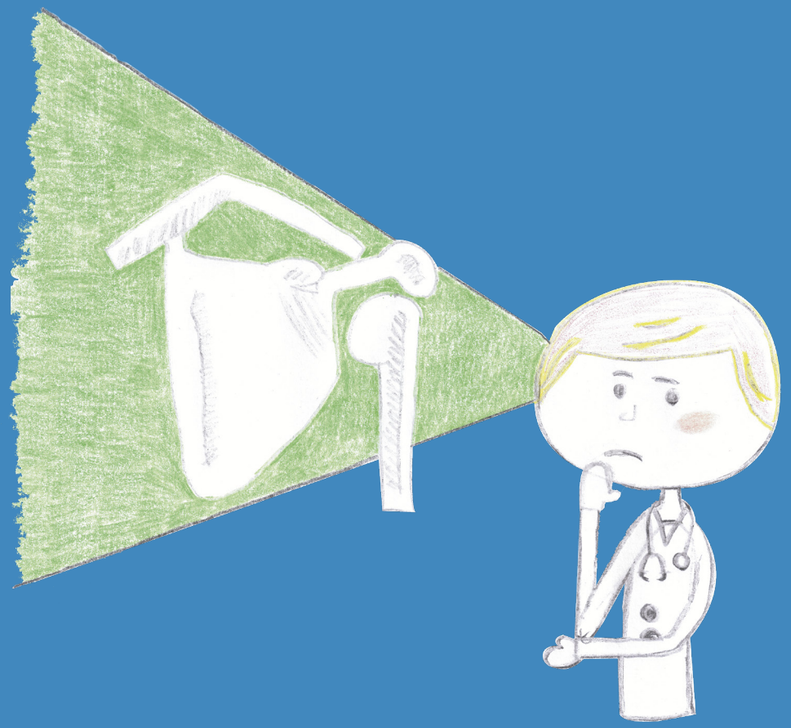
SHOULDER ARTHROPLASTY FOR GLENO-HUMERAL OSTEOARTHRITIS PIETER GEERVLIET

# SHOULDER ARTHROPLASTY FOR GLENO-HUMERAL OSTEOARTHRITIS



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**Shoulder arthroplasty for gleno-humeral osteoarthritis**

Pieter C. Geervliet

**Shoulder arthroplasty for gleno-humeral osteoarthritis**

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# TABLE OF CONTENTS

# CHAPTER 1

## Introduction and outline of the thesis

Shoulder pain is a common problem in general practice, occurring in 30 out of 1000 patients every year in general practice.[1] Recovery from shoulder pain can be slow and recurrent episodes of shoulder pain are seen in up to 25% of the patients.[2] Subacromial impingement syndrome is, at nearly 50%, the most frequently recorded shoulder disorder in general practice.[3] Closely followed by acromioclavicular joint disease and gleno-humeral joint disorders.[4]

Gleno-humeral osteoarthritis is characterized by a gradual, progressive, mechanical, and biochemical degeneration of the articular cartilage and joint soft tissues. As the articular surface degenerates, friction within the joint increases and causes progressive loss of the normal loadbearing surface, resulting in pain, stiffness and disability. Patients typically experience pain at night, especially when the patient lies on the affected shoulder and subsequently patients report progressive loss of range of motion. Patients perceive the impact of gleno-humeral osteoarthritis is comparable to chronic medical conditions such as congestive heart failure, diabetes, and acute myocardial infarction.[5]

Gleno-humeral osteoarthritis is prevalent in 16-20% of adults above the age of 65. In cadaver and radiographic studies, osteoarthritis of the shoulder has been seen to affect up to 33% of patients over the age of sixty years and to be equally debilitating.[6] The prevalence of shoulder osteoarthritis increases with age; however, other risk factors include female gender, Caucasian race and obesity.[7,8]

The cause of gleno-humeral osteoarthritis can be divided into primary and secondary types, resulting from trauma (fracture or instability), inflammatory arthropathies (such as rheumatoid arthritis), avascular necrosis, and massive rotator cuff tears or genetic predisposition. Painful gleno-humeral osteoarthritis is difficult to treat and is highly disabling.[9,10]

**Non-operative treatment**

In clinical practice, the most effective nonoperative treatment of gleno-humeral osteoarthritis is a combination of different treatment modalities, customized to patient symptoms. Physical therapy can be advised to keep range of motion and muscle strength. However, an incongruent shoulder joint can lead to increased pain. In literature, there is insufficient evidence either in favor or against the positive effect of physical therapy.[11]
Pharmacological treatments, including acetaminophen (first pharmacological option), nonsteroidal anti-inflammatory drugs (NSAIDs), narcotics and nonnarcotic analgesics and intra-articular injections of corticosteroid of hyaluronic acid, have been the mainstay of nonsurgical treatment. According to the literature, NSAIDs seems to be effective by knee and hip osteoarthritis;[12] however, there is no evidence of a positive effect for shoulder







osteoarthritis.[11] In addition, analgesics, such as, NSAIDs, can be associated with well-known adverse effects, especially in elderly patients and should be prescribed with care.[13] In **chapter 2**, in a systematic review, we describe and evaluate the evidence regarding efficacy of the several intra-articular infiltration treatment options of patients with gleno-humeral osteoarthritis.

