Bone Quality Indenter: Replacement for Thumb Test During Total Shoulder Arthroplasty

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Abstract

Exactech, a manufacturer of replacement shoulder joints, wants to create a tool to measure bone quality quantitatively. Exactech asked the FAMU-FSU College of Engineering to make such a device. Bone quality is an important factor in shoulder replacement surgery.

Age, injury, disease, or a combination of these, can cause damage to the shoulder joint. When a joint is damaged, shoulder replacement surgery is a treatment option. The surgery removes the damaged joint, replacing it with an artificial joint. These artificial joints fall into two general categories, stemmed and stemless implants. Stemless implants provide shorter recovery times and less invasive surgeries. However, these need a sufficient humeral bone quality. If the bone quality is not acceptable for a stemless implant, the surgeon uses a stemmed implant.

To determine the quality of the bone, the surgeon uses a “Thumb Test.” The humeral head is cut off; then, the surgeon places their thumb on the cut plane of the bone. The surgeon then uses their thumb to apply pressure to the bone. The surgeon discovers the bone quality and implant type based on the bone’s deflection. However, this is a qualitative measurement based only on the surgeon’s experience.

The team designed a tool that replaces the subjective “Thumb Test” with a handheld indenter, creating a quantitative bone quality score. The indenter uses a spring to accelerate an indenting pin. This force causes the pin to strike the cut face of the bone. The tool measures the maximum distance the pin penetrates the bone. The distance the indenter traveled identifies the bone quality. The pin enters the portion of the bone that

is removed as part of the surgery, which prevents interference between the measurement and the replacement joint.

Keywords: Shoulder replacement surgery, bone quality, bone density

Background

Age, injury, disease, or a combination of these, can cause damage to the shoulder joint. When a joint is damaged, shoulder replacement surgery is a treatment option. The surgery removes the damaged joint, replacing it with an artificial joint. These artificial joints fall into two general categories, stemmed and stemless implants.

The stemless implant is the preferred method because it is less invasive for the patient and requires less time during surgery, but it requires a certain level of bone quality and is still relatively new in the field. Research is ongoing to better understand the advantages and disadvantages of stemless implants.

Methods

The sample-set included four sawbones of different densities, measured in pounds per cubic foot or PCF. The sawbone set supplied by Exactech included 12.5, 15.0, 20.0, and 30.0 PCF blocks. The sponsor indicated that 15 PCF and above were considered adequate for a stemless implant.

To differentiate between the sawbones, testing was done by three different methods. The first method was drop testing. Pyramidal weights were dropped from a consistent height, and the indentations created were measured. The next method was drop testing with a flat-point indenter tip with added weights to simulate different impact forces. Both methods utilized constant masses at set heights to determine the energy needed to create the indentation. These values were used to determine the spring constant for the device used in the final method. A spring was selected based on the spring constant calculated. Using these spring dimensions, a housing and compression system was designed.

Results

Through the concept selection process, a linear spring concept was selected. However, a few modifications were made through discussions with Exactech and the FAMU-FSU College of Engineering machine shop. Since the force applied by each surgeon and each use would vary and the point defined as “deflection” would be an objective call, the team decided to use the spring in a different way.

The first prototype designed by the team was 3D printed to learn any kinks or faults of the design. That iteration held the device in the locked position using pegs on the side of the indenter rod that would slide up the device as the handle was pulled and then rest on a shelf when the handle was twisted. When the user was ready, they would twist the handle in the opposite direction allowing the spring to push the indenter tip into the bone. The team found that the twist method was difficult, and the transition between the free and locked positions was very rough. This discovery inspired the team to design a new locking mechanism which can be shown in Figures 3 and 4.

To resolve this, changes were made to the design and locking mechanism. The concept presented on design day can be found in Figure 2.

Figure 2 Final Machined Prototype

In the final design the surgeon pulls the handle back until they feel it lock in place. This is the locked, or compressed position. This would compress the spring in the same position each time, with the same potential energy. The face of the device is then placed on the face of the humerus. The surgeon then pushes the button, and this creates an indentation on the bone. The depth of the indentation is related to the quality of the bone and can be measured to assist the surgeon in choice of implant during surgery. The inside of the device is pictured in more detail in Figures 3 and 4.

