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Artificial Reverse Shoulder Arthroplasty Joint Project

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Biomedical Engineering Senior Design Project
Dr. Lawrence Noble Team 3 Final Report

The University of Akron

Zimmer Biomet Comprehensive Reverse Shoulder System Modification

The Shoulder Savers
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Abstract

Shoulder dislocation is a large problem with shoulder replacements in most patients. This paper reflects upon alterations on a reverse shoulder design already commercially made from Zimmer Biomet and creates a device that will resist dislocation. The team explored different options and completed a model of the device using 3D software that should fit the requirements requested by the customer and where the benefits of the device should outweigh the risks of the device.

Clinical Need:

The shoulder is connected by the humerus and the scapula bones, where the head of the humerus meets the glenoid of the scapula. The muscles consist of the deltoid and the rotator cuff that is made of four major muscles: subscapularis, supraspinatus, infraspinatus, and teres minor (Figure 1C) [1]. The deltoid muscle pulls the humerus up, whereas the rotator cuff balances it out by contradicting that force inferiorly (Figure 1B) [1,2]. When one elects for a shoulder replacement, the replacement mimics that of the anatomical shoulder, replacing the head of the humerus with a hemisphere of titanium and the glenoid is fitted with a metal base plate along with a polyethylene spacer for a smooth articulation of the joint. When the rotator cuff is not viable and can no longer support the shoulder, a reverse shoulder implant is utilized to move the load of the shoulder to the deltoid. The glenoid is then fitted with the hemisphere of titanium called the glenosphere and the humerus is fitted with the polyethylene spacer to cup the joint (Figure 1A) [3]. A severe clinical problem with reverse shoulder implants is the dislocation of the joint after arthroplasty. Dislocation can be caused by component malposition, inadequate tensioning of the soft tissue envelope, insufficient subscapularis tendon for repair, or the approach used in surgery [4]. There is no way to prevent dislocation other than with added lifestyle precautions. If a dislocation does happen, one of the ways to fix it is through a revision surgery which is why the team has decided to find a way to prevent dislocation of the implanted joint all together.

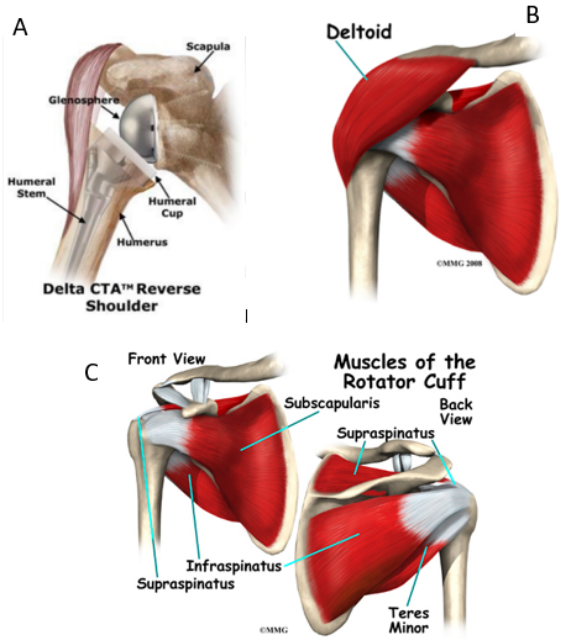

Figure 1: Different views of the shoulder. (A) with a device implanted, (B) Deltoid muscle, (C) muscles of the rotator cuff.

Engineering Requirements:

Engineering requirements were established based on the specified customer requirements. The design enhancement included a positive locking feature between the humeral component and the glenosphere to prevent separation. The Zimmer Biomet implant has two available sizes of the glenosphere that will be accomodated. Normal range of motion of the shoulder shall not be limited by the enhancement.

Design:

Ideas ranged from a simple cup changing geometry all the way to creating a mechanism that would tighten the glenosphere and the humeral components together. The ultimate decision landed on creating a system onto the device with bungee cord-like technology through an evaluation chart. The bungees were used to secure the implant in place, like how ligaments function in the knee, while allowing the device to have slack so the applied forces do not transfer all of the impact load to the humeral bone that would possibly end up with bone fracture. In this design, the bungees acted as ligaments keeping the components together to avoid dislocation.

