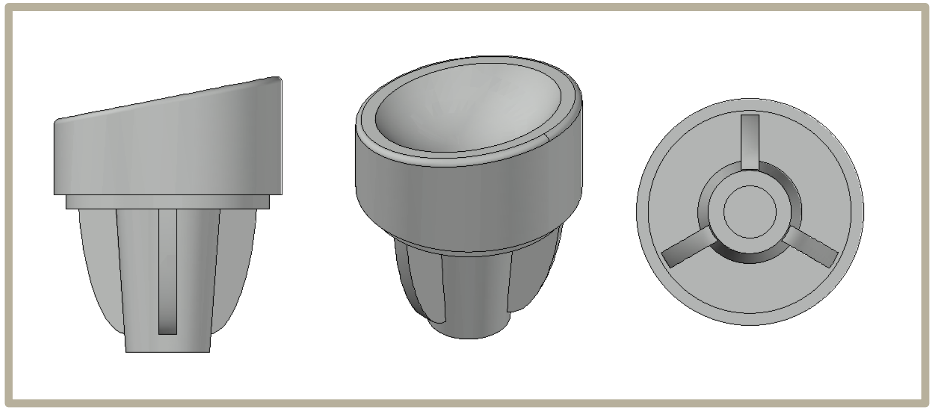
exactech

Cold Shoulderz
Team 114



Team Introductions

Matthew Mohammed
Mechanical Engineer

Nickolas Wolniewicz
Mechanical Engineer

Alexandra Nowzamani
Biomedical Engineer

Ethan Corey
Biomedical Engineer

Valeria Aguilera
Biomedical Engineer

William Crittenden
Biomedical Engineer

Matthew Mohammed

Sponsor and Advisors

<u>Engineering Mentor</u>
Thomas Vanasse
Director of Engineering, Upper Extremities

<u>Academic Advisor</u>
Stephen Arce, Ph.D.
Teaching Faculty II

<u>Academic Advisor</u>
Shayne McConomy, Ph.D.
Teaching Faculty I

Matthew Mohammed

Objective

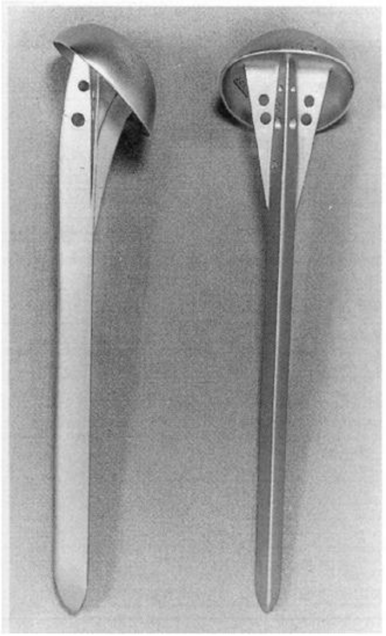
Design a reverse stemless shoulder implant to improve range of motion, strength in the shoulder and reduce overall pain. Create testing procedures to ensure the implant would not fail.

Matthew Mohammed

Motivation

To go beyond the current designs of shoulder arthroplasty and improve the reduction of shoulder pain

Jules Emil Pean, 1892
First Shoulder
Arthroplasty



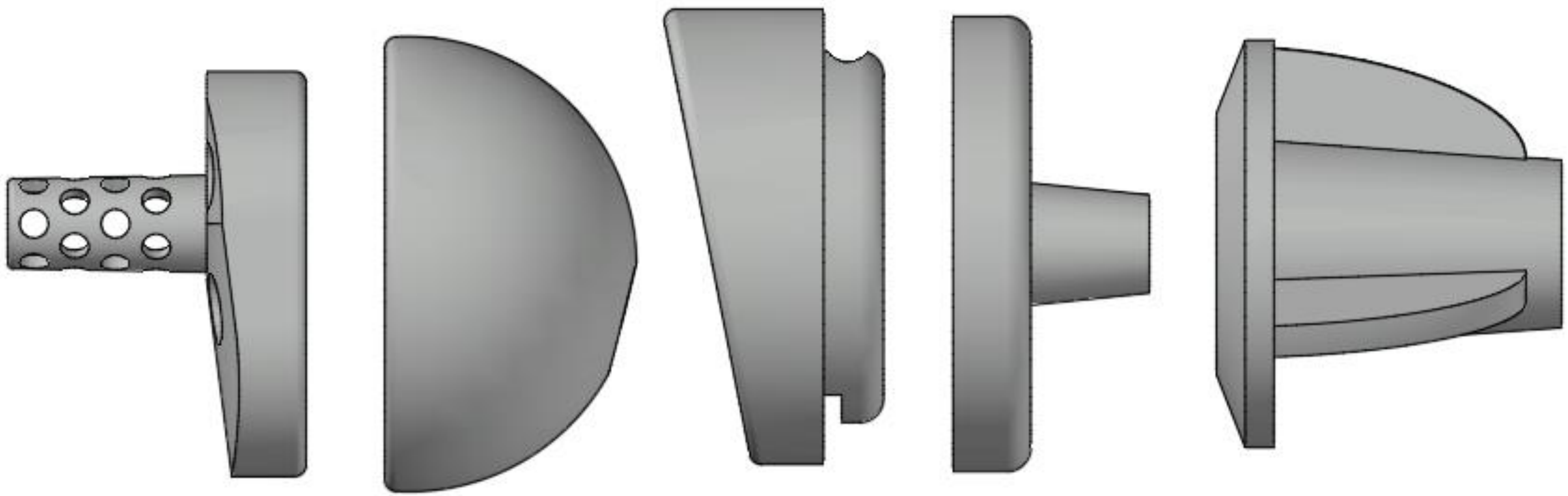
Charles Neer, 1953
First Stemmed
Shoulder Implant

