J Shoulder Elbow Surg (2014) 23, 1427-1436

ELSEVIER

Journal of Shoulder and Elbow Surgery

www.elsevier.com/locate/ymse

Evaluation of periprosthetic bone mineral density and postoperative migration of humeral head resurfacing implants: two-year results of a randomized controlled clinical trial

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Background: Implant migration, bone mineral density (BMD), length of glenohumeral offset (LGHO), and clinical results were compared for the Copeland (Biomet Inc, Warsaw, IN, USA) and the Global C.A.P. (DePuy Int, Warsaw, IN, USA) humeral head resurfacing implants (HHRIs).
Methods: The study randomly allocated 32 patients (13 women), mean age 63 years (range, 39-82 years), with shoulder osteoarthritis to a Copeland (n = 14) or Global C.A.P. (n = 18) HHRI. Patients were monitored for 2 years with radiostereometry, dual-energy X-ray absorptiometry, Constant Shoulder Score (CSS), and the Western Ontario Osteoarthritis of the Shoulder Index (WOOS). LGHO was measured preoperatively and 6 months postoperatively.
Results: At 2 years, total translation (TT) was 0.48 mm (standard deviation [SD], 0.21 mm) for the Copeland and 0.82 mm (SD, 0.46 mm) for the Global C.A.P. ($P = .06$). Five HHRI were revised, and in the interval before the last follow-up (revision or 2 years), TT of 0.58 mm (SD, 0.61 mm) for revised HHRI was higher ($P = .02$) than TT of 0.22 mm (SD, 0.17 mm) in nonrevised HHRI. A comparison of TT at the last follow-up (revision or 2 years) found no difference between the HHRIs ($P = .12$). Periprosthetic BMD decreased initially but increased continuously after 6 months for both HHRIs. At 2 years, BMD was 48% higher around the Copeland HHRI ($P = .005$). The mean difference in LGHO was significantly higher for the Copeland than for the Global C.A.P. HHRI ($P = .02$). Clinical results evaluated with CSS and WOOS improved over time for both implant groups ($P < .01$), with no differences between the groups.
Conclusion: Both implants had only little migration and good clinical results. Periprosthetic BMD and LGHO both increased for the Copeland HHRI more than for the Global C.A.P HHRI.

This study was approved by The Central Denmark Region Biomedical Research Ethics Committee (Journal No. 20060165; Issue date: November 2. 2006).

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1058-2746/$ - see front matter
http://dx.doi.org/10.1016/j.jse.2014.05.012

Level of evidence: Level II, Randomized Controlled Design, Treatment Study.

Keywords: Implant migration; bone mineral density; humeral head resurfacing implant

Treatment of shoulder osteoarthritis is debated,[27,32] but the most effective pain treatment of severe osteoarthritis seems to be joint arthroplasty.[4] A surgical modality for the treatment of shoulder osteoarthritis is the humeral head resurfacing implant (HHRI), which aims to replace the worn humeral head cartilage and restore individual anatomy while preserving the bone stock of the humeral head. The indications for HHRI are proposed to be osteoarthritis, rheumatoid arthritis, avascular necrosis stages 2 to 4, and stable forms of cuff tear arthropathy.[9,18,37] Several observational studies[1,3,15,23,33] and register-based studies[7,24] have reported outcomes after HHRI, but to our knowledge, no randomized studies have been performed.

If the primary position and fixation of the HHRI is suboptimal, then micromotion is likely to occur at the bone–implant interface and induce formation of a fibrous membrane instead of a bone bridge to the implant. However, implants that are stable at primary fixation are more apt to stay fixed and survive for longer periods.[30] Also, the periprosthetic bone mineral density (BMD) of the proximal humerus is important to provide strong fixation for the implants and reduce the risk of implant loosening.[34] The relation between BMD and primary implant stability has, in particular, been demonstrated in tooth implants.[6,35] In patients with cementless hip implants, Aro et al[2] showed that the femoral stem subsided more in patients with low BMD than in those with normal BMD during the first 3 months after surgery. Stress shielding resulting in diminished BMD after HHRI may increase the risk of migration and loosening of the prosthesis, but except for computational models,[21,26] little is known about changes in periprosthetic BMD after HHRI.

The Copeland HHRI (Biomet Inc, Warsaw, IN, USA) has been used for more than 25 years, whereas the Global C.A.P. HHRI (DePuy Int, Warsaw, IN, USA) is newer on the market, and currently, only sparse scientific documentation is available. There are small design differences between these 2 HHRIs. The Global C.A.P. implant design considers variability in humeral head size in normal shoulders to enhance anatomic reconstruction of the humeral heads, and further, the apical undersurface of the implant is flat and allows for intimate bone contact and avoids joint stuffing. Both implants have a central cruciform tapered stem to provide rotational stability. The Copeland implant features an extended skirted rim for a circumferential press fit and restores the preosteoarthritis joint conditions by adding +2 mm offset to the resurfaced humeral head. Reaming and implant thickness for the Global C.A.P. is neutral in offset.

