Spring 2016

Reducing Fretting Corrosion at the Femoral Neck to Taper Junction in Total Hip Arthroplasty

Andrea M. Carly
University of Akron, amc190@zips.uakron.edu

Nicholas S. Moyer
University of Akron, nsm12@zips.uakron.edu

Abel S. Pietros
University of Akron, asp33@zips.uakron.edu

Recommended Citation
Carly, Andrea M.; Moyer, Nicholas S.; and Pietros, Abel S., "Reducing Fretting Corrosion at the Femoral Neck to Taper Junction in Total Hip Arthroplasty" (2016). *Honors Research Projects*. 275.
http://ideaexchange.uakron.edu/honors_research_projects/275

Reducing Fretting Corrosion at the Femoral Neck to Taper Junction in Total Hip Arthroplasty

Andrea Carly, Nicholas Moyer, Abel Pietros

Department of Biomedical Engineering

Honors Research Project

Submitted to

The Honors College

Approved:

James Keszenheimer Date 4/28/16
Honors Project Sponsor (signed)

JAMES KESZENHEIMER
Honors Project Sponsor (printed)

Date 4/29/16
Reader (signed)

L.D. NOBLE Jr.
Reader (printed)

Date 4/29/16
Reader (signed)

MARY C VERSTRAETE
Reader (printed)

Accepted:

Date 4/29/2016
Department Head (signed)

BRIAN DAVIS
Department Head (printed)

Date 4/29/16
Honors Faculty Advisor (signed)

MARY C VERSTRAETE
Honors Faculty Advisor (printed)

Date
Dean, Honors College

INTRODUCTION

Our project focuses on prosthetic hip implants at the connection between the femoral neck and the femoral head of the prosthetic itself. We are developing a method to properly surgically install the modular femoral head implant onto the femoral neck to minimize the amount of fretting and corrosion at the junction. If taper fretting and corrosion occur between the head and neck of the implant, the corrosion and debris material can cause localized tissue death and mechanical failure. These malfunctions are dangerous to the patients and costly to hospitals.

Our client is Zimmer Biomet, an orthopedic product development company with an interest in quality prosthetic implants and devices. We are working with Project Engineer Jacob Macke to address design requirements as well as fill any additional needs for the development of the device.

BACKGROUND INFORMATION

Modular prosthetic hips like the one shown in Figure 1 require a basic rod and mallet for installation in the current surgical process. The head of the implant is placed over the stem as depicted in Figure 2. The rod shaped impaction device as seen in Figure 3 is placed over the head and is then impacted with the mallet to fix the head to the stem portion of the implant. The amount of force applied to the impactor determines how secure the head will be on the stem. Higher amounts of impaction force have shown to help prevent future failure of the implant due to fretting corrosion. Fretting corrosion is a degenerative process that occurs between two metal faces and can cause harm if it occurs inside of a patient. The issue with the current method is that there is no accurate way to gauge how much force is applied during impaction. Using a force sensor on the end of the device will allow surgeons to acclimate to the amount of force necessary and reduce error during surgery.

Figure 1: Femoral Head and Stem Implant[1]

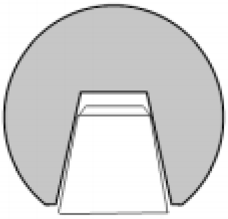


Figure 2: Head to Stem Taper Interface[2]

Figure 3: Femoral Head Impactor

PROJECT OBJECTIVES AND GOALS

Our goal is to decrease the corrosion rate of the taper junction between the femoral head and stem by controlling the impact force on the femoral head of the implant during installation. This will improve the quality of life for hip arthroplasty patients by increasing the success rate of surgeries involving prosthetic femoral neck to head insertion. We plan to fill this need by building a device that will help secure a femoral head firmly with the correct amount of force while minimizing higher than necessary amounts

---

[1] *Figure 1.* Bi-Metric with 28mm CoCr modular head. Adapted from "Not all Tapers Are Created Equal," by Imran Khan, PhD, 2015, *Biomet Orthopedics,* p. 1.

[2] *Figure 2.* Taper angle mismatch. Adapted from "Not all Tapers Are Created Equal," by Imran Khan, PhD, 2015, *Biomet Orthopedics,* p. 1.

of impaction force that might be considered overexertion. The instrument should help reduce corrosion as well as tissue health issues for the patient by providing a tighter fit between the stem and head. The device will include a force impact sensor to help prevent destruction to both the femur and the taper junction. This tool will allow the physician to keep a precise measurement history record of impaction force which will reduce the possibility of harming the patient or insufficient impact force during implantation. Figure 13 in the appendix is a Gantt chart showing the schedule of the development process used.

METHODS/PROCEDURES/MANUFACTURING

Brainstorming

When our design team discussed possible solutions, the team and client agreed that designing an instrument instead of an implant system was a more reasonable scope for this senior design project. A system diagram of the current method for impacting the femoral head implant can be seen in Figure 3 below.

