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ORTHOPAEDIC SURGERY

The Copeland resurfacing humeral head implant does not restore humeral head anatomy. A retrospective study

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Abstract
Purpose Recently, there has been concern that the Copeland resurfacing humeral head implant (RHHI) leaves the shoulder joint overstuffed. The purpose of this study was in a selected cohort of patients operated with a Copeland RHHI (1) to evaluate the Length of the Gleno-Humeral Offset (LGHO), (2) to assess the patient-reported quality of life and functional outcome measured by Western Ontario Osteoarthritis of the Shoulder Index (WOOS) and (3) to determine the number of revisions in the cohort.
Methods Pre- and postoperative radiographs were retrieved from 71 of 91 possible patients operated with a Copeland RHHI from 2005 to 2009. The cohort consisted of 30 males and 41 females at a mean age of 61 (38–89) years. One radiologist measured the LGHO and performed double measurements. The WOOS score 1 year after surgery and the number of revisions from all patients operated with a Copeland RHHI in Denmark was requested from the Danish Shoulder Arthroplasty Registry.
Results The mean LGHO was 4.99 ± 0.53 cm before surgery and 5.39 ± 0.58 cm after surgery, ($p < 0.001$). 95 % limits of agreement for measurements of LGHO were ± 0.11 cm. One year after surgery, the WOOS score was 67 for the cohort and 64 for all patients operated with a Copeland RHHI in Denmark. 13 of 71 RHHI in the cohort were revised.
Conclusion The Copeland RHHI causes significantly increased LGHO and leads to overstuffing in the shoulder joint. The WOOS score in the cohort was comparable to that for all other Danish patients operated with a Copeland RHHI.

Keywords Resurfacing humeral head implant · Overstuffing · WOOS · Shoulder

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Introduction

The number of patients presenting with symptoms attributable to glenohumeral arthritis has increased tremendously over the past decade [1]. The reasons are multifactorial, and include the aging of the population as well as an increased awareness of arthritis in the shoulder joint.

Cementless resurfacing humeral head implants (RHHI) is a viable treatment option for glenohumeral arthritis with acceptable clinical results for young [2, 3] as well as older [4] patients and with results comparable to those obtained with a modern stemmed shoulder implants [5, 6]. RHHI necessitate minimal bone resection compared to conventional stemmed shoulder implants and problems with humeral stress fracture in proximity of the diaphyseal stem are avoided.

The Copeland RHHI (Biomet) has been in clinical use for more than 20 years and in Denmark the treatment

indication for this RHHI is primarily osteoarthritis and to a lesser degree rheumatoid arthritis in the shoulder joint [7].

There has been concern that the Copeland RHHI leaves the shoulder joint overstuffed because the reaming process only removes 2 mm of the humeral surface, while the average thickness of the prosthesis is 4 mm. The design of the Copeland HHRI was in 2010 changed by the manufacturer (Copeland thin shell) to comply with concerns of overstuffing.

The purpose of this study was (1) to evaluate the Length of the Gleno-Humeral Offset (LGHO) in a selected cohort of patients operated with a Copeland RHHI, (2) to assess the patient-reported quality of life and functional outcome measured by Western Ontario Osteoarthritis of the Shoulder Index (WOOS) in the cohort and in all Danish patients operated with the Copeland RHHI in the same time period and (3) to determine the number of revisions in the cohort and in the Danish population operated with the Copeland RHHI in the same time period.

Patients and methods

Between 2005 and 2009, 91 patients were operated with a Copeland RHHI at two Regional Hospitals in Denmark. Digital pre- and 6 months post-operative radiographs were retrieved from 71 of the patients (Table 1). The cohort consisted of 30 males and 41 females with a mean age of 61 (38–89) years. The patients in the cohort were operated by three senior orthopaedic surgeons. The operations were performed via the deltopectoral approach and the RHHI were inserted after the surgeons had validated that the osteoarthritis was primarily visible on the humeral head and that there was no need for a glenoid component. The Copeland RHHI has a Closed Pore, Porous Coating and hydroxyapatite for cementless fixation, and further the implant design features an extended skirted rim for a circumferential press-fit and a tapered cruciform peg to provide rotational stability.