**Operative treatment**

*Arthroscopy*

Arthroscopy of the shoulder is an accepted alternative in the treatment of gleno-humeral osteoarthritis.[14] Partly because of the low complication risk and low morbidity. It can play a role in the diagnosis of local cartilage damage and as a therapeutic treatment for biceps tenotomy or tenodesis. [14] In addition, capsular release and joint manipulation can improve postoperative range of motion of the shoulder.[14] The above treatment options will generally be of benefit in patients with mild gleno-humeral osteoarthritis.[14] While arthroscopic surgery is unlikely to stop the further progression of the osteoarthritis, it can provide a time of reduced pain and improved function, postpone a larger, but often necessary more complex surgery for a short time.[14]

*Arthroplasty*

The first shoulder arthroplasty has been implanted in 1893 by the French surgeon Jules-Émile Péan. He inserted a platinum cylinder with a rubber head in a 37-year-old baker with debriding tuberculous arthritis of the shoulder. The patient reportedly had increased strength and range of motion. Unfortunately, the infection recurred, requiring removal of the prosthesis 2 years later.[15] Since then, the design of the shoulder arthroplasty has been changed significantly among others by Neer and Grammond.[16]
Literature has described total shoulder arthroplasty to be superior to hemi shoulder arthroplasty.[8,11,14,17–19] Studies reported improved range of motion, better pain relief and successful results in 90% of the patients after total shoulder arthroplasties.[8,18,20]

However, several studies have shown a high incidence of complications, especially glenoid component failure, as a result of aseptic or septic loosening, wear, soft tissue insufficiently, fracture and instability.[14,19–23] Failure of the glenoid component is often shown as pain, loss of range of motion and the presence of instability.[24]
Hasan et al.[25] reported in their study 59% glenoid component loosening and 23% glenoid malpositioning in symptomatic total shoulders. In a study by Bohsali et al.[26] 39% of all complications after total shoulder arthroplasty was due to glenoid component loosening. Sperling et al.[27] reported similar high rates of glenoid failure and declining survival of the glenoid implant after 5-8 years. In patients with rheumatoid arthritis, glenoid failure after total shoulder arthroplasty was seen by Søjbjerg et al.[28] in 42% of the patients, and in 87% of patients by Betts et al.[29]

The rate of glenoid component failure may be higher than reported in literature, especially if revision is seen as the end point. This is supported by 4 main reasons. First, glenoid failure is normally seen after short-term to mid-term follow-up when the end period is concluded. Second, patients with glenoid failure may choose to accept their situation to avoid revision surgery.[25] Third, complications are more common in the FDA database compared to the data presented in the literature. Last, revision surgery is often performed by a surgeon other than the initial surgeon, making the revision possibly less likely to be reported.[21,30,31] Although, new designs of glenoid component appear each year, little progress has been made regarding glenoid component failure. Because of its eccentric load and the limited bone stock of the glenoid, the component should provide joint stability and avoid loosening. Therefore, finding a solution for glenoid failure is challenging.[24]

Optimal management of patients with severe gleno-humeral osteoarthritis remains challenging. Shoulder surgeons should be aware of glenoid failure.[8] Some shoulder surgeons seem to avoid the use of glenoid components in patients with a concentric glenoid, due to the high risk of glenoid failure.[31] In addition, the expectations of both the patient and surgeon may not be realistic in of the understanding of the limitations of the procedure.[20] Some surgeons believe specific revisions of hemi shoulder arthroplasties could be avoided by centering the prosthetic humeral articular surface on the glenoid concavity. This is managed by using proper humeral component positioning, soft tissue balancing, and avoiding valgus positioning.[32]

Unconstrained prosthetic arthroplasty of the shoulder is now used widely to treat gleno-humeral osteoarthritis, gleno-humeral fractures, rheumatoid arthritis, and osteonecrosis, with positive outcomes and reproducible results.[33] However, there has been a shift between the anatomical prosthesis and the reverse shoulder prosthesis. In 2014, 834 anatomical shoulder arthroplasties were performed in the Netherlands. This number decreased to 797 (4.4%) in 2015.[34] In Belgium, a decrease of the anatomical prosthesis of 13.7% (350 to 302) was seen between 2015 and 2016.[35] Nevertheless, in the Netherlands, the number of reverse shoulder arthroplasties increased from 1225 in 2014, to a total of 1501 in 2015 (22.5%). And in Belgium, the reverse shoulder prosthesis increased between 2015 and 2016 by 31.9% (1626 to 2144).[34,35]

In **chapter 3**, we describe a survey that presents an overview of the pre-operative planning, preferred type of implants, preferred surgical technique and postoperative procedures that are commonly applied in shoulder arthroplasty.

If non-operative treatment for gleno-humeral osteoarthritis fails, the surgical options commonly considered are humeral head arthroplasty (with or without stem) and total





shoulder arthroplasty. The optimal surgical treatment of end-stage primary or secondary gleno-humeral osteoarthritis remains controversial.[8]

In **chapter 4**, a systematic review is described between hemiarthroplasty and total shoulder arthroplasty.

In the mid to late 70's, different orthopedic surgeons from different countries performed the first shoulder resurfacing procedures.[23] In 1975, Zippel from Germany was the first to publish a report describing the use of a metallic surface replacement of the humeral head which were fixed by a transosseous screw.[23,36] In the USA, Moore and Steffee(1984) and Jóhnsson (1986) implanted a small hip resurfacing implant in the shoulder.[37] Rydholm and Sjögren from Sweden reported the results of the "SCAN" (Scandinavian)-Cup. This cup was used as a hemispherical cemented surface replacement.[23,37]
In 1979, Copeland designed the Mark I implant, which had a central smooth peg and lateral screw. The second-generation implant was introduced in the early 1990s with a tapered, central fixation peg. These were also cemented, and the lateral screw was abandoned. In 1993, the Mark III design had hydroxyapatite added for cementless fixation[23].

