Anatomic Humeral Head Resurfacing

Review of Clinical Outcomes and Case Presentations

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Abstract

Background: Humeral head resurfacing has recently gained increased interest with clinicians. A novel anatomic resurfacing technology has been introduced to the market that allows for intraoperative mapping of the joint surface geometry. The objective of this investigation is to quantify the effectiveness of the HemiCAP® contoured articular shoulder prosthesis in the management of pain and restoration of shoulder function. This review examines short term multicenter clinical results.

Materials and Methods: Between March 2004 and January 2006, 62 patients underwent humeral head resurfacing at six participating institutions. Thirty-six patients were male, 26 female. The mean age at the time of surgery was 60 years (range 25-84). The mean follow-up was 8 months (range 3-23). Forty-five patients were treated for glenohumeral osteoarthritis, eight for avascular necrosis, four received treatment for focal full thickness chondral defects, four were treated for humero-acromial arthritis, and one for rheumatoid arthritis.

Results: Defect sizes were effectively covered with the following diameters: 35mm (32 implants), 30mm (24 implants), and 25mm (6 implants). Mean WOOS (range 1234 to 243), ASES (range 38 to 70), pain VAS (range 54 to 18), SST (range 3.3 to 8.4), and Constant scores (range 55 to 78) demonstrated marked improvement over the follow-up period. The most frequent concomitant procedure was rotator cuff repair in 13 patients. Advanced glenoid wear, found at the time of implantation, lead to one clinical failure due to unimproved shoulder pain. Ninety-five percent of the patients reported a good to excellent result at last follow-up.

Conclusion: Intraoperative mapping of the joint surface geometry permits an anatomic restoration of the humeral head. Compared to existing shoulder arthroplasty procedures, the HemiCAP® system is a joint preserving procedure with minimal removal of bone stock and preservation of healthy cartilage. The surgical technique is reproducible, has a short learning curve and causes minimal impact on future surgery. Treatment outcomes provide pain relief and return to activities across a variety of indications.

Level of Evidence: Therapeutic study, Level IV (case series).

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Introduction

The earliest known report of shoulder arthroplasty dates back to 1893: Péan, a French surgeon, replaced the glenohumeral joint with a platinum and rubber implant in a patient with tuberculosis. Modern shoulder arthroplasty was initiated by Krueger, who reported on a vitallium hemiarthroplasty in a patient with avascular necrosis in 1951. Neer shaped the future of shoulder arthroplasty with his work. He replaced the humeral head with an unconstrained prosthesis in 1951 with initial reports in 1955. Further development led to the introduction of total shoulder arthroplasty in the 1970s with the addition of conformed glenoid replacements. Modular systems were introduced in the 1980s to accommodate glenohumeral joint variations. Despite many new techniques in soft tissue balancing and physiological joint stabilizations introduced over the past 15 years, restoration of normal joint kinematics with an anatomic shoulder reconstruction remains challenging. Many studies have demonstrated satisfactory short- and mid-term results in both hemi- and total shoulder arthroplasty, however humeral shaft related complications (excluding humeral head fracture related arthroplasty) and glenoid component loosening have been the most frequently reported obstacles in conventional stemmed shoulder replacement.

Articular cartilage and bone stock preservation are gaining significant importance as procedure numbers increase worldwide and a younger patient population undergoes shoulder replacement. The younger, active patient is at the highest risk for possible future revision procedures. Shoulder hemiarthroplasty has seen more than a three-fold increase in the United States in the past decade (Table 1).
As part of a novel clinical treatment strategy in the management of pain and restoration of shoulder function, a new humeral head resurfacing system has been introduced to the market in August 2003: The HemiCAP® Contoured Articular Shoulder Prosthesis (Arthrosurface®, Franklin, MA). It is intended for the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic, degenerative joint disease (DJD), or avascular necrosis (AVN).

The HemiCAP® technology provides instrumentation that allows real-time, intra-operative mapping of the surface joint geometry with measurements of the radius of curvature in both the superior/inferior and medial/lateral planes under direct visualization. This facilitates anatomic reconstruction of a smooth and congruent articular joint surface using symmetric or non-symmetric off-the-shelf articular components.

Material And Methods

Study Design
This clinical investigation is a multi-center case series to evaluate initial outcomes of HemiCAP® humeral head resurfacing at six participating institutions.

Pre-operative inclusion criteria required verification of a grade IV articular defect measuring 15-40 mm in diameter on pre-operative radiographs, MRI, or previous arthroscopic imaging. Preoperative and intraoperative exclusion criteria were defects with significant subchondral erosion extending beyond the perimeter of the largest resurfacing device available; evidence of metabolic disorders, which may impair the formation or healing of bone; evidence of gross joint destruction; evidence of instability or deficient soft tissues precluding concurrent repair, or neurovascular impairment. The humeral head and neck must have sufficient bone stock to support loading.

