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Precision of novel radiological methods in relation to resurfacing humeral head implants: assessment by radiostereometric analysis, DXA, and geometrical analysis

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Abstract
Background Resurfacing humeral head implants (RHHI) are used to preserve bone stock and restore normal anatomy in the osteoarthritic shoulder joint. The purpose of this study was: (1) to describe the use of novel radiological methods in relation to evaluation of RHHI; (2) to estimate the precision of these methods; and (3) to present preliminary clinical and radiological results at 6 months follow-up after Copeland and Global Cap RHHI.
Methods Twenty-one patients (10 females) at a mean age of 64 (39–82) years and with shoulder osteoarthritis were randomized to a Copeland ($n = 11$) or Global C.A.P ($n = 10$) RHHI. Migration of the RHHI was analyzed with radiostereometric analysis (RSA), and bone mineral density (BMD) was measured with dual energy X-ray absorptiometry (DXA). The length of gleno-humeral offset (LGHO) was measured on radiographs. The patients were followed clinically with questionnaires.
Results Precision of the radiological methods was high for the LGHO and acceptable for RSA and for DXA. At 6 months, shoulder function had improved significantly for both RHHI groups. LGHO increased significantly for the Copeland RHHI and was slightly reduced for the Global C.A.P. RHHI. The implant migration and BMD change around the implant from baseline until 6 months follow-up was comparable for both RHHI.
Conclusion Radiostereometric analysis and DXA can be used for evaluation of RHHI, but expectedly with a lower precision as compared to standards of TKA or THA. Geometric analysis of the prosthetic shoulder is precise. We interpret that the early radiological and clinical results of the two RHHI are comparable.

Keywords Resurfacing humeral head implants · Precision · RSA · DXA

Introduction

Osteoarthritis of the shoulder is a common condition, the prevalence of which increases with age, and shoulder arthroplasty is the third most common joint replacement after hip and knee arthroplasty [1]. Approximately, 600 shoulder prostheses are inserted yearly in Denmark and the number of operations is expected to increase because of the growing number of elderly in the population. Resurfacing humeral head implants (RHHI) mimic the natural shape of the normal humeral head and restore normal anatomy for osteoarthritic patients and potentially allow for fast functional recovery with limited pain. The indications for use of RHHI are the same as for conventional stemmed shoulder implants (SSI), namely osteoarthritis, rheumatoid arthritis, avascular necrosis and shoulder osteoarthritis secondary to trauma [2]. RHHI necessitate minimal bone resection compared to SSI, and also problems with humeral stress fracture in the proximity of the diaphyseal stem of SSI are avoided.

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Cementless implants leave the humeral bone in good conditions for revision implant surgery, and cementless RHHI are therefore optimal for younger patients where future revisions are to be expected. The primary surgical fixation of cementless RHHI is "press fit"; however, secondary bony fixation is essential for the final result. Cementless implants are porous coated to aid in bone ingrowth to the implant surface, and some implants are further hydroxyapatite coated to catalyze bone-on growth and aid bridge small bone–implant gaps. If the primary position and fixation of the implant is sub-optimal, then micro-motion is likely to occur at the bone–implant interface and induce formation of a fibrous membrane instead of a bone bridge to the implant. On the contrary, implants that are stable at primary fixation are more apt to stay fixed and survive for longer periods [3]. Mechanically, there are various material factors that influence implant fixation, i.e., the surface coating [4], material elasticity, corrosion resistance and biocompatibility [5]. Biologically, the periprosthetic bone quality, quantity and turnover are also considered important. From investigations on hip and knee arthroplasty, it is well known that the periprosthetic bone mineral density (BMD) decreases in a period of 2 or more years following arthroplasty [6–9]. Presumably, there will also be postoperative stress shielding of the bone in conjunction with RHHI; however, it has only been experimentally investigated previously [10].

We designed a randomized clinical trial (RCT) featuring radiological methods never used with RHHI previously in which two different RHHI designs were compared with a hypothesis of no expected difference. At this point, we publish a pilot study on 1/3 of the included patients with the goal of (1) describing the new methods used to evaluate the outcome after RHHI, (2) estimating the precision of the radiological methods and (3) presenting preliminary clinical and radiological results at 6 months follow-up.

Materials and methods

After informed consent, 21 patients (10 females) at a mean age of 64 (39–82) years and with shoulder osteoarthritis were included (Table 1). The study was approved by the Biomedical Research Ethics Committee (Journal number 20060165; Issue date: November 2nd 2006), registered at ClinicalTrials.gov (NCT00408096) and with the Data Protection Agency (Journal number 2008-41-2103). The patients were randomized intra-operatively to either Copeland (Biomet Inc.) (11) or Global C.A.P. (DePuy Int) (10) un-cemented RHHI with titanium-sprayed, hydroxyapatite-coated articulating surfaces after the surgeon had validated that the osteoarthritis was primarily visible on the humeral head and that there was no need for a glenoid component. There are small design differences between these two RHHI, as 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 under-surface 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. Copeland features an "extended skirted rim" for a circumferential press fit and restores the pre-osteoarthritis joint conditions by adding +2 mm offset to the resurfaced humeral head. For the Global C.A.P., reaming and implant thickness are neutral in offset.