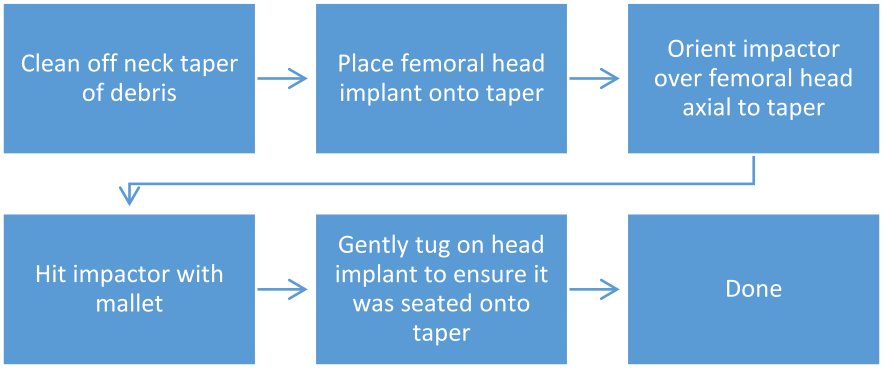


Figure 3: Current process for seating femoral head

Based on this process, our team researched potential failure modes that lead to increased fretting corrosion. The failure modes are provided in the list below:

- Inadequate impaction force
- Force not oriented axial to the taper
- Debris left on the taper
- Smaller diameter femoral implant heads
- Cobalt chromium CoCr head on alloy Ti6Al4V necks
- Low surface area tapers
- Longer neck lengths

Some of these are failure modes that are from implant selection and cannot be fixed with an instrument (such as small femoral heads and longer neck lengths). However, two of the failure modes that frequently were identified in our research were low impaction forces and femoral implant heads being impacted off-axis from the taper. Therefore, our solution would consist of (1) the head being seated safely with the right amount of force and (2) the applied force being aligned with the impact device’s longitudinal axis.

Our next step was establishing design parameters (in Appendices) to focus our design efforts. Our initial design solution is explained in the next section.

Evaluation of Initial Solution Approaches

Our initial approaches to the solution were:

- Pneumatic Device
- Compression Device
- Impaction sensor

In order to systematically pick the best solution we ranked the approaches on different design factors and multiplied that score by the weighted importance of that particular design factor. We then added up those scores and it gave us the final weighted score value. All of this work can be seen in Table 1 below.

Table 1: Weighted Scores for Solution Approaches (5 is a perfect score)

Weighted Importance	Design Factors	Impaction Sensor	Pneumatic	Compression Device
0.1	Alignment	4	4	3
0.2	Proper force output	4	5	3
0.05	Time of procedure	5	3	1
0.2	Cost	4	3	3
0.1	Manufacturing feasibility	5	2	3
0.05	Need for additional training	5	2	1
0.1	Easily Sterilized	3	2	4
0.2	Safety	5	3	2
Total=1	Final Weighted Score:	4.3	3.25	2.7

The top solution based on this analysis was the impaction sensor and therefore the teamed moved forward based exclusively on this approach. The pneumatic device was ranked second, and the compression device had the lowest ranking of our designs. The pneumatic device was 1.05 points lower (out of a possible 5) than the impaction sensor idea and the compression device is 1.6 points lower, hence we chose the impaction sensor. After consulting the functional requirements of Tables 3, the constraints and limitations of Table 4, as well as the customer requirements of Table 5 in the appendix, we were sure that this the best approach for our group.

The impaction sensor solution uses the same impactor design currently used in operating rooms. Our modification adds an impaction force sensor that will inform the surgeon of the impaction force being applied. Using trade literature provided from Zimmer Biomet we know that an impaction force of 4kN (the current surgeon average is 2kN) will decrease the amount of fretting corrosion wear by 50% as shown in Figure 4 below. The output from the force sensor would display the impact force in engineering units. This will allow surgeons to verify that they are impacting with manufacturer specified forces.