This design as well as similar designs gained popularity since the 90's as an alternative to conventional shoulder arthroplasty for the treatment of osteoarthritis. In contrast to conventional shoulder arthroplasty, which involves removal of the entire humeral head followed by placement of an intramedullary stem into the proximal aspect of the humerus, shoulder resurfacing consists of reaming the proximal portion of the humeral head and fitting a metal-alloy cap over the remainder of the head. This cap may or may not be implanted with a glenoid component.
Potential advantages of humeral resurfacing are decreased bone resection, shorter operative times, a lower prevalence of perioperative fractures, and the potential for straightforward revision to a conventional total or reverse shoulder replacement. In addition, it may be straightforward to restore normal offset, inclination, and version of the gleno-humeral joint because no osteotomy of the neck is performed, and the head-neck angle remains intact. Moreover, periprosthetic fractures, which are a concern in a more active population, are less likely to occur than they are with stemmed shoulder replacement. This is because the stem does not pass through the surgical neck.[23,38]

In literature, it has been reported by Copeland and Levy that long term follow-up after resurfacing shoulder arthroplasty reported good results.[39–41]

In **chapter 5** and **chapter 6** we describe the short- and midterm results of the uncemented Global CAP resurfacing hemi shoulder prosthesis.

According to Gadea et al.,[42] hemi shoulder arthroplasty in patients with RA is a good indication.

In **chapter 7** we present the long-term results of a stemmed hemi-arthroplasty in patients with secondary gleno-humeral osteoarthritis, rheumatoid arthritis.

*Revision*
According to literature, the risk of an infection after a shoulder arthroplasty is 0-3.9%.[43,44] Matsen et al. [45] showed in their study positive cultures in revision operation for apparently aseptic shoulder arthroplasty.

In **chapter 8**, we present a case of a low-grade infection of the Global CAP resurfacing hemi shoulder prosthesis.

Glenoid erosion is a main concern in shoulder hemi arthroplasty.[46] The condition of the glenoid may be critical in determining whether humeral head replacement alone will be successful. In particular, patients with concentric glenoid wear and primary osteoarthritis seem to have better outcomes than those with eccentric glenoid wear and secondary osteoarthritis.[6] However, patients with severe glenoid erosion after a hemiarthroplasty seem to have better PROM's compared to patients with mild glenoid erosion.[6]

In **chapter 9**, we present a study to determine if we can predict if the Global CAP resurfacing shoulder prosthesis will fail at long term follow-up.

Both hemiarthroplasty and total shoulder arthroplasty may achieve positive short-term and mid-term results. However, while total shoulder arthroplasty may provide superior and more reproducible pain relief, this must be balanced against the technical difficulties of inserting a glenoid component, and the long-term durability of glenoid prostheses in terms of loosening and wear. Alternatively, despite positive early and mid-term results with hemiarthroplasty, glenoid erosion and the need for revision to total shoulder arthroplasty have been demonstrated after longer-term follow-up.[47]

As mentioned by Streubel et al.,[48] Hartel et al.,[49] Sajadi et al.,[50] and Dines et al.,[51] revision of a resurfacing shoulder arthroplasty to a total shoulder arthroplasty provides unsatisfying results.

In **chapter 10**, we present our clinical results of the revision of the Global CAP resurfacing hemi shoulder prosthesis to a total or reverse shoulder prosthesis.





This thesis aims to answer the following questions:

1. ***Can we postpone an arthroplasty of the shoulder with intra-articular infiltration in gleno-humeral osteoarthritis?***
2. ***Do strategies differ between countries regarding the choice for using resurfacing hemiarthroplasty?***
3. ***Does the (resurfacing) shoulder hemiarthroplasty provide similar patient reported outcomes compared to the total shoulder arthroplasty?***
4. ***Does the Global CAP resurfacing hemiarthroplasty provide satisfactory patient reported outcomes in primary osteoarthritis and does a hemi shoulder arthroplasty provide satisfactory patient reported outcomes in secondary gleno-humeral osteoarthritis (Rheumatoid arthritis) on the long term?***
5. ***Why does the Global CAP resurfacing hemiarthroplasty fail and what are the reported outcomes after revision?***

There are many different shoulder prosthetic designs and manufacturers. In this thesis the Global Conservative Anatomic Prosthesis (CAP) (DePuy Synthes, Warsaw, IN, USA), Aequalis Hemi Shoulder (Tornier, Edina, MN, USA), Total Evolutive Shoulder System (TESS), Total Shoulder Arthroplasty (Biomet, Warsaw, IN, USA), Global Anatomic prosthesis (AP) Total Shoulder Arthroplasty (DePuy Synthes, Warsaw, IN, USA), and Delta Xtend Reverse Shoulder Arthroplasty (DePuy Synthes, Warsaw, IN, USA) were used.

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# CHAPTER 2

## Intra-articular infiltration therapy for patients with gleno-humeral osteoarthritis: A systematic review of the literature

**Introduction**
Conservative treatments are especially in patients with gleno-humeral osteoarthritis important, since shoulder arthroplasty has its limitations. In this systematic review, we will evaluate the current evidence regarding the efficacy of intra-articular infiltration treatment options in patients with gleno-humeral osteoarthritis.

**Materials and Methods**
The following databases are searched: Pubmed/Medline, Cochrane Clinical Trial Register, Embase and the WHO clinical trial register. All intra-articular injection products used for the treatment of shoulder OA in humans are included.