Paul Grammont, 1991
First Reversed Shoulder
Implant

Biomet, 2004
First Stemless
Shoulder Implant

Matthew
Mohammed

Reverse Stemless Shoulder Implant



From left to right- glenoid anchor, glenosphere, glenosphere tray, liner, humeral anchor

Matthew Mohammed

Customer Needs

- Over 800,000 people in the United States live with a shoulder prothesis
- From 2000 to 2010, prevalence of shoulder arthroplasty almost tripled
- Total shoulder arthroplasty (TSA) is usually required due to osteoarthritis, but can also be needed due to external trauma to the joint
- The major configurations of TSA are stemless or stemmed and anatomical or reverse

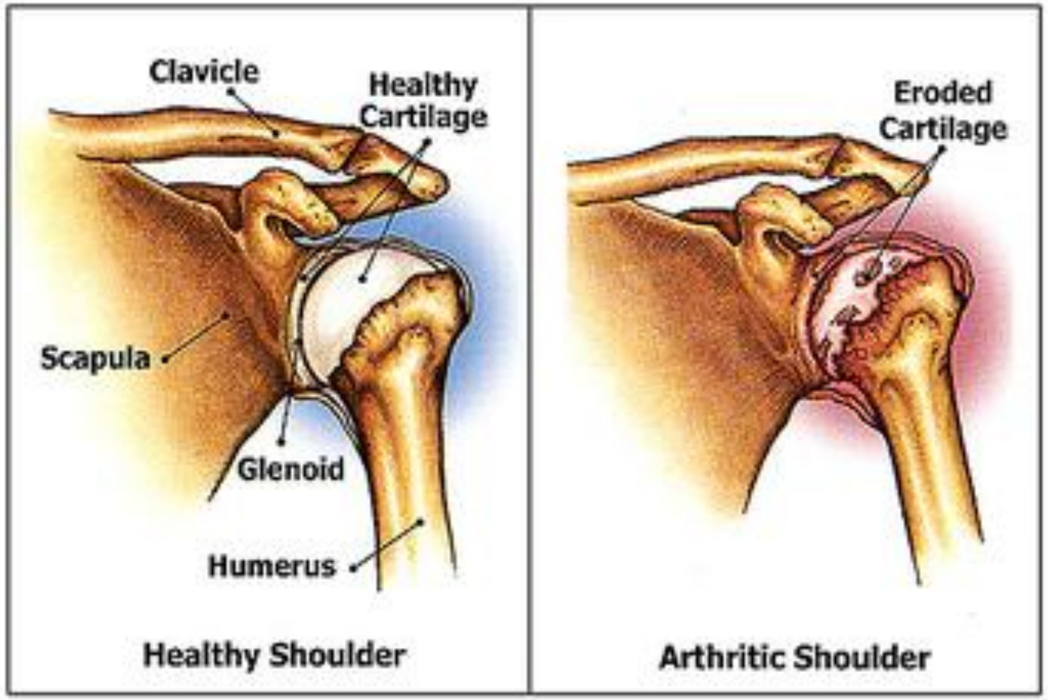


Figure 1. Image showing cartilage erosion in a shoulder with arthritis versus a healthy shoulder

William Crittenden

Concept Generation – Existing Solutions

- Stemless shoulder implants conserve far more bone and are much easier to initially implant and revise, but are relatively new
  - Revisions cost over $206 million in 2017 alone
- Reverse implants provide a different angle allowing for less stress to be generated on the rotator cuff

