hip

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Introduction/Background

Total hip arthroplasty (THA), also known as a hip replacement, is a cost-effective and consistently successful orthopedic procedure. The procedure is commonly performed to help provide reliable outcomes for patients with end-stage degenerative hip osteoarthritis (OA). Most notably, the procedure helps provide significant pain relief, restoration of hip mobility and function, and improved quality of life [1]. THA is also used in orthopedic trauma cases involving the repair of an acute femoral neck fracture or treatment of post-traumatic arthritis (PTA) following an acetabular fracture. Though commonly successful, it is important to note that THA is not without complications. For example, a study tracking dislocation rates for THA post-PTA following an acetabular fracture found a dislocation rate of 4.4%, with a subsequent surgical revision rate of 2.2%, which is higher than modern THA revision post-dislocation rates [2,3]. This finding demonstrates that previous fractures or surgeries, such as open reduction and internal fixation of acetabulum fractures, can augment complication rates for THA and therefore require additional preoperative planning.

It is necessary to understand the anatomy of the hip before delving into the history and significance of THA. A brief overview of the relevant anatomy will be provided. The hip is a ball-and-socket joint which is known as a diarthrodial joint and is where both bone ends are covered in a thin cartilaginous sheet [1]. Diarthrodial joints are also joined by a capsule lined with a synovial membrane that secretes synovial, or joint, fluid. The hip consists of both osseous and soft tissue components. The osseous components include the proximal femur which ends in the ball of the joint, and the acetabulum which forms the socket of the joint. It is also important to note that the ball of the joint is the femoral head and is connected to the distal femur by the femoral neck. The relevant soft tissue structures are the labrum, joint capsule, and ligaments. The labrum is a rim of fibrous cartilage that surrounds the acetabulum to generate negative joint

pressure and increase the stability of the joint. The relevant ligaments are the iliofemoral, pubofemoral, and ischiofemoral ligaments, which serve to increase the stability of the joint during movement [4].

The evolution of THA designs over time began in the late 1800s when Dr. Themistocles Gluck experimented with joint replacements in animals. This work culminated in a reported implantation of total joint arthroplasty using an ivory femoral head inserted into a human patient. On September 28th, 1940 in Columbia, SC, Dr. Harold Bulhman performed the first hemiarthroplasty of the hip joint by replacing the femoral head with a vitallium prosthesis. The use of vitallium for hip arthroplasty was suggested by Dentist John Cooke and was based on prior work by Dr. Charles Venable. The next advancement came when Dr. Austin Moore had a patient pathological femoral neck fracture due to a bone tumor. The case resulted in the creation of a femoral stem that was inserted into the medullary canal of the femur. Notably, the stem was fenestrated to allow for bony ingrowth [5]. Later on in the 1960s, Sir John Charnley introduced the idea of low friction arthroplasty by creating a metallic femoral head and stem prosthesis that articulates with a polyethylene component cemented to the acetabulum [1]. Modern improvements since then have been directed at increasing the durability and longevity of implants and reducing failure rate due to wear, loosening, and instability [6].

Current devices are limited in the prevention of dislocation post-surgery. This can result from the labrum being removed during the surgery when the acetabulum is prepared for cementing the acetabular component. This removal causes the negative joint pressure effect of the labrum to not be preserved post-THA. It is, therefore, necessary for innovations to center on creating anchors, tethers, or an artificial labrum that can compensate for the lack of negative joint pressure that stabilizes the hip joint post-THA. The use of anchors to prevent dislocation would

also augment the function of the iliofemoral, ischiofemoral, and pubofemoral ligaments post-THA. In some THA cases, the surgeon chooses to preserve the aforementioned ligaments in order to increase the stability of the hip prosthesis and joint. The use of tethers running from the rim of the acetabular component to the neck of the femoral prosthesis would augment the function of the ligaments and help compensate for the loss of negative joint pressure by providing tension that holds the femoral head prosthesis against the acetabular cap. This paper will therefore propose a new hip prosthesis design that will aid in increasing the stability of the hip joint post-THA, thereby decreasing the rate of dislocations post-THA and the resulting rate of surgical revision due to a dislocation post-THA.

