Seven-year survival analysis of the Global CAP[®] (Conservative Anatomic Prosthesis) shoulder resurfacing

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Abstract

Background: Shoulder resurfacings represent approximately one-third of shoulder arthroplasties and have the highest revision rates of any shoulder arthroplasty. We present a survival analysis of the Global CAP hemi-resurfacing implanted by multiple surgeons with up to 10 years of follow-up.

Methods: A life-table survival analysis of the Global CAP hemi-resurfacing was undertaken in a single site with multiple surgeons. Two survival analyses were performed; first, where failure was defined as component exchange and, second, where failure was defined as re-operation for any reason. Postoperative functional outcome was quantified using the Quick Disability Arm Hand and Shoulder Score (Quick DASH) and Oxford Shoulder Score (OSS).

Results: Eighty-seven Global CAPs were implanted in 75 patients. At a mean (SD) follow-up of 5.4 years (2.5 years) (range 0.9 years to 10 years), five patients had revision surgery and three patients underwent a reoperation for any reason. Survival at year 7 with component exchange as the endpoint was 80% (95% confidence interval = 93 to 65) and survival with re-operation for any reason as the end point was 62% (95% confidence interval = 82 to 50). The mean OSS and Quick DASH were 35 and 27.6, respectively.

Conclusions: The Global CAP has similar survivorship in the short to medium term and produces similar clinical outcomes compared to other shoulder resurfacings.

Keywords

arthroplasty, Global CAP, resurfacing, shoulder, survival

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Introduction

Shoulder resurfacing arthroplasties have been implanted ever since the 1980s following the newly designed Copeland resurfacing shoulder arthroplasty (CRSA).¹ Compared with conventional total shoulder arthroplasties, a hemi-resurfacing avoids the need to replace the glenoid, and avoids later glenoid loosening. Compared with stemmed hemi-arthroplasties, humeral surface replacements are relatively bone preserving because they do not require resection of the humeral head, reaming of the medullary canal or cementation.² They are often generally considered to be quicker and simpler to implant than most other designs of arthroplasty. Resurfacing hemi-arthroplasties are a commonly used implant with 1938 being registered on the National Joint Registry (NJR) for England, Wales,

Northern Ireland and the Isle of Man accounting for 11.3% of all shoulder arthroplasties.³

The Global[®] CAP[®] (DePuy Synthes, Warsaw, IN, USA) hemi-resurfacing is designed to maximize bone preservation and has variable sizing to match the patient's anatomy. It has a cruciate stem designed to enable a good primary fixation when bone ingrowth occurs into the hydroxyapatite coated porous surface. Resurfacings are designed to replicate the natural version of the humeral head. A cuff tear arthropathy

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(CTA) or extended head is offered as a resurfacing option in those patients with a deficient rotator cuff. The extended head geometry is designed to stabilize the joint and produce a low coefficient of friction at the interface with the acromion.

A literature search identified only one existing published study reporting the clinical outcomes of the Global CAP.⁴ There are numerous large studies of the CRSA up to the latest Mark III model, which has been used since 1993. However, the scarcity of studies of the Global CAP means that surgeons cannot be confident that it has a similar survival to the CSRA. The cruciate stem and porous hydroxyapatite coating are the main differences between the Global CAP and the CRSA. These features are designed to improve the implant; however, in the absence of evidence, these differences could represent a weakness.

We present the largest and longest survival analysis to date of the Global CAP hemi-resurfacing with up to 7 years of follow-up.

Materials and Methods

All Global CAP shoulder hemi-resurfacings implanted in a single hospital trust up to October 2015 were reviewed retrospectively to ascertain survival and functional outcome. Patients had a range of conditions, including osteoarthritis, avascular necrosis and rheumatoid arthritis. Each had routine clinical follow-up at 6 weeks with postoperative radiographs confirming position and alignment. Postoperative functional outcome was quantified using the Oxford Shoulder Score (OSS) and Quick Disability Arm Hand and Shoulder Score (Quick DASH) collected simultaneously in October 2015. Patients were specifically asked if further surgery had been undertaken on their shoulder since the primary replacement and also a general satisfaction with their shoulder replacement on a linear scale from 0 to 10. Indication for any revision procedure was also recorded. The latest postoperative radiographs were reviewed by two investigators aiming to assess glenoid wear and evidence of heterotopic ossification.

All operations were performed by either consultant surgeons or by senior trainees under direct consultant supervision. Within the organization, all joint replacements are performed in lamina flow theatres with routine antibiotic prophylaxis. All were implanted through a deltopectoral approach. If the rotator cuff was deficient and not repairable, a CTA prosthesis was used. The glenoid was not resurfaced in any patient. A sling was used for 4 weeks and a standard progressive physiotherapy regime was delivered to all patients.

