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Orthopedics Corner: Catalyst Looks To Clinical Data To Distinguish Its Shoulder Arthroplasty Technology

by [Reed Miller](#)

Orthopedics Corner is a new series highlighting new developments in spine and orthopedics technology you may have missed. Catalyst OrthoScience CEO Carl O’Connell, along with surgeon and researcher Matthew Budge, talked to *Medtech Insight* about Catalyst’s innovation in shoulder arthroplasty.

[Catalyst OrthoScience](#) is counting on clinical research to show that its stemless shoulder arthroplasty system promotes faster healing and the restoration of a patient’s normal range of motion.

Shoulder arthroplasty technology has not changed much since [Charles Neer](#) first developed total shoulder implants in the 1950s and 1960s, Matthew Budge, an orthopedic surgeon with Kaiser Permanente in Oregon, explained to *Medtech Insight*. In the 1950s the only effective way to fix a metal shoulder joint into the [humerus bone](#) was to “take big piece of metal and stick it into the bone.”

“That requires the removal of a large amount of bone to find a place to put this big metal stem,” Budge said. “That’s the way we started doing it back in ‘50s and that’s the way we continued to do it up until, essentially, now.”

In the last 20 years, surgeons developed techniques to cut part of the “ball” from

Takeaways

- A recent retrospective study showed patients treated with Catalyst OrthoScience’s Catalyst CSR shoulder

the top of the humerus and then affix a metal prosthesis in its place. “The problem with that was the bone up at the top of the humerus isn’t very solid,” Budge said. “There were a fair amount of problems getting that to initially work.”

To get around those problems, Budge helped develop the Catalyst CSR anatomic shoulder system, which features a stemless elliptical head affixed to the [humerus](#) following a multiplanar osteotomy that preserves about 90% of the native bone.

“Instead of cutting the whole ball off the head, we make square cuts around it that preserve the very strong bone underneath the head, and then just lay a cap of metal across the top,” he explained. Catalyst CSR is “covering the top of the bone – much more like a total knee [replacement] where you’re just covering the surfaces with metal as opposed to removing something and putting a big prosthetic in there.”

The orthogonal cuts on the top of the bone create prevent the Catalyst CSR implant from twisting, while pegs hold it in place.

Clinical Data To Support Catalyst CSR’s Benefits

[The US Food and Drug Administration cleared Catalyst CSR about five years ago](#), but the company continues to support clinical research to show how it can improve patient outcomes.

Catalyst CEO Carl O’Connell told *Medtech Insight*, “Collecting good data – and generating good data – is really important, because you want to be able to distinguish yourselves from other products in the marketplace.”

Budge and Nathan Orvets, another surgeon at Kaiser Permanente in Oregon, led a retrospective study of 25 total shoulder arthroplasties with a standard stemmed humeral component with a circular humeral head followed by 25 procedures with the Catalyst CSR. [Results of the study](#) are published in the [Journal of Shoulder and Elbow Surgery](#).

Patients treated with Catalyst CSR showed significantly better range of motion at both the 6-week and 12-week follow-up evaluations compared to patients treated with stemmed implants. The Catalyst CSR patients also showed improved restoration of their center of rotation.

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- Catalyst CSR is less invasive because the procedure to implant it is more precise.
- Catalyst OrothoScience expects compelling clinical results to drive market adoption of its technology.

MEDTECH INSIGHT

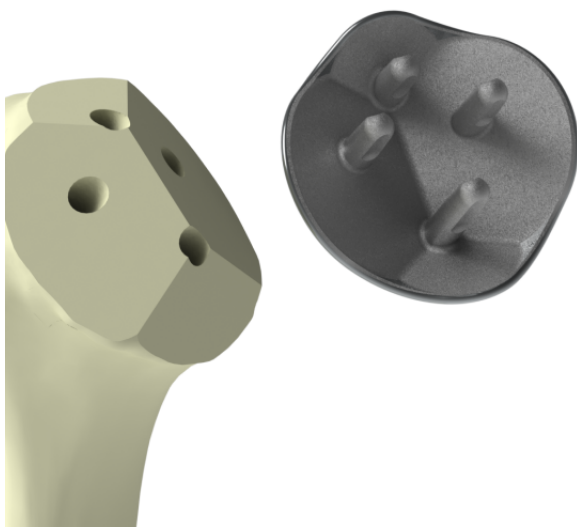
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Budge said many of the patients treated with Catalyst CSR showed full range of motion within six weeks, without requiring extensive physical therapy. By contrast, total patient arthroplasty patients usually need three to six months and extensive physical therapy to restore their full range of motion.

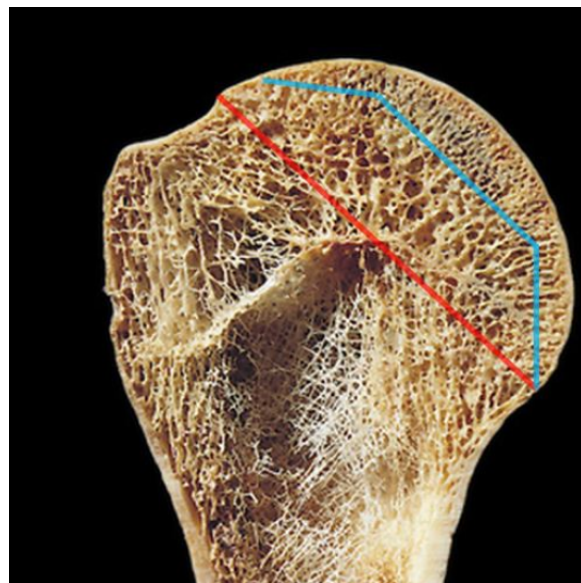
“That’s a big difference and patients were very happy with it,” he said.