Preliminary Sketches

The initial concept began with three bungees in the middle of the implant with a configuration like a bowling ball (Figure 2A). The design included screws on the glenosphere to match with the screw placement in the base plate. Three screws also fit into the humeral spacer but not deep into the humeral tray. Wear particle formation in the articulation of the joint could increase as the two components articulate together.

The second evolution was to have the bungees to go around the implant almost like a cage (Figure 2B). Due to the design, a 360-degree view would need to be visible in surgery for insertion of the bungee addition. The final design involved modifying both the base plate and the humeral tray, where added material on the anterior and posterior sides of the components, almost creating a petal like shape (Figure 2C). This design allowed for the entire modification to be completed during the manufacturing process and most of the surgery process will remain the same. The bungee material was glued into the holes on the side using a strong, curable glue during the manufacturing process on both the glenoid baseplate as well as the humeral tray. The base plate as well as the tray was inserted during surgery in the same way as the original procedure, however, someone would need to ensure the bungee material was not in the way during the process.

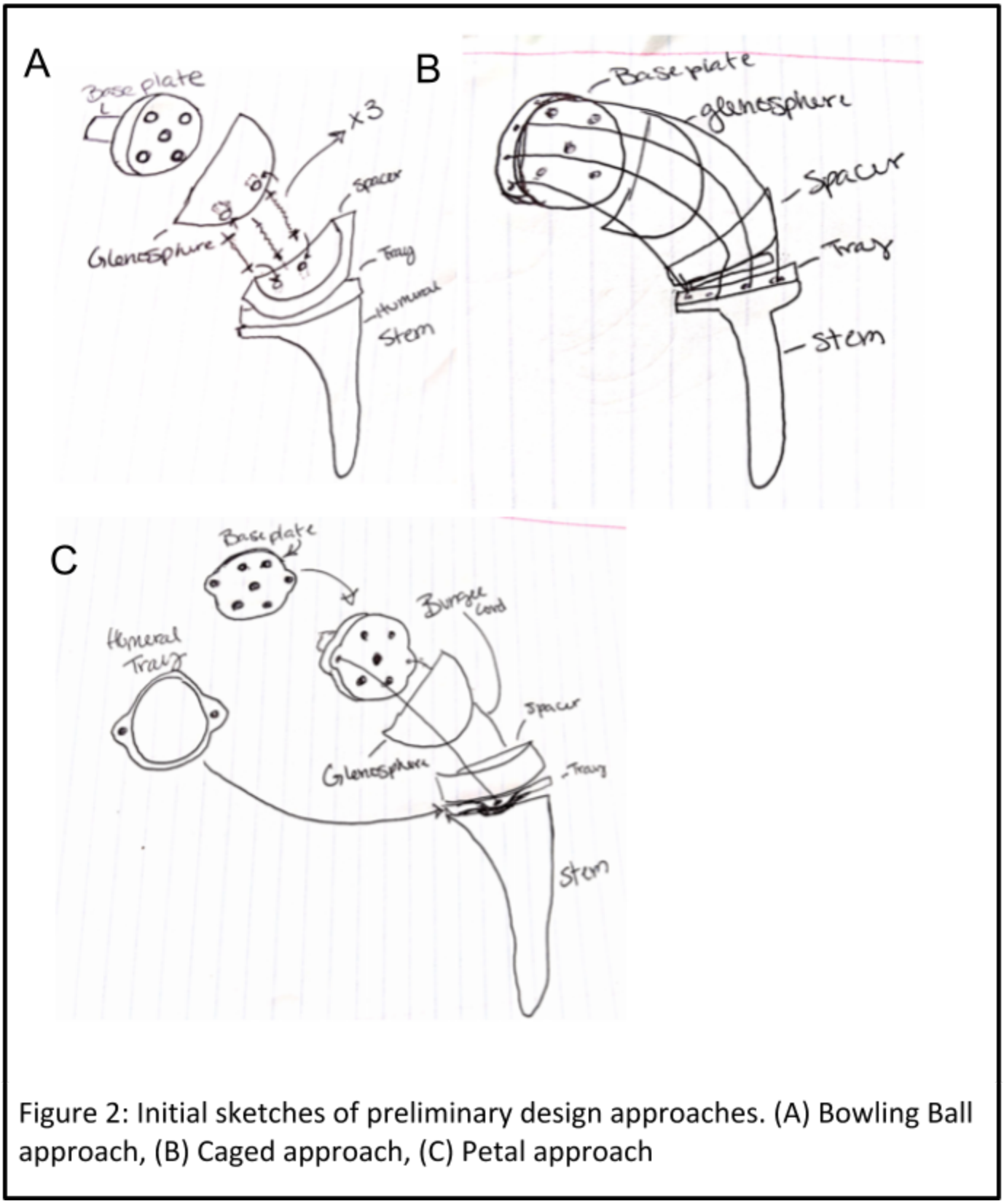

Figure 2: Initial sketches of preliminary design approaches. (A) Bowling Ball approach, (B) Caged approach, (C) Petal approach

3D Modeling

3D models were rendered using SOLIDWORKS® software. The models followed the final design idea which is best articulated with the top view of the full assembly (Figure 3A), but all components can also be seen from the anterior view as a representation in the body (Figure 3B). The utilized SOLIDWORKS® software allows the concept of the design to be created into 3D models and provides component and assembly drawings the team used to show measurements and critical dimensions of the design.