A life-table analysis was undertaken of all implanted prosthesis up to and including the month

of October 2015. Two analyses were undertaken; in the first, failure was defined as component removal and revision with another implant. In the second analysis, failure was defined as any reoperation on the shoulder. Patients who died within the study period were included in the analysis until their date of death and were then withdrawn from the total number of patients left in the sample. Those patients who were lost to follow-up were not classed as failed but were discounted from the total number of patients left in the sample. Life tables with a confidence interval of 0.95 as described by Armitage et al.⁵ were constructed. The survival analyses are reported up to 7 years; beyond this follow-up, the 95% confidence intervals (95% CI) are greater than 28 months and so the potential for error is large.

Results

Eighty-seven Global CAPs were implanted from October 2006 to November 2014 in 75 patients. Twelve patients had bilateral implants. Eighteen patients were male and 57 patients were female. Forty-three left shoulders and 44 right shoulders were resurfaced. The CTA prosthesis was used on ten occasions. The mean (SD, median, range) age of patients at the time operation was 69 years (11 years, 71 years, and 44 years to 87 years).

Postoperative follow-up was achieved in 61 patients and postoperative functional scores completed; 11 patients were lost to follow-up in October 2015. Mean (SD, range) follow-up was 5 years (2.5 months, 6 months to 9.5 years). At the latest follow-up, nine patients had died at a mean (SD, range) of 5 years (2 years, 1 year to 7 years) following the operation. No death was attributable to the surgery.

Five patients underwent component exchange and were classed as failed at the date of their revision surgery. The mean (SD, range) time to component exchange was 5 years (3 years, 1 year to 7 years). No CTA prostheses were revised. Survival up to year 7 in which component exchange was the point of failure was 80% (95% CI = 93 to 65) (Fig. 1).

Four patients underwent a reoperation without component exchange in addition to the five patients who underwent component exchange. In a second analysis, these were considered to have failed at the date of reoperation. The survival up to year 7 was 62% (95% CI = 82 to 50) (Fig. 2).

Forty-three patients (70%) representing 50 (68%) Global CAPs had postoperative functional scores. The mean (median, interquartile range) OSS was 35 (40.5, 29.3 to 44.8), the mean (median, interquartile range) Quick DASH Score was 27.6 (20.5, 11.4 to 36.4) and the mean (median, interquartile range)

Year	Starting Number	Withdrawn	Failure	Lost to Follow up	Number at risk	Cumulative success	Annual success	Upper 95%CI	Lower 95%CI
1	87	2	0	0	86	100	100.0	100	93.3
2	85	4	2	2	83	97	97.6	99.9	90.5
3	77	3	0	0	75.5	97	100.0	99.9	90.1
4	74	8	0	0	70	97	100.0	99.9	89.1
5	66	15	1	0	58.5	93	98.3	98.7	83.7
6	50	11	1	1	44.5	89	97.8	96.8	76.5
7	37	9	1	2	32.5	80	96.9	93.3	65.5

Figure 1. Survival analysis using component exchange as reason for failure.

satisfaction score was 7.2 (8, 6 to 9). A bimodal distribution of OSS and quick DASH was observed, with patients having a tendency to either have a good patient-reported outcome measures (PROMs) score or a poor PROM score (Figs. 3 and 4). The bimodal distribution was also present when comparing sex and prosthesis type separately. Heterotopic ossification was seen in four cases of whom three patients were deceased and one patient attained reasonable function with an OSS of 39. We did not identify any parameters that were associated with PROMs score.

Discussion

This is the first published study of survivorship of the Global CAP resurfacing in the medium term. This is a high volume single centre study culminating data from three senior shoulder arthroplasty surgeons. It is assumed that the learning curve to perform this procedure would be resolved by the numbers undertaken within the series. The intention is to discuss the survivorship and the functional outcome of the Global

CAP in comparison with similar resurfacings and implants on the market and current registry data.

New implants are produced at a rate that currently exceeds our ability to analyse their outcomes effectively. Shoulder implant outcomes are now largely based on joint registry data which became available in the UK in 2012.³ There are only nine national shoulder registries, none of which have compulsory recording of data and only four of these have 5000 implants or more registered on them.⁶⁻⁸ Most registries do not collect PROMs data.^{7,9} Recording of PROMs for the NJR is not compulsory and compliance is variable. Shoulder registries aim to reduce the risk of undetected high revision rates. The Australian registry has a high completion rate of over 98.5% and has identified high failure implants that have been subsequently withdrawn from the Australian market.⁸ The NJR has only 385 Global CAPs recorded, the Norwegian registry has only 92 (since 1994)¹⁰ and the Australian 143 (since 2008).⁸ It is likely that many more Global CAPs have been implanted and, until recording implants on registries is compulsory, survival analyses remain the most comprehensive way to report

Year	Starting Number	Withdrawn	Failure	Lost to Follow up	Number at risk	Cumulative success	Annual success	Upper 95%CI	Lower 95%CI
1	87	2	2	0	86	98	100.0	100	91.1
2	83	4	4	2	83	92	95.2	96.8	83.5
3	73	3	1	0	77.5	90	98.7	95.7	81.2
4	69	8	0	0	72	89	100.0	95.2	79.4
5	61	15	1	0	60.5	83	98.3	92.5	72.4
6	45	11	1	1	47.5	73	97.9	88.1	61.9
7	32	9	1	2	36.5	62	97.3	81.8	49.7

Figure 2. Survival analysis using reoperation for any reason as failure.