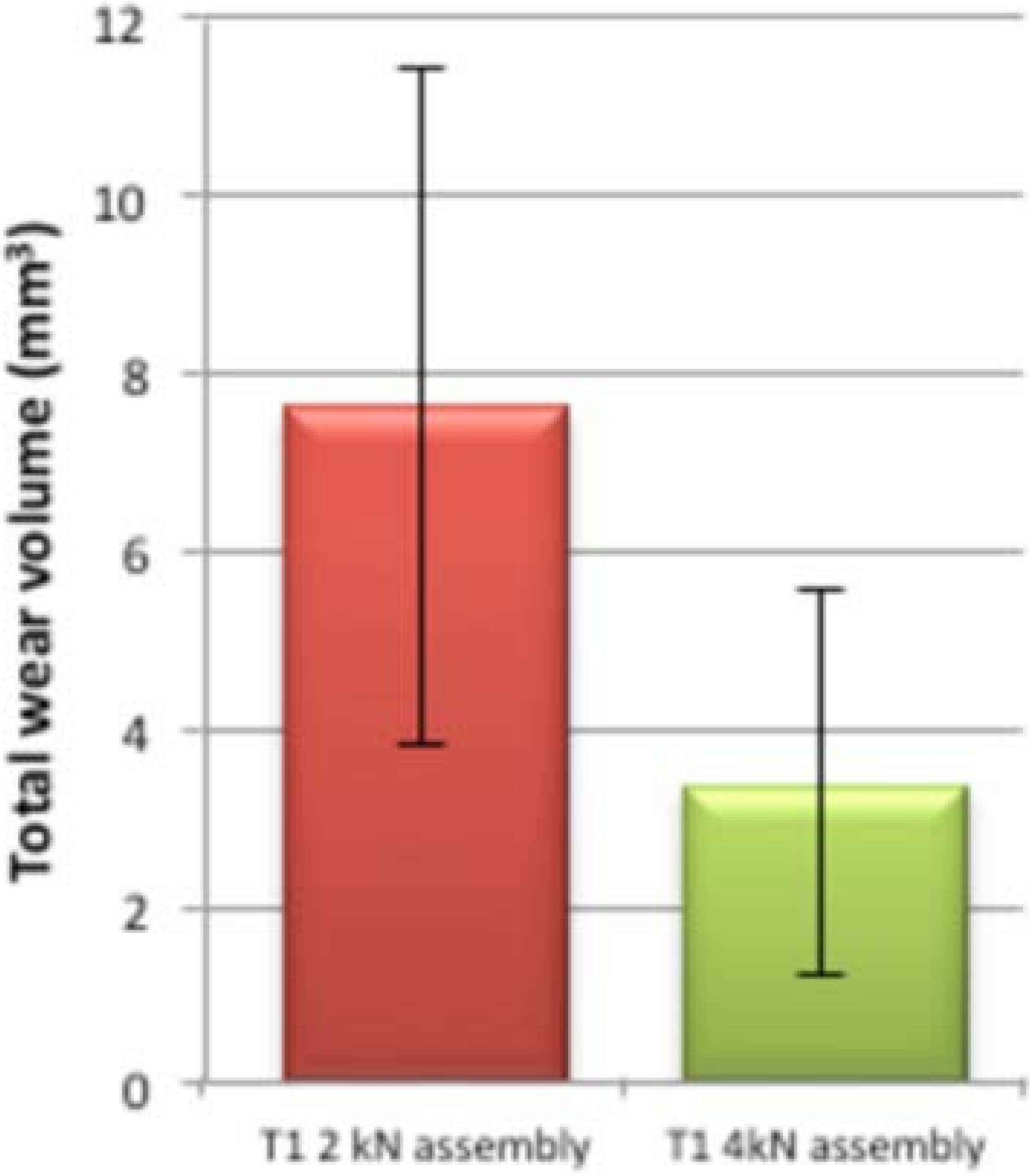


Figure 4: Volumetric wear loss of tapers assembled under different assembly conditions: 2kN static load (red) and 4 kN statically load (green)[3]

---

[3] *Figure 4.* Volumetric wear loss of tapers assembled under different assembly conditions. Adapted from "Not all Tapers Are Created Equal," by Imran Khan, PhD, 2015, *Biomet Orthopedics,* p. 6.

Impaction Sensor Solution Approaches:

Once the team decided on the impact sensor approach, we needed to decide on a specific sensor design and signal acquisition electronics. We also needed to determine if the electronics would be in the device or outside of the impact device. Several iterations of designs can be seen in Figures 5-11, which were discussed and evaluated. The team ultimately decided to locate the electronics outside of the device, as electronic circuit boards cannot tolerate the level of shock and vibration expected from the impactions as it would be damaging. The final model in Figure 12 depicts the full assembly containing the impactor, sensor, and a plate connection piece with drill holes for attachment to the other components.

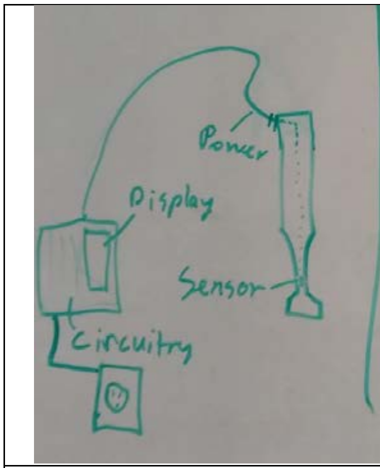
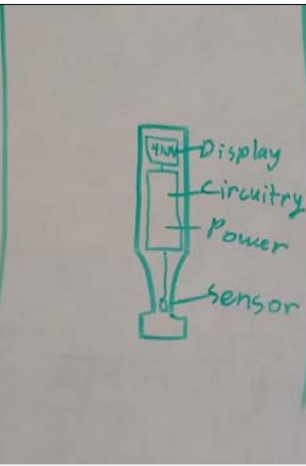
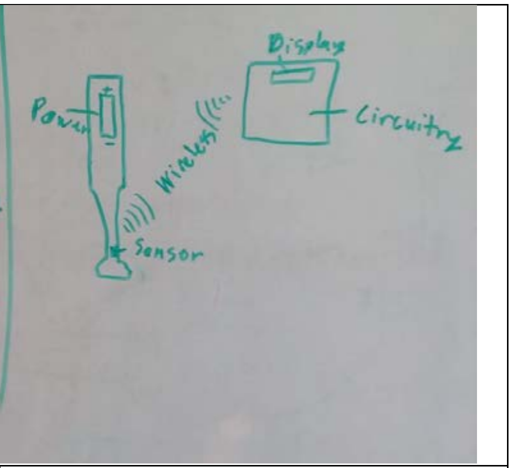
		

Figure 5a: Wired external display	Figure 5b: Complete internal configuration	Figure 5c: Wireless external display

Description	Feature/Parts
Both power and data connection are indicated in each of these designs, Figure 5a, 5b, 5c. The three figures represent the design location regarding the functional requirements of the sensor. Figure 5a and Figure 5b were possible options, but we needed to see if the sensor was to be located internally or externally.	All Wired External Display: All computing is done outside of the body. This is ideal for testing and was thought to be the initial beta design. This design is also sturdy in resisting impaction forces and the vibrations will not impact the sensor in any manner. All Internal: The internal system is meant to resist all of the forces conditioned from impaction forces. The internal configuration will be modeled with a microcontroller capable of translating the impaction forces to the display piece of the device.