Figure 3 Final Prototype: Free Position

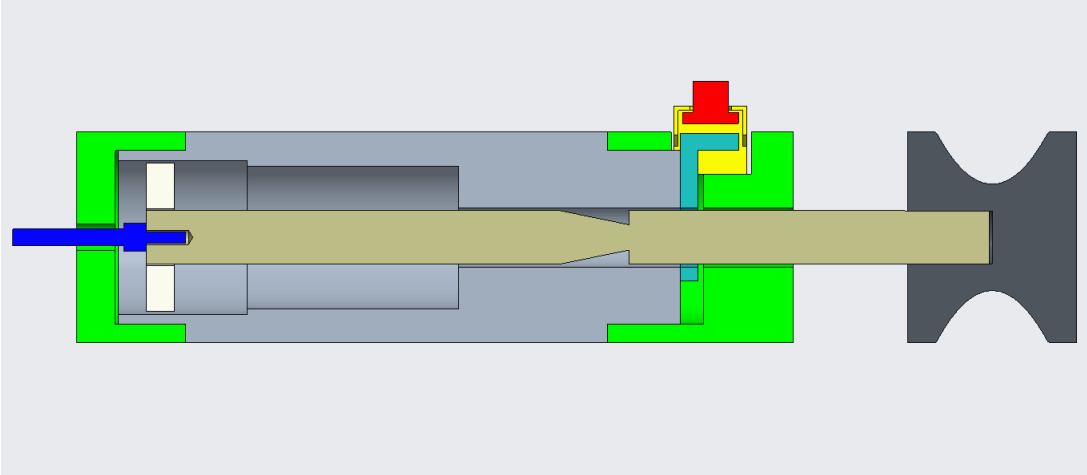
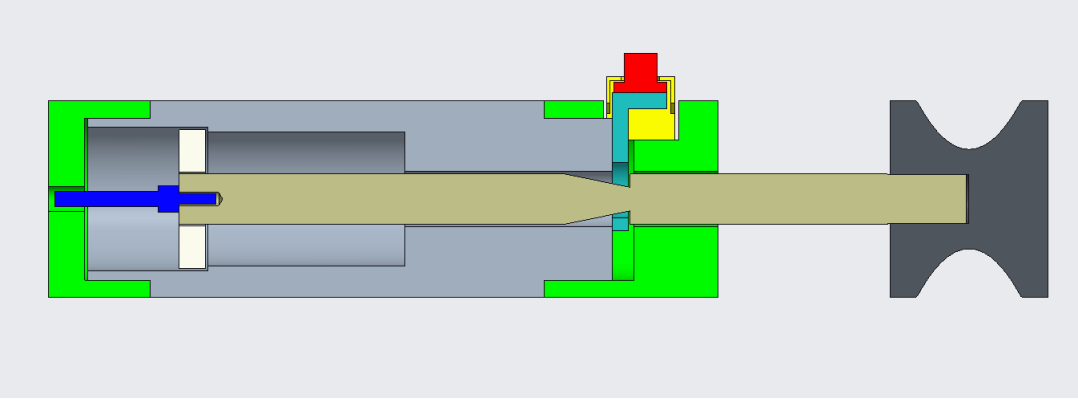


Figure 4 Final Prototype: Locked Position



This locking mechanism design utilizes an extra spring located under a plate. The plate has a hole large enough for the indenter rod to move freely when it is aligned with the largest section of the rod. When the handle is pulled, and the plate passes the shelf located on the rod, the small spring causes the plate to lift as the shelf passes, catching the edge. The constant force supplied by the spring pushes the plate underneath the shelf holding the larger spring in the housing to be locked in a compressed position. When the surgeon is ready to use the device, they press the button, which aligns the hole on the plate with the largest cross-section of the rod, allowing the main spring to push the indenter tip into the bone.

Discussion

The completed device began validation testing upon completion. This testing was done to ensure the device met all targets outlined earlier in the design process. The results are shown in Table 10 below.