The overall aim of this study was to compare the 2 different HHRIs radiologically and clinically in a randomized controlled trial with 2 years of follow-up. The primary outcome was migration assessed 2 years after surgery. Secondary outcome measures were periprosthetic BMD, length of glenohumeral offset (LGHO), and clinical outcome measured by questionnaires.

Materials and methods

The study was registered at ClinicalTrials.gov (NCT00408096) and with the Data Protection Agency (Journal No. 2008-41-2103) and was performed in compliance with the Helsinki Declaration. An a priori power analysis suggested 30 patients would be required in each group to have adequate power (0.8) to show a clinically relevant difference of 0.3 mm in migration between the 2 HHRIs at 2 years of follow-up. However, the design of the Copeland HHRI was changed by the manufacturer in 2011, and the surgeons did not want to continue using the Copeland implant; thus, we had to stop inclusion before scheduled, and 32 patients were included at that time. We therefore calculated the power of the study post hoc based on the actual standard deviations (SDs) and found the study had a power of 0.76 to detect a difference of 0.32 mm in migration between the groups. From 2007 to 2010, 13 women and 19 men, at a mean age of 63 years (range, 39-82 years) and with shoulder osteoarthritis, were included after informed consent (Table I).

The random allocation sequence was generated by the first and last authors by drawing labels from a box, and the labels were then concealed in sequentially numbered closed envelopes. The surgeons enrolled the patients into the study and assigned them to a Copeland (n = 14) or a Global C.A.P. (n = 18) cementless HHRI with plasma-sprayed titanium-coated and hydroxyapatite-coated undersurfaces after having validated intraoperatively that the osteoarthritic shoulder joint could be treated with an HHRI without the need of a glenoid component. One patient randomized to a Copeland HHRI was excluded because an insufficient number of bone-markers were inserted at surgery due to failure of the bead gun.

The inclusion criteria were individuals aged 18 to 85 years with shoulder osteoarthritis and cartilage defects involved on the humeral rather than on the glenoid side of the joint. The exclusion criteria were previous shoulder arthroplasty or other major shoulder surgery, severe shoulder instability with large rotator cuff defect, rheumatoid arthritis, metabolic bone disease, patients unable to avoid nonsteroidal anti-inflammatory drugs after surgery, patients requiring regular systemic steroid treatment, women in the fertile age range who did not use safe contraception, and women taking hormone replacement therapy.

The operations were performed at 2 hospitals by 2 shoulder surgeons (T.K. and K.D.). Both surgeons were trained and had sufficient experience with both implants and the surgical procedure before the study started. All patients were operated on using a standard deltopectoral approach. The tendon of the

Table I Summary of demographics and clinical data at baseline for patients operated on with humeral head resurfacing implant (n = 31)

Variables*	Copeland HHRI† (n = 13)	Global C.A.P. HHRI‡ (n = 18)
Gender		
Male	8	10
Female	5	8
Age, y	61 (40-82)	63 (53-83)
Height, cm	172 (153-185)	173 (152-197)
Weight, kg	87 (60-130)	82 (54-108)
Pain (VAS)§	53 (15-97)	44 (8-99)
Western Ontario Osteoarthritis Shoulder Index	939 (441-1574)	1088 (504-1870)
Constants Shoulder Score	57 (9-70)	35 (10-65)
Post-op periimplant BMD, g/cm^2	0.66 (0.08-1.25)	0.50 (0.12-0.90)
Osteopenia (T-score: −1 to −2.5)	3	10
Implant size	3 (2-4)	48 (40-52)

BMD, bone mineral density; *HHRI*, humeral head resurfacing implant; *VAS*, visual analog scale.
* Continuous data are shown as the mean (range) and categoric data as the number.
† Biomet Inc, Warsaw, IN, USA.
‡ DePuy Int, Warsaw, IN, USA.
§ Measured by the Western Ontario Osteoarthritis Shoulder Index at rest.

subscapularis was split just medial to the insertion on the minor tubercle and reinserted at closure. A balanced capsular release and trimming of the labral complex was performed if needed. During the operation, a bead gun (Wennbergs Finmek, Gunnilse, Sweden) was used to place 5 to 8 tantalum beads in the humeral metaphysis and diaphysis to determine prosthesis migration with model-based radiostereometric analysis (RSA). Except for the 2 surgeons and the observers evaluating RSA and LGHO, all other assessors, care providers, and physiotherapists were blinded to the patient's implant assignment.

The postoperative course was as at present after insertion of HHRI, with an arm sling for 6 weeks. After the first postoperative day, unweighted, passive movement, supervised by a physiotherapist, was allowed to a maximum of 60° outward rotation, whereas only pain limited abduction and flexion. After 6 weeks, free, active movement, respecting the pain threshold, was encouraged under supervision of a physiotherapist.

Radiostereometric analysis

Immediately after surgery, a stereo radiograph was taken, and the initial position of the HHRI was determined in relation to the tantalum beads in the bone. Thereafter, at 6 and 12 weeks and at 6, 12, and 24 months, follow-up stereo radiographs were taken. Standardized stereo radiographic examinations were performed at our institution as described by Stilling et al.[31] Computer analysis was performed on digital computed radiography stereoradiographs (Fuji FCR AC–3CS/ID, Brooklyn, NY, USA) with model-based RSA 3.32 software (Medis Specials, Leiden, The Netherlands), and computer-aided design models of the HHRIs were matched with the contour of the radiographic projection of the implant.[10,31] Implant micromotion, with respect to the rigid bone reference of the tantalum beads, was calculated in 3 dimensions from baseline until 24 months of follow-up.