Proposed Detachable Sensor:

The design options in Figures 6-9 show dynamic force sensor attachment ideas which were produced in a separate brain storming session. We chose to take another perspective to our design that had not been considered before: a detachable impaction sensor on top of the standard head impactor. Economically, this design would provide an easier removal for testing purposes.

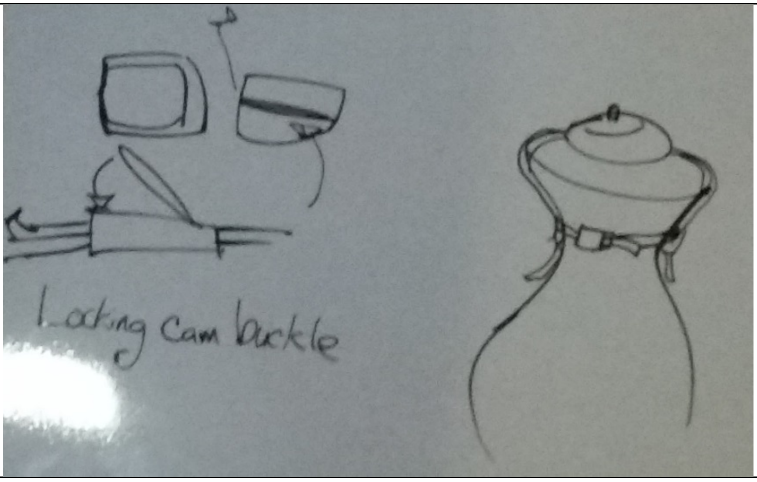


Figure 6: Loading cam buckle. Developed by Andi Carly

Description	Feature/Parts
The locking cam buckle derived from the idea of a watch clip. The clips are meant to attach to the sides of the sensor similar to a wrist watch. The cam buckle is to be used for both the attachment of the impaction sensor. The dual cam buckle piece is shown in later designs.	The cam buckle is to have silicon straps that are to be either dual access or single access straps depending on accessibility requirements. The buckle itself is to be made of stainless steel.

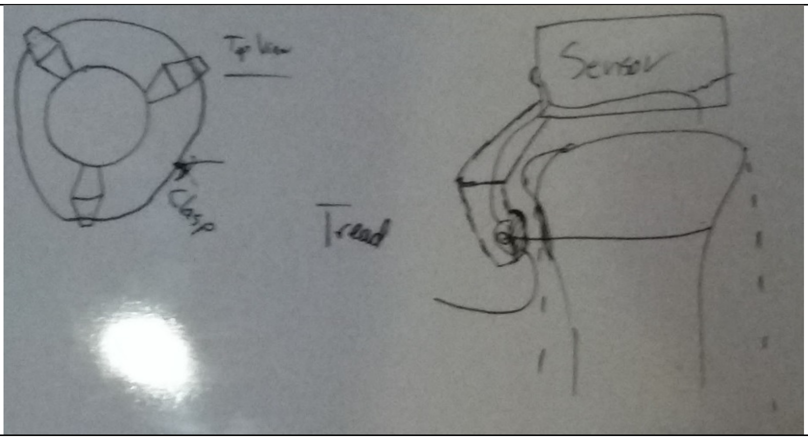


Figure 7: Tri-clasp. Developed by Domenic Carobine

Description	Feature/Parts
The device is a three-armed clamp that clips onto indents of the impaction instrument. The mount for the sensor is meant to be a self-tightening metal clip around the design. The arms act as both stabilizers for the sensor and detachable pieces for easy removal.	There will be a modification to the instrument geometry by creating an indent along the shaft. Treading on the inside tips of the arms pieces will allow for a tight grip strength. The arm pieces themselves are to be made of stainless steel.