Table 1 Summary of demographics for the cohort of patients operated with a Copeland RHHI, presented for females and males

Copeland RHHI	Females ($n = 41$)	Males ($n = 30$)
Age (range) years	66 (45–89)	58 (38–79)
Diagnose OA/RA	32/9	27/3
Size of resurfacing implant	1–4	2–8
Operated side (right/left)	30/11	20/10
Prior shoulder surgery[a] (yes/no)	29/12	23/7
Additional surgery[b] at time of insertion of RHHI (yes/no)	22/19	19/11

OA osteoarthritis, *RA* rheumatoid arthritis

[a] Synovectomy, cuff reconstruction, subacromial decompression, acromioclavicular joint resection, arthroscopic surgery

[b] Cuff reconstruction, subacromial decompression, acromioclavicular joint resection, biceps tenotomy, biceps tenodesis

The postoperative course after insertion of Copeland RHHI was immobilization with an arm sling on the first postoperative day. Hereafter, un-weighted, passive movement supervised by a physiotherapist was allowed to maximum 60° outward rotation, whereas only pain limited the motion in abduction and flexion. After 6 weeks, free, active movement, respecting the pain threshold, was encouraged under supervision of a physiotherapist.

One radiologist measured the LGHO [8, 9] using a modified method on the 71 pre- and postoperative radiographs. The X-ray technique of the two hospitals was standardized; the patients were positioned standing with the back against the image receptor and the non-affected side was turned 35–45° 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 15–20° in cranial–caudal direction and was centered towards the shoulder joint (Fig. 1).

First a line from the top to the bottom of the glenoid cavity was drawn. Then the centre 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. 2). In theory, LGHO after surgery should be identical to LGHO before the shoulder morphology changed due to arthritis if no soft tissue is changed in that period. But as osteoarthritis progresses with narrowing of the joint space, loss of the articular cartilage, destruction of the humeral head and capsule tightening, the soft tissue adapts to the changed morphology by shrinking and the LGHO should not be wider after surgery than before. Classically, the measure of LGHO is performed by measuring from the base of the coracoid process to the greater tubercle [8, 10]. But this measure shows systematic errors in inter-tester reliability [10] because it is difficult to locate the base of the coracoid process and thus one tester is likely to locate it more medially than the other tester. Due to the reported problems with inter-tester reliability of the standard LGHO measurements, we chose to apply the modified LGHO in this study and the radiologist performed repeated measurements using the modified LGHO method on preoperative and postoperative AP radiographs from 15 patients (60 radiographs) to estimate the intra-tester reliability of the method.

The WOOS score 1 year after surgery and the number of revisions from all patients operated with a Copeland RHHI in Denmark from primo 2005 to ultimo 2009 were requested from the Danish Shoulder Arthroplasty Registry (662

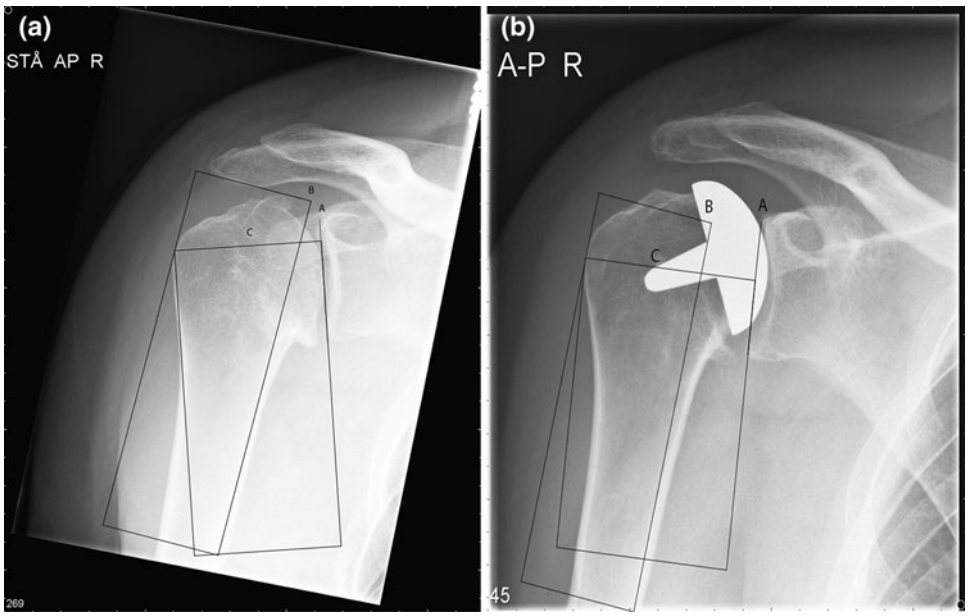

Fig. 1 X-ray of the *left shoulder* before and 6 months after implantation of shoulder humeral head resurfacing implant. Length of Gleno Humeral Offset is measured by a modified method in which the first step is drawing a line from the *top* to the *bottom* of the glenoid cavity (*A*). Then the centre 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*)

