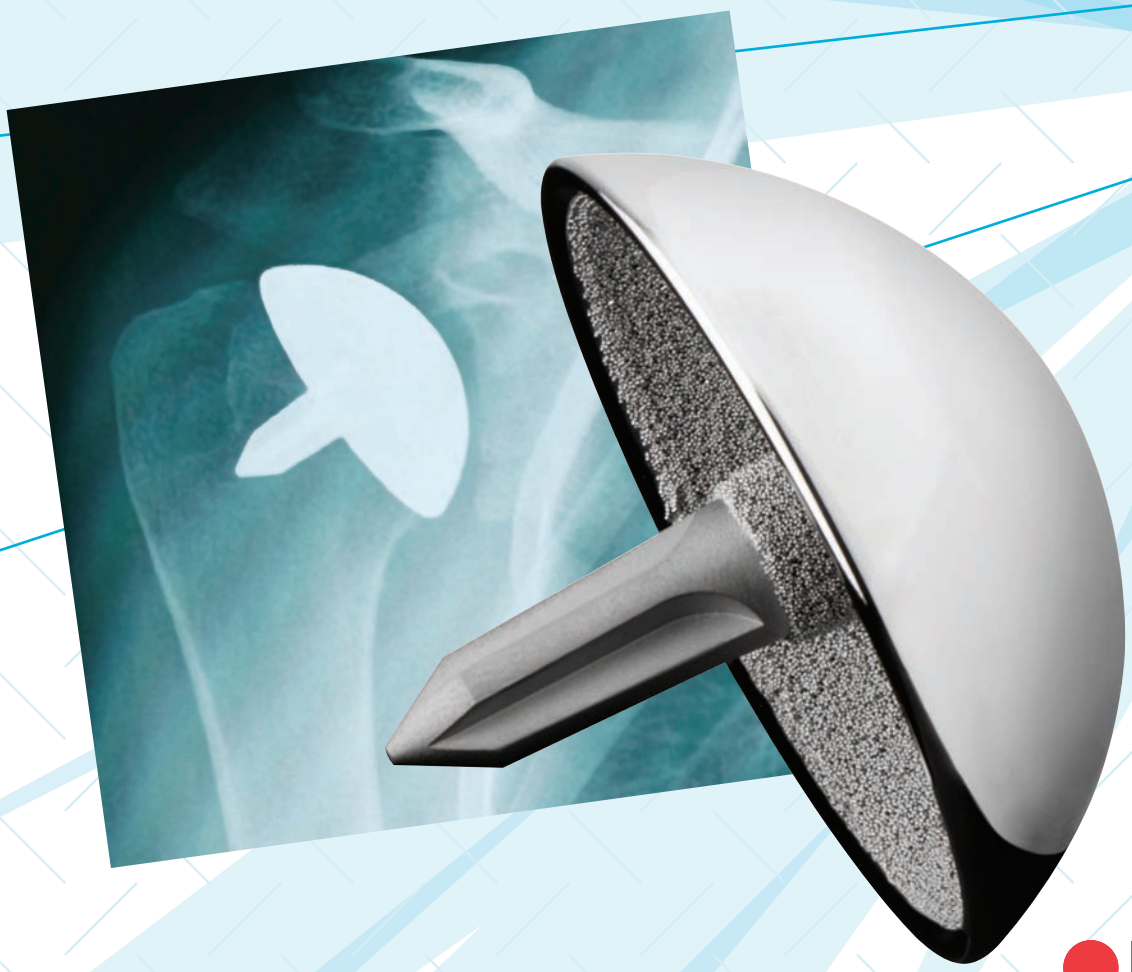
GLOBAL C.A.P.™
CONSERVATIVE ANATOMIC PROSTHESIS

GLOBAL C.A.P.
SURGEON PERSPECTIVES



DePuy
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SURGEON PERSPECTIVES IN THE CLINICAL USE OF THE GLOBAL C.A.P.™ RESURFACING HUMERAL HEAD SYSTEM

With the release of the Global C.A.P. resurfacing prosthesis and other resurfacing shoulder devices, many surgeons ask, "When is a resurfacing device really necessary? If I am getting good to excellent results with a traditional stemmed device, when is the appropriate time to implant this type of device? How would my patients benefit?"

Resurfacing arthroplasty has been a treatment option for patients in Europe for the last 15 years. According to Levy and Copeland's study, results from resurfacing shoulder arthroplasty and traditional stemmed arthroplasty are similar.[1] Now an option in the U.S., surgeons are trying to determine how this option fits in their practices.

We asked some shoulder experts how they choose their patients for resurfacing compared to a traditional stemmed device.

"I typically use the Global C.A.P. with patients with avascular necrosis. The glenoid side of the joint by and large should be close to normal. The glenoid may have some arthritic changes, but generally not very much.