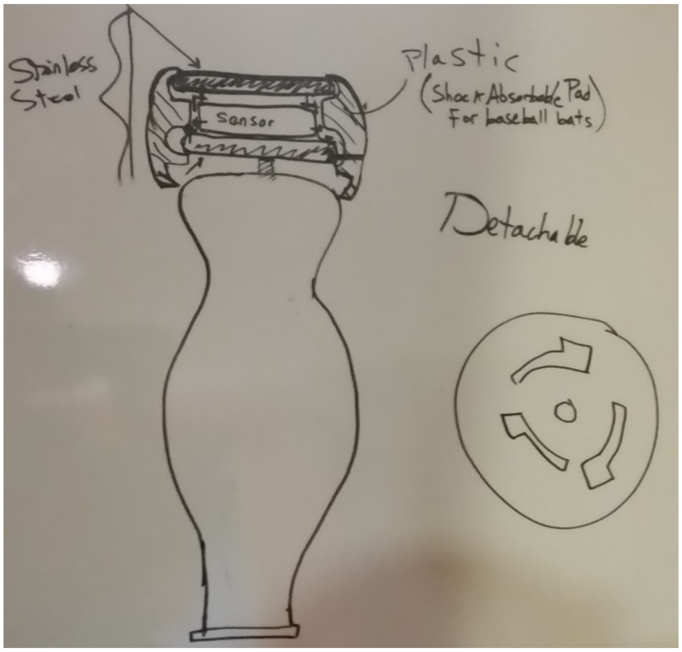
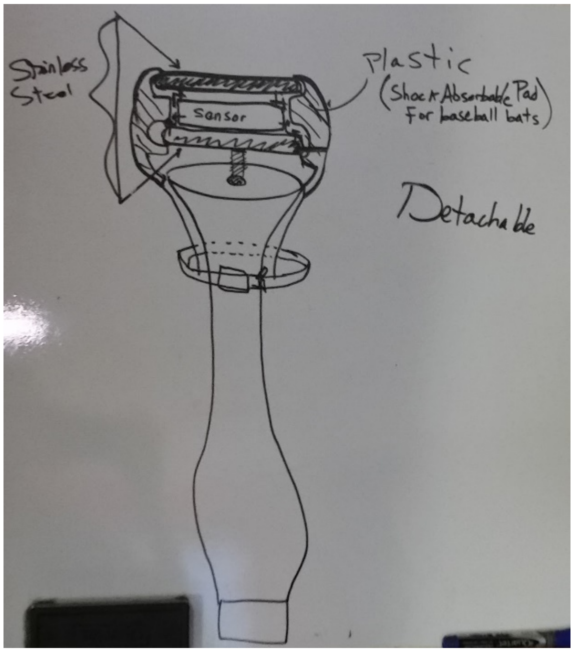
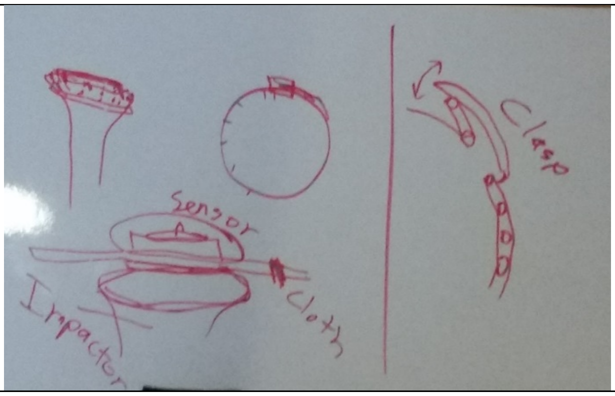
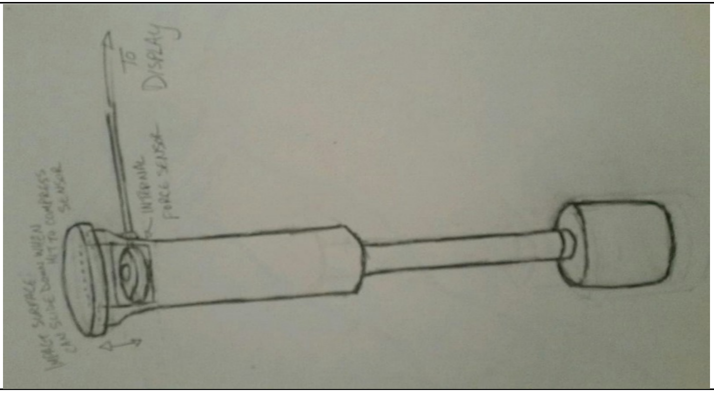
	

Figure 8a: “Shock absorbing” sensor case. Developed by Daniel Gerber.	Figure 8b: “Shock absorbing” sensor case adapted with loading cam buckle.
Description	Feature/Parts
This device is built to be a detachable sensor case that contains the sensor while being attached to the end of the head impactor. There would be one stainless steel disk above the sensor to recreate the original impaction surface. The plate will be fastened with 90 degree struts onto the sensor. The flexible rubber inside, unfolds and holds the small strap to keep the case from sliding off. The drawing above shows a screw connecting the sensor to the head impactor, but this may be excluded due to potential thread stripping due to large impaction forces. The distribution of forces to the screw caused confusion to the design but the use of the rubber case was noted for use.	Detachable rubber piece, screws, metallic disk, buckle strap, and sensor. The screw is located inside of the impaction instrument. This is for a sensor that has a screw attachment in between the two surfaces.

<table>
<tr><td colspan="2">
</td></tr>
<tr><td colspan="2">Figure 9: Single clasp mount. Developed by Nick Moyer and Abel Pietros</td></tr>
<tr><td>Description</td><td>Feature/Parts</td></tr>
<tr><td>Sensor is centered with a thin film that is held onto the impaction instrument by a clasp. The clasp is made similar to the clasps found on a wrist watch, the device is meant to hold the sensor in place to control any unwanted shifting.
The design is out of corrections it was of question that it will be able to hold all of the fatigue forces upon the instrument. The clasp was noted as being a solid piece in use for future design.</td><td>The clasp in the design is built for holding the sensor in the center position of the device. The design centers the sensor and removes unwanted movement of the sensor.</td></tr>
</table>

<table>
<tr><td colspan="2">
</td></tr>
<tr><td colspan="2">Figure 10: Internal sensor. Developed by the Taper Titans</td></tr>
<tr><td>Description   Sensor Inside the Impaction Instrument</td><td>Feature/Parts</td></tr>
<tr><td>Dynamic load sensor is contained within the impaction instrument once struck on the top the instrument will distribute the load straight to the dynamic load sensor. The dynamic load sensor is placed in a compartment that is capable of compressing onto the sensor not applying enough fatigue to cause damage. The device due to being placed in a compartment has less ability for creating noise.</td><td>This is a solid body design with a replaceable top for the ease in access to the sensor. The material for the body is mostly stainless steel with a non-deformable sleeve for resonating load forces. Only peak values from the sensor shall be read to the user.</td></tr>
</table>