Table 1 Summary of demographics and clinical data at baseline ($n = 21$) (median, range)

Input variables	Copeland group ($n = 10$)	Global C.A.P. group ($n = 11$)
Gender (male/female)	6/3	4/6
Age (years)	66 (40–82)	61 (53–83)
Height (cm)	176 (153–185)	172 (152–185)
Weight (kg)	82 (60–130)	77 (54–108)
Pain (VAS)*	62 (17–97)	59 (8–99)
Western Ontario Osteoarthritis of the Shoulder Index (total score)	1,137 (441–1,574)	1,270 (495–1,771)
Constant Shoulder Score (total score)	39 (10–70)	42 (9–54)
Operated side (Right/left)	2/7	10/1

* Measured on Western Ontario Osteoarthritis of the Shoulder Index

Randomization was performed by drawing labels from a box (blocks of 10), and the labels were then concealed in sequentially numbered closed envelopes. The inclusion criteria were persons aged 18–85 years with shoulder osteoarthritis primary located on the humeral head and therefore suitable for treatment with hemiarthroplasty. The exclusion criteria were previous shoulder arthroplasty or other major shoulder surgery, severe shoulder instability with large rotator cuff defects, rheumatoid arthritis, metabolic bone disease, patients unable to avoid NSAID after surgery, patients requiring regular systemic steroid treatment, female patients in the fertile age range who did not use safe anti-contraception (oral contraception, intrauterine devices, vaginal hormone rings) and female patients taking hormone substitution.

The operations were performed by one orthopedic surgeon, who was sub-specialized in shoulder surgery. All patients were operated using a standard delto-pectoral approach. The tendon of the subscapularis was split just

medial to the insertion on the minor tubercle and reinserted at closure. If needed, a balanced capsular release and trimming of the labral complex was performed. The postoperative course after insertion of RHHI implied a fixed arm sling the first postoperative day. Hereafter, unweighted, passive motion supervised by a physiotherapist was allowed to a maximum 60° external rotation, whereas only pain limited passive abduction and flexion. After 6 weeks, free, active shoulder motion, respecting the pain threshold, was encouraged under the supervision of a physiotherapist.

Before surgery and at 3 and 6 months after surgery, clinical parameters were evaluated by the Constant Shoulder Score (CSS) [11] and Western Ontario Osteoarthritis of the Shoulder Index (WOOS) [12]. Preoperative and 6 months postoperative conventional AP radiographs were obtained for a geometrical analysis of the length of the gleno-humeral offset (LGHO) [13]. Stereoradiographs were taken at fixed time intervals; immediately after surgery, and at 6, 12 and 24 weeks postoperatively follow-up stereoradiographs were taken. Bone mineral density around the RHHI Copeland and Global C.A.P. was evaluated with dual energy X-ray absorptiometry (DXA) at 3–5 days after surgery and at 3 and 6 months.

Constant Shoulder Score

The CSS is validated and it is the most frequently used outcome measurement tool for assessing shoulder function in Europe [14]. The maximum score on the CSS is 100 points (no shoulder symptoms), split in 35 points in the subjective part and 65 in the objective. The subjective part of CSS was filled out by the patient with a project physiotherapist present, and afterward the physiotherapist measured the range of motion and muscle strength of the shoulder joint.

WOOS

Western Ontario Osteoarthritis of the Shoulder Index is a validated disease-specific quality of life patient-reported outcome measurement tool for osteoarthritis. WOOS contains 19 items, each with a visual analog scale response option for the four domains (six questions for pain and physical symptoms, five questions for sport, recreation and work, five questions for lifestyle function and three questions for emotional function). The instrument is proven to be valid by demonstrating predicted correlations with previously published shoulder measures, global health status measure and range of motion [12]. In the WOOS, the range of points goes from 1,900 (the worst possible outcome) to zero (asymptomatic shoulder).

Length of gleno-humeral offset (LGHO)

A radiologist, blinded to the type of RHHI, measured the LGHO [13] using a modified method. First, a line from the top to the bottom of the glenoid cavity was drawn. Then the center axis of the humeral bone was drawn and a parallel line was shifted till 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 modified measure of LGHO (Fig. 1). Classically, the measure of LGHO is performed by measuring from the base of the coracoid process to the greater tubercle [13, 15]. But this measure shows systematic errors in inter-observer reliability [15], because it is difficult to locate the same point on the base of the coracoid process between observers. Due to the reported problems with inter-observer reliability, we chose to apply the modified LGHO in this study and the radiologist performed repeated measurements on preoperative and postoperative AP radiographs from 15 patients (60 radiographs) to estimate the precision of the method.

