TECHNICAL BRIEF

The Effects of Bone Density on Shoulder Implant Fixation

Catalyst OrthoScience Research and Development

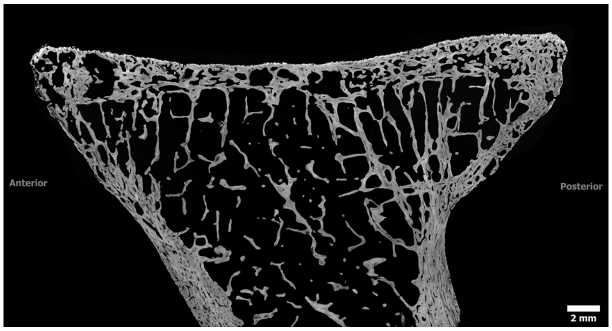
Background

The long term success of a total shoulder replacement is largely dependent upon the long term fixation of the implants within the bone. The greatest levels of fixation should come from either increasing the total surface contact area with bone and/or placing the implants in the densest regions of the bone.

Favre[1] showed that when bone density drops below a 0.1g/cm^3 threshold, implant micromotions in excess of 150µm can occur. Multiple studies have shown that micromotion above this level can inhibit bone growth[2,3].

Glenoid Bone Properties

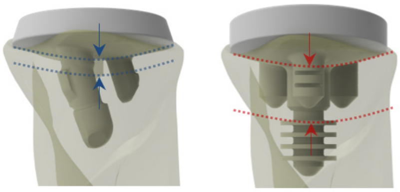
The glenoid subchondral plate thickness has been measured to be an average of 1.9mm (range: 1.2 - 2.9mm)[4]. Simon[5] measured the glenoid subarticular layers in 42 males with osteoarthritis and measured three distinct zones: calcified cartilage (≤ 1.5mm), subchondral plate (2.0-4.5mm), and cancellous bone (≥ 5mm). Anglin[6] found that just 3.5mm from the subchondral plate, the bone strength decreased by 75% and the modulus reduced by 58%. At 10.5mm the strength was reduced by 89%. Frich[7] had similar findings, in which one millimeter underneath the subchondral plate, the average bone strength decreased by 25% and at two millimeters the strength level decreased by 70%.



*Exemplary cross-sectional SEM image of the anterior glenoid. *Image courtesy of the University of Utah Bone & Joint Research Laboratory*

Glenoid Implant Design

Each of the pegs on the Catalyst CSR™ Total Shoulder System 3-Peg Glenoid implant has features that directly contact the bone, placing the construct in a compression fit. Proximal features on the pegs are designed to be captured underneath the denser subchondral bone, as opposed to predicate designs which engage the less dense cancellous bone, which can lead to inherently less rigid constructs.



The Catalyst CSR 3-Peg Glenoid has bone-engaging features ~3.0mm or less from the implant backside, while other common glenoid designs have bone engaging features that are in excess of 8.0mm from the backside.

Humerus Bone Properties

Exemplary image of humeral head demonstrating the densest bone proximal to the anatomic neck (red line). The blue line is representative of where the Catalyst CSR implant rests on the bone.

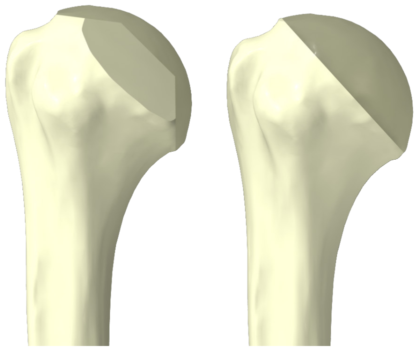
Alidousti[8] found the bone density decreased proximally to distally in the humeral head, with the majority of the higher bone density proximal to the anatomic neck of the humerus. They determined the apparent bone density to be a maximum at the apex of the humeral head and a minimum just below the anatomic neck. They also measured the bone density to increase centrally to peripherally within each cross-sectional slice.

Saitoh[9] found that bone above the anatomic neck showed twice the bone mineral and three times higher mechanical strength that bone of the humeral neck.

Barvencik[10] found the highest bone mass in the most superior and medial part of the humeral head, with the values decreasing inferiorly and laterally.

Humeral Implant Design

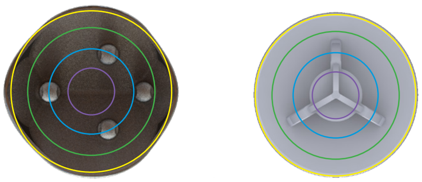
On an average sized humeral head, the Catalyst CSR system will cut approximately 7.5mm down from the proximal apex of the head, while cutting at neck will cut down approximately 20.0mm from the apex. The average total volume of bone removed is around 10,000 mm^3 with the Catalyst CSR system, while cutting at the neck will remove around 22,000 mm^3 of bone.



Prepared bone surfaces with native anatomy silhouette. Catalyst CSR (left) versus a typical anatomic neck cut (right).

Four pegs and four planar surfaces of the Catalyst CSR humeral implant are all placed proximal to the anatomic neck. Furthermore, these eight features will all primarily resist axial, torsional and shear forces closer to the periphery of the head (Zones 3-4).

Alternatively, typical short stem (or stemless) designs have a small stem that typically is placed in the bone beneath the anatomic neck, with the majority of the stem in the central region (Zones 1-2) where the bone density is at the lowest levels in the head.



Zone 1 (purple), Zone 2 (blue), Zone 3 (green), Zone 4 (yellow) per zones as defined by Aldusti[8]

Conclusions

The challenge with existing stemless humeral implants compared to traditional stemmed implants is that they are required to achieve similar levels of fixation over a reduced surface area. Utilizing the bone proximal to the anatomic neck for fixation allows the Catalyst CSR humeral implant to be fixed in stronger and denser bone with maintaining a low profile and preserving all the bone below the anatomic neck for potential future revision procedures.

With glenoid loosening being the primary concern in total shoulder arthroplasty, strong initial and long term fixation within the glenoid bone are critical to the success of the construct. Exploiting the regions of the strongest and densest bone, the Catalyst 3-Peg Glenoid maximizes this fixation potential while preserving the central glenoid vault bone stock that is utilized in potential future rTSA procedures.

References

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