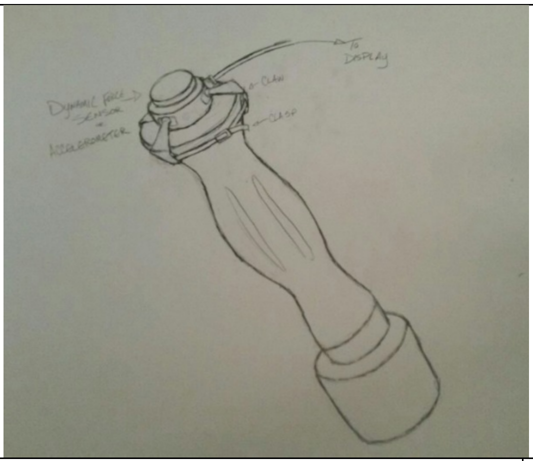
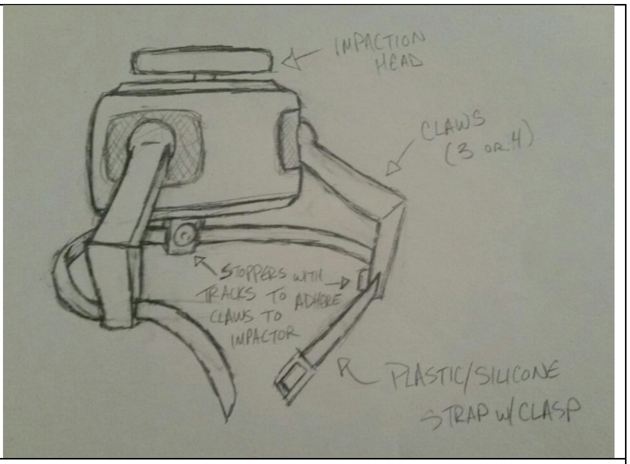
	

Figure 11a: Attachable sensor. Designed by the Taper Titans	Figure 11b: Detailed drawing of attachable sensor
Description Sensor Outside the Impaction Instrument	Feature/Parts
New placement of the dynamic load sensor outside of the body. Design was inspired by the ideal design from earlier parts. Load sensor for such device would take all of the impact directly and read out forces to the display.	Arms clip on as either three or four arm grip that holds the device in place. The buckle and strap acts as a secondary restraint in movement. Everything except the buckle and straps will be manufactured with stainless steel. The strap will most likely be made of silicon while the buckle is debatable for stainless steel or another anti-corrosive bacterial resistant material.

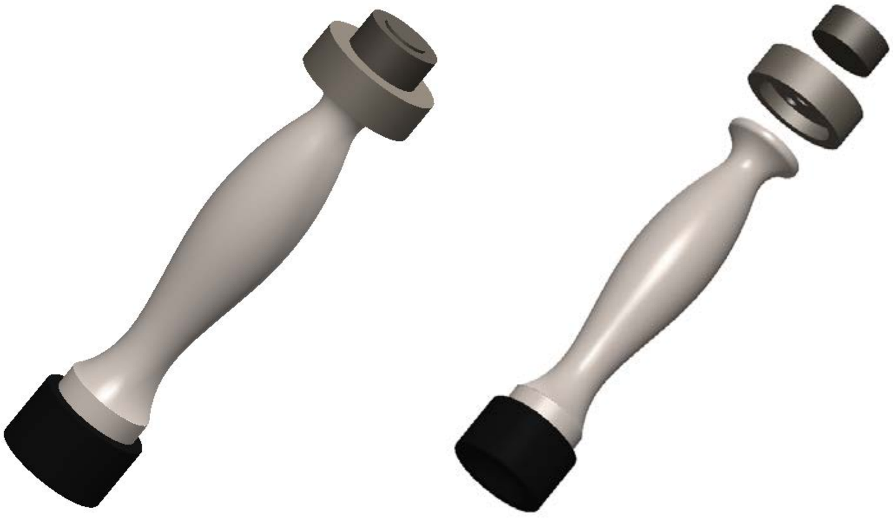


Figure 12: Final design. Developed by the Taper Titans	
Description Final Design	Feature/Parts
After consulting Zimmer-Biomet contact, Jacob Macke, we came to this design due to the fact we were allowed to change the instrument geometry and possibly use adhesives to attach the sensor.	Screw, ED09, Sensor type

Final Solution Morphological Chart:

In order to come to a final design decision, a morphological chart of the design factors was formulated, as seen in Table 2. According to the results, Figure 5a fit our design requirements. The costs of the components in this solution can be found in the appendix as Table 6.

Table 2: Final Solution Morphological Chart

Weighted Importance	Design Factors	Outside Sensor Attachment	Sensor Inside Impactor
0.2	Proper force output	5	5
0.05	Time of procedure	3	5
0.2	Cost Effective	4	3
0.2	Manufacturing feasibility	5	3
0.05	Need for additional training	4	5
0.1	Easily Sterilized	4	2
0.1	Output clarity	5	5
0.1	Sensor attachment strength	3	5
1			
	Weighted Value:	4.35	3.9

PLANNED ANALYSIS AND TESTING

A finite element model (FEM) analysis was created to understand the forces being applied onto the sensor, attachment piece, and impaction instrument. This model calculates stress, strain, reaction forces, and moments. A color coded legend will show where the largest amount of stress is located in the sensor, attachment piece, and impaction instrument all together and individually.