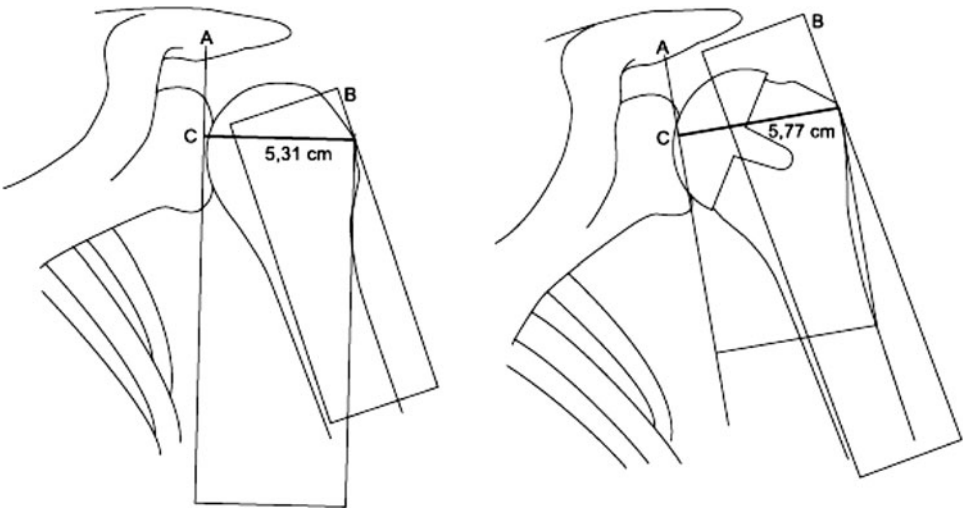

Fig. 1 Length of gleno-humeral offset is measured by a modified method in which the first step was to draw a *line* from the *top* to the *bottom* of the glenoid cavity (*A*). Then the center axis of the humeral bone was drawn and a parallel line was shifted till it touched the most lateral part of the major tubercle (*B*). This point was marked and the perpendicular distance from the glenoid line "A" to this point was noted (*C*)

Radiostereometric analysis (RSA)

Before initiation of this study, we performed a phantom study using a humerus saw bone. The phantom data suggested that model-based RSA is a precise method for evaluation of migration of RHHI implants, and we proceeded with the present study.

During surgery, five to eight tantalum beads were spread in the proximal humeral metaphysis and diaphysis as a rigid body reference of the bone. This was necessary to determine prosthesis migration with model-based radiostereometric analysis (MB-RSA). Stereoradiographic examinations were performed with the patient in a supine position, with the arm lying close to the thorax and the hand supported against a foam cushion. Water bags were placed around the shoulder joint as a tissue equivalent to visualize all beads in the uniplanar calibration box (Carbon Box 24 Aarhus, MEDIS, Netherlands) placed beneath the patient. The calibration box defined a 3D coordinate system for investigation of the micro-motion of the HHRI. Two ceiling-fixed roentgen tubes at 20° to the vertical plane were positioned above the patient, and the X-rays intersected in the HHRI implant. The approximate technique was 85–90 kV and 15 mAs but adjusted according to the size of the patient, and female patients held their mammae medially. Computer analysis was performed on digital computed radiography (CR) stereoradiographs (Fuji FCR AC—3CS/ID) with the software "Model-Based RSA vs 3.32" (*Medis specials*, Leiden, NL) and Computer Aided Design (CAD) models of the HHRI (symmetric model) were matched with the contour of the radiographic projection of the implant [16] (Fig. 2). The posed estimation difference (difference in the match of model and radiographic implant contour) was a mean 0.08 mm (SD 0.03 mm). Implant micro-motion, with respect to the rigid bone reference of tantalum beads, was calculated in three dimensions from baseline until 6 months follow-up. Total translation (TT) was calculated by use of Pythagoras theorem [TT = square root ($X^2 + Y^2 + Z^2$)]. At 6 months follow-up, double stereoradiographs with complete reposition of the patient and system were obtained to estimate the precision of the method. Nineteen patients had double stereoradiographs with a sufficient number of visible bone markers in both examinations and could be assessed for precision.

DXA scanning and analysis

To quantify BMD around the resurfacing prostheses, a Lunar Prodigy Advance bone densitometer (General Healthcare, Madison, WI, USA) was used. The scan was undertaken in the AP plane (20-cm length × 18-cm width) using the knee software (76 kV; 0.75 mA; 9 μGy) with an exposure time of 50 s. The arm was positioned in a relaxed position while kept close to the thorax, and with the palm of the hand flat against the examination bed and touching the buttock. The shoulder was padded with tissue-equivalent material (rice). The enCORE software vs. 11.40 was used for analysis of scan data. By a dynamic tissue detection algorithm in the software, all areas in the scan were point typed as bone, tissue, air, metal and neutral. The metal component was thus automatically marked and removed from the densitometry measurement and the edge of the bone was automatically outlined, but manually adjusted when needed. A template of one region of interest (ROI) that included the periprosthetic area in the proximal humerus around and just below the short implant stem was used and placed parallel with a line through the apex of the resurfacing implant (Fig. 3). Once the template with the ROI was applied and positioned on the first scan, the template was "locked" to the bone contour and could be copied from the baseline scan to subsequent scans