Table 10 *Validation Results*

Target	Validation
Compliant with FDA regulations	Exempt or 510k
Device withstands temperatures up to 284 °F	Yes
Creates indentation less than or equal to 1 in.	Yes
Weighs less than or equal to 5lbs	Yes
Length of device is smaller than 6 in.	Yes
Lifespan greater than 50 uses	Yes
Reports results with 95% accuracy	Yes

The FDA approval target cannot be tested without applying for and receiving this approval. This approval was not sought as part of the project, because the FDA approval process is very timely and costly, and ultimately not in the scope of what

Exactech asked us to complete. However, research was done on the path required to get the approval. The FDA provides that devices which are significantly similar to existing medical devices may be approved without an analysis, exempt devices, or with a filing explaining the similarity to existing devices, a 510k. A review of existing devices leads to the belief that the device could be classified as a Class I medical device, meaning approval would be achieved with the device qualifying as exempt or with a 510k.

The physical requirements were also compared to the targets initially set. These targets included a weight of less than 5 lbs. and a width of less than 5 inches. The device has a measured diameter of 1.5 inches at its maximum width. When placed on the scale, the device weighed 2.7 lbs., just over half of the target maximum weight. To prevent damage to the part of the bone that would not be removed during surgery, the maximum distance the device could indent the bone was set at 1 inch. The final device was designed to prevent the tip from exceeding 1 inch of indentation; the indenter tip extends less than 1 inch past the front face of the device. This was confirmed by allowing the device to indent in the air and confirming the tip was less than 1 inch past the front of the device. The stainless-steel design of the device was selected for its durability and biocompatibility. However, this material also provides the device the ability to endure temperatures of 284°F without damage. The device was placed in an autoclave that reached this temperature and functioned reliably after the process. This result confirms the device’s ability to survive this temperature target and the more general target of sterilization.

Due to the high variation in the number of surgeries performed by surgeons, a target based on use was difficult to determine. Therefore, the target was chosen based on an assumption of one year with one surgery a week and two weeks for holidays. The device did not show signs of deterioration at the resulting target of 50 uses. Instead, the device did not encounter a malfunction until use 92. The deterioration consisted of slight rounding of the indenter tip and the tip becoming loose in the rod. However, the production version of the device would use a welded indenter tip to prevent it from becoming loose. Additionally, the rounding of the tip did not affect the indentation depth

to a level beyond that of typically occurring variation in the results. The resulting durability exceeded the target number of uses. Based on discussions with the machine shop, the wear on the indenter tip could be reduced by changing to hardened stainless steel, further improving device durability.

The most critical test of the device was its ability to determine bone density. Since the surgeon may not create a perfectly level or perpendicular plane by respecting the humeral head, the accuracy testing was conducted at multiple angles: vertical, horizontal, and 45 degrees. The results are shown in Figures 5 and 6.