In humeral resurfacing arthroplasty, the bone must be of good quality and quantity. If the patient does not have collapse, if the bone is not soft, then that patient may be a good patient for resurfacing. If the cancellous bone is very soft, then that may not be a good indication for resurfacing.

For the less active patient, I prefer using a stemmed implant over a resurfacing with a glenoid because the results are reliable with traditional total shoulder surgery. That is a reliable operation. You can do a C.A.P. in that population, but you need to make sure the bone quality is good and the glenoid resurfacing is not needed.

If there is severe collapse on x-ray, then you may want to go to a stemmed implant. To further make your evaluation for a Global C.A.P. prosthesis, you will then have to do the surgery. You will need to ream the head for the Global C.A.P., then curette away all the bad bone. Then you have to look at the head and see how much of the undersurface will be contacting solid, high quality bone. If you get more than the 25-30 percent range where there is poor or deficient bone, then you are probably best served going to a stemmed implant. But if about 70 percent or more of the implant undersurface is going to contact solid, bleeding, high quality bone, then it appears a resurfacing arthroplasty would be sufficient under these circumstances.

Some of your determination should also be from x-ray. If wear is severe, then preoperatively the decision should be a stemmed implant. If wear is not so severe, then your assessment and determination of the appropriateness of the C.A.P. can be made intraoperatively. Once you ream the head and see that the head quality is not sufficient, it is relatively easy to cut the head and simply put in a stemmed implant. It's very easy to convert from one implant to another."

Joseph Iannotti, MD, Ph.D, Cleveland, OH – Cleveland Clinic Foundation

"The decision to use a C.A.P. vs. a traditional stemmed arthroplasty is an individual one and will be dependent on individual surgeon preferences. I personally do not use a glenoid prosthesis when using a C.A.P. Therefore, in my practice, anytime I am considering a hemiarthroplasty and there is adequate humeral head bone, I will consider a Global C.A.P. Most often, I use a C.A.P. for patients in whom I am trying to preserve bone stock. Therefore, my indications are patients with post-traumatic arthritis and arthritis of instability. Avascular necrosis may also be a good indication if the amount of remaining viable bone represents 75 percent of the humeral head. If the glenoid surface is not concentric and requires bone grafting or significant reaming, exposure may be difficult, especially if the patient is a young, muscular male. Under these circumstances, removing the head for a traditional stemmed implant will simplify the procedure."

Gerald Williams, MD, Philadelphia, PA – University of Pennsylvania

“I use the Global C.A.P. as a bone/tissue sparing operation for a patient with (arthritic) disease on the humeral side. It is for a surgeon who believes in "hemis" vs. totals. AVN of the humerus with destruction of the head may pose boney support issues that preclude use of the C.A.P. Access to the glenoid is difficult when performing a "C.A.P." procedure because the head is in the way! Loosening of the humeral component has never been a major issue, so I favor totals when there is disease of the glenoid as well.

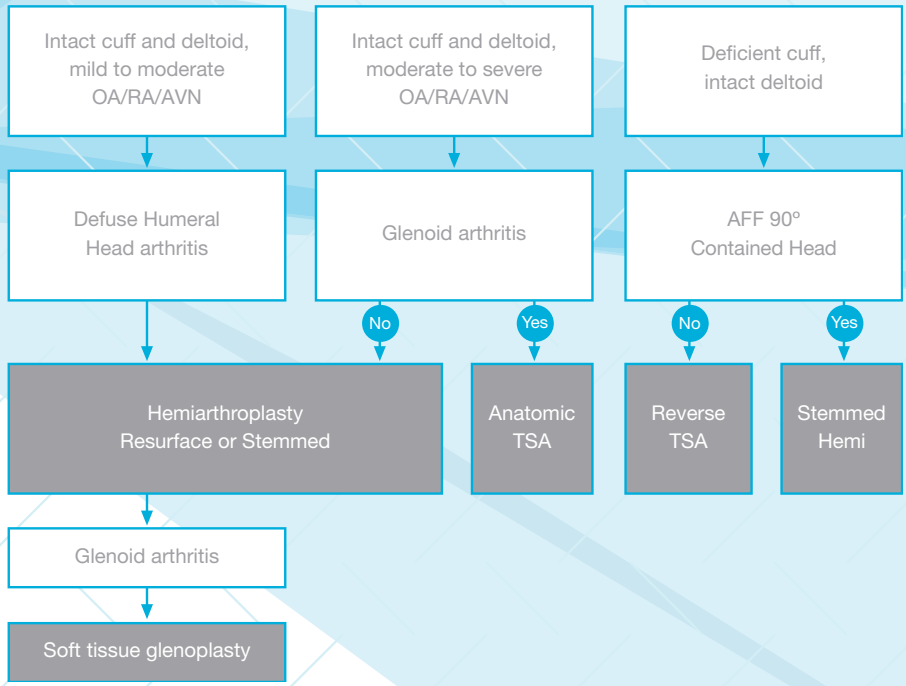
If the patient has a healthy glenoid with isolated humeral involvement, then the Global C.A.P. is a nice technique. Patients with early AVN with a negative MRI for disease on the glenoid side may do well with a C.A.P. Large articular lesions (traumatic) of the humeral head may be treated with a C.A.P. Older patients with head disease usually have glenoid disease, and I favor totals for these cases for predictability.”
Jack Siegel, MD, Virginia Beach, VA – Jordan-Young Institute