Total translation (TT) was calculated by use of the Pythagorean theorem (TT = square root $[x^2 + y^2 + z^2]$). At 6 months of follow-up, double stereo radiographs with complete reposition of the patient and system were obtained to estimate the precision of the method (SD of differences between double examinations ×1.96).

Bone mineral density

BMD near the Copeland and Global C.A.P. HHRIs was measured with a Lunar Prodigy Advance bone densitometer (General Healthcare, Madison, WI, USA) within 1 week after surgery and at 3, 6, 12, and 24 months, as described by Stilling et al.[31] All examinations were performed at our institution. Scan data were analyzed with enCORE 11.40 software (GE Healthcare, Madison, WI, USA). Measures of BMD (g/cm^2) were obtained for the one region of interest. A single technician completed all BMD analyses to ensure identical positioning of the region of interest. At the 6-month follow-up, double scanning was performed with complete repositioning of the patient to determine the precision of the method.[31]

At the 3-month dual-energy X-ray absorptiometry scan, BMD in the lumbar spine and the femoral neck was also measured to assess if any patients had osteoporosis or osteopenia based on the World Health Organization diagnostic criteria for osteoporosis. The reason for not doing the osteoporosis scan before surgery was primarily logistical, because the dual-energy X-ray absorptiometry scanner and RSA facilities were located in a different hospital, 50 km from the treating hospital.

Length of glenohumeral offset

Conventional anteroposterior radiographs were obtained preoperatively and at 6 months postoperatively for a geometric analysis of LGHO. The x-ray technique of the 2 hospitals was standardized. Patients were positioned standing with the back against the image receptor, and the nonaffected side was turned 35° to 45° away from the image receptor. The affected arm was flexed 90° in the elbow, and the underarm was internally rotated. The angle of the beam was tilted 15° to 20° in a cranial–caudal direction and was centered toward the shoulder joint.

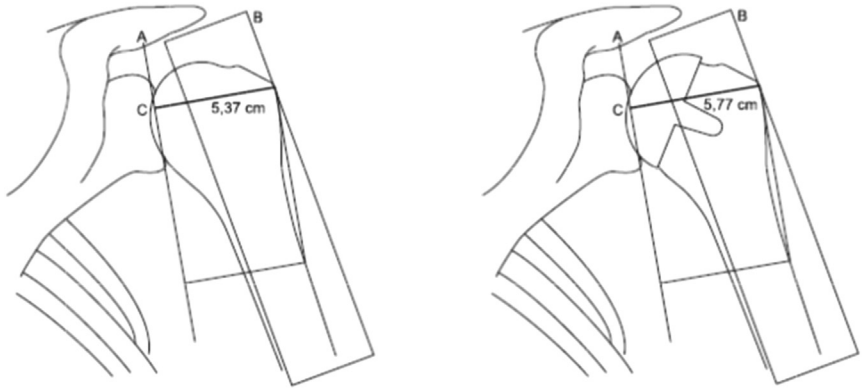

Figure 1 Length of glenohumeral offset is measured by a modified method in which the first step is drawing a line from the top to the bottom of the glenoid cavity (*A*). Then, the center axis of the humeral bone is drawn and a parallel line is shifted until it touches the most lateral part of the major tubercle (*B*). This point is marked and the perpendicular distance from the glenoid-line *A* to the *B* point is noted (*C*).

An experienced radiologist (A.A.) used a modified method to measure the LGHO.[31] First, a line was drawn from the top to the bottom of the glenoid cavity. Then, the center axis of the humeral bone was drawn, and a parallel line was shifted until it touched the most lateral part of the major tubercle. This point was marked, and the perpendicular distance from the glenoid line to this point was noted as the LGHO (Fig. 1). We have previously found the precision of the method is high, with a 95% limit of agreement of ±0.11 cm.[31]

Clinical measures

Before surgery and at 3, 6, 12, and 24 months of follow-up, clinical parameters were evaluated with 2 questionnaires, the Constant Shoulder Score (CSS)[5] and Western Ontario Osteoarthritis of the Shoulder Index (WOOS).[13] The surgeons assessed the CSS, and a shoulder physiotherapist used a myometer (Mecmesin AFG Myometer, Ab Unimerco A/S, Sunds, Denmark) to measure isometric muscle strength. The WOOS was assessed by the patients.

Statistics

All continuous variables were tested for normality by the Shapiro-Wilk test and Q-Q plots, and normal distribution was assumed for the implant migration, periprosthetic BMD, and LGHO data. Data for these variables within the 2 groups were tested with a paired *t* test and between the groups by the Student *t* test. Because some implants were revised, a sensitivity analysis for RSA data concerning revision was also performed. Calculations of the correlation coefficient between migration and BMD were performed with the Pearson correlation analysis. Data for measurements of CSS and WOOS over time within the 2 groups were tested by the Kruskal-Wallis test. The difference between baseline and 2 years of follow-up between the 2 groups was tested by the Mann-Whitney test. Intercooled Stata 11.0 software (StataCorp LP, College Station, TX, USA) was used for statistical computations.