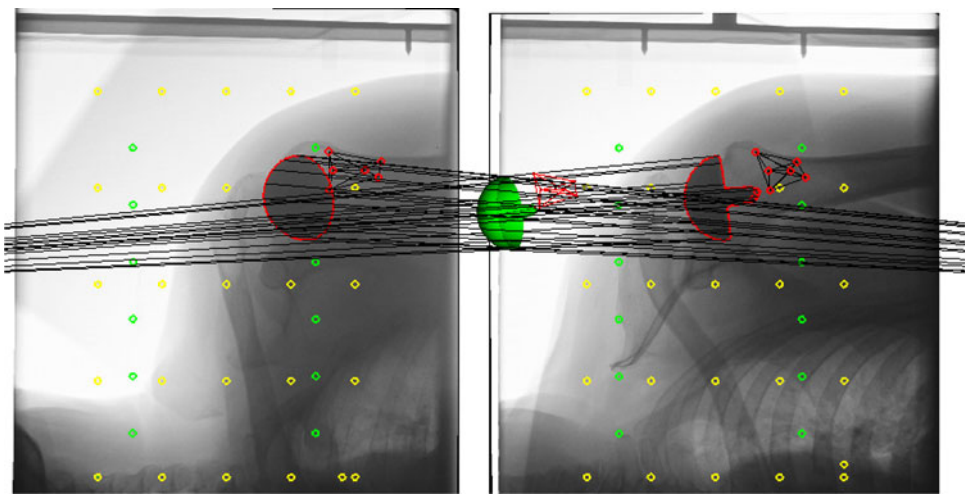

Fig. 2 Computer analysis of migration (RSA) of a Copeland HHRI performed on digital stereoradiographs matching a CAD model of the prosthesis on the radiological contour of the patient's implant

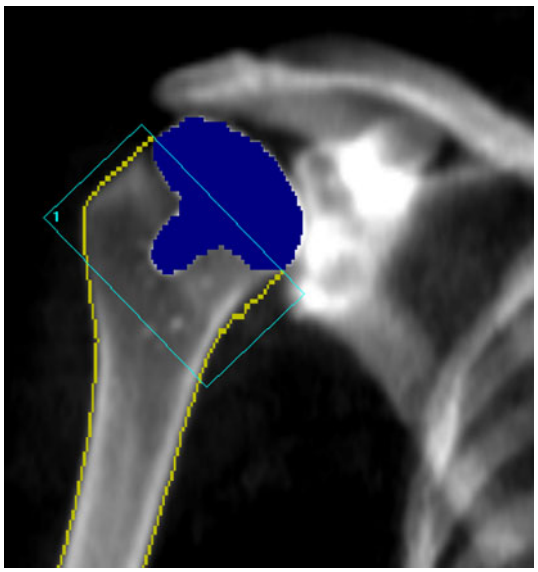

Fig. 3 A template of 1 region of interest (ROI) used for analysis of BMD in the DXA scans. The ROI was placed parallel with a line through the apex of the resurfacing implant

improving the similar positioning of the ROI in follow-up investigations. Manual adjustment of the width of the ROI was performed to account for individual anatomy (excluding costae and scapula). Measures of BMD (g/cm^2) were obtained for the one ROI. All BMD analyses were completed by a single technician to ensure identical positioning of the ROI. At the 6-month follow-up, a double scanning was performed with change of position to determine the precision of the method.

Statistics

Data for CSS and WOOS within the two groups was tested by Wilcoxon signed rank test. Data for LGHO between the groups were compared by Mann–Whitney test. Data for change in migration and BMD (differences) within the two groups were tested by Wilcoxon rank test and between the groups by Mann–Whitney test.

For analysis of the clinical precision of measurements, we calculated the random variation within the method and the 95 % repeatability limit calculated as SD $\times \sqrt{2} \times$ 1.96. Bias $\pm$ the 95 % repeatability limit is identical to the 95 % limits of agreement (LOA) as described by Bland and Altman [17]. The systematic variation (bias) between the double examinations was estimated as the mean difference between the two measurements. The difference between the two measurements followed a normal distribution (Shapiro–Wilk test) and was tested by a paired *t* test. The variance (random variation) between double examinations was tested by Pitmans test.

Intercooled Stata software version 11.0 (StataCorp, College Station, TX) 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. 4. None of the RHHI was revised within the 6 months follow-up period and no major surgical complications were encountered.

Precision

The precision of the applied radiological methods was estimated based on double examination and measurement. We calculated the random and systematic variation within each method; 95 % confidence interval for the systematic variation was estimated and it was tested if there was bias between the measurements (Table 2), and 95 % limits of agreement (LOA) for measurements of LGHO were narrow indicating a precise method and there was no significant systematic variation between the first and second measurement. LOA for RSA measurements were wide for both total translation and translation in the x, y and z direction. This is due to random variation within the method and there was no significant systematic variation between the first and second RSA measurement. Determining BMD in a selected ROI with DXA lacked precision judged by the wide LOA. There was no evidence of systematic variation between the first and second BMD measurement.

In Table 3, examples are given on sample size estimation for clinical studies with the presented radiological methods based on the precision found in this study.

Clinical results

At 6 months, 20 patients completed CSS and WOOS. In the group with a Copeland prosthesis, CSS progressed from median 39 to 59 ($p = 0.02$) and WOOS improved from median 1,020 to 237 ($p = 0.01$). For the patients with a Global C.A.P. prosthesis, CSS improved from median 42 to 62 ($p = 0.02$) and WOSS from median 1,305 to 372 ($p = 0.01$), (Table 4).