Market Analysis

The largest four biotechnology companies associated with THA are Stryker, DePuy Synthes, Zimmer Biomet, and Smith+Nephew. Stryker has become a distinguishing competitor in the THA market due to its partnership with Conformis Technology. This collaboration has led to FDA 510(k) clearance for Stryker to sell patient-specific instruments (PSI) in 2021 and has expanded the Stryker portfolio significantly. DePuy Synthes developed and received FDA 510(k) clearance on their VELYS Robotic-Assisted Solution to help surgeons acquire real-time data during THA to provide better information for quick decisions during surgery. Zimmer Biomet is primarily known for the ROSA hip system, a robotically assisted anterior total THA that received its FDA 510(k) approval in 2021. Smith+Nephew works largely with handheld robotics systems that help improve imaging and 3D modeling of joints during surgery without the need for CT or MRI scans. Several additional companies are important in the improvement of THA, however, these four companies currently hold the largest impact on the development [7].

Considerable research is being conducted to introduce sensors into joint replacements, which will be able to broadcast important information such as range of motion, number of steps,

and walking speed to monitor the integrity of the implant after surgery. Such technology is already being utilized in knee replacement surgery [8]. The integration of sensors in THA will alert patients and healthcare professionals to potential complications early on, promising improvements in the quality of life for patients who have undergone THA procedures.

Recent advancements in the field of 3D printing offer the potential for exciting, new processes for the manufacturing of THA, as 3D printed metal offers the ability to replicate the porous microenvironment of trabecular bone. Furthermore, the highly customizable nature of computer-aided design allows for the personalization of hip implants, which will help increase patient comfort and implant integrity. However, because metal 3D printing is an emerging field, this process remains expensive and is not yet easily accessible [6].

When designing a new model for THA, there are several key criteria that must be satisfied. Affordability plays a vital role for not only the biotechnology company but also for the customers. The device must be cost-effective while also staying competitive in the buyer market. Patient comfort and practicality are also crucial for the success of a new medical device. This can include qualities such as range of motion, exhaustion levels, comfort during standing/sitting, frequency of hospital check-ups, implant lifetime, etc. A novel idea is also essential in new THA development since the foundational device already poses an effective solution to patient discomfort.

In 2022, there were approximately 450,000 THAs conducted in the US. Most THAs are a result of pain and discomfort for patients with chronic hip pain from osteoarthritis, inflammatory joint problems, rheumatoid arthritis, fractures, and more [9]. Since these surgeries must be conducted by an orthopedic surgeon, the hospitals or medical practices purchasing the implant directly from the biotechnology companies are the target buyers. The patient and patients'

medical insurance company will be the downstream target buyers, or customers since they indirectly purchase the product in order to improve their pain.

The large biotechnology companies already stated would serve as the largest competition. Since these companies already hold such strong power over the THA portfolio, it is difficult for start-ups or other small companies to compete. This is why a novel, affordable, and practical idea is critical when improving the design of the modern-day THA.

Model Design/Intent

The design for this unique hip implant consists of four key components: the acetabulum cap, plastic insert, femoral head, and femoral stem [10]. The acetabulum cap's main function is to connect bone to the hip implant. This is accomplished by fitting three 6.5mm cannulated screws through the holes in the cap and securing them to the patient's bone. This specific acetabulum cap is made of a titanium alloy, Wrought Titanium 6-Aluminum 4-Vanadium (Ti6Al4V), and has a diameter of 50mm and thickness of 6mm but can vary depending on the size and gender of the patient. Ti6Al4V was chosen due to its well-studied and -used mechanical properties, which offer great durability and manufacturing qualities [11]. The plastic insert's role is to connect the acetabulum cap to the femoral head of the implant. The plastic used in the insert is Ultra-High Molecular Weight Polyethylene (UHMWPE) to reduce metal-on-metal interactions and maintain the mobility of the implant. The diameter of this insert is 44mm and also has a thickness of 6mm. The femoral head and stem are attached and inserted into the plastic insert to complete the assembly of the implant. The femoral head is made of Ti6Al4V and has a diameter of 30 mm with an 11.93 mm diameter hole that the femoral stem is fitted into.

In order to limit surgical complications, dimensions for the design relied on widely used and studied dimensions suggested by literature [12]. Dimensions and materials were also made to

follow current FDA guidelines on hip implants, specifically that of metal-on-polyethylene design [13].