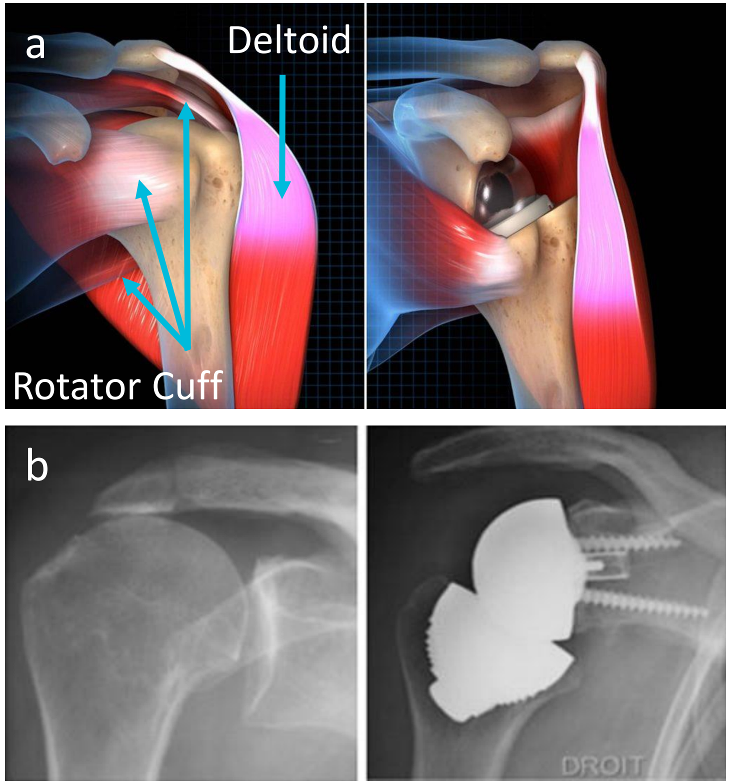


Figure 2. (a) Exactech Reverse Implant (b) Stemless Reverse Shoulder Implant

William Crittenden

Stress and Shoulder Relationship

- Lever out is a primary concern with stemless reverse implants.
- Lever out component of force has been shown to reach up to 180N
- Values obtained through moderate daily actions – may be higher!

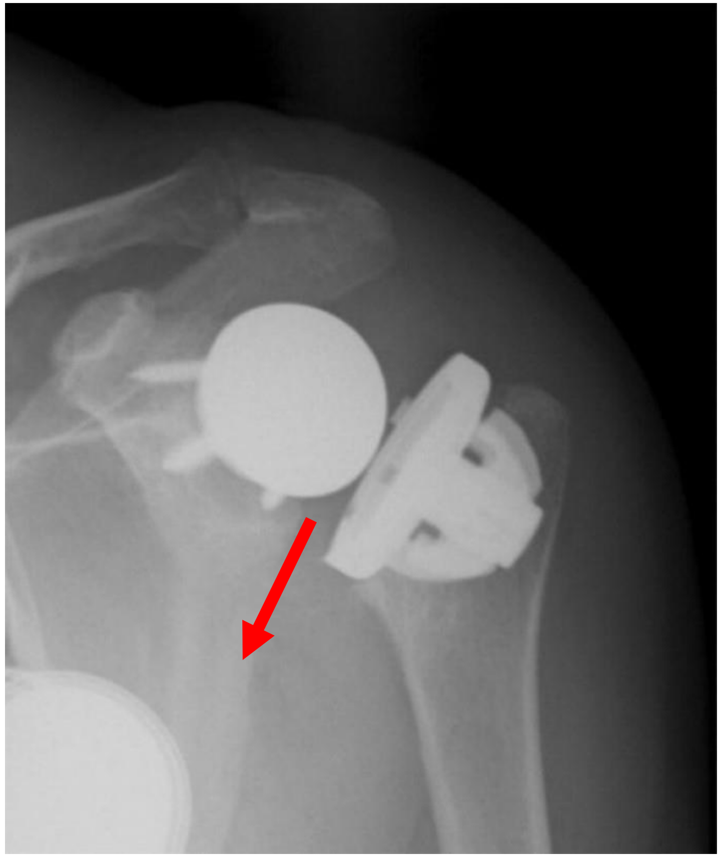


Figure 3. Direction of lever out forces

William Crittenden

Reverse Stemless Implant Benefits

<u>Potential Benefits:</u>

- Prevents rotator cuff damage.
- Better joint stabilization.
- Easier revisions.
- Decrease of fractures.
- Preservation of bone.
- Shifts emphasis to deltoid muscle.