**Results**
A total of 8 studies could be included in this review. Hyaluronic acid (HA) showed effect sizes of 2.07, 2.02 and 2.11 at 6, 12- and 26-weeks follow-up, respectively. Placebo (1.60, 1.82 and 1.68) also showed stable effect sizes at the same time points. The efficacy of corticosteroids (CS) decreased rapidly at follow-up (1.08, 0.43 and 0.19). Although statistical significant, the maximum difference in effect sizes between HA and placebo was only 0.43 with absolute values between 2.0 and 6.4 on a 100-point visual analogue score for pain.

**Conclusion**
Intra-articular treatment with HA has a good efficacy at follow-up compared to baseline. However, the difference in efficacy between HA and placebo never reaches the minimal clinically important difference at any of the follow-up points. We are not able to give clear recommendations for the use of intra-articular CS injections in patients with gleno-humeral osteoarthritis. In future research, we recommend focusing on sufficiently powered randomized trials to compare the efficacies of HA, CS, placebo and other intra-articular treatment options in patients with gleno-humeral osteoarthritis.

**Key words: Anesthetics, corticosteroid, hyaluronic acid, hyaluronan, osteoarthritis, shoulder, sodium hyaluronate, systematic review, viscosupplementation**
**Level of evidence: IV**







## INTRODUCTION

Gleno-humeral osteoarthritis is characterized by a gradual, progressive, mechanical, and biochemical breakdown of the articular cartilage and other joint tissues, including bone and joint capsule. As the articular surface wears, friction within the joint increases and causes progressive loss of the normal loadbearing surfaces with pain, stiffness and disability as a result. Patients can have pain at night, especially when the patient lies on the affected shoulder.[1–5] The cause of gleno-humeral osteoarthritis can be divided into a primary or secondary type, resulting from trauma (fracture or instability), inflammatory arthropathies, or genetic predisposition.[6] Painful gleno-humeral osteoarthritis is difficult to treat and highly disabling.[1,2,4] Shoulder arthroplasty is effective at reducing pain and improving range of motion,[1,7] but complications such as periprosthetic fractures, infections and instability of the joint are not unusual.[8] In clinical practice, the most effective nonsurgical treatments of shoulder osteoarthritis are a combination of therapies, customized to patient's requirements, rather than a single drug or a single nonsurgical intervention.[1,9] Several nonsurgical treatment options for gleno-humeral osteoarthritis are widely known. Changes in daily activities and occupation should be considered.

Physical therapy can be advised to keep range motion and muscle strength. However, an incongruent shoulder joint can lead to an increase of pain.[10] Pharmacological treatments, including acetaminophen (first pharmacological option), nonsteroidal anti-inflammatory drugs (NSAIDs), narcotic and nonnarcotic analgesics and intra-articular injections of corticosteroids (CS) or hyaluronic acid (HA), have been the mainstay of nonsurgical treatment.[11–13] Analgesics and NSAIDs can be insufficient and can be associated with (well-known) adverse effects, especially in the elderly patient.[14–17] The use of intra-articular CS and HA in patients with osteoarthritis is well documented. Especially concerning knee osteoarthritis, a large number of studies is published about the efficacy of different intra-articular administered treatments. Several reviews conclude that HA has a positive effect on pain.[18,19] However, in the systematic review and meta-analysis of Colen et al., a large placebo effect was shown in the knee and hip.[18,20] The difference between the efficacies of intra-articular administered HA and placebo was considered significant, but not reaching the minimum clinically important difference (MCID). Bannuru et al.[21] showed in a meta-analysis that HA is superior to CS after 8 weeks. However, CS is more effective up to 4 weeks after intra-articular administration. We are not aware of a published review concerning the efficacy of the different intra-articular infiltration treatment options for gleno-humeral osteoarthritis. In this systematic review, we will describe and evaluate the current evidence regarding efficacy of the several intra-articular infiltration treatment options of patients with gleno-humeral osteoarthritis with or without a rotator cuff tears.

## MATERIALS AND METHODS

**Inclusion criteria**

*Types of studies*

A search of the literature performed for this review was limited to published original reports concerning the intra-articular injection treatment of adults with gleno-humeral osteoarthritis. Studies form levels I to IV were included (Table 1). Abstracts from scientific meetings, unpublished reports, case reports, expert opinions and review articles were not included.

**Table 1** | Level of evidence

| | |
|---|---|
| Level I | High-quality prospective randomized clinical trial |
| Level II | Prospective comparative study |
| Level III | Retrospective case control study |
| Level IV | Case series |
| Level V | Expert opinion |

*Types of participants*

Inclusion was limited to articles on male and female adult humans with primary and secondary gleno-humeral osteoarthritis. The diagnosis of gleno-humeral osteoarthritis was made by history, physical examination and radiology. Patients with bilateral gleno-humeral osteoarthritis were also included. Studies focusing on "osteoarthritis of the acromion-clavicular joint," "shoulder impingement," "rotator cuff tendinopathy," "adhesive capsulitis" and "periarthritis" were not included in the current review. A mixed population of osteoarthritis and other pathologies was included if the osteoarthritis population could be analyzed separately.

*Types of intervention*

All intra-articular injection products (corticoids, HA, platelet rich plasma, stem cells, and anti-inflammatory drugs) used for the treatment of shoulder osteoarthritis in humans were included. Studies comparing one of the intra-articular injections with another active or placebo treatment were also included. All approaches (posterior and anterior) and techniques (ultrasound or fluoroscopic guided or no guidance) of intra-articular administration were included.