Results

The number of patients randomly assigned and analyzed for the outcome variables in this study is shown in Fig. 2. One patient was excluded after randomization and HHRI insertion because the bead gun jammed during surgery and only 1 bone marker was visible on the radiograph. The demographics for the patients at baseline are reported in Table I. Within the 2-year follow-up period 3 of 13 Copeland and 2 of 18 Global C.A.P. HHRIs were revised ($P = .63$), and 2 patients (2 implants) were lost to follow-up. Radiologic and clinical data for the 5 patients who were revised are described in Table II.

Radiostereometric analysis

At 2 years, the mean total translation (TT) was 0.48 mm (SD, 0.21 mm) for the Copeland HHRI and 0.82 mm (SD, 0.46 mm) for the Global C.A.P. HHRI ($P = .06$; Fig. 3). Between 1 and 2 years, TT for the Global C.A.P. increased ($P = .04$) by 0.17 mm (SD, 0.29 mm), whereas the Copeland HHRI (0.09 mm; SD, 0.19) had no significant TT migration ($P = .23$).

At the last follow-up (revision or 2 years), the Copeland HHRI tended to migrate laterally and rotate into valgus, whereas the Global C.A.P. HHRI translated distally and laterally, but there was no difference between groups ($P > .27$; Table III). Evaluating absolute migrations at the last follow-up (revision or 2 years), we found similar TT ($P = .98$) and similar absolute translations and varus/valgus rotation ($P > .07$; Table IV). The precision of the method (SD of differences between double examinations ×1.96) is reported in Table V.

Of the implants that were not revised, 3 Global C.A.P HHRIs and no Copeland HHRIs migrated above the precision limit of 0.37 mm TT between 1 and 2 years of follow-up. Three of 5 revised implants (all Copeland) and 4 of 24 nonrevised implants (1 Copeland, 3 Global C.A.P.) migrated above the 0.37 mm TT precision limit ($P = .08$). For the 5 revised implants, migration was higher ($P = .02$) between the last 2 RSA examinations, with TT at 0.58 mm (SD, 0.60 mm) compared with the nonrevised implants with TT at 0.22 mm (SD, 0.17 mm). There was a tendency for

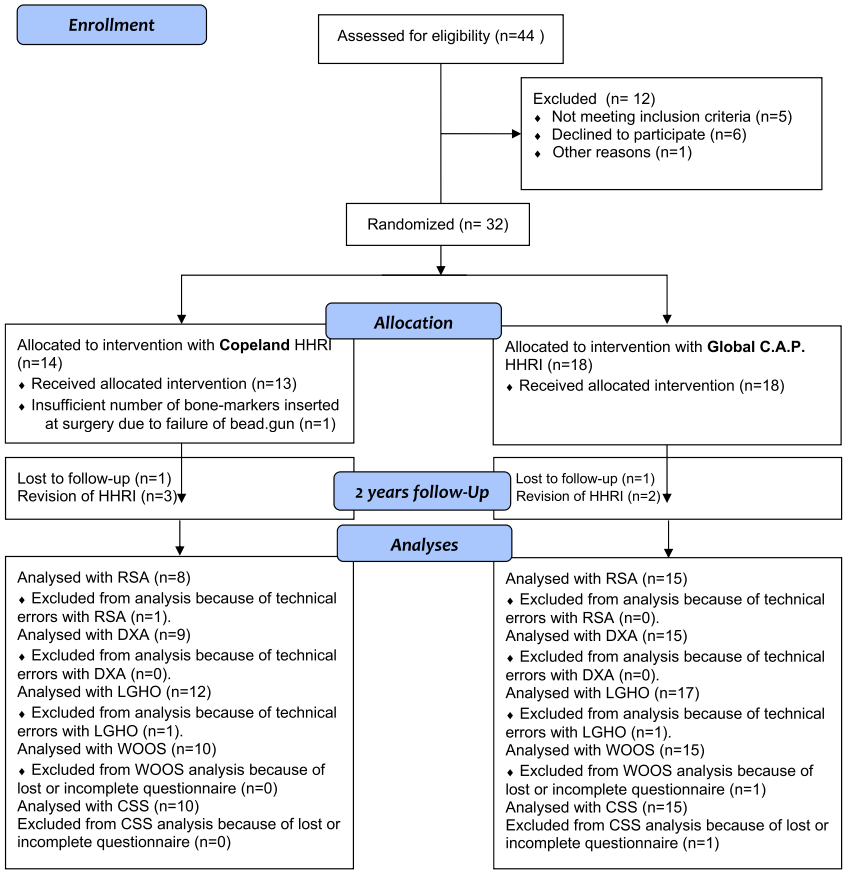

Figure 2 Flow diagram shows the number of patients randomly assigned and analyzed at 2 years of follow-up for the primary and secondary outcome measures. *Copeland*, Biomet Inc, Warsaw, IN, USA; *CSS*, Constant Shoulder Score; *DXA*, dual-energy X-ray absorptiometry; *HHRI*, humeral head resurfacing implant; LGHO, length of glenohumeral offset; *RSA*, radiostereometric analysis; *WOOS*, Western Ontario Osteoarthritis Score.

the revised HHRIs to translate in anterior, distal, and lateral directions and rotate into valgus ($P > .09$; Table IV). TT at the last follow-up (revision or 2 years) was 1.11 mm (SD, 0.74 mm) for revised implants and 0.70 mm (SD, 0.41 mm) for nonrevised implants ($P = .08$). A difference in absolute miration was found in x-translation ($P = .009$) with 0.83 mm (SD, 0.59 mm) for the Copeland and 0.18 mm (SD, 0.15 mm) for the Global C.A.P. HHRI.