The surface of the acetabular cap and the femoral stem are roughly textured to allow for more surface area for contact with bone cement. In this unique design, the acetabular cap and the femoral stem contain loops that anchor polypropylene (PP) sutures. These sutures provide added stability to reduce dislocation rates and therefore subsequent surgical revision rates. This added stability is especially vital in PTA-related THA.

PP, a common polymer for artificial tendons, is used for the suture due to its biocompatibility and mechanical properties [14]. The compressive and tensile strength of PP (29.3 MPa, 36.7 MPa respectively) is similar to that of the bone cement used in the femoral neck (24.5, MPa, 79 MPa respectively) [15,16]. Therefore, the sutures will be able to withstand the everyday forces that the user will experience without restricting the mobility of the user. Furthermore, the strength of the sutures is small enough that in the event of a serious accident, the sutures will snap, preventing the sutures from placing great stress on the THA.

CAD Drawings/Figures

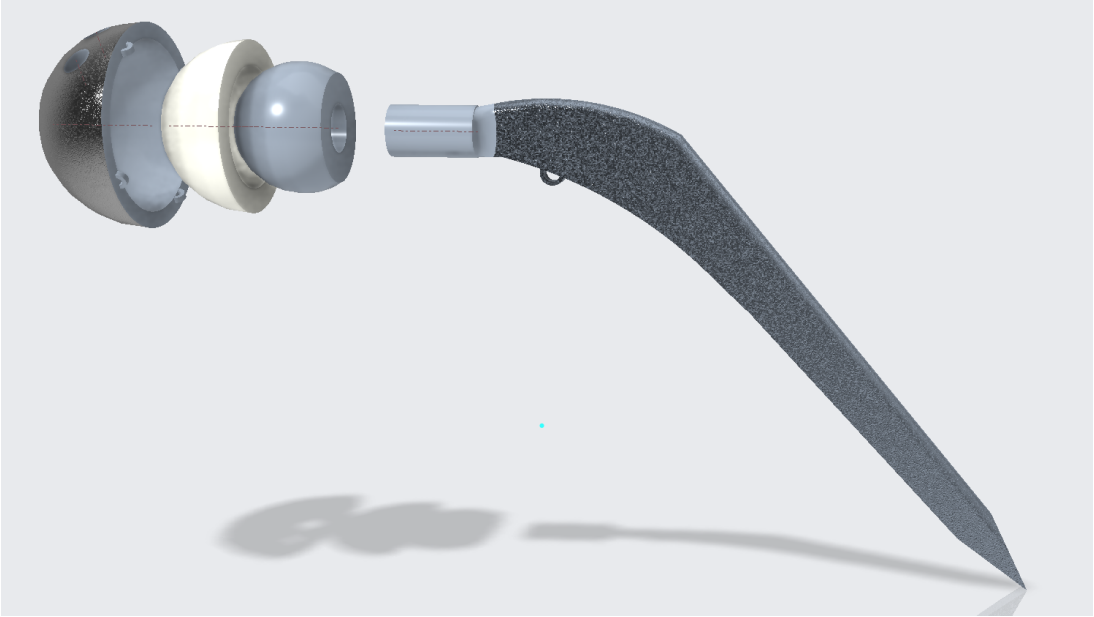

Figure 1. The exploded view of the THA implant. From left to right: the acetabular cap, plastic insert, femoral head, and femoral stem

Figure 2. The assembled view of the THA device.