patients). From the data set, we could calculate the WOOS score and the number of revisions for the population and for our cohort ($n = 71$). In 2011 (2–5 years after surgery) we asked the patients in the cohort to fill out the WOOS questionnaire once again to obtain a more recent follow-up and 62 patients returned their answers. The WOOS is used in this study because the data are already collected in the Danish Shoulder Arthroplasty Registry and thus we had access to these patient-reported data on quality of life and functional outcome after RHHI. The 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 [11]. In the WOOS the range of points goes from 1900 (the worst possible outcome) to 0 (asymptomatic shoulder). In orthopaedic studies, there is a tradition to report scores out of 100 and present a percentage of normal score (100). Thus in this study, the aggregate score is subtracted from 1900 and divided by 19.

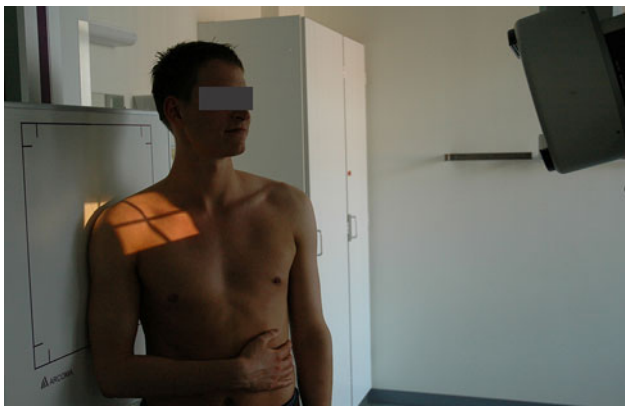

Fig. 2 Standardized X-ray projection. Patients were positioned standing with the back against the image receptor and the non-affected side was turned 35–45° away from the image receptor. The affected arm was flexed 90° in the elbow and the underarm was internally rotated. The angle of the beam was tilted 15–20° in cranial–caudal direction and was centered towards the shoulder joint

Data for LGHO per- and postoperatively was tested by a paired *t* test. The 95 % limits of agreement were calculated as described by Bland and Altman [12]. The systematic variation (bias) between the double measurements 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.

Results

The mean LGHO increased from 4.99 ± 0.53 cm before surgery to mean 5.39 ± 0.58 cm after surgery, ($p < 0.001$). In the two hospitals LGHO was 4.96 and 5.08 cm preoperative and 5.39 and 5.40 cm postoperative.

95 % limits of agreement for measurements of LGHO were ± 0.11 cm indicating a high intra-tester reliability of the method. No systematic variation between the first and second measurement was found, the difference being −0.01 (95 % CI −0.03 to 0.01).

One year after surgery, the WOOS score was mean 67 (20–100) for the cohort and mean 64 (5–100) for all

patients operated with a Copeland RHHI in Denmark in the same period of time. Two to five years later, the WOOS score for the cohort was mean 66 (7–100).

One to five years after RHHI, 13 of 71 implants (14 %) in the cohort were revised, eight due to persistent pain. In those cases, overstuffing of the shoulder joint was suspected to cause the pain. Figure 3 shows an example of one of the cases observed. One patient had the RHHI revised due rotator cuff problems, one due to glenoid attrition, one had a technically failed primary operation, one due to luxation and one due to infection in shoulder joint. In the Danish population of Copeland RHHI operated in the same period, 25 of 662 implants (4 %) were revised. The causes for revision were luxation (2), loosening (3), glenoid attrition (12), infection (3), rotator cuff problems (2), and persistent pain (8).

Discussion

We evaluated the LGHO in a selected cohort of patients operated with a Copeland RHHI and found the mean LGHO to be significantly 4 mm wider after surgery compared to before. The measurements were precise with a high intra-tester reliability. The design of the RHHI is sought to recreate the normal anatomic relationships and contours of the humeral head but we consider the Copeland RHHI to potentially overstuff the shoulder joint caused by the reaming process that removes only 2 mm of the humeral surface while the average thickness of the prosthesis is 4 mm. Due to these design parameters, the RHHI may result in overstuffing and pain when the shoulder capsule is tight. There may be differences in the laxity of the joint capsule between patients so that some patients can adapt to the added offset with the Copeland RHHI while others cannot.