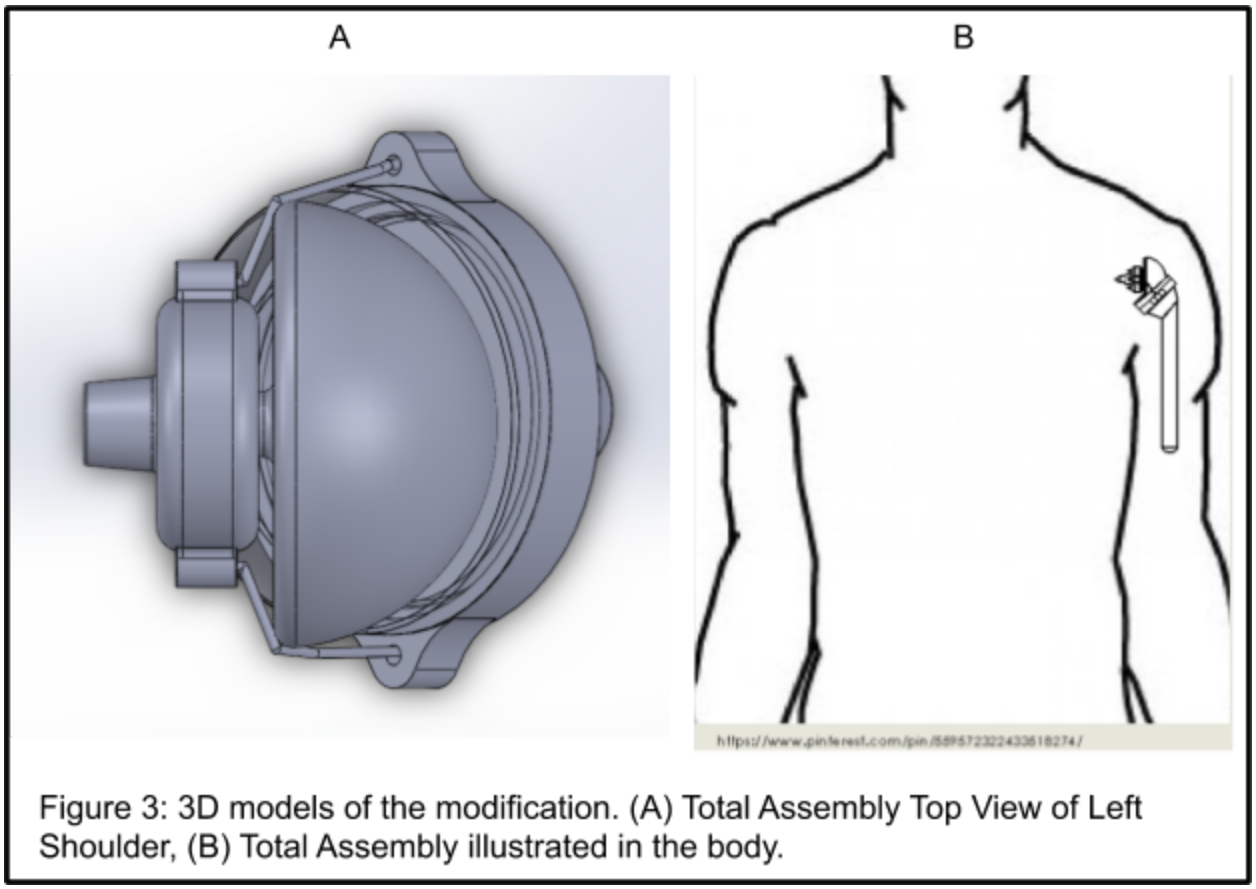

Figure 3: 3D models of the modification. (A) Total Assembly Top View of Left Shoulder, (B) Total Assembly illustrated in the body.

Device Risks:

One of the main risks that could occur by modifying the design to prevent dislocation is fracturing the humerus. When in a situation of experiencing a high impact force directly, such as a fall that contacts the shoulder joint, that direct force transfers to the joint resulting in dislocation. By removing the ability to dislocate at the joint, the force can transfer to the humerus that could cause fracture of the bone. The modification allowing movement in the joint decreased that risk. The joint can take the impact, but the elasticity of the design should allow the joint to return to its proper place.

Another main risk with joint implants in general is the formation of wear particles from the material rubbing. Wear particles are formed in all types of orthopedic implants, whether shoulders or hips [5], but since the modification adds extra material to its components, including straps that are in contact with the components, it increases surface area and the possibility of wear particles. The reason

this risk was considered heavily in the design was because wear particles can cause inflammation in nearby surrounding tissue as well as increase osteoclast efforts while decreasing osteoblasts efforts [2]. These effects result in the resorption of bone that can ultimately lead to a revision surgery. By choosing highly durable materials, like titanium and polyurethane, this risk is decreased and should not allow wear particles to occur at a dangerous level.

Conclusion:

As a result of this project, the team was able to come up with complete, preliminary 3D models from the 2D concept in the design sketches to create a modified reverse shoulder implant to address dislocation. The project worked through all stages of common medical device protocols that started with detail-oriented research on the clinical need and working devices on the market. This led to developing a few concepts and choosing the one that satisfied the specifications created.