Radiological results

The length of the gleno-humeral offset was measured for 20 patients at 6 months. The median difference in LGHO preoperative compared to postoperative for the Global C.A.P. was -0.17 (-0.73 to 0.37) cm and the median difference for the Copeland was 0.46 (0.01–0.93) cm ($p = 0.002$) (Table 4).

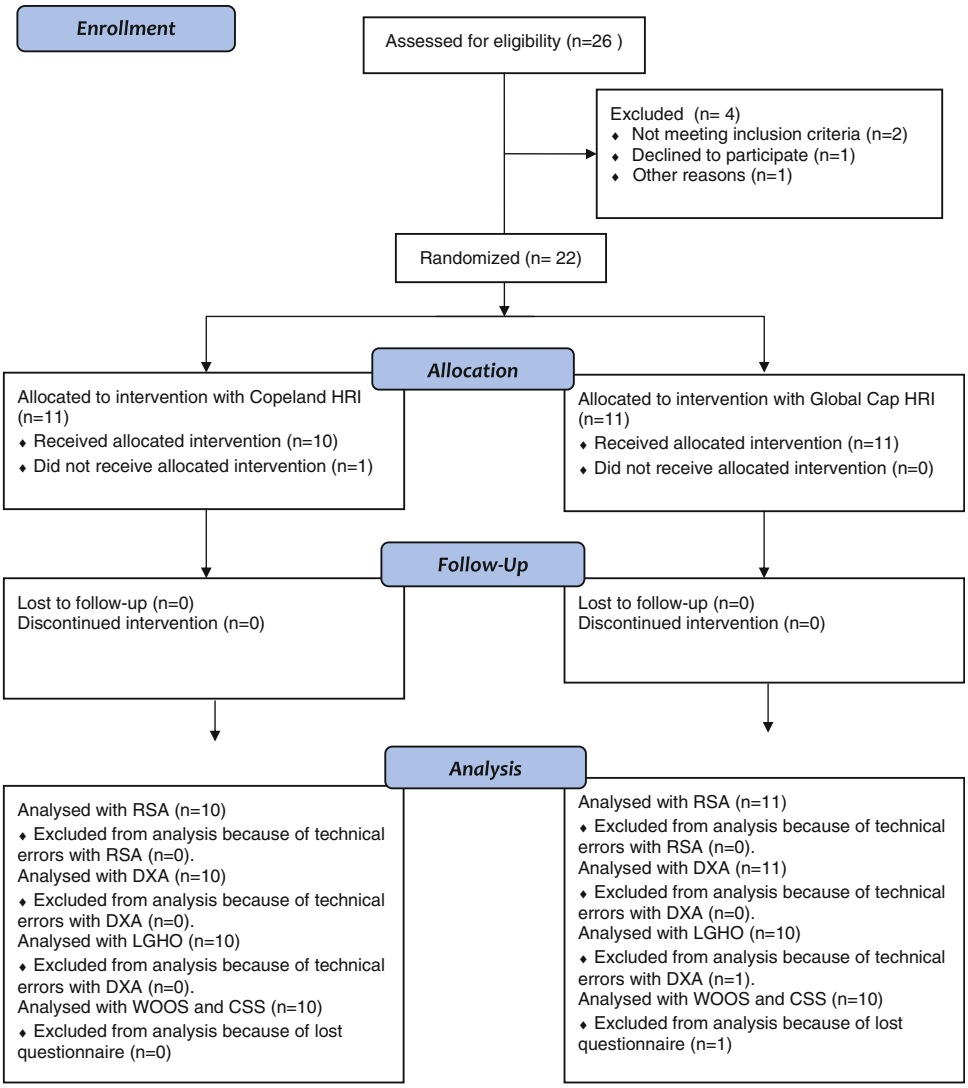

Fig. 4 Flow diagram showing the number of patients randomly assigned and analyzed for the outcome measures

Twenty-one patients could be evaluated for prostheses migration. The median total translation was 0.88 (0.71) mm for the Copeland prostheses and 0.94 (0.83) mm for the Global Cap (Table 4).

Twenty-one patients had BMD measured 6 months after surgery. Around the Copeland prostheses, BMD decreased from a mean 0.59 to 0.43 g/cm^2, and around the Global Cap, BMD changed from a mean 0.44 to 0.36 g/cm^2 (Table 4).

Discussion

The focus of this paper was to describe methods used to evaluate outcome after RHHI, estimate the precision of the radiological methods and finally to present the preliminary clinical and radiological results after RHHI at 6 months follow-up.

Discussion of the applied methods

In the objective part of CSS, there are potential sources of errors affecting the results, namely the measurement of range of motion (ROM) and muscle power. ROM in the shoulder joint was noted at intervals of 30° and, if ROM was on the border between two intervals, a goniometer was used. But even with a goniometer, it was difficult to differentiate between the intervals. Also, patients sometimes made a compensatory movement during ROM measurement, and if the physiotherapist was not aware of it, this may skew the measurement. Before initiating this study, a test protocol was written to standardize the measurement of muscle strength with the myometer, because the CSS does not entail a description on how to perform this measurement. We decided that the test position was standing with the arm in 90° scaption and the hand in a neutral position (palm down) to avoid elbow flexion.