Preoperative Patient Assessment
Patient assessment time intervals were set for preoperative and at 3, 6, 12 and 24 months after implantation. At each of these follow-ups, patients were asked to complete a combination of the following outcomes measures: The Western Ontario Osteoarthritis of the Shoulder Index (WOOS®), the American Shoulder and Elbow Surgeons evaluation form (ASES®), the Simple Shoulder Test (SST®), a visual analog pain scale (VAS), and the Constant Score®.

Consent
The study protocol was reviewed and approved by the local institutional review boards. All patients provided a written informed consent prior to their participation in the study. Patient confidentiality was maintained by issuing anonymous study ID numbers.

Patient Population
Between March 2004 and January 2006, 62 patients (58% male, 42% female) underwent HemiCAP® humeral head resurfacing at six participating institutions. The average age at time of surgery was 60 years (range 25 to 84). The mean follow-up was 8 months (range 3-23). No patients were lost to follow-up (Table 2).

Indication for all operations was shoulder pain that had been unresponsive to medical treatment and that negatively impacted activities of daily living. Most patients were treated for gleno-humeral DJD (73%, n=45), followed by eight patients who were treated for AVN of the humeral head (13%), four were treated for focal chondral defects (6%), the same number for humero-acromial arthritis, and one patient for rheumatoid arthritis (Table 2).

Table 1: Linear Growth of Shoulder Hemiarthroplasty in the United States

<table>
<thead>
<tr>
<th>Year</th>
<th>Linear (Shoulder Hemiarthroplasty)</th>
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<tbody>
<tr>
<td>1992</td>
<td>4000</td>
</tr>
<tr>
<td>1993</td>
<td>6000</td>
</tr>
<tr>
<td>1994</td>
<td>8000</td>
</tr>
<tr>
<td>1995</td>
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<td>12000</td>
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<td>1997</td>
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<td>1999</td>
<td>18000</td>
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<td>2000</td>
<td>20000</td>
</tr>
<tr>
<td>2001</td>
<td>22000</td>
</tr>
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</table>

Device Description
The HemiCAP® Contoured Articular Shoulder Prosthesis consists of two components: a fixation component and a modular articular component, which are connected via a morse taper interlock (Figure 1). The fixation component is a titanium cancellous screw with full-length cannulation. The cobalt chrome articular component is available in 25mm, 30mm, and 35mm diameter sizes for the shoulder. Each diameter comes in a variety of incremental offset sizes which correspond to the superior/inferior and medial/lateral radius of curvatures at the implant site.

Operative Technique
Most cases are performed through a standard delto-pectoral approach in the beach chair position. This incision is utilitarian and can be converted to an extensile approach if necessary. As an alternative, a posterior, or a deltoid split approach can be used to gain access to the humeral head. For standard procedures, the delto-pectoral interval is developed and the cephalic vein identified. The deltoid and pectoralis major muscles are retracted and the conjoined tendon is developed and retracted medially while protecting the musculocutaneous nerve. The axillary nerve as well is isolated and protected. The subscapularis is incised one centimeter lateral to the musculotendinous junction and sutures are placed into the edge of the subscapularis and capsule to help retract and repair the tendon and ligaments at the conclusion of the procedure. The joint capsule is incised and released along the anatomic neck until sufficient exposure of the humeral head defect is achieved. The glenoid is evaluated and any pathology can be addressed as indicated. As an alternative, arthroscopic intervention can be used to treat concurrent pathologies at the beginning of the procedure.

Utilizing the drill guide, maximum coverage of the defect is verified and a guide pin is placed perpendicular to the joint surface and into the center of the defect. The cannulated instrumentation set ensures that the vertical axis is maintained throughout the procedure. After drilling a pilot hole, the fixation component is inserted. A contact probe determines the radius of curvature in two planes (Figure 2).

Offset increments in 0.5mm sizes allow for a precise fit to the existing articular surface. A matching reamer, prepares the site for the prosthetic implantation. A sizing trial with corresponding diameter and offsets allows for final verification of proper fit. The selected articular component is oriented into the correct planes and impacted thereby engaging the morse taper interlock. The glenohumeral joint capsule and subscapularis are repaired and the incision is closed according to standard procedure.
**Radiographic Findings**
Routine radiographs (anteroposterior and axillary lateral views) were performed at all follow-up periods. Postoperative x-rays were reviewed for evidence of radiographic loosening, including radiolucent lines around the fixation component, osteolysis and device migration.

**Postoperative Care**
Most patients were discharged from the hospital the following day. Many patients had the procedure performed on an outpatient basis. After surgery, the operated arm was kept in a sling at the side. During the first postoperative week, active assisted range of motion exercises were conducted with emphasis on forward elevation and external rotation which was initially limited to 30 degrees. Four weeks after the procedure, active range of motion exercises were encouraged. Strengthening exercises were initiated 8 weeks postoperatively. Return to normal activities of daily living progressed as tolerated over the course of three to six months.