Figure 5 Validation Testing: Angled Indentations

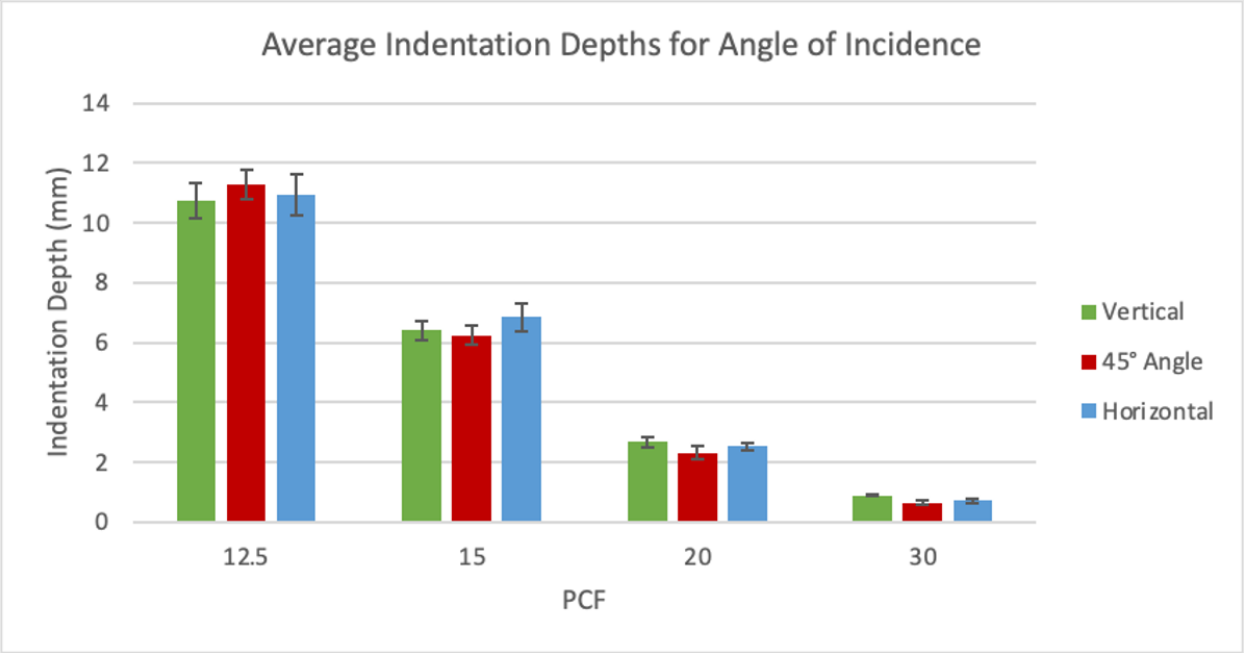
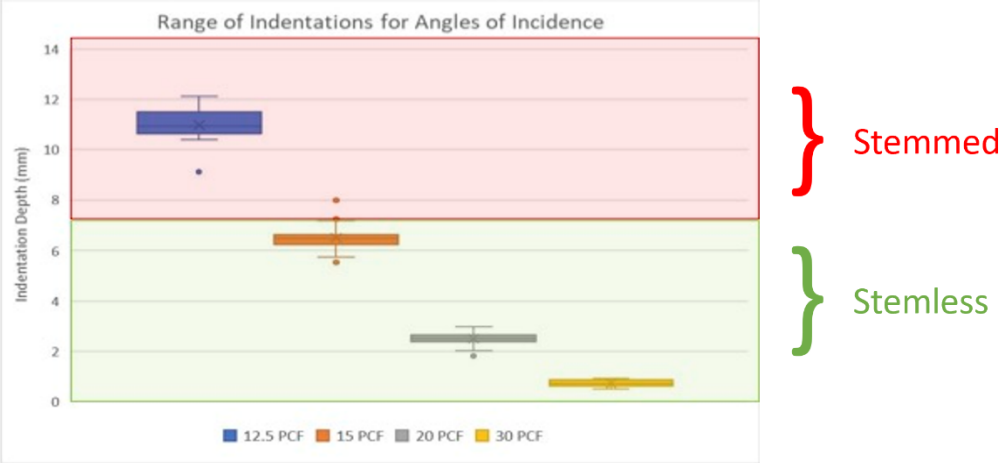


Figure 6 Validation Testing: Stemmed vs Stemless



The figures above show the device read stemmed versus stemless correctly 91 of 92 tests/ this is a reporting accuracy of 98.9%. This result exceeds the accuracy target set; however, the device requires further testing because all of this was done with one prototype. This constraint limits the ability to determine if the device, when mass-produced, can replicate these results. It needs to be validated that these results are repeatable dependable, but this is not within the project's scope.

Conclusions

Except for FDA approval which exceeded the project's scope, the device successfully met all targets. This confirms the device meets its intended purpose of distinguishing bone qualities that will or will not support a stemless shoulder implant. This removes the subjective thumb test and provides consistent results without regard to the force applied by the surgeon.

Future Work

While the device has met all the provided targets, it is a prototype. To fully replace the thumb test, large numbers of the device must be produced. Mass-production will require changes in the design to improve manufacturing efficiency and ensure the accuracy of every device manufactured. Following changes such as a perinatally fixed hardened stainless steel indenter tip and welded end caps, the device will need to repeat the validation testing.

Additionally, an operating room calibration test should be developed. This will provide a way for surgery personnel to confirm the device is functional and accurate prior to use on the patient. Before any use on any patient, the production device will need to apply for and receive approval from the FDA. While these improvements and goals exceed this project's scope, they provide a necessary next set in developing the device and replacing the thumb test.

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