

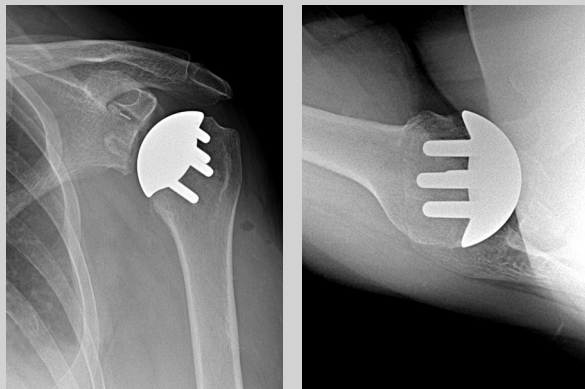
# TECHNICAL BRIEF

## Scientific Basis for the Use of Non-Spherical Humeral Heads

Catalyst OrthoScience Research and Development

### Background

According to Neer, "The ideal total shoulder replacement system would most closely restore the normal, healthy anatomy within the joint. Implants made with this principle in mind have provided the best function and durability<sup>1</sup>." Though extensive research studies have demonstrated that the natural shape of the humeral head is non-spherical, most humeral head implants used in total shoulder arthroplasty remain as spherical surfaces.



Catalyst CSR humeral implant demonstrating excellent fit with the native bone in both the SI (left) and AP (right) views.

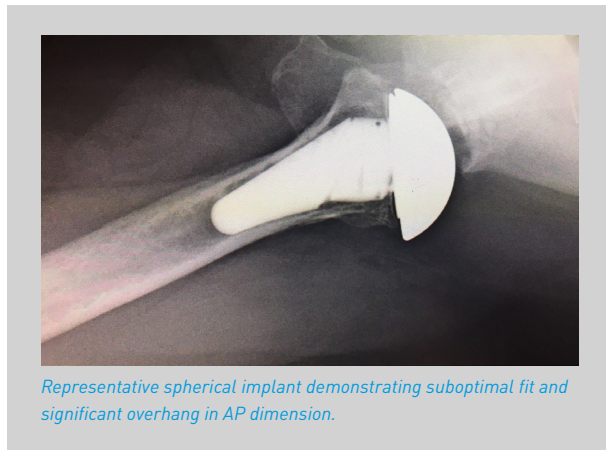
### What is a Non-Spherical Humeral Head?

A non-spherical, or elliptical, humeral head has differing radii of curvature in the Superior-Inferior (SI) and Anterior-Posterior (AP) planes. An osteotomy at the anatomic neck of the humeral head will reveal an elliptically shaped cross-section with a reduced AP dimension relative to the SI dimension.

Significant evidence exists to confirm this non-spherical nature of the anatomically healthy humeral head<sup>2-13</sup>. Some of the key research studies are highlighted below:

1. Ianotti<sup>2</sup> measured the peripheral radius to be two millimeters less in the axial plane than the coronal plane, resulting in the peripheral contour of the articular surface having an elliptical ratio of 0.92.
2. Hertel<sup>3</sup> demonstrated a 12 percent difference in the radius of the head between the front and sagittal planes.
3. Harrold<sup>4</sup> found that replacement of the osteotomized head segment with a spherical implant does not restore the original humeral head geometry in terms of inclination, retroversion, radius of curvature and head diameter.
4. Phillips<sup>5</sup> developed a computational model of the humeral head that showed ellipsoid and ovoid shapes better fit the articular surface of the humeral head with roughly 3 times less average error than a spherical shape.

- Utilizing a separate computational model, Humphrey<sup>6</sup> compared the accuracy of spherical and elliptical humeral heads in their ability to replicate the native anatomy. They found that the elliptical implants were able to restore the native anatomy within 3 mm in 100 percent of elliptical implants and only 78 percent of spherical implants available in 1 mm size increments.



## The Catalyst Solution

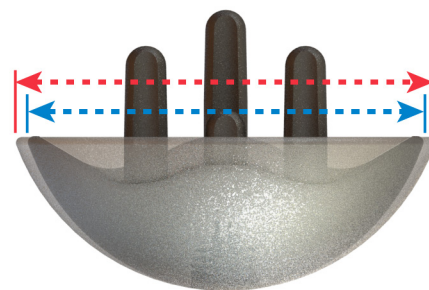
The Catalyst CSR humeral head was designed with differing radii in the SI and AP planes to replicate the native anatomy as the literature referenced herein suggests.

In a cadaveric study<sup>14</sup> utilizing eight different specimens and three different surgeons, the humeral implant of the Catalyst CSR™ Total Shoulder System was able to restore the joint line in nine different locations on the articulating surface with an average deviation of 0.9 mm, with 100 percent of points under the 3 mm threshold of deviation from the original intact humeral head geometry. This study demonstrated the ability of the Catalyst CSR humeral implant to reproducibly restore the native geometry using different sized specimens and surgeon users.