“I consider the C.A.P. for a hemiarthroplasty because for most surgeons it will be very difficult to replace the glenoid when the head is not removed. The C.A.P. can be used in most patients when the surgeon plans to perform a hemiarthroplasty. The humeral head has to be reasonably well preserved in order to use the C.A.P. A small defect can be bone grafted, but large deficiencies make it necessary to use a stemmed implant.”
Anders Ekelund, MD, Sweden – St. Gorans Hospital

“I think the applications are not as yet clearly defined for shoulder resurfacing. The Global C.A.P. by and large must be performed as a hemi, due to limited access to the glenoid. Since humeral loosening with the Global Advantage® has been negligible, the C.A.P. will have to have a good long-term track record indeed to match the existing loosening rates of an uncemented hemi with a Global Advantage stem.

In my practice, the real advantage of resurfacing shoulder arthroplasty is that it leaves enough bone stock for fusion if the patient does develop glenoid erosion from hemiarthroplasty, and is still not a good candidate for glenoid resurfacing.”
Stephen Weber, MD, Sacramento, CA – Sacramento Knee & Sports Medicine

ALGORITHM FOR PROSTHETIC ARTHROPLASTY



IMPORTANT

This essential product information does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

INDICATIONS

Total shoulder or hemi-shoulder replacement is indicated for:

1. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis;

2. Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory and malunions of the humeral head;

3. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g., revision of a failed primary component).

Hemi-shoulder replacement is also indicated for:

1. Ununited humeral head fractures;

2. Avascular necrosis of the humeral head;

3. Rotator cuff tear arthroplasty. **The Global C.A.P. Shoulder is indicated for patients with intact or repairable rotator cuff.**

POROCOAT® POROUS-COATED COMPONENTS

Porocoat porous-coated humeral stem prostheses are indicated for cemented or cementless use with fixation provided by biological tissue in-growth into the porous coating. **The Global C.A.P. is intended for cementless use only.**

CEMENTED COMPONENTS

Humeral stem and glenoid components labeled "For cemented use only" are indicated only for use with bone cement.

PRESS-FIT OR CEMENTED COMPONENTS

Humeral stem prosthesis without porous coating and labeled "For press-fit or cemented use only" are indicated for press-fit uncemented use or for use with bone cement.

CONTRAINDICATIONS

The following conditions are contraindications for total shoulder and hemi-shoulder arthroplasty.

1. Active local or systemic infection.

2. Inadequate bone stock in the proximal humerus or glenoid fossa for supporting the components.

3. Poor bone quality, such as osteoporosis, where there could be considerable migration of the prosthesis and/or a chance of fracture of the humerus or glenoid.

The following condition is a contraindication for total shoulder arthroplasty.

1. Absent, irreparable or nonfunctional rotator cuff or other essential muscles.

WARNINGS AND PRECAUTIONS

The use of a glenoid prosthesis in patients with cuff tear arthropathy could increase the risk of glenoid component loosening due to non-anatomic loading conditions. The following conditions tend to adversely affect shoulder replacement implants: excessive patient weight, high levels of patient activity, likelihood of falls, poor bone stock, metabolic disorders, disabilities of other joints.

ADVERSE EVENTS

The following are the most frequent adverse events after shoulder arthroplasty: change in position of the components, loosening of the components, dislocation, infection, hematoma, pneumonia and cardiovascular disorders.

REFERENCES

1. Levy, Copeland. "Cementless Surface Replacement Arthroplasty for Osteoarthritis of the Shoulder." *Journal of Shoulder and Elbow Surgery* 13(3), May/June 2004: 266-271.

For more information about DePuy products, visit our web site at **www.jnjgateway.com**.

DePuy
a Johnson & Johnson company

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581-0988
USA
Tel: +1 (800) 366 8143
Fax: +1 (574) 267 7196

DePuy International Ltd
St Anthony's Road
Leeds LS11 8DT
England
Tel: +44 (113) 387 7800
Fax: +44 (113) 387 7890

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