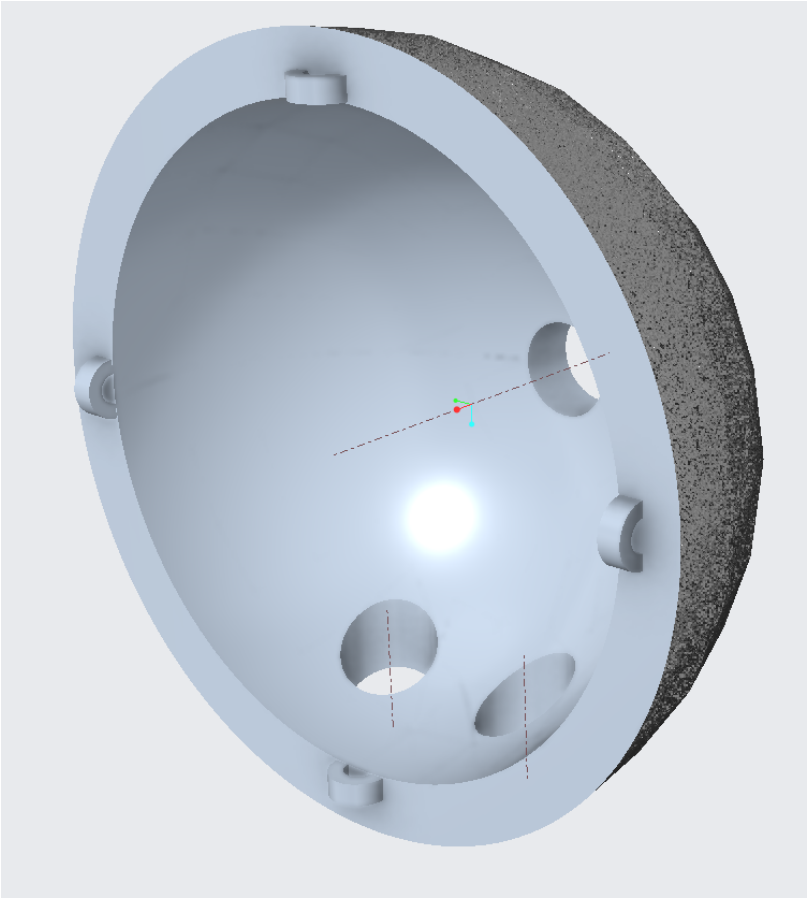

Figure 3. The acetabular cap with four anchor points about the rim and three screw holes. The outer surface of the cap is rough.

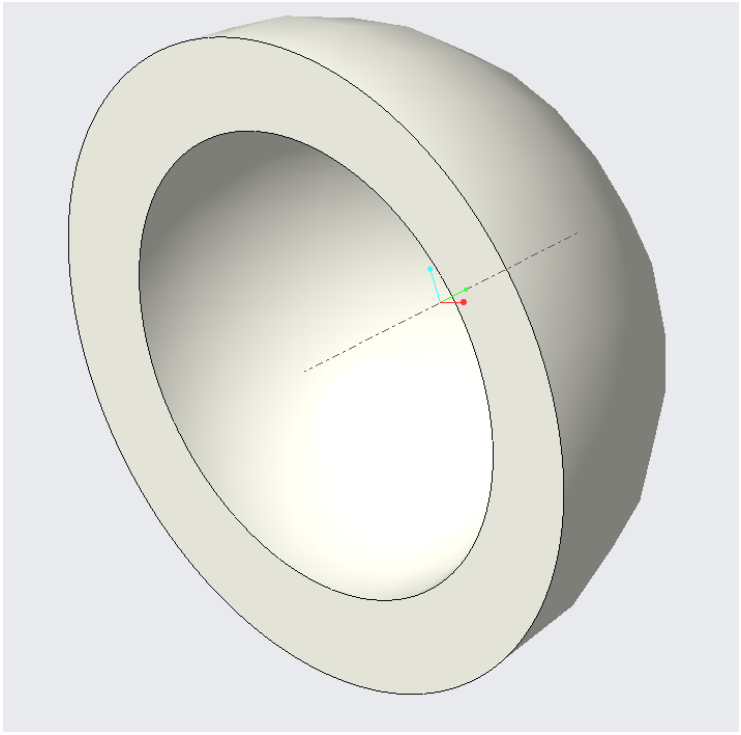

Figure 4. The plastic, UHMWPE insert.