Table 2 Precision of radiographic double examination measurements

Analysis method	Mean (range)	$SD^{a}_{dif\text{-}intra}$	Bias[b] ± LOA[c]	95 % CI[d]
LGHO (cm)[e]	5.02 (4.06 to 5.92)	0.06	−0.01 (±0.11)	−0.03; 0.01
BMD (g/cm^2)[f]	0.39 (0.06 to 0.85)	0.12	−0.01 (±0.24)	−0.31; 0.48
T_x (mm)[g]	0.00 (−1.02 to 0.84)	0.31	−0.01 (±0.60)	−0.14; 0.14
T_y (mm)[g]	0.19 (−1.08 to 2.32)	0.44	−0.05 (±0.88)	−0.01; 0.39
T_z (mm)[g]	0.03 (−1.32 to 1.22)	0.40	−0.04 (±0.80)	−0.15; 0.21
R_z (mm)[g]	−0.41 (−14.23 to 3.14)	5.53	0.88 (±10.67)	0.87; 0.11
TT (mm)[h]	0.92 (0.18 to 2.76)	0.54	−0.19 (±1.05)	−0.69; 1.17

Baseline measurements were compared to double measurements 6 months after RHHI and the differences assessed as described by Bland and Altman [17]

[a] $SD_{dif\text{-}intra}$ is the random variation within a method comparing double examinations

[b] Bias: systematic variation within a method

[c] LOA: limits of agreement around the bias (95 % prediction interval = $SD_{dif\text{-}intra} \times 1.96$)

[d] 95 % confidence interval for the bias

[e] LGHO: length of gleno-humeral offset measured on conventional AP radiograph

[f] BMD: measurement of bone mineral density in region of interest below the HHRI measured by DXA

[g] Migration: implant migration as measured by radiostereometric analysis (RSA)

[h] TT: total translation calculated by the use of Pythagoras theorem = square root = $(T_x^2 + T_y^2 + Tz^2)$

Table 3 Sample size estimation for clinical studies with the presented radiological methods

Method	Follow-up	Expected group difference (%)	Mean	SD of mean	Sample size per group (n)
LGHO (mm)	Postoperative	10	5.02	0.52	18
BMD (g/cm^2)	2 years	30	0.39	0.20	46
TT RSA (mm)	2 years	40	0.93	0.64	47

Sample size determination was based on power of 80 % and α 0.05. Group differences are fictive. Means and standard deviations (SD) from this study ($n = 21$) were used

The WOOS questionnaire is a quality of life measurement tool for patients with osteoarthritis of the shoulder that presents the patient's own perception of well-being. We experienced that certain questions could confuse some patients and cause the questionnaire to be incompletely filled out, i.e., when a bald male was asked: "How much difficulty have you experienced styling your hair because of your shoulder?" We found the WOOS questionnaire to give a good outline of the patients' quality of life. When we looked into the dimensions "sports/recreation" and "lifestyle", we also acquired a relevant overview of the patients' functional capacity.

The measurements of LGHO were easy to perform in a standardized manner and the results of the measurements turned out to be very informative in relation to show a difference in shoulder geometry after Copeland RHHI. Ideally, LGHO should remain the same before surgery to after to avoid joint stuffing. The implication of the difference in LGHO between the two RHHI is unknown as at 6 months postoperatively, there is no difference in functional capacity and quality of life between the two groups. We applied the modified LGHO and also recommend others to use it, because it is straightforward for identifying the relevant anatomical landmarks (the most lateral part of the major tubercle and the glenoid line).

It has been recommended that fixation of all new joint implants designs should be evaluated with RSA [18]. So far, the bony fixation of RHHI has only been evaluated by standard radiographs and survival rate [19]. In this randomized study, we were the first to apply the radiostereometric micro-motion analysis concept to RHHI. The patients could not be positioned in the stereo setup as with hip and knee implant patients (tubes placed 40° on each other in the medial–lateral direction), because the short stem on the RHHI would then be overprotected in both stereoradiographs making the matching of the CAD model to the implant contour in the radiograph difficult. Further, the left and right calibration markers would be lost due to the attenuation of the abdominal organs and mammae in a standard hip/knee stereoradiographic setup. Consequently, the tubes were turned 90 degrees compared with the hip/knee setup, so that the tubes were located at 40° to each other cranio-caudal direction), which helped the visibility markers. We almost had difficulties with occlusion of bone markers in every series of stereoradiographs, but we were able to locate the markers by the "occluded marker model".