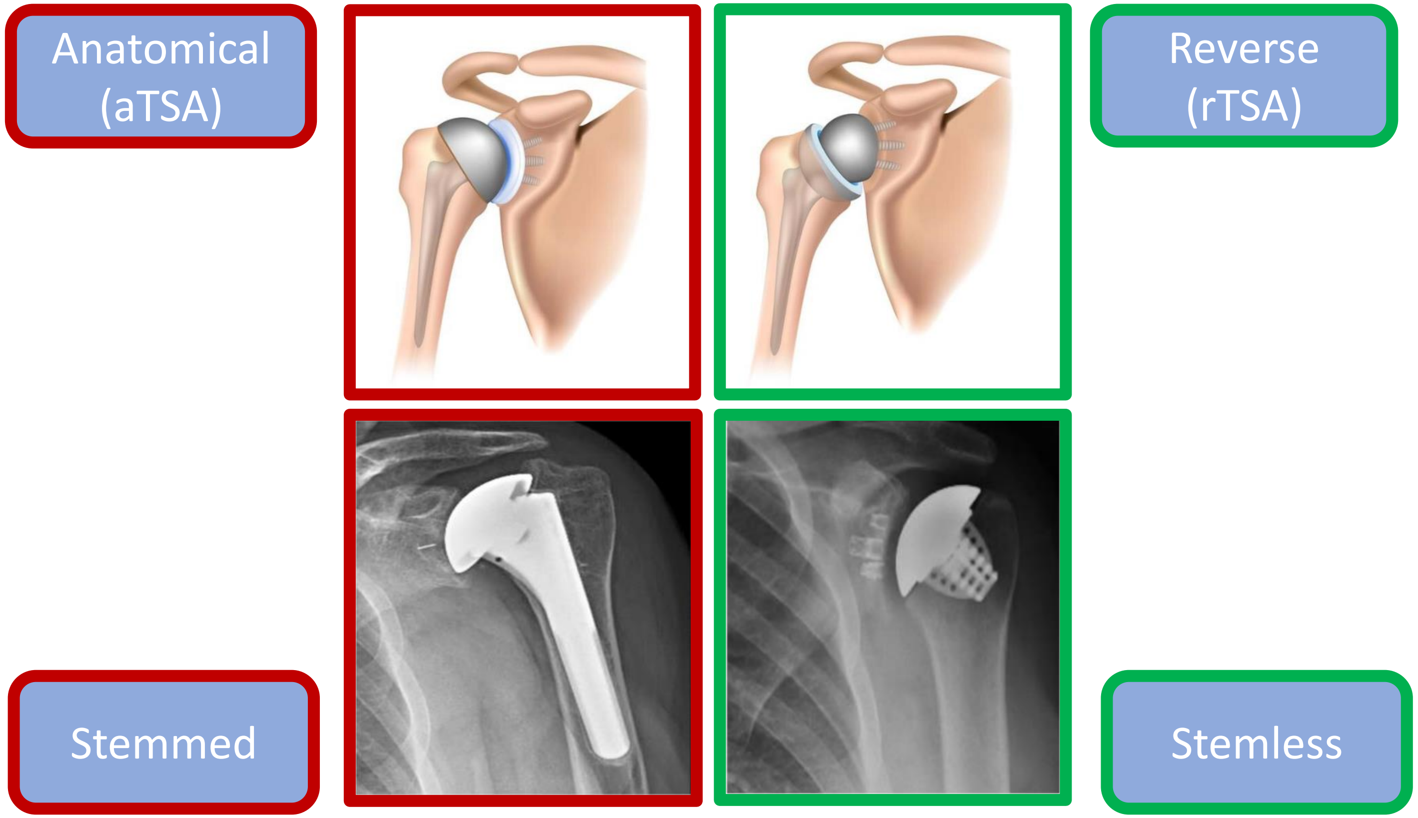
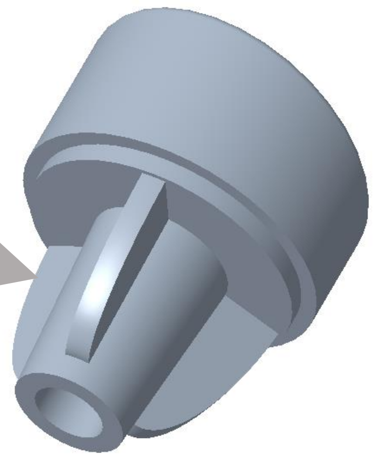


Figure 4. Comparison of Implant Variations

Nickolas Wolniewicz

Prototyping

Our focus will be Modifying these **fins.**



- An array of implants were created based on modifications of the current Exactech stemless implant
- **Preliminary testing**
  - LulzBot TAZ Pro 3D Printer
  - PLA filament
- **Final Testing**
  - Formlabs Form 3B+ Resin 3D Printer
  - Formlabs Tough 1500 resin