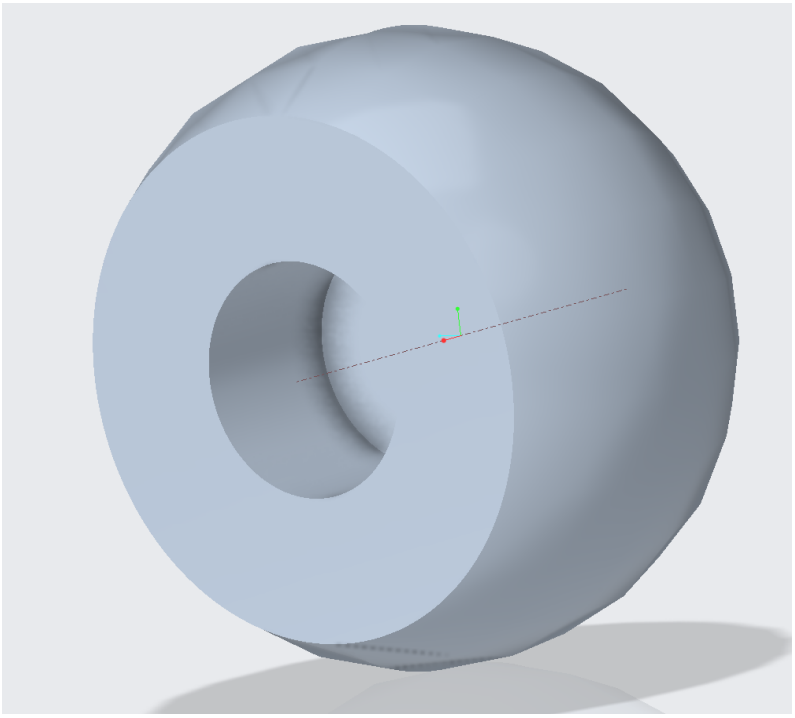

Figure 5. The femoral head with an indent for the femoral stem to be inserted into.

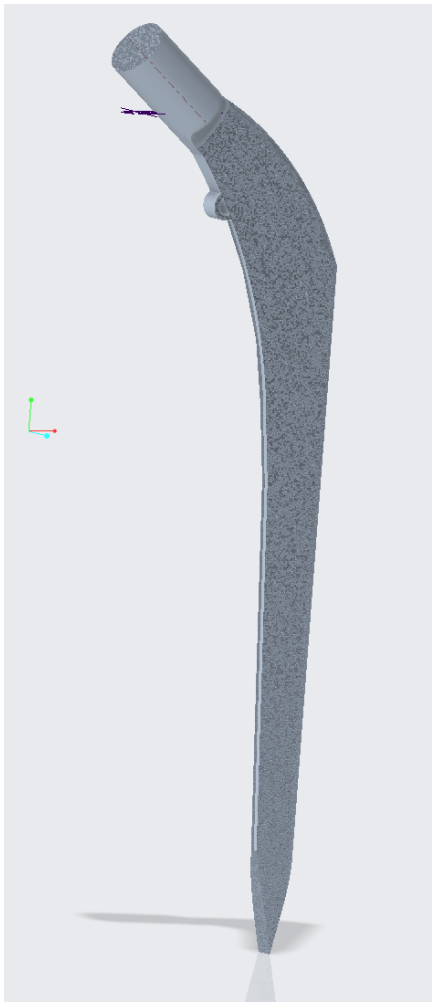

Figure 6. The femoral stem, with a similar rough surface to the acetabular cap.

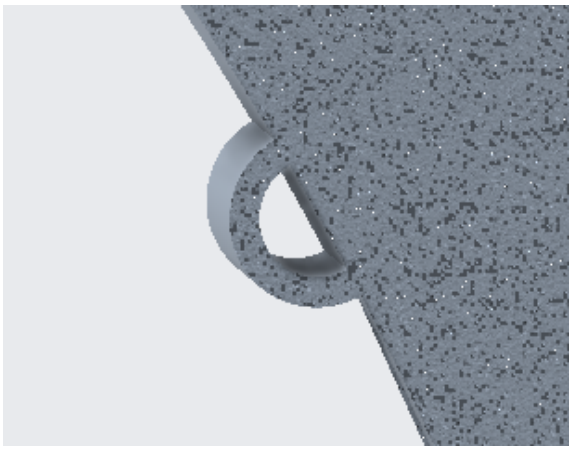

Figure 7. Enlarged view of an anchor point on the neck on the femoral stem.

Conclusion

Despite the widespread popularity of THA, it does not remain without complications. Mainly, the dislocation of the implanted femoral head and the acetabular socket is somewhat commonplace, often requiring surgical revision [2]. Modern hip implants typically incorporate a titanium alloy acetabular cap connected to the acetabulum of the patient that acts as the socket of the ball-and-socket joint of the hip; a high molecular weight plastic lining the acetabular cap; a titanium alloy femoral head that acts as the ball of the joint, and a femoral stem that is connected to the femur of the patient [10,11]. Herein, we report the integration of anchors attached to the surface of the acetabulum cap and femoral stem; The anchors will hold PP sutures, providing tension between the acetabulum and femur, thus discouraging the dislocation of the implant whilst not affecting the mobility of the implant.

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