Bone mineral density

Postoperative BMD was mean 0.69 g/cm^2 (SD, 0.35 g/cm^2) near the Copeland HHRI and 0.50 g/cm^2 (SD, 0.19 g/cm^2) near the Global C.A.P. ($P = .07$). Periprosthetic BMD around both implants decreased up to 6 months after surgery and then increased continuously up to 2 years after surgery (Fig. 4). At both 1 and 2 years of follow-up, BMD was significantly higher around the Copeland HHRI compared with the Global C.A.P HHRI ($P < .01$).

The BMD measurements of the lumbar spine/femoral neck showed that osteopenia was present in 13 patients (10 Global C.A.P.) and that BMD was normal in the remaining 19 patients. The correlation between postoperative BMD and migration was insignificant ($r = 0.17$, $P = .41$).

Length of glenohumeral offset

The mean difference in LGHO preoperatively compared with 6 months postoperatively for the Global C.A.P. was 0.002 cm (95% confidence interval –0.15 to 0.15 cm; $P = .97$), and the mean difference for the Copeland was 0.28 cm (95% confidence interval, 0.08-0.48 cm; $P = .01$). The mean difference in LGHO was significantly higher for the Copeland HHRI compared with the Global C.A.P. ($P = .02$).

Clinical outcome scores

Clinical outcomes were assessed with the WOOS and the CSS before surgery and at 3, 6, 12, and 24 months after surgery and improved for both groups. In the group with a Copeland HHRI, CSS increased continuously, from a median of 57 to 61, 71, 72, and 77 ($P = .007$), and WOOS improved from a median of 939 to 645, 296, 295, and 113 ($P = .002$). For the patients with a Global C.A.P. HHRI, CSS improved from a median of 35 to 51, 65, 73, and 73 ($P = .0001$), and WOSS improved from median of 1060 to 568, 383, 381, and 300 ($P = .0001$). There were no significant differences in the scores between the groups (Fig. 5).

Table II Radiological and clinical data for the 5 patients who were revised within the first 24 months after insertion of the humeral head resurfacing implant

Patient	Implant	Time to revision (mon)	Clinical reason for revision	Treatment at revision	Clinical implant fixation at revision	TT at revision (mm)	TT between 2 last FU (mm)	Peri-implant BMD post-op (g/cm^2)	Osteopenia	Gender	Age (y)	VAS_{rest} revision	WOOS revision
1	Copeland*	6	Major Tubercle fracture, impingement	Converted to Cuff tear arthropathy hemiprosthesis	Good	1.30	+0.46	0.88	No	M	65	25	1105
2	Global C.A.P.†	12	Pain, pseudo-paralysis	Converted to Delta† inverse prosthesis	Partial	0.64	−0.16	0.27	Yes	F	67	80	944
3	Copeland	16	Pain, traumatic cuff rupture	Converted to cuff tear arthropathy hemiprosthesis	Good	2.25	+1.61	0.70	No	M	77	15	595
4	Copeland	19	Pain, impingement, peri-implant osteoarthritic changes	Converted to total shoulder prosthesis	Good	0.29	−0.59	0.93	Yes	M	49	14	850
5	Global C.A.P.	23	Degenerative cuff-rupture	Converted to cuff tear arthropathy hemiprosthesis	Good	1.11	−0.10	0.66	Yes	M	53	48	1106

BMD, bone mineral density; *F*, female; *FU*, follow-up; *M*, male; *TT*, total translation; *WOOS*, Western Ontario Osteoarthritis Shoulder Index; VAS_{rest}, visual analog scale at rest.

* Biomet Inc, Warsaw, IN, USA.

† DePuy Int, Warsaw, IN, USA.

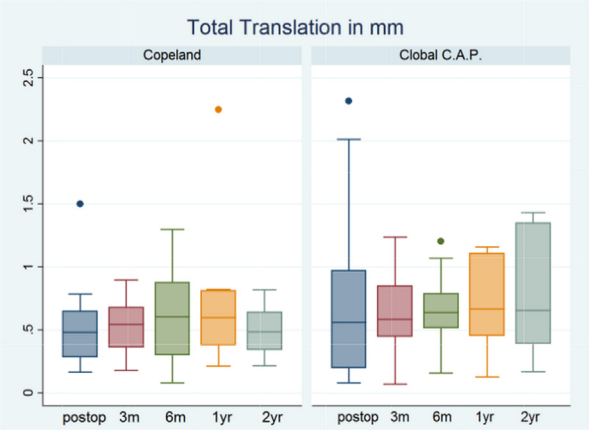

Figure 3 Total translation (in mm) of the Copeland (Biomet Inc, Warsaw, IN, USA) and Global C.A.P. (DePuy Int, Warsaw, IN, USA) humeral head resurfacing implants determined at 6 weeks, and at 3, 6, 12, and 24 months after surgery. The *horizontal line* in the middle of each box indicates the median, the *top and bottom borders* of the box mark the interquartile range (75th and 25th percentiles), the *whiskers* mark the 90th and 10th percentiles, and the *dots* indicate outliers. There was no significant difference in migration between the 2 HHRI at any follow-up assessment.