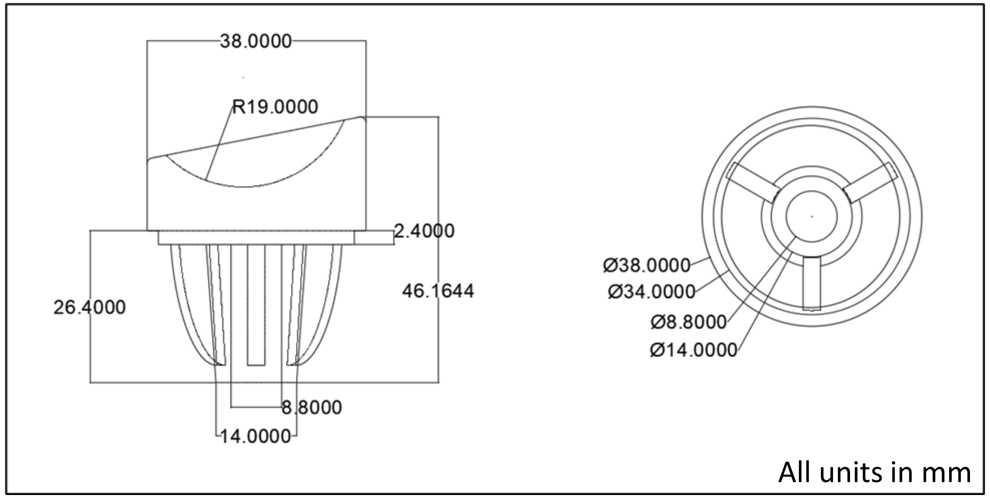


Figure 3. (top) Exactech Reverse anatomical Implant (bottom) Stemless Reverse Shoulder Implant Prototype Dimensions

Nickolas Wolniewicz

Primary Concept Selection

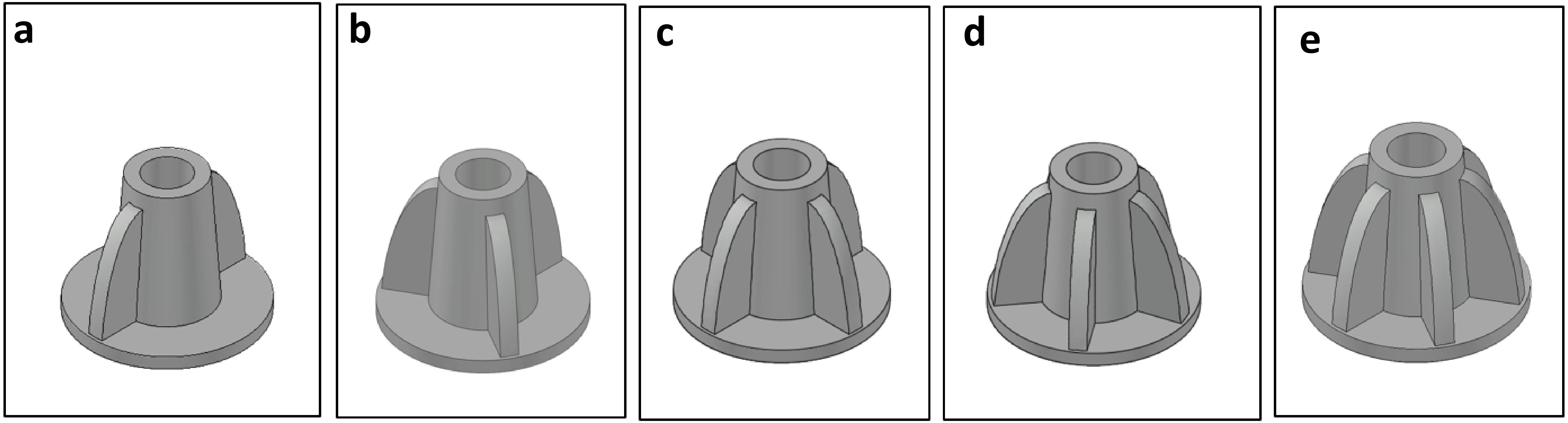


Figure 4. Stemless Reverse Concept Designs. (a) two-fin, (b) three-fin (Exactech), (c) four-fin, (d) five-fin, (e) six-fin

Nickolas Wolniewicz

Preliminary Testing – Foam Boards

Main Components

- 2, 3, 4, 5, and 6 Fin Designs
- Extruded Polystyrene Insulation
- Adjustable C-clamps
- 10 kg Force Meter