**Results**

**Operative Findings**
In order to effectively cover humeral head lesions, 51% of HemiCAP® implants used in this study had a diameter of 35mm, followed by 39% with 30mm and 10% with 25mm (table 3).

**Concomitant Procedures**
In this study, 23% of the patients (n=14) had rotator cuff tears. 13 of 14 were repaired during the same procedure, one massive tear with chronic retraction was not repairable. 10% of all patients (n=6) demonstrated labral pathology that required either surgical repair, debridement, or reconstruction. 19% (n=12) underwent subacromial decompression and distal clavicle resection for acromio-clavicular pathology. When present, marginal osteophytes and loose bodies were removed.

**Complications**
None of the patients had any intraoperative complications. Postoperatively, there were no infections, dislocations, or neurological complications. One patient underwent a secondary procedure for removal of a loose body. One patient was considered a clinical failure due to unresolved shoulder pain which was attributed to the preexisting glenoid wear found at the time of implantation. Revision total shoulder arthroplasty is planned.

**Outcomes Measures**
The mean preoperative WOOS score (worst=1900, best=0) improved by 80% from 1234 to 247 at last follow-up. The mean ASES score (worst=0, best=100) increased by 50% from 38.4 to 69.3. The average preoperative pain VAS scores (100=extreme pain, 0=no pain) improved by 67% from 54 to 18 at a mean follow-up of 8 months. The Simple Shoulder Test score (worst=0, best=12) increased by 76% from 3.3 to 8.4 in patients followed for one year. The mean Constant (best=100, worst=0) score rose by 51% from 55 to 78. Based on pain and range of motion, 95% of patients indicated a good to excellent result at last follow-up.

**Radiographic Results**
Postoperative radiographs have been reviewed for signs of loosening, osteolysis and device migration. To date, all x-rays demonstrated solid fixation of both implant components without any radiolucent lines or evidence of device migration.

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**Table 3: Summary of Implants**

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>25mm (n=6)</th>
<th>30mm (n=24)</th>
<th>35mm (n=32)</th>
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<td>Degenerative Joint Disease</td>
<td>n=1</td>
<td>n=18</td>
<td>n=26</td>
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<tr>
<td>Avascular Necrosis</td>
<td>-</td>
<td>n=5</td>
<td>n=3</td>
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<tr>
<td>Focal Chondral Defect (n=4)</td>
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<td>-</td>
</tr>
<tr>
<td>Humero-Acromial Arthritis (n=4)</td>
<td>-</td>
<td>n=1</td>
<td>n=3</td>
</tr>
<tr>
<td>Rheumatoid Arthritis (n=1)</td>
<td>n=1</td>
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**Table 4: Average Percent Improvement at a Mean Follow-up of 8 Months**
Case Presentations

Case 1. Glenohumeral Degenerative Joint Disease

Fifty-one year old male with glenohumeral degenerative joint disease. The patient was treated with a labral repair, subacromial decompression, rotator cuff repair, and humeral head resurfacing with a 30mm HemiCAP® implant (Figure 3).

<table>
<thead>
<tr>
<th>Glenohumeral Degenerative Joint Disease</th>
<th>Avascular Necrosis</th>
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</thead>
<tbody>
<tr>
<td><strong>Scoring System</strong></td>
<td><strong>Baseline</strong></td>
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<tr>
<td>SST (raw, best score 12)</td>
<td>3</td>
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<tr>
<td>VAS Pain (worst score 100)</td>
<td>60</td>
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Case 2. Avascular Necrosis

Fifty-three year old female patient with avascular necrosis; five years following humeral head fracture. The patient was treated with a 35mm HemiCAP® implant. She is pain free at 6 months after surgery with excellent upper extremity function (Figure 4).

**Figure 3a:** Humeral head defect

**Figure 3b:** 30mm HemiCAP® resurfacing implant

**Figure 3c:** Preoperative AP x-ray

**Figure 3d:** Postoperative AP x-ray at 3 months

**Figure 4a:** Preoperative AP x-ray

**Figure 4b:** Preoperative coronal MRI demonstrating zone of AVN demarcation

**Figure 4c:** Humeral head defect after debridement

**Figure 4d:** 35mm HemiCAP® resurfacing implant

**Figure 4e:** Postoperative AP x-ray

**Table 1:**

<table>
<thead>
<tr>
<th>Scoring System</th>
<th>Baseline</th>
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<th>Improvement</th>
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<tbody>
<tr>
<td>SST</td>
<td>3</td>
<td>10</td>
<td>78%</td>
</tr>
<tr>
<td>VAS Pain</td>
<td>60</td>
<td>0</td>
<td>100%</td>
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**Table 2:**