With DXA, changes in BMD in the periprosthetic bone can be monitored regularly to investigate if BMD in a

Table 4 Preliminary radiological and clinical outcome after Global C.A.P and Copeland resurfacing humeral head implants

	Global C.A.P. baseline	Global C.A.P. 3 months	Global C.A.P. 6 months	Copeland baseline	Copeland 3 months	Copeland 6 months
WOOS (1900-0)	$n = 10$	$n = 10$	$n = 10$	$n = 10$	$n = 10$	$n = 10$
Median	1,305	550*	372	1,020	622*	237
(min;max)	(1,771; 498)	(1,374; 104)	(1,200; 126)	(1,574; 441)	(1,101; 40)	(1,372; 46)
CSS (0-100):	$n = 10$	$n = 10$	$n = 10$	$n = 10$	$n = 10$	$n = 10$
Median	42	44	62*	39	58*	59
(min;max)	(9;54)	(28; 83)	(35; 87)	(10; 70)	(29; 79)	(11; 83)
LGHO (cm)	$n = 10$		$n = 10$	$n = 10$		$n = 10$
Mean (SD)	4.78 (0.35)		4.68 (0.42)	5.16 (0.51)		5.55 (0.47)
(min;max)	(4.32; 5.33)		(4.05; 5.47)	(4.09; 5.79)		(4.57; 6.16)
BMD (g/cm^3)	$n = 11$	$n = 11$	$n = 11$	$n = 10$	$n = 10$	$n = 10$
Mean (SD)	0.44 (0.19)	0.35 (0.25)	0.36 (0.16)	0.59 (0.33)	0.45 (0.25)	0.43 (0.25)
(min;max)	(0.12; 0.65)	(0.04; 0.89)	(0.05; 0.63)	(0.08; 1.01)	(0.06; 0.83)	(0.08; 0.85)
RSA TT (mm)	$n = 11$	$n = 11$	$n = 11$	$n = 10$	$n = 10$	$n = 10$
Mean (SD)	1.17 (1.07)	0.79 (0.75)	0.94 (0.83)	1.05 (1.29)	0.68 (0.59)	0.88 (0.71)
(min;max)	(0.10; 3.57)	0.07; 2.74)	(0.15; 3.26)	(0.16; 4.57)	(0.16; 2.18)	(0.21; 2.35)
RSA T_x (mm)	$n = 11$	$n = 11$	$n = 11$	$n = 10$	$n = 10$	$n = 10$
Mean (SD)	0.18 (1.04)	0.20 (0.80)	0.05 (0.38)	0.09 (0.81)	−0.17 (0.31)	0.31 (0.75)
(min;max)	(−0.92; 3.16)	(−0.46; 2.41)	(−0.42; 0.78)	(−0.76; 2.22)	(-0.95; 0;18)	(−1.21; 0.62)
RSA T_y (mm)	$n = 11$	$n = 11$	$n = 11$	$n = 10$	$n = 10$	$n = 10$
Mean (SD)	0.09 (0.82)	0.11 (0.42)	0.21 (0.75)	0.34 (1.22)	0.17 (0.31)	0.02 (0.50)
(min;max)	(−1.55; 1.39)	(0.43; 1.07)	(−2.19; 0.40)	(−1.25; 3.51)	(−0.35; 0.69)	(−0.68; 2.04)
RSA T_z(mm)	$n = 11$	$n = 11$	$n = 11$	$n = 10$	$n = 10$	$n = 10$
Mean (SD)	0.09 (0.92)	0.09 (0.53)	0.18 (0.94)	0.21 (0.74)	0.26 (0.48)	−0.03 (0.67)
(min;max)	(−0.90; 1.75)	(−0.74; 0.86)	(−2.28; 1.11)	(−0.78; 1.9)	(1.08; 1.08)	(−1.34; 0.97)
RSA R_z (°)	$n = 11$	$n = 11$	$n = 11$	$n = 10$	$n = 10$	$n = 10$
Mean (SD)	−0.21 (1.75)	0.90 (1.74)	0.36 (1.97)	−0.42 (1.18)	−1.16 (0.93)	0.06 (1.37)
(min;max)	(−3.54; 1.61)	(−1.61; 4.91)	(−2.60; 3.75)	(−6.79; 1.18)	(−1.83; 1.31)	(−3.37; 1.47)

TT total translation [Pythagoras theorem: square root $((T_x^2) + (T_y^2) + (T_z^2))$], T_x translation along the x axis, T_y translation along the y axis, T_z translation along the z axis, R_z rotation about the z-axis

* Statistically significant difference (p value < 0.05) between the shown value and the value measured at the previous time point for the same implant

region of interest changes after RHHI as a result of stress shielding. The position of the RHHIs in the humerus depends on the patients' anatomy, as some implants are inserted in retroversion, some are neutral in rotation, some have a more horizontal stem orientation and some a more vertical stem orientation. A standardization of patient pose at radiological follow-up will therefore not ensure identical radiological presentation of the implants and surrounding bones. Therefore, it was difficult to evaluate similar bone areas in all patients.

Discussion of precision of the applied methods

The double geometrical analysis of LGHO on preoperative and postoperative AP radiographs from 15 patients showed that the LGHO measurements were precise with an LOA of ±0.11 cm, meaning that if we have a first LGHO measurement of 5 cm, the difference to the next measurement on the same patient could potentially range from 4.89 to 5.11 cm. This is sufficient to identify the changes in LGHO seen in this pilot study. As the 95 % CI contains 0, it is evident that there is no significantly systematic variation between first and second measurement of LGHO.

Double RSA examination and analysis resulted in an LOA of ±1.05 mm. The mean total translation was 0.92 mm, measured 6 months after RHHI, and the random variation within the method comparing double examinations was 0.54 mm. Similar values were found in an experimental phantom study on RHHI [20]. A possible way of improving RSA precision is to use standard marker-based RSA and mount beads on the evaluated implants; however, it will be difficult to place the markers without

changing the fixation principles and at the same time avoid marker occlusion in the stereoradiographs.