Discussion

This study randomized patients with osteoarthritis of the shoulder to a Copeland or a Global C.A.P. HHRI. The median TT was minor for both HHRIs, but the Global C.A.P. implant migrated continuously between 1 and 2 years. There were a high number of patients with osteopenia in the Global C.A.P. group (10 of the 13 patients), which may have influenced the migration of the implant.

The migration pattern and cutoff for "risk of later aseptic implant loosening" has not yet been established for shoulder implants. From what we know from cementless hip and knee implants, continuous migration is problematic and related to premature revision.[19,25] However, the period of osseointegration in the implant hydroxyapatite-coated undersurface should be similar to other joints, and cementless HHRIs are expected to stabilize within 6 months after surgery. Because the shoulder has a different loading and lever arm compared with hip joints, a direct parallel for the migration pattern is not expected. Although there are indications, we cannot conclude that the observed migration pattern at group level for the Global C.A.P. found in this study is problematic.

Table III Summary of radiostereometric analysis data at last available follow-up (revision or 2 years) sorted by type of humeral head resurfacing implant

Variables	Copeland HHRI* (n = 12)	Global C.A.P.† (n = 17)	*P*
	Mean (SD)	Mean (SD)	
Signed RSA data			
x-translation: proximal (+)/distal (−)	0.05 (0.61)	−0.15 (0.32)	.33
y-translation: lateral (+)/medial (−)	0.21 (0.43)	0.13 (0.67)	.74
z-translation: anterior (+)/posterior (−)	0.04 (0.46)	−0.02 (0.59)	.78
x-rotation; valgus (+)/varus (−)	0.77 (1.52)	0.02 (2.00)	.28
Absolute RSA data			
TT difference‡	0.35 (0.43)	0.24 (0.18)	.98
TT (total translation)	0.67 (0.58)	0.83 (0.43)	.12
x-translation	0.35 (0.50)	0.26 (0.23)	.43
y-translation	0.29 (0.38)	0.52 (0.42)	.08
z-translation	0.37 (0.24)	0.44 (0.38)	.79
x-rotation	1.03 (1.34)	1.49 (1.28)	.18

HHRI, humeral head resurfacing implant; *RSA*, radiostereometric analysis; *SD*, standard deviation; *TT*, total translation.

* Biomet Inc, Warsaw, IN, USA.

† DePuy Int, Warsaw, IN, USA.

‡ TT difference: the difference in TT between the last and second last follow-up, with last follow-up defined as revision or 2 year.

Table IV Summary of radiostereometric analysis data at last available follow-up (revision or 2 years) sorted by nonrevised and revised humeral head resurfacing implant

	Non-revised HHRI (n = 24)	Revised HHRI (n = 5)	*P*
	Mean (SD)	Mean (SD)	
Signed RSA data			
x-translation: proximal (+)/distal (−)	−0.05 (0.23)	−0.17 (1.09)	.10
y-translation; lateral (+)/medial (−)	0.13 (0.56)	0.30 (0.68)	.56
z-translation; anterior (+)/posterior (−)	−0.05 (0.54)	0.28 (0.45)	.20
x-rotation; valgus (+)/varus (−)	0.07 (1.66)	1.58 (2.25)	.09
Absolute RSA data			
TT difference*	0.22 (0.17)	0.58 (0.61)	.02
TT (total translation)	0.70 (0.41)	1.11 (0.74)	.08
x-translation	0.18 (0.15)	0.83 (0.59)	.01
y-translation	0.39 (0.39)	0.47 (0.56)	.74
z-translation	0.39 (0.35)	0.45 (0.25)	.74
x-rotation	0.09 (1.18)	2.03 (1.73)	.11

HHRI, humeral head resurfacing implant; *RSA*, radiostereometric analysis; *TT*, total translation.

* TT difference: the difference in TT between the last and second last follow-up, with last follow-up defined as revision or 2 year.

More interestingly, we found a higher migration for the 5 revised implants compared with nonrevised implants for the final interval of the follow-up period. Migration of the individual implants is of high interest, and the precision limit is applicable for judgment of individual migrations between 2 follow-up assessments (ie, between 1 and 2 years). At the last follow-up (revision or 2 years), 3 Copeland and 2 Global C.A.P. implants had migrated more than the 0.37 mm TT precision limit.