<table>
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<tr>
<th>Scoring System</th>
<th>Baseline</th>
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<th>Improvement</th>
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<tbody>
<tr>
<td>WOOS</td>
<td>790</td>
<td>110</td>
<td>86%</td>
</tr>
<tr>
<td>VAS Pain Today</td>
<td>50</td>
<td>0</td>
<td>100%</td>
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**Table 3:**

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**Table 4:**

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<tr>
<td>WOOS</td>
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<td>110</td>
<td>86%</td>
</tr>
<tr>
<td>VAS Pain Today</td>
<td>50</td>
<td>0</td>
<td>100%</td>
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**Table 5:**

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<th>Scoring System</th>
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<th>Improvement</th>
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<tbody>
<tr>
<td>SST</td>
<td>3</td>
<td>10</td>
<td>78%</td>
</tr>
<tr>
<td>VAS Pain</td>
<td>60</td>
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**Table 6:**

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<th>Scoring System</th>
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<th>Improvement</th>
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<tbody>
<tr>
<td>WOOS</td>
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<td>110</td>
<td>86%</td>
</tr>
<tr>
<td>VAS Pain Today</td>
<td>50</td>
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<td>100%</td>
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Case 3. Focal Chondral Defect

Focal Chondral Defect

<table>
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<tr>
<th>Scoring System</th>
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<th>Improvement</th>
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<tr>
<td>WOOS (raw, worst score 1900)</td>
<td>1355</td>
<td>330</td>
<td>76%</td>
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<tr>
<td>Constant (best score 100)</td>
<td>68</td>
<td>97</td>
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<tr>
<td>VAS Pain Today (worst score 100)</td>
<td>80</td>
<td>0</td>
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<tr>
<td>ASES (best score 100)</td>
<td>47</td>
<td>100</td>
<td>100%</td>
</tr>
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</table>

Forty-six year old male patient with a focal full thickness defect in the postero-superior aspect of the humeral head. The patient underwent HemiCAP® resurfacing with a 25mm implant. Twenty-three months after surgery, the patient is essentially pain free, while maintaining excellent function (Figure 5).

Discussion

HemiCAP® humeral head resurfacing has increasingly found acceptance into the mainstream treatment algorithm of shoulder arthroplasty. Key advantages over conventional stemmed arthroplasty are based on newer surgeon-driven clinical strategies of removing minimal bone stock, leaving functional structures intact and preserving articular cartilage. The patient's unique joint geometry guides convexity matching, while not necessarily increasing the articular volume, or imparting non-native curvature to the joint. Joint biomechanics are maintained since joint height, inclination angle, and version are unchanged and alterations to the soft tissue tension are avoided. Humeral shaft and tuberosity related complications are prevented, since they are not involved in the site preparation and delivery of the HemiCAP® implant.

In this patient population, patients were treated for degenerative joint disease with a concentric glenoid, avascular necrosis, focal full thickness defects, humero-acromial arthritis without anterior-superior escape, and rheumatoid arthritis. Contraindications are a markedly deformed humeral head, an eccentric glenoid, humero-acromial arthritis in patients with anterior-superior escape, and fractures.

Warner et al. reported evidence of glenoid wear in all study patients using conventional hemiarthroplasty at a mean follow-up of 43 months post implantation. Büchler and Faron described the importance of anatomic reconstruction to restore the physiological motions and original forces in the muscles and limit eccentric loading of the glenoid. Precise anatomic reconstruction of the humeral head with the HemiCAP® device may reduce the effects on the opposing side and may delay long-term degenerative changes to the glenoid. Many studies have described the complexity and variability of the humeral head geometry. The central articulating portion changes from a spherical humeral surface to an aspherical shape towards the periphery. With increasing HemiCAP® resurfacing diameters, the variety of spherical and aspherical implant offsets provide the closest match to the native human anatomy.

Surgical intervention of AVN in stage II or III (pre-collapse, Ficat) can possibly delay the progression and may prevent further deterioration of the glenohumeral joint. Drilling and HemiCAP® device placement with the cannulated system has a decompressing effect. Sclerotic bone is removed while reaming, allowing the undersurface of the HemiCAP® implant to sit on a vascularized bone bed in most cases.

Superior migration of the humeral head usually indicates a massive rotator cuff tear. Several authors concluded that small reparable tears of the supraspinatus tendon do not adversely affect the outcome of shoulder arthroplasty. Superior humeral head resurfacing in humero-acromial arthritis may provide pain relief; however with the existence of an anterior-superior escape sign, resurfacing will likely not offer an improvement in shoulder function.

Limitations of this study are primarily the short follow-up time interval due to the relatively recent introduction of the HemiCAP® shoulder resurfacing technology. We will continue to follow-up our multicenter patient population to provide a better understanding of the medium and long-term benefits offered by this system in a variety of indications.
References