In order for this device to function properly, force testing is necessary for verification of our design. Our sensor will need to be calibrated and tested before it can display correct values of impaction. This will be done using the University of Akron's Instron testing systems. In order to find values from impacting the sensor, a rubber mallet is applied three times with a 4kN amount of force to the sensor while the device is powered and operational. These results are recorded multiple times to make sure the sensor is displaying values consistently and precisely. Durability tests will also be done to determine if the device will last through multiple uses and not dislocate from the impactor surface when hit or being aligned.

FUTURE DIRECTION

Our future direction would be developing a standalone system that would not need the data acquisition system from the sensor vendor. The standalone system would be capable of being sterilized and displaying outputs from the sensor. The standalone system should also be able to meet necessary stress test requirement so to prove durability.

APPENDICES:

Table 3: Functional Requirements description

FUNCTIONAL REQUIREMENTS	
Force Required	The new instrument should impact the head onto the femoral neck with enough force to reduce the threat of fretting corrosion. The greater force applied, the lower the chance of implant failure. 4kN is proven to reduce the chances of fretting corrosion by more than half compared to a 2kN impaction. Therefore, our developing device should reach at least 4kN force.
Device Size	The instrument must be handheld and not much heavier than current impactors and mallet systems. No more than 7 lbs. so all surgeons can use it.
Device Use Time	The current instrumentation only takes 8 seconds between placing the femoral head on the femoral neck and impacting it into place. Because we do not want the amount of surgery time to be significantly increase we want to ensure our instrument does not take more than 16 seconds to complete the seating of the femoral head (double the time). Our max amount of time we would consider is 24 seconds (three times the normal length of the procedure).
Compatibility	The new instrument must be able to be used with multiple total hip replacement systems. Current impactors do not require interchangeable impaction surfaces for different sizes and systems so our developed instrument should not either.

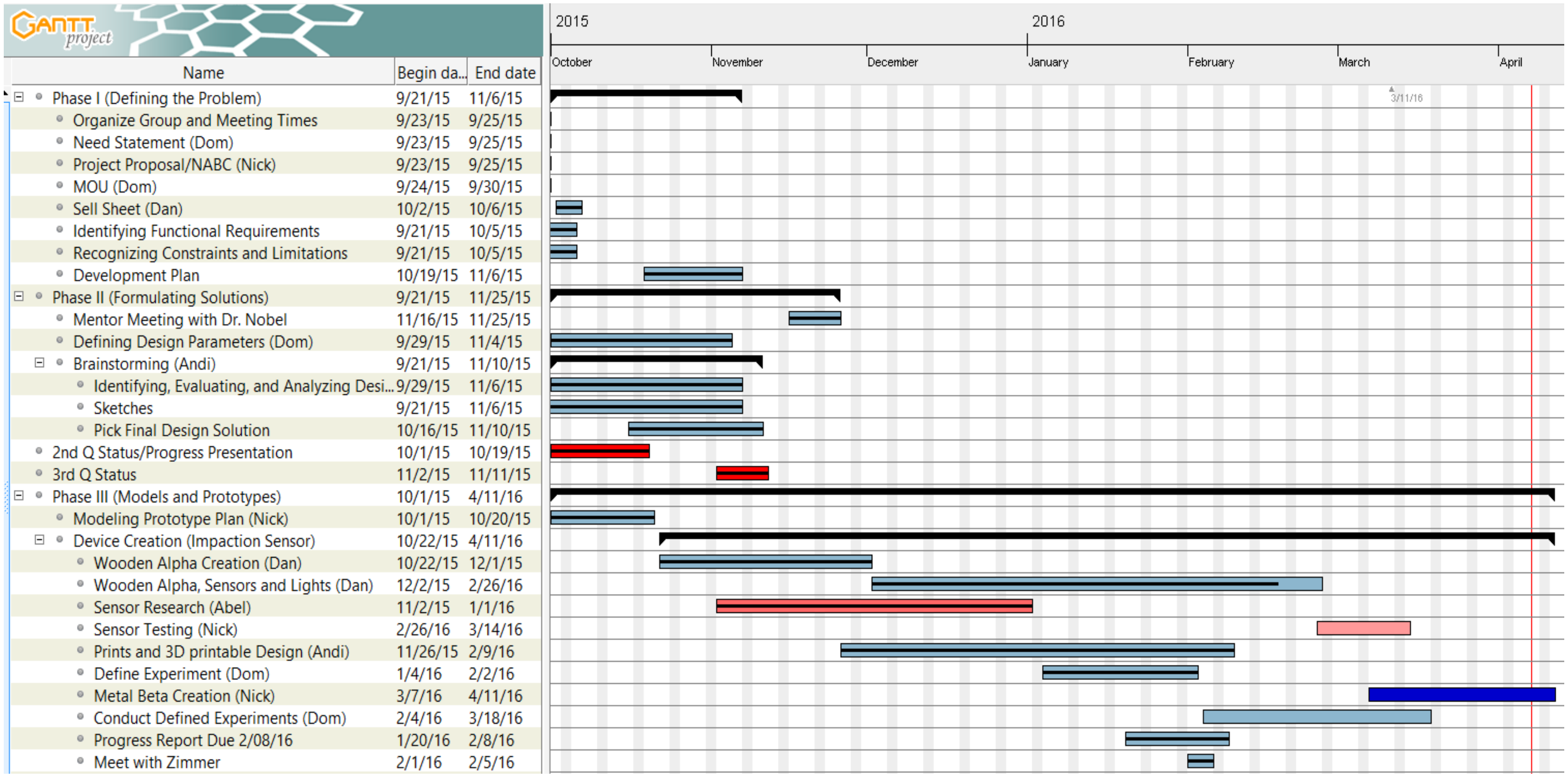
Table 4: Constraints and limitations description