While the modification led to an outcome of preliminary designs to be further tested, it also produced a great amount of knowledge obtained by the team for making a medical device. It provided chances to brainstorm novel concepts and weigh benefits and risks of those concepts. Opportunities came to further develop communication skills with clients and between team members to solve the problem. A great amount of technical skills were further developed through the use of SOLIDWORKS® to create the 3D models and drawings of the design components for a reverse shoulder implant. If time were not an issue for the team, validation would have required a 3D printed prototype for observation of the range of motion for the device as well as strength and fatigue data could have been gathered for the polyurethane and adhesive materials. Overall, this modification to the reverse shoulder implant helped the team grow as engineers in all aspects.

References

[1] Seymortier, P. V. (n.d.). *Fig 1*. Photograph. Available from https://eorthopod.com/shoulder-anatomy/

[2] University of Washington Orthpaedics and Sports Medicine. Reverse Shoulder Replacement. (n.d.). Available from: https://orthop.washington.edu/patient-care/articles/shoulder/reverse-shoulder-replacement.html [Accessed 3 April 2020].

[3] MMG. (n.d.). *Muscles of Rotator Cuff*. Photograph. Available from https://www.researchgate.net/figure/The-components-of-the-Delta-CTA-reverse-shoulder-prosthesis_fig1_6784673

[4] Chalmers PN, Rahman Z, Romero AA, Nicholson GP. Early dislocation after reverse total shoulder arthroplasty. Journal of Shoulder and Elbow Surgery. 2014;23(5):737-44

[5] Lochner, K., Fritsche, A., Jonitz, A., Hansmann, D., Mueller, P., Mueller-Hilke, B., & Bader, R. (2011). The potential role of human osteoblasts for periprosthetic osteolysis following exposure to wear particles. International Journal of Molecular Medicine, 28, 1055-1063.