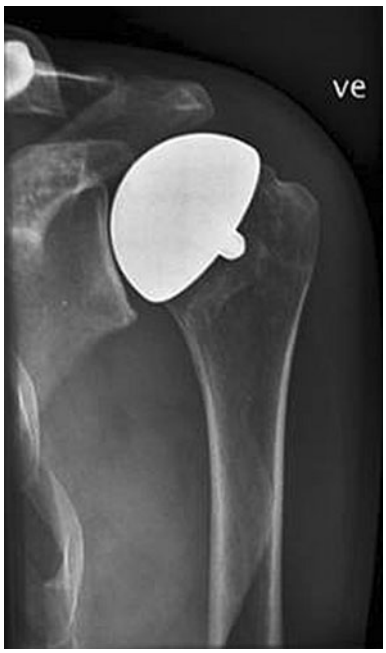

Fig. 3 An example of too large offset and overstuffing of *left shoulder joint* in one of the included patients. The Copeland RHHI does not allow the surgeon to reame the humeral head smaller and thus the offset becomes too large and the joint overstuffed

The problem the surgeons experienced when using the Copeland RHHI was that the reamer for the Copeland RHHI did not allow the surgeon to reame the humeral head smaller. Then, the surgeon had the option of using an implant with a small diameter which resulted in an implant that looked like a "hat" put on the humeral head. Or the surgeon could use an implant that fitted the diameter of the humeral head but ended up with overstuffing the joint. Recently, the design of the Copeland HHRI was altered by the manufacturer to comply with concerns of overstuffing.

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. We applied the modified LGHO and we recommend others to use that also because it is easy to identify the relevant anatomical landmarks used to perform the measurements. We used the 6-months radiographs for post-operative measurements and therefore we do not believe that intraarticular oedema or blood falsely increased the LGHO measurements.

We set out to assess the patient-reported quality of life and functional outcome measured by WOOS and found the score to be comparable in the cohort to the Danish population of patients operated with the Copeland RHHI in the same time period. This indicates that there was nothing unusual about the functional results for the cohort. Two to five years later, the WOOS score for the cohort was unchanged (WOOS score 66) for those patients not revised. Does a WOOS score of 66 out of possible 100 represent an acceptable functional capacity? Thomas et al. [5] applied the Constant Score [13] to evaluate the outcome 34 months after Copeland RHHI and reported a mean score of 54 out of possible 100. In Copeland's own series [14], the Constant Score at 5–10 year follow-up was 73. The results from the WOOS and the Constant Score are based on very different measurements and cannot be compared; however, the level of the scores after RHHI indicates that rehabilitation should be granted a higher focus after HHRI surgery. Early postoperative range of motion exercises and progressive strengthening exercises, have been shown to result in decreased pain, improved range of motion, and fast return to work following hemiarthroplasty [15]. Usually, rehabilitation after RHHI focuses on range of motion and functional exercise but it is plausible that a protocol of progressive strengthening as used after total hip and knee arthroplasty would be more effective in re-gaining functional capacity and coping with activities of daily living for these patients.

The rate of revisions in the cohort 1 year after RHHI was 14 %, for eight patients due to persistent pain and possible overstuffing and for five patients due to rotator cuff problems, glenoid attrition, technically failed primary operation, luxation and infection in the shoulder joint. In the Danish population operated with the Copeland RHHI in the same time period, only 4 % were revised. Although, a cohort of 71 patients is a small sample, questions arise on why the rate of revisions was higher in the cohort, compared to the population operated in the same time interval. A number of revisions can happen if inexperienced surgeons perform few procedures with a new prosthesis. However, the surgeons who operated this cohort are specialized shoulder surgeons with vast experience from shoulder replacement surgery and fracture osteosynthesis and therefore we believe that the design of the Copeland RHHI may lead to overstuffing and eventually revision. Another explanation could be that the patient selection has been different in the cohort compared to the population and that some of the patients in the cohort had been better off with a total shoulder arthroplasty. Attention on overstuffing and discussions of the subject among the surgeons who operated the cohort may theoretically have affected the rate of revision for these patients but it is not very likely as the primary cause of revision was persistent pain in both the cohort and in the general Danish population of Cope RHHI. In a 5–10 year follow-up of the Copeland RHHI, the rate of revision was 7.7 % [14]. Studies on outcome with hemiarthroplasty to glenohumeral arthritis have reported results ranging from no revisions at 2 year [16] and at 5 year [17] to 28 % revision at 10 year follow-up [18].

In conclusion, the LGHO was significantly increased after Copeland RHHI and the high rate of revisions points to a problem with overstuffing associated with this prosthesis design. The design of the Copeland HHRI has been changed by the manufacturer to comply with the concerns of overstuffing and therefore this version of the Copeland HHRI will not be further used. Shoulder surgeons should be aware of potential overstuffing when they see a patient with persistent pain after RHHI.

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Conflict of interest The authors declare that they have no conflict of interest.

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