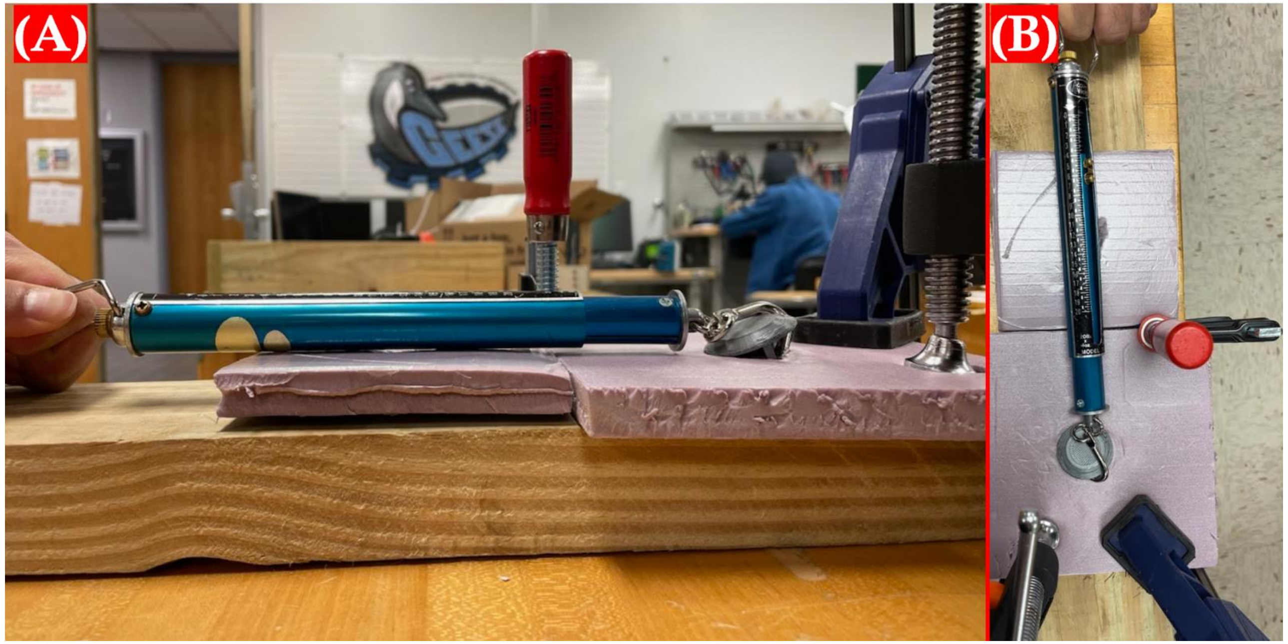


Figure 5. Testing setup from (A) the side view and (B) top view

Alexandra Nowzamani

Preliminary Results – Foam Boards

- Highest lever-out force was experienced by the current Exactech model.
- Only results that were statistically significant: Exactech model vs. six-fin model.
    - More testing is needed to find significant data between number of fins and lever out force.