*Types of outcomes measures*

The Outcome Measures in Rheumatology (OMERACT) III core set of outcome measures was considered for analysis; pain, physical function and patient global assessment.[22] The





minimum criterion for inclusion of the trial in the review was the adequate reporting of at least one of the outcome variables. Information regarding other outcome measures and adverse events was extracted and analyzed when feasible.

*Search strategy for identification of studies*

The following databases were searched: Pubmed/Medline (period 1966 to June 1st, 2013), Cochrane Clinical Trial Register (1988 to June 1st 2013), Embase (January 1988 to June 1st 2013) and the WHO clinical trial register to identify all articles concerning the intra-articular injection therapy for gleno-humeral osteoarthritis. The search was independently performed by two authors (SC and PG). When using the search terms (Viscosupplementation OR HA OR CS OR platelet rich plasma OR stem cells OR anti-inflammatory drugs AND shoulder) we initially found 1492 papers.

Osteoarthritis was not used as a search term, because of the risk of missing studies. The references of retrieved publications were also manually checked to add studies potentially meeting the inclusion criteria and missed by the electronic search. Papers not written in English language were considered if translation was possible. The flowchart is defined in Figure 1.

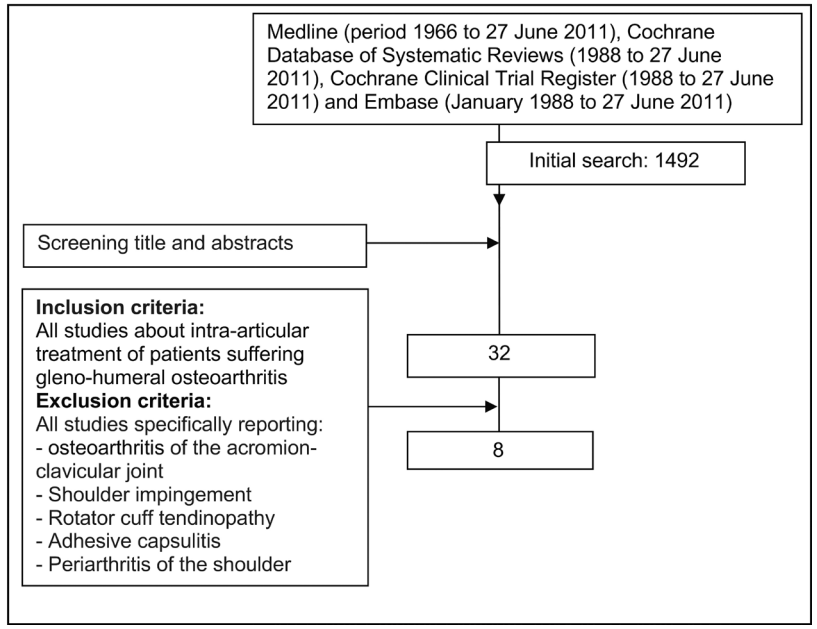


**Figure 1** | Flowchart summarizing the selection of relevant articles

**Methods of the review**

*Selection of trials*

Trial selection was done by two authors (SC and PG) reviewing title and abstract to identify potentially relevant articles for our review. The full manuscript was retrieved when the title, keywords or abstract revealed insufficient information to determine the appropriateness for inclusion. Disagreement was resolved by discussion, with arbitration when necessary by a third reviewer (MB) when differences remained.

*Data collection*

From the included studies, data for meta-analysis was extracted by one reviewer (PG), using a pre-piloted data extraction-tool. Extraction was verified by a second reviewer (SC). Disagreements were resolved in a consensus meeting or, if necessary, by third party adjudication (DH). Articles were not blinded for author, affiliation, and source.[23–25] If necessary, authors were contacted for additional information.

*Assessment of methodological quality*

Differences in quality amongst trials indicate a possible difference in bias between these trials. Therefore, it is important to evaluate the quality of the trials when evaluating the effectiveness of an intervention. Two independent reviewers (SC and PG) obtained the full text of all potentially eligible articles for independent methodological assessment. Studies were scored according to the Level of evidence and recommendations for clinical practice were formulated (Tables 1 and 2). The strength of these recommendations was classified with a grade (Table 2).

**Table 2** | Grades of recommendation (given to various treatment options based on the level of evidence supporting that treatment)

| | |
|---|---|
| Grade A | Treatment options are supported by strong evidence (consistent with level I or II studies) |
| Grade B | Treatment options are supported by fair evidence (consistent with level III or IV studies) |
| Grade C | Treatment options are supported by either conflicting or poor-quality evidence (level IV studies) |
| Grade D | When insufficient evidence exists to make a recommendation |

*Quantitative analysis*

Since many studies used different subjective outcome scoring systems, the average improvement is calculated as an effect size, this is a well-established measurement in which the improvement of the score is divided by the standard deviation of the pretreatment score. The average effect sizes pretreatment will be compared using Student's t-test. $p < 0.05$ was considered to be significant.





## RESULTS

The initial search using the above-mentioned search strategy resulted in 1492 studies, after reading the title and abstract, 32 articles were screened for eligibility. We included two randomized controlled trials (RCTs) comparing the efficacy of intra-articular administered HA with placebo, five prospective case series (all using intra-articular administered HA), and one retrospective study comparing the efficacy of HA and CS.[1,10,13,14,26–29] A total of 895 patients was included in these 8 studies; 579 patients received HA (Hylan G-F 20 (Synvisc®, Genzyme Corporation, Cambridge, MA, USA), Supartz® (Smith & Nephew, Inc, Andover, MA, USA) or Hyalgan® (Sanofi -Aventis, Bridgewater, NJ, USA and Fidia Farmaceutici, SpA, Abano Terme, Italy), 33 patients CS (6-methylprednisolone acetate, Depo-Medrol®, Pfizer, Latina, Italy) and 283 patients phosphate-buffered saline (PBS) (Table 3). The first article was published in 1988 and the most recent in January 2013.