O’Connell said one of the company’s core design principles is to try to mimic the patient’s natural anatomy, so this study validated that principle, and will help the company gain the trust of patients and surgeons.

“CSR is, arguably, one of the best anatomic systems in the



THE CHAMFER CUT PROCESS FOR THE CATALYST CSR TOTAL SHOULDER *Catalyst OrthoScience*



EXAMPLE OF TRADITIONAL HUMERAL "HEADCUT" FOR A SHOULDER IMPLANT *Source: Catalyst OrthoScience*

marketplace and this sort of data gets us there,” he said. “[These outcomes] are especially important for a surgeon to be able to articulate. But also, for patients, [we can show,] ‘This is what you’re going to get with this product and surgery.’”

The shoulder replacement market is worth about \$1.5bn annually and dominated by [Zimmer Biomet](#), [Johnson & Johnson/DePuy Synthes](#) and [Stryker](#). Florida-based Catalyst is one of about a dozen competitors that make up the other 8.5% of the market, according to [Meddevicetracker](#).

Although Catalyst is small, it is well-known in the orthopedic surgery community, and O’Connell believes that, over time, impressive clinical results will convince more and more surgeons to try Catalyst CSR.

O’Connell expects that shoulder arthroplasty patients may eventually ask for specific devices and create an opportunity for direct-to-consumer education to support Catalyst CSR. “As we progress, patients are going to be more aware of it and come in and ask for it – [as they do] with hip and knee [surgery].”

Direct-to-consumer marketing is currently rare in the shoulder surgery market, because it is a relatively small part of the overall orthopedic surgery space – hip and knee surgeries are about 10 times as common as shoulder replacements. But satisfied patients are promoting Catalyst CSR informally.

“Once I have shown patients [the Catalyst CSR option] and they do well with it, I get a lot of repeat referrals from patients,” he said. “Whether they attribute that to me or to the prosthetic, they certainly see the difference between what is offered [elsewhere] in the community and what I’m offering [with Catalyst CSR], and that spreads virally among the patient population.”

Precision Makes It Possible

The critical innovation that made Catalyst CSR more successful than previous stemless designs is the multiplanar osteotomy technique that spares the strong subchondral bone in the humerus and holds the implant in place. The Catalyst CSR system includes precision instruments that reduce the need for any tissue retraction.

Surgeons have been developing [stemless](#)

Catalyst Introduces Convertible Stemmed Shoulder

Catalyst boasts it is now the only company offering anatomically shaped non-spherical heads on both stemmed and stemless total shoulder arthroplasty implants.

Catalyst OrthoScience recently announced the first series of total shoulder arthroplasty procedures using the Catalyst Stemmed CSR TSA, a unique, fully convertible total shoulder arthroplasty system with an ellipsoid humeral head.

[The US Food and Drug Administration cleared the system in April](#). Surgeon Theodore Blaine of HSS Orthopedics in Stamford, CT, completed the first series of procedures with it in May.

Catalyst Stemmed CSR TSA system is “fully convertible” because it be used in conventional or so-called “reverse” shoulder arthroplasty surgeries.

[shoulder arthroplasty systems](#) for about the last 20 years, but frequently, the bone in the proximal humerus cannot hold an implant securely.

And those procedures have often been imprecise, Budge said. “There were a lot of problems with accuracy and getting it into the right position.”

The Catalyst systems instruments serve as a navigation system to facilitate accurate placement within two millimeters, “which is what you need for full range of motion, every single time.” The Catalyst CSR implant’s surfaces allow for bone ingrowth to secure it in place.

Budge also pointed out that Catalyst CSR has an elliptical head – about two to three millimeters shorter along the posterior-to-anterior plane than the proximal-to-distal plane.

“Most total shoulder systems for the last 70 years have used a circle, but the native humerus' head isn't a circle. It's an ellipse,” he explained. “We've been trying to fit a circular head into an elliptical shape for 50 years and wondering why it didn't work fabulously.”

Budge said Catalyst CSR is the only alternative to stemmed shoulder arthroplasty currently on the market that has been shown to make a difference on patient outcomes. “That's something that surgeons I think will respond very positively to. I certainly did.”

Conventional shoulder arthroplasty procedures replace all or part of the damaged ball-and-cup joint in the shoulder.

In patients with severe rotator cuff damage, reverse shoulder arthroplasty switches the positions of the ball and the cup, putting a metal ball into the shoulder’s socket and a synthetic cup on the top of the humerus bone. Following a reverse total shoulder replacement, the patient learns to use their deltoid muscle, instead of the rotator cuff, to move their arm.

Blaine emphasized the advantages of Catalyst Stemmed CSR TSA’s anatomical ellipsoid humeral head. “This is an important distinction because the ellipsoid head allows for more accurate restoration of the natural joint kinematics compared to spherical head designs.”