Figure 3. Bimodal distribution of the Oxford Shoulder Score (OSS) and Quick Disability Arm Hand and Shoulder Score (Quick DASH) in postoperative Global CAP patients at mean.

Figure 4. Q-Q plot of the Oxford Shoulder Score (OSS) and Quick Disability Arm Hand and Shoulder Score (Quick DASH) showing two separate deviations from the expected normal distribution values representing a bimodal distribution.

implant survival data and represent an important method of implant surveillance. Australian and Norwegian Registry data show that, year on year, less Global CAPs are being implanted.^{8,10} Despite higher reported revision rates, surgeons within the UK are still implanting hemi-resurfacings.³

Early work completed by another centre reports two year results of Global CAP with no revisions.⁴ It is difficult to identify failed implants in the first 2 years because there is a lead time to revision as a result of recovery from the index operation, identifying implant failure and scheduling revision surgery. The present study significantly adds to this because of the larger sample size and longer follow-up. Our series reports a survival similar to other resurfacings in the short term. As a group, resurfacing hemi-arthroplasties have been shown to have one of the highest early revision rates on the NJR, with over 4% being revised at 3 years.³ The reason for the high revision rate is not available from the NJR and is poorly understood. Compared to the NJR data for all hemi-resurfacings, the Global CAP in our series appears to be performing slightly better, with a survival of 97% at 3 years.

The CRSA III has the most data for comparison quoting up to 18 years of follow-up from an independent centre.¹¹ A 95% component survival is quoted following a Kaplan–Meier analysis that is calculated from the original eighty-five patients. Only 49 patients were alive at 18 years for follow-up and, of those, three had revision surgery. Functional outcomes at 18 years were good, with an OSS of 36, making it comparable to our cohort.

At the principal centre, no revisions of the CRSA III had been undertaken after following up patients for an mean of 4.4 years.² This series of patients were an older cohort and only consisted of 37 resurfacings. These data have a significantly lower revision rate compared to registry data for all shoulder resurfacings independent of design. Our series showed a 4-year and 5-year survival of 94% and 90%, respectively. The Global CAP survival rate appears to be lower than the published data on the CRSA III.

The reason for revision in our five patients was multifactorial. Two patients had rotator cuff failure, which has a relatively simple surgical solution of revision to a reverse total shoulder arthroplasty. The other three revisions had ongoing pain, which was considered to be from the glenoid. On axial radiographs, two patients had central glenoid erosion to the level of the coracoid and one had anterior glenoid erosion to the same level. One of these was found to be aseptically loose at the time of revision and one required bone grafting of a contained defect at revision. There was no bone loss for any patient that was sufficiently great to preclude revision surgery.

A revision of the Global CAP is often easier than a prosthesis involving a glenoid component or a humeral stem, which may in part explain the higher revision rate of hemi-resurfacings in general. Resurfacings have been used in younger individuals with a higher demand on their shoulders, and sometimes as a procedure to ‘buy time’ before conversion to total shoulder arthroplasty. Revision arthroplasty expertise within our unit is such that revision surgery is potentially offered more frequently and a lower threshold to revise is tolerated.

Patients in our cohort were younger than the mean age in the NJR.³ The factors described could all increase the revision rate and our results should be applied to the population only after taking this into consideration.

Survival when reoperation for any reason was used as the endpoint was low for the Global CAP with 62% survival (95% CI = 82 to 50) at year 7. The main indication for reoperation was an arthroscopic subacromial decompression for impingement. This suggests that the treating clinicians considered subacromial impingement to be a common cause of persistent pain. The diagnosis was not standardized and this likely represents variations in surgical practice.

The results from the 2015 NJR have shown the first PROMS data, with an average OSS for a resurfacing postoperatively at 6 months of 34, which is comparable to our results.³ An OSS of 35 or more is often present in the asymptomatic population.¹² The OSS and Quick DASH did show a previously undescribed bimodal distribution of functional outcomes (Figs. 3 and 4). This may occur because a single binary factor, such as rotator cuff tendinopathy or no rotator cuff tendinopathy, leads to either good or poor function. We cannot currently reliably predict this and no statistically significant difference was found between age, sex or prosthesis type for OSS or Quick DASH. It is beyond the scope of the present study to identify reasons for this bimodal distribution beyond these variables. However, the reasons for such a distribution of scores need to be explored in future studies.

Conclusions

The Global CAP prosthesis has a similar survival to registry data but lower survival against the CRSA III at the principle site. It has a higher early revision rate compared to conventional shoulder arthroplasties, which may be a result of both the ease of revision and implant-related factors. We have shown a previously undescribed bimodal distribution of functional outcome with patients either having very good or very poor function. Future studies should identify the factors that predict good functional outcomes.

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Declaration of Conflicting interests

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Ethical Review and Patient Consent

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