**Table 3** | Characteristics of included studies

| Author | Year | Country | Study | Number of = shoulders with osteoarthritis (male/female) | Mean age (years) | Amount and product of infiltration | Number and frequency of infiltrations | Adverse effects related to injection | Level of evidence |
|---|---|---|---|---|---|---|---|---|---|
| Blaine et al.[14] | 2008 | USA | RCT | PBS: 133<br>HA: 129<br>HA + PBS: 136 | PBS: 63.3 ± 12.3<br>HA: 63.4 ± 12.4<br>HA + PBS: 62.3 ± 12.7 | 2 ml PBS<br>20mg/2ml Hyalgan® 5 times<br>20mg/2ml Hyalgan® 3 times + PBS 2 times | 5 (weekly) | PBS: 54 %<br>HA: 54 %<br>HA + PBS: 55 % | I |
| Brander et al.[1] | 2010 | USA | PCS | 36 (16/20) | 67 (range 36-88) | 16mg/2ml Synvisc® | 2 (2-week interval) | 6 (16.7%) | IV |
| Kwon et al.[10] | 2013 | USA | RCT | HA: 133 (53/80)<br>PBS: 130 (67/63) | HA: 65.9 ± 10.7<br>PBS: 65.7 ± 11.8 | 25mg/2.5ml Supartz®<br>2.5ml PBS | 3 (weekly) | HA: 18 (13.5%)<br>PBS: 26 (20.0%) | I |
| Leardini et al.[26] | 1988 | Italy | PCS | 6 | 61 (range 40-78) | 10 mg/1ml Hyalgan® | 3 (3-day interval) | None | IV |
| Merolla et al.[27] | 2011 | Italy | RCCS | HA: 51 (13/38)<br>CS: 33 (10/23) | HA: 61 ± 4.9<br>CS: 63 ± 5.6 | 16mg/2ml Synvisc®<br>40 mg/ml Depo-Medrol | 3 (weekly) | HA: 7 (13.7%)<br>CS: 2 (6.1%) | III |
| Noël et al.[28] | 2009 | France | PCS | 33 (18/15) | 56.7 ± 9.3 | 16mg/2ml Synvisc® | 1† | 10 (24.2%) | IV |
| Silverstein et al.[13] | 2007 | USA | PCS | 27 (17/10) | 62 (range 47-79) | 16mg/2ml Synvisc® | 3 (weekly) | None | IV |
| Valiveti et al.[29] | 2006 | USA | PCS | Hyalgan®: 9<br>Synvisc®: 2 | Unknown | Amount not mentioned Hyalgan®<br>Synvisc® | Hyalgan®: 5 (weekly)<br>Synvisc®: 5 (weekly) | None | IV |

PBS: phosphate-buffered saline, HA: hyaluronic acid, CS: corticosteroid, RCT: Randomized Controlled Trial, RCCS: Retrospective Case Control Study, PCS: Prospective Case Series

† 16 of the 33 patients received a second infiltration a month after the first





*Randomized clinical trials*

The first performed RCT (Blaine et al.) studied 660 patients with persistent shoulder pain.[14] Patients were treated with a weekly series of 3 injections of Hyalgan® and 2 injections with PBS (three-injection group), 5 injections of Hyalgan® (five-injection group), or 5 injections of PBS (control group). A subgroup of the study population had radiographic signs of gleno-humeral osteoarthritis. Of the patients with gleno-humeral osteoarthritis 136 patients were included in the three-injection group, 129 in the five-injection group, and 133 in the control group. The visual analog score (VAS: 100-point scale) for pain showed a difference of 7.5 (standard deviations [SD]: 2.5) comparing the efficacy of the treatment in the three-injection group with the control group (in favor of the three-injection group: $p = 0.003$). Similar results were shown between the five-injection group and the control group with a difference of 7.8 (SD: 2.5) ($p = 0.002$). At all follow-up visits (7, 9, 17, and 26 weeks) there was a significant improvement using the VAS for pain compared to baseline in both three and five-injection groups ($p < 0.05$). No difference in efficacy was noted between the three- and five-injection groups during the 26 weeks follow-up period.

The second RCT (Kwon et al.) also studied the efficacy of intra-articular administered HA (Supartz®) and compared this with intra-articular administered PBS.[10] Three weekly injections of either HA or PBS was given in patients with chronic shoulder pain associated with gleno-humeral osteoarthritis. The injections were performed without the support of ultrasound or fluoroscopy. A total of 300 patients were included (150 patients with HA and 150 with PBS). The improvement in VAS for pain between baseline and 26 weeks follow-up was 19.88 for the HA treated patients and 16.3 for the PBS treated patients. The least-squares difference in VAS between the groups (at 7-, 13-, 20- and 26-weeks follow-up) was 2.8 in favor of the HA treated patients ($p = 0.112$). For the patients only with gleno-humeral osteoarthritis and no other shoulder pathologies the improvement in VAS between baseline and 26 weeks follow-up was 21.0 for the HA treated patients and 15.7 in the PBS treated patients. The repeated-measures longitudinal analysis showed a significant difference between these groups ($p = 0.038$). Similar results were observed using the OMERACT-Osteoarthritis Research Society International (OARSI) high responder rates (a score evaluating treatment effects in osteoarthritis). The HA treated patients showed a higher OMERACT-OARSI high responder rate, with an odds ratio of 1.45 (95%CI: – 0.97 to 2.17) and 6.92% difference in responder rate at 26 weeks follow-up. In the patients only with gleno-humeral osteoarthritis the OMERACT-OARSI high responder rates were similar (1.62 [95%CI: – 1.06 to 2.50] and an 8.37% difference in responder rate) at 26 weeks. This odds ratio also showed a significant difference between the HA and PBS treated patients (in favor of the HA treated patients: $p = 0.028$).