CONSTRAINTS AND LIMITATIONS	
User Error	The instrument should provide the same impaction force consistently every time it is used; no variation between users.
Sterilization	The new instrument must not have materials or a complex geometry that limits the effectiveness of sterilization.
Safety	4kN might be a proven impaction force to decrease the risk of fretting corrosion, but it might be too much force to apply to some patients. Therefore, the impaction force on the pneumatic device must be adjustable to customize for specific patients with weaker bone quality (such as patients with varying degrees of osteolysis).
Cost	The budget for this design project is $500.00, but we have received confirmation from our client (Zimmer Biomet) that they are willing to contribute funds to the project. Just to stay practical we will try to limit our budget to $1000.00 so we aren't relying on the client too much.
Development Time	There is a time limit on development. All work must be complete within the two semester time period of nine months. Other classes as well as work hours limit availability.

Table 5: Customer and Engineering Requirements

		Customer Requirements							
		Develop a new method to properly assemble the modular femoral head onto the femoral stem to minimize the amount of fretting and corrosion at the junction.	Establish a consistent standard with impaction forces during training exercises to ensure they are impacting the head with the correct amount of force during a surgery.	Team decided on developing an instrument to satisfy the user need due to an implant system being too large of a scope for this two semester long class.	The new instrument must reduce variability between surgeons so that every surgeon is impacting the femoral head onto the stem with the proper force. This will ensure proper seating of the head onto the taper and reduce fretting corrosion.	The instrument must be compatible with the femoral head and different surgery positions and incisions.	The instrument will be multiuse, so the instrument must be easily cleaned between uses (i.e. dirt, saw bone dust, etc)	The instrument will be multiuse, so the instrument must be sturdy enough to withstand multiple impaction forces through the lifetime of the device.	The FDA classifies orthopedic impactors as Class 1 devices (Product Code: HWA) and have the recognized consensus standards: ISO 13402 First Edition 1995-08-01 Surgical and dental hand instruments – Determination of resistance against autoclaving, corrosion and thermal exposure ASTM F565-04 (Reapproved 2013) Standard Practice for Care and Handling of Orthopedic Implants and Instruments ASTM F1089-10 Standard Test Method for Corrosion of Surgical Instruments ISO 7153-1 Second Edition 1991-04-01 Surgical instruments – Metallic materials – Part 1: Stainless steel [Including: Amendment 1 (1999)]
Engineering Requirements	Instrument properly seats the femoral head to reduce improper assembly leading to fretting corrosion	x	x		x				
	Design Does Not vary significantly from old in terms of geometry and use	x		x					
	Instrument compatible with current THA systems	x	x		x				
	Training Surgical Technique	x	x		x				
	Materials			x	x		x	x	x
	Testing			x	x			x	x
	Impaction Force		x						
	Compatibility	x				x			
	Instrument Life						x	x	
	Ease of Use				x	x			
	Accuracy	x	x		x	x			
	Display	x	x		x				
	Durability							x	
	Equipment			x	x			x	x

TIMELINE:



Name	Begin da...	End date
Phase I (Defining the Problem)	9/21/15	11/6/15
Organize Group and Meeting Times	9/23/15	9/25/15
Need Statement (Dom)	9/23/15	9/25/15
Project Proposal/NABC (Nick)	9/23/15	9/25/15
MOU (Dom)	9/24/15	9/30/15
Sell Sheet (Dan)	10/2/15	10/6/15
Identifying Functional Requirements	9/21/15	10/5/15
Recognizing Constraints and Limitations	9/21/15	10/5/15
Development Plan	10/19/15	11/6/15
Phase II (Formulating Solutions)	9/21/15	11/25/15
Mentor Meeting with Dr. Nobel	11/16/15	11/25/15
Defining Design Parameters (Dom)	9/29/15	11/4/15
Brainstorming (Andi)	9/21/15	11/10/15
Identifying, Evaluating, and Analyzing Desi...	9/29/15	11/6/15
Sketches	9/21/15	11/6/15
Pick Final Design Solution	10/16/15	11/10/15
2nd Q Status/Progress Presentation	10/1/15	10/19/15
3rd Q Status	11/2/15	11/11/15
Phase III (Models and Prototypes)	10/1/15	4/11/16
Modeling Prototype Plan (Nick)	10/1/15	10/20/15
Device Creation (Impaction Sensor)	10/22/15	4/11/16
Wooden Alpha Creation (Dan)	10/22/15	12/1/15
Wooden Alpha, Sensors and Lights (Dan)	12/2/15	2/26/16
Sensor Research (Abel)	11/2/15	1/1/16
Sensor Testing (Nick)	2/26/16	3/14/16
Prints and 3D printable Design (Andi)	11/26/15	2/9/16
Define Experiment (Dom)	1/4/16	2/2/16
Metal Beta Creation (Nick)	3/7/16	4/11/16
Conduct Defined Experiments (Dom)	2/4/16	3/18/16
Progress Report Due 2/08/16	1/20/16	2/8/16
Meet with Zimmer	2/1/16	2/5/16

Figure 13. Gantt Chart showing progress goals throughout the semester.

Component Costs

Table 6: The costs of the components used in the final solution.

Item	Price
Dynamic Load Cell	$596.00
Other Fixation Components	$98.00
Hardware and Display	No Cost
Impactor Instrument	No Cost
Shipping Costs	$15.00