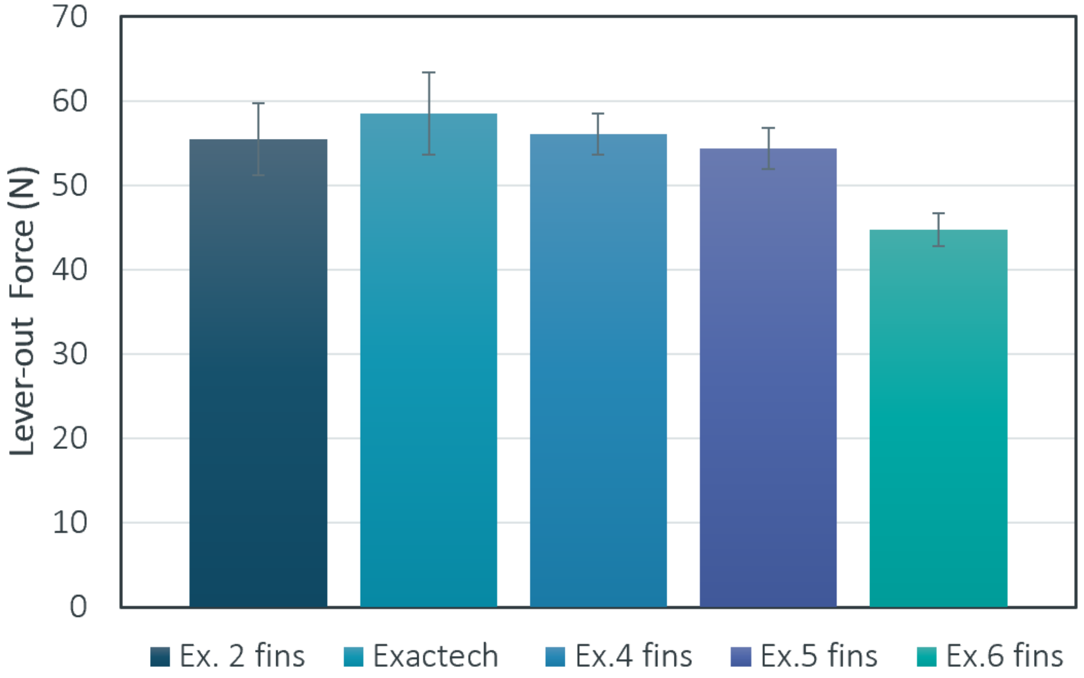


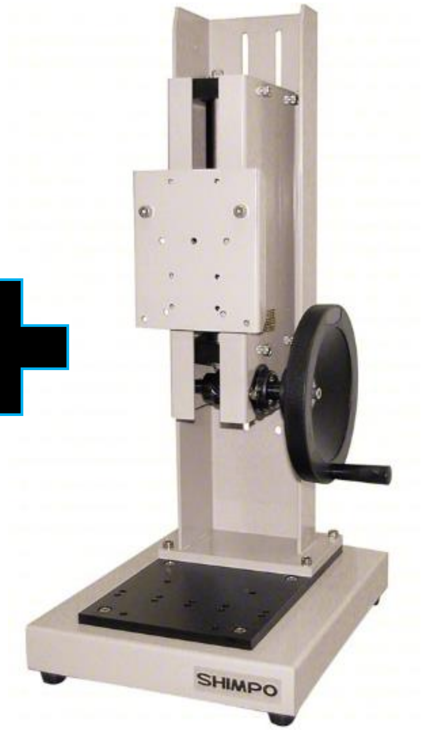
Figure 6. (Left to Right) Lever-out force for the preliminary testing of two-fin, three-fin, four-fin, five-fin, and six-fin models.

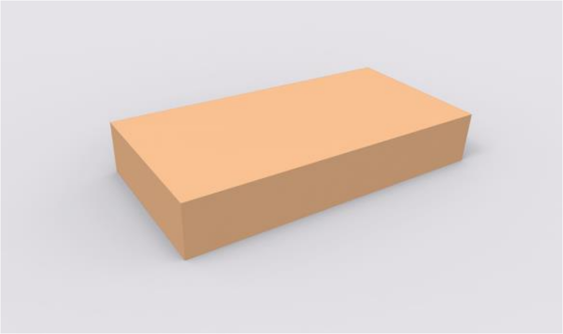
Alexandra Nowzamani

Final Testing – Bone Blocks

Main Components

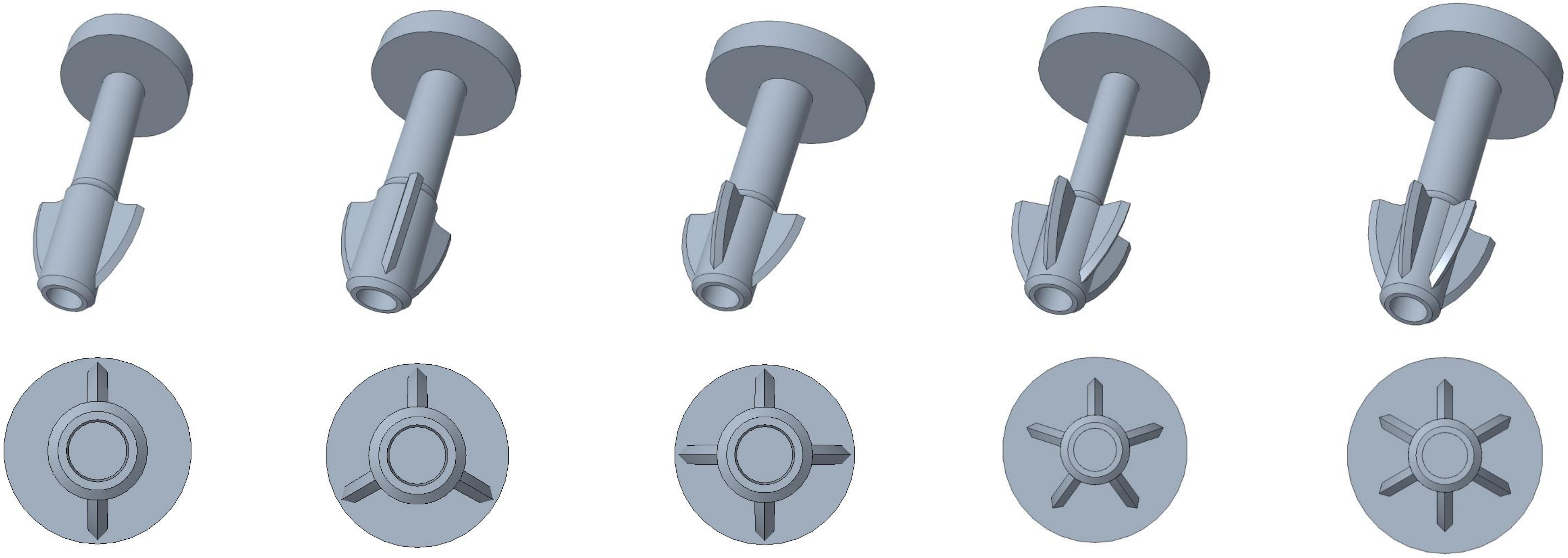
- 2, 3, 4, 5, and 6 Fin Designs
- 10, 15, and 20 PCF Bone Blocks
- Shimpo FGE-50XY Digital Force Gauge
- Shimpo FGS-100H Manual Hand Wheel Operated Test Stand
- Insertion Plunger for 2, 3, 4, 5, and 6 Fin Designs