Although the revised implants migrated more in the last period of RSA follow-up, indicating risk of failure by aseptic loosening, the clinical observations by the shoulder surgeons during surgery did not confirm loose implants. We do not have an explanation for this, but speculate that shoulder surgeons revise patients earlier than hip and knee surgeons, perhaps due to fear of pain and immobilization, leading to a stiff shoulder joint and poor range of motion (ROM). If this is the case, it could explain why the revised shoulder implants were only microloose (measured by RSA), rather than macroloose (clinical impression at revision).

Sköldenberg et al[29] applied marker-free RSA in their experimental shoulder study and found an accuracy of 0.22

Table V Radiostereometric analysis precision from double examination stereo radiographs (to be used on patient individual basis)

Variable	*x*	*y*	*z*	Rz	TT
Mean difference	0.05	0.05	0.09	0.73	0.08
SD difference ×1.96	0.24	0.43	0.45	4.51	0.37

SD, standard deviation; *TT*, total translation.

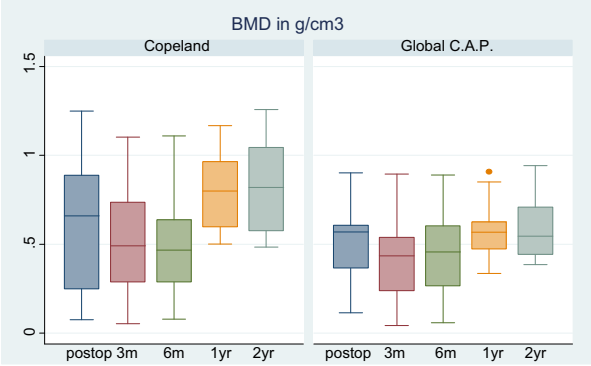

Figure 4 Bone mineral density (*BMD*), in g/cm^3, around the Copeland (Biomet Inc, Warsaw, IN, USA) and Global C.A.P. (DePuy Int, Warsaw, IN, USA) humeral head resurfacing implants determined postoperatively and at 3, 6, 12, and 24 months after surgery. The *horizontal line* in the middle of each box indicates the median, the *top and bottom borders* of the box mark the interquartile range (75th and 25th percentiles), the *whiskers* mark the 90th and 10th percentiles, and the *dots* indicate outliers. At 1 and 2 years, periprosthetic BMD was higher ($P < .01$) around the Copeland HHRI compared with the Global C.A.P.

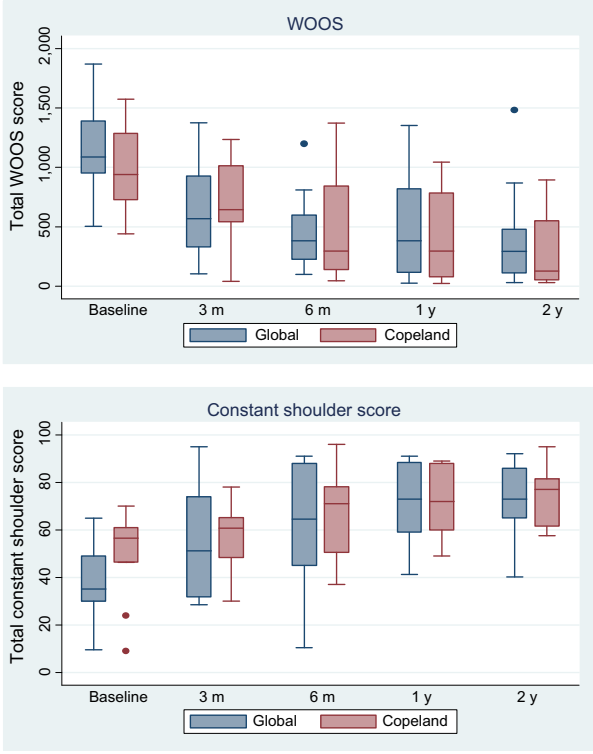

Figure 5 The Western Ontario Osteoarthritis Scores (*WOOS*) and Constant Shoulder Scores for the patients with the Copeland (Biomet Inc, Warsaw, IN, USA) and Global C.A.P. (DePuy Int, Warsaw, IN, USA) humeral head resurfacing implants completed preoperatively, and at 3, 6, 12, and 24 months after surgery. The *horizontal line* in the middle of each box indicates the median, the *top and bottom borders* of the box mark the interquartile range (75th and 25th percentiles), the *whiskers* mark the 90th and 10th percentiles, and the *dots* indicate outliers. There was no statistical difference in scores between the 2 groups at any follow-up.

to 0.47 mm for translations and 0.92° to 1.56° for rotations. In this clinical study, we determined a precision of 0.24 to 0.45 mm for translation and 4.51° in rotation around the z axis, underlining that our data have equally high accuracy in translation but a far lower accuracy in rotation than can be achieved in an experimental setting.

The BMD values increased from 6 months after surgery for both implants, and postoperative BMD values at 1 year were higher than the preoperative values, indicating increased loading and active use of the operated shoulder after HHRI surgery. At both 1 and 2 years of follow-up, BMD was significantly higher around the Copeland implant compared with the Global C.A.P. implant. The patients with a Copeland implant had a tendency to start out with a higher periprosthetic BMD; yet, the BMD for Copeland HHRIs also increased significantly compared with BMD around the Global C.A.P. HHRI. Furthermore, BMD for the Copeland HHRI continued to increase between 1 and 2 years to a difference of 48% BMD content between the 2 implants. This is a clinically important finding displaying bone remodeling due to regained loading and active use of the shoulder joint and affected arm.