## Biomechanical Advantages of Non-Spherical Heads

Numerous computational and mechanical studies have provided empirical evidence that a non-spherical prosthetic head will more accurately restore the native humeral geometry, range of motion and glenohumeral joint kinematics compared to a spherical design.

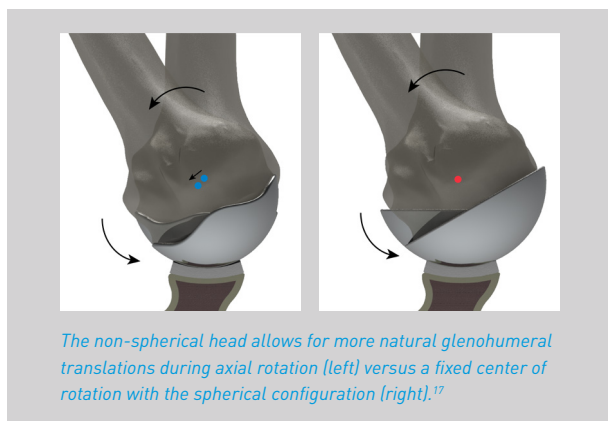
- Buchler<sup>15</sup> utilized a 3D numerical model to compare the biomechanics of a shoulder joint with and without a humeral implant. Their results showed that anatomic reconstruction of the head restored the physiological motions and limited eccentric loading of the glenoid.
- Jun<sup>16</sup> conducted mechanical testing on cadaveric shoulders with spherical and non-spherical implants. They found that the spherical implants significantly reduced range of motion compared to the non-spherical implants, and that non-spherical implants demonstrated no difference from the native intact shoulder. The increased AP dimension of the spherical head likely restricted rotational range of motion. Furthermore, the non-spherical head more closely approximated translations of the humeral head apex and geometric center of the humeral head during humeral rotation.



*The increased AP width of the spherical implant can result in an average reduction in ROM of 7.8°.<sup>16</sup>*

- Jun<sup>17</sup> conducted a similar second mechanical study demonstrating that a non-spherical head shape increased glenohumeral translations during axial rotation, which is indicative of the normal motion in the shoulder. This suggests that the use of a

spherical head will result in improper placement of the center of rotation compared to the native humeral head.



Numerous studies have confirmed that in normal healthy shoulders, small humeral translations occur during mid-range motions, while larger translations occur during end-range motion<sup>18-20</sup>.

4. Matsushashi<sup>19</sup> mechanically tested cadaveric shoulders to demonstrate that glenohumeral stability is dependent upon axial humeral rotation. As previously described, the joint kinematics during humeral rotation differ between spherical and non-spherical heads. This study confirmed increased stability using a non-spherical head.

All of this research supports the notion that shoulder joint kinematics are not governed by ball-and-socket principles. Hence, the use of a spherical humeral will not appropriately replicate the natural movements of the humerus relative to the glenoid.

## Implant Survivorship and Glenoid Loading

Spherical implants result in alterations to the head geometry that change the line of force through the prosthetic joint, producing eccentric loading at the glenoid which may contribute to early failure<sup>4</sup>.

Denard<sup>20</sup> followed TSA patients over a period of up to 10 years and found that when the humeral head was not positioned anatomically, the glenoid was 6.6 times more likely to require removal due to loosening.

The Buchler<sup>15</sup> study also found that a non-anatomic implant design produced contact forces in the superior extremity of the glenoid leading to stresses up to 8 times higher than a normal intact shoulder. These increased stresses could result in increased wear of the polyethylene glenoid over time. In addition, eccentric loading and increased stresses may increase the risk of glenoid loosening over time as a result of the rocking horse phenomenon.

Others<sup>21</sup> have noted that the smaller AP dimension in non-spherical designs results in less stress on the subscapularis repair, potentially reducing the risk of post-operative rotator cuff failure.

## Conclusion

Research to date has suggested that the use of a non-spherical humeral head in total shoulder arthroplasty will have benefits to the patient in both the short and long term. In the short term, the patient may potentially experience improved range of motion and regain the functionality of a healthy shoulder. In the long term, the glenoid implant may be exposed to lower stresses and less eccentric loading potentially reducing wear and the risk of loosening and could ultimately increase the life of the shoulder replacement system.

The Catalyst CSR humeral implant was specifically designed to restore the native anatomy and joint kinematics as this extensive research has suggested. These benefits, coupled with the bone preserving design, and the simple, yet highly accurate surgical technique, position the Catalyst CSR system as an attractive solution for anatomic total shoulder replacement surgery.

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**Catalyst OrthoScience Inc.**

14710 Tamiami Trail N. | Suite 102

Naples, FL 34110 | (800) 587-5137

info@catalystortho.com | www.catalystortho.com

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