Alexandra Nowzamani

Final Testing – Punch for Bone Blocks



Nickolas Wolniewicz

Final Testing – Shear/Lever out

- Tests the peak force required to completely shear the implant out of the bone block.
- Performed by directly applying a force on the glenosphere tray vertically.

Ethan Corey

Final Testing – Torque out

- Tests the peak force required to completely dislodge the implant from the bone block through a twisting motion.
- Performed by directly applying a vertical force on a metal rod attached to glenosphere tray.

Ethan Corey

FDA Strategy

Risk	Pathway	Desired Outcome	Time
Moderate-High Class 2	510(k) Submission Receive a 510(k) number	FDA Clearance. Substantially equivalence to predicate device	3-6 months after submission for FDA clearance

Valeria Aguilera

Other Tests

- Device can be cleared by the FDA without animal testing or clinical trials
- Benefits of clinical testing
  - Comparative advantage
  - More appealing to customers
  - Significant in the reimbursement strategy

Animal Testing	Clinical Trial
Not Needed	Beneficial in terms of competitive landscape.

Valeria Aguilera

Reimbursement Strategy

Coverage →
- Demonstrate implant's effectiveness in improving the health of patients through clinical trials

Coding →
- Current procedural terminology (CPT) codes
- International Classification of Diseases, 11th revision (ICD-11)

Payment →
- Usually, Medicare covers procedure, but not the device
- Exemption: If the device shows substantial clinical improvements, Medicare can give special 'provisions'

Valeria Aguilera

CPT Codes and Intellectual Property

CPT Code	Code Description
23470	Arthroplasty, glenohumeral joint; hemiarthroplasty
23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement [e.g., total shoulder])
23473	Revision of total shoulder arthroplasty, including allograft when performed; humeral or glenoid component
23474	Revision of total shoulder arthroplasty, including allograft when performed; humeral and glenoid component

U.S. Patent and Trademark Office

European Patent Office

Valeria Aguilera

Safety, Intended Use, and Packaging

Safety

Biocompatibility and sterilization - ISO 10993-10, ISO 10993-4, ISO 10993-5, ISO 11137-1, 10 CFR 37, USP <161> , USP <85><85>, and ANSI/AAMI ST72

Cytotoxicity - ISO 10993-5, ISO 10993-1, and ISO 10933-12

Carcinogenicity assessment - ISO 10933-10, ISO 10933-1, and ISO 10933-18

Hemocompatibility - ISO 10993-4

Intended Use

“The implant is intended for use in reverse shoulder arthroplasty for pain reduction and improved arm motion for adult patients.”

Labeling

Package will include:
(ISO 6018:1987)

1. Name
2. Registered trademark
3. Manufacturer’s address
4. Content description
5. Indications of use
6. Sterilization procedures
7. Recommended methods (opening and handling)
8. Manufacturing data (ISO 2014)

Valeria Aguilera

Ethical Considerations

Ethical considerations for implantable devices:

- End of life issues (Does not apply)
- Mental/Personal identity changes (Does not apply)
- Supernatural enhancements (Does not apply; restores basic function with minimal pain)

BMES Code of Ethics:

- Promote accessibility, affordability, and availability
- Enhance the standard of care
- Adherence to biomedical regulations

Valeria Aguilera

Most Important Points

1. We are developing new methods of testing lever, shear, and torque out.
2. There are currently no reverse stemless implants on the market in the United States.
3. Testing the effects of variables such as fin count to establish a foundation for a future design.

Ethan Corey

References

- https://www.hrosm.com/john-aldridge-introduces-the-equinoxe-stemless-shoulder/
- P. Westerhoff et al., “In vivo measurement of shoulder joint loads during activities of daily living,” J. Biomech., vol. 42, no. 12, pp. 1840–1849, 2009, doi: 10.1016/j.jbiomech.2009.05.035.
- C. Witney-Lagen, P. Consigliere, L. Natera, and O. Levy, “Stemless RTSA,” Shoulder Arthroplast., pp. 103–112, 2020, doi: 10.1007/978-3-030-19285-3_12.