Four of the revised implants had good osseointegration at revision, and 1 had partial bone integration according to the macroscopic judgment of the surgeon. On the basis of a computational remodeling model, Quental et al[21] concluded that stress shielding is not a key factor for the humeral component failure of shoulder implants in healthy bone, and in line with that, the surgeons did not think aseptic loosening was the clinical reason for revision in this study. We know from knee implants that BMD decreases during the first 3 months postoperatively, whereafter the bone mass stabilizes and remodeling is complete after approximately 24 months.[12] In this study, we will continue to monitor the remodeling of bone near the shoulder implants for 5 years to investigate the pattern of BMD activity.

LGHO increased for the Copeland HHRI after surgery and resulted in a significantly longer LGHO in the Copeland compared with the Global C.A.P. The clinical consequences of a postoperatively increased LGHO for the Copeland HHRI are unknown, and the clinical outcome scores in the Copeland group were comparable to the scores for the Global C.A.P group. Yet, the increased LGHO verifies a potential overstuffing problem with the Copeland HHRI caused by the reaming process that only takes 2 mm of the humeral surface, whereas the apical thickness of the implant is 4 mm.[14] The manufacturer altered the design of the Copeland HHRI in 2011 to comply with clinical concerns of overstuffing.

Clinical scores increased continuously from before surgery and during the 3, 6, 12, and 24 months after surgery for both groups. Large improvements were already found at 3 months after surgery in all 4 dimensions on the WOOS: physical symptoms, function, life style, and emotions. At that time, there were no restrictions in movement of the shoulder joint and the patients had completed the physiotherapy-supervised rehabilitation program at the hospital.

Pain was reduced and movement had improved, whereas strength measured by a myometer on the CSS was unchanged compared with before surgery. The increase in CSS at 2 years of follow-up was similar to the clinical results reported by Raiss et al,[23] where mean CSS increased from 33 to 61 points at 3 years postoperatively. Other studies have presented varying CSS scores after HHRI, ranging from 54 points 3 years after surgery reported by Thomas et al,[33] to 61 points 4 years after surgery found by Alizadehkhaiyat et al,[1] to 73 at 5 to 10 years of follow-up reported by Levy et al[11] and to 82 points at 3 years of follow-up.[8]

However, the CSS has potential sources of errors affecting the results, namely, the measurement of ROM and muscle power. ROM in the shoulder joint was noted at intervals of 30°, and a goniometer was used if ROM was on the border between 2 intervals. However, differentiating between the intervals was difficult, even with a goniometer. The CSS does not entail a description on how to measure muscle strength with the myometer (eg, standing or sitting, position of arm, elbow and hand), and this will hamper comparison of the CSS score between different cohorts of patients. Moreover, the CSS was assessed by the operating surgeons, who may overestimate the improvements in function after HHRI. Although there were no differences between the groups, a limitation of the study is that we did not engage a blinded observer to assess the CSS in patients.

The rate of revision 2 years after HHRI was 15.6% in our study. Alizadehkhaiyat et al[1] found a revision rate of 10.4% among their patients with osteoarthritis in a 4-year mean follow-up study of the Copeland HHRI, and Levy et al[11] reported 7.7% revisions in a 5 to 10 years of follow-up of the Copeland RHHI. Obesity and younger age are risk factors for a higher revision rate after humeral head replacement.[28] The body mass index for the women (28.8 kg/m^2) and men (28.5 kg/m^2) included in this trial was rather high, and the mean age of 63 years was fairly young, which may explain the higher rate of revisions in our study. The surgical expertise in the study was high and was not expected to negatively influence the results.

Evaluating the outcome after HHRI with radiographs, patient-reported outcome measures,[1] and survival rates[20] is not sufficient. Evaluation with RSA is recommended for fixation of all new joint implants designs,[16,36] which is also becoming a standard examination for hip and knee implants, whereas studies applying RSA for shoulder implants are lacking. Sköldenberg et al[29] verified in an experimental study that marker-free RSA can be used to measure migration of HHRIs, and Rahme et al[22] and Nuttall et al[17] used RSA to investigate the migration pattern of the glenoid component. Our randomized study is the first to report results from RSA applied to investigate the migration of HHRI in vivo.

Conclusion

The Copeland HHRI was associated with increased BMD but also enlarged LGHO. The clinical results were good for both implants. However, the rate of revisions was high, which should be considered when balancing benefits and harms of a HHRI. These 2-year results can be generalized to patients with shoulder osteoarthritis in whom implanting a glenoid component is not required.

Disclaimer

This study was financially supported by the Danish Rheumatism Association, The Aase and Ejnar Danielsen Foundation, The AP Møller Foundation, The Danish Medical Association, Cooperative organizations Humanitarian and Cultural Foundation, The Hede Nielsen Family Foundation, Jacob Madsen & Olga Madsen's Foundation, Protesekompagniet/DePuy Denmark, and Biomet Denmark.

The authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

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