*Prospective case series*

Leardini et al.[26] were in 1988 the first to report the outcome of intra-articular administered HA in 29 patients with a painful shoulder including six patients diagnosed with osteoarthritis. Each patient received three injections with a three days interval. The total follow-up was only 11 days and of the patients with shoulder osteoarthritis three had a fairly good result, while the other three experienced good to very good results.

Noël et al.[28] were the first to study clearly defined and uniform population (33 patients) who had primary gleno-humeral osteoarthritis and an intact rotator cuff. All patients were treated with Hylan G-F 20. A second infiltration with HA was possible on demand of the patient at 1-, 2- or 3-months follow-up. The VAS for pain decreased from 61.2 at baseline to 37.1 at 3 months follow-up ($p < 0.001$). The Western Ontario Osteoarthritis of the Shoulder score (a disease-specific quality of life score) (45.7% at baseline to 63.1% at 3 months follow-up) and SF-36 score (38.6 at baseline to 40.7 at 3 months follow-up) also showed improvement. However, only the results of the Western Ontario osteoarthritis of the shoulder score were significant ($p < 0.001$).

In a letter to the editor Valiveti et al.[29] reported the results of 11 courses of intra-articular administered HA (Hylan G-F 20: Weekly for 3 weeks and Hyalgan: Weekly for 5 weeks). Five patients had moderate improvement; five had mild improvement, and one had no improvement. The average time of improvement was 4 months (range: 2-12 months).

Brander et al.[1] in their prospective case series included 36 patients with gleno-humeral osteoarthritis that were intra-articularly infiltrated with a series of 2 injections of Hylan G-F 20 14 days apart. The VAS for pain improved from 63.0 (SD: 14.5) at baseline to 38.9 (SD: 27.6), 41.4 (SD: 23.9), and 34.9 (SD: 21.7) at 6-, 12- and 26-weeks follow-up, respectively ($p < 0.001$ at all follow-up visits). The Western Ontario Rotator Cuff Index (a quality of life index using the VAS including 5 domains: Physical symptoms, sports and recreation, work social function, and emotions) showed similar results with a score of 65.3 (SD: 18.4) at baseline improving to 48.4 (SD: Not available), 49.9 (SD: Not available) and 45.9 (SD: 22.4) at 6-, 12- and 26-weeks follow-up respectively ($p < 0.001$ at all follow-up visits).

Silverstein et al.[13] in their prospective study reported the results of 27 patients with gleno-humeral osteoarthritis who were intra-articular injected with Hylan G-F 20. The infiltrations were blind performed. The VAS for pain improved from 54.0 at baseline to 42 ($p = 0.01$), 36 ($p < 0.001$), and 30 ($p < 0.001$) at 1-, 3-, and 6-months follow-up, respectively. The modified University of California at Los Angeles score (a score consisting of the sum of the individual scores for pain, function, motion, and strength) improved significant at all 3 follow-up visits (15.7 at baseline to 20.0, 20.8, and 20.5, respectively).





The simple shoulder test (a patient completed form that measures a patient's ability to perform 12 common tasks in normal activities of daily living and work) improved from 5.7 at baseline to 7.2 ($p = 0.012$), 7.2 ($p = 0.001$), and 7.6 ($p = 0.001$) at 1-, 3-, and 6-months, respectively.

*Retrospective case-control study*

Merolla et al.[27] reported a retrospective case-control study comparing intra-articular CS and HA in patients with gleno-humeral osteoarthritis. Fifty-one patients received HA and 33 CS. The VAS for pain in the HA injected group decreased from 61.0 (SD: 9.1) to 33.7 (SD: 9.4), 35.1 (SD: 8.9) and 36.5 (SD: 9.0) at 1-, 3- and 6-months follow-up, respectively ($p < 0.05$ at all follow-up visits). The effect of intra-articular administered CS was less. At baseline, the VAS for pain was 62.5 (SD: 16.7) which decreased to 44.2 (SD: 11.7; $p = 0.0431$), 55.4 (SD: 18.4; $p = 0.0626$), and 59.4 (SD: 15.8; $p = 0.0691$) at 1, 3 and 6 months follow-up, respectively. The shoulder pain and disability index and the Constant-Murley scale as clinical outcome parameters improved significant showing improvement at 1-, 3- and 6-months follow-up for the HA injected group and only at 1-month follow-up in the CS injected group.

*Statistical analysis of available data*

For 5 studies (6 groups) data could be extracted, and effect sizes could be calculated at 6 weeks, 12 weeks and 26 weeks for HA.[1,10,14,27,28] Pooling these data resulted in stable effect sizes at each of these time points, respectively 2.07 (±0.53), 2.02 (±0.53) and 2.11 (±0.40) (Figure 2).

From the studies of Blaine et al.[14] and Kwon et al.[10] an effect size for placebo could be calculated. As for HA these effect sizes are stable during follow-up at 6, 12 and 26 weeks (1.60 (±0.04), 1.82 (±0.04) and 1.68 (±0.23), respectively) (Figure 3).