The precision of BMD based on double DXA scanning and analysis of BMD resulted in an LOA of ± 0.24 g/cm^2. The mean value for BMD in the applied ROI was 0.39 g/cm^2 and the LOA showed that the precision was acceptable, but still the protocol used for DXA in this study should be improved to enhance the precision of the method. DXA has been shown to be a precise and useful method in relation to knee implants with variability in patient positioning causing the main error, though specialized foam positioners were used [21]. We did not use a specialized foam positioner for the arm in this study, and patients had much pain and difficulties in relaxing at the first DXA baseline scan. No specific shoulder software was available, and therefore we aimed at mimicking the conditions of a knee scan and used the software designed for knees. We aimed at positioning the patient's hand with the palm facing the scanner bed; however, we had to change this because patients had too much pain at the postop scan to endure this. We further aimed for the humerus to be parallel with the scanner bed; however, this was difficult with heavy patients as they had to be positioned obliquely on the scanner bed. As a result of these experiences, we positioned the hand in neutral position supported by a vertical foam pillow. We suspect the difficulties in positioning of the patients to be the main cause of the imprecise measurements we present here. Further, the automatic tissue point typing of the software failed in several cases and, as a consequence, we had to manually outline the edges of the bone and implant in most images ($\sim$90 %) which aided in imprecision.

Discussion of the preliminary clinical and radiological results after RHHI

In this study, patients with osteoarthritis of the shoulder were randomized to either a Copeland or a Global C.A.P. RHHI. Based on these preliminary results, the performance of the two RHHI is comparable and the clinical and radiological results are acceptable for both. Clinical scores increased comparably in both groups and the functional progress was significant, as measured on WOOS 3 months after surgery for both groups. Preoperatively, the patients had high scores on the WOOS due to many physical symptoms negatively affecting function, lifestyle and emotions. Three months after surgery, a large improvement in all four dimensions was seen. At that time, there were no restrictions in motion of the shoulder joint and the patients had completed physiotherapy at the hospital. Six months after RHHI surgery, the patients continued to improve on WOOS and CSS. However, ROM had not improved and was actually quite limited (28 out of 40 points measured on CSS). Full ROM cannot be expected after RHHI, but further rehabilitation intervention aimed at improving ROM is indicated because a moderate ROM is a requirement for basic activities of daily living like dressing and undressing. Muscle strength only improved marginally (8 of possible 25 points measured by a myometer in the CSS), which points to a need for a more intensive resistance training rehabilitation program and information to the patients about the importance of continuing home-based training after the rehabilitation has ended.

The length of the gleno-humeral offset increased for the Copeland RHHI after surgery and resulted in a significantly longer LGHO in the Copeland compared to the Global C.A.P. The clinical implications of a median increase of 4.6 mm in LGHO postoperatively for the Copeland are not known, but we consider it a potential overstuffing problem caused by the reaming process that only takes 2 mm of the humeral surface, whereas the average thickness of the prosthesis is 4 mm. Restoration of normal glenoid and humeral anatomy in the arthroplasty is correlated with diminished radiographic loosening as well as improved functional results [13], and in our series this is better achieved with the Global C.A.P as shown by LGHO.

The median total translation was minor for both the Copeland and the Global C.A.P. RHHI and there was no significant difference in how much the prostheses migrated in the two groups within the first 6 months after surgery. Thus, the degree of migration of these RHHI does not appear to be a problem. The implants stabilized between 3 and 6 months follow-up according to the criteria of Ryd et al. [22] with $<$0.2 mm migration between the first and second year of follow-up.

The clinical survival of joint prostheses is dependent on the quality of the surrounding bone, and BMD is a measure of bone strength and quality. In this study, BMD around both RHHI decreased insignificantly 3 months after surgery and was unchanged from 3 to 6 months postoperatively. This is in line with what has been observed in the proximity of total knee implants where BMD decreases during the first 3 months postoperatively, after which the bone mass stabilizes and after 24 months remodeling is complete [23]. We will continue to monitor the activity and remodeling of bone near the RHHI for 5 years, because if BMD continuously reduces, prosthesis fixation may be affected and prosthesis failure can result, making operative revision more difficult [24].

Conclusion

We designed an RCT featuring novel radiological methods to use with RHHI. It is our hope that this paper will enable clinicians to identify relevant methods to monitor and evaluate the outcome after RHHI. Since the patient's own

perception of changes in health status is the most important indicator of the success of treatment, we suggest that WOOS should be used to assess the outcome in clinical studies of RHHI and for monitoring patients over time. The precision of the radiological methods was high for the LGHO and acceptable for RSA and DXA. In general, both RSA and DXA are precise methods when applied in the proximity to knee and hip implants; however, the arm is not as easily positioned in the same way and the examination protocols need to be improved to make these method applicable to RHHI. Based on these preliminary radiological and clinical results, the performance of the two RHHI is comparable. Yet, we consider that the Copeland RHHI causes overstuffing of the shoulder joint and the consequences of this problem need further attention on a larger scale.

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