Only the study of Merolla et al.[27] allowed calculation of effect size for CS (Figure 4). The effect size between placebo and HA are significantly different at 6-, 12- and 26-weeks follow-up (all $p < 0.01$). Although statistically significant, the maximum difference in effect size at any of the time points is only 0.4 and the pooled differences between HA and placebo ranches between 2.0 and 6.4 on a 100-point VAS for pain.

*Safety data*

None of the included studies reported severe adverse effects.1,10,13,14,26–29 Five studies reported mild local adverse effects, such as local pain and local reaction at the injection side.1,10,14,27,28 Local adverse effects occurred in the patients treated with intra-articular administered HA, CS and placebo (PBS) (Table 3).

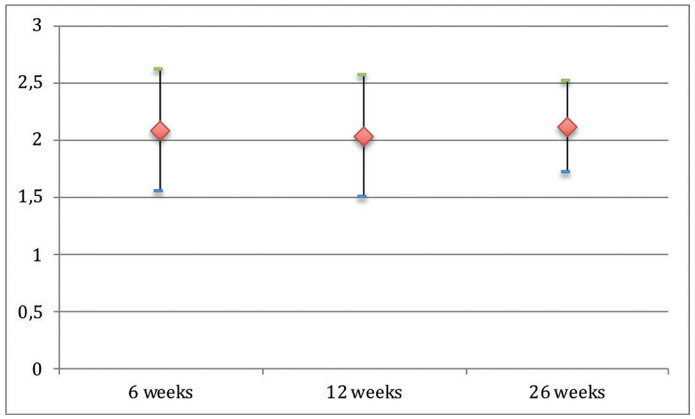


**Figure 2 |** Pooled effect sizes and SD hyaluronic acid

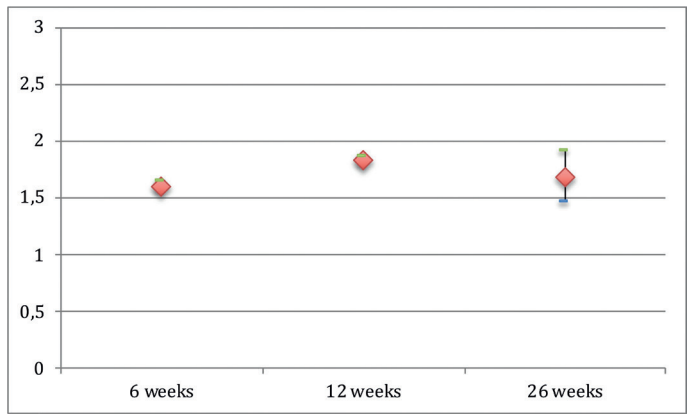


**Figure 3 |** Pooled effect sizes and SD placebo

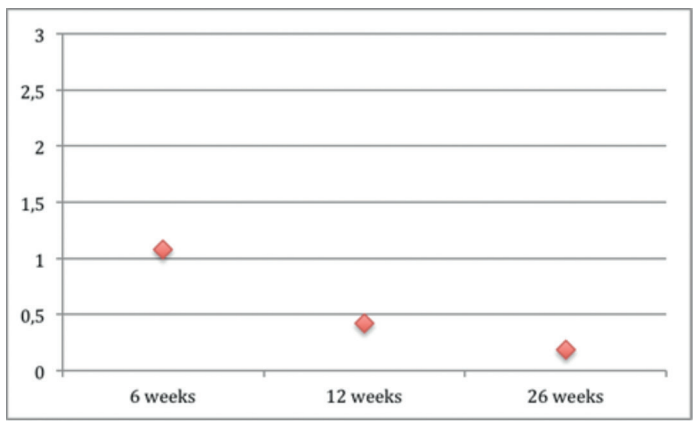


**Figure 4 |** Effect sizes corticostroids





## DISCUSSION

The objective of this systematic review was to collect the available evidence reported on the outcome of intra-articular injection treatments for patients with gleno-humeral osteoarthritis. The efficacy of intra-articular administered HA was described in 8 studies, of intra-articular administered CS in 1 study and intra-articular administered PBS (placebo) in two studies. We found no studies reporting the efficacy of intra-articular injection treatment with platelet rich plasma, stem cells or other more experimental therapies for patients with gleno-humeral osteoarthritis. The level of evidence of most of the included studies was low (Table 3). The retrospective case-control series (Merolla et al.) was the only study reporting on the efficacy of intra-articular administered CS.[27] Other concerns regarding the quality of the reported studies in this review include the not well-defined characteristics of the baseline characteristics, and the blindly and not ultrasound guided performed infiltrations in most studies. Blind infiltrations, especially performed in the study setting, can affect the outcome of the treatment since only 28-100% of the injections seem to be performed intraarticularly.[30–33]

We were able to show that the improvement in pain and function using intra-articular HA as treatment for patients with gleno-humeral osteoarthritis compared to baseline at all the follow-up points (6-, 12- and 26-weeks) was significant, showing effect sizes of more than two (Figure 2). However, the effect sizes of intra-articular administered PBS were also at least 1.5 at the same follow-up points. The efficacy of intra-articular administered HA compared with PBS showed an efficacy in favor of HA ($p < 0.01$), but the maximum absolute difference in efficacy using the VAS for pain was 6.4 on 100 points. This difference is not reaching the MCID and the question should be asked whether intra-articular treatment with HA is in clinical practice superior to intra-articular administered PBS.[34] The efficacy of intra-articular administered CS (although the level of evidence is very poor) is even less. At 6 weeks follow-up the effect size was 1.08 compared with baseline, but at 12 and 26 weeks the effect sizes were even lower, 0.43 and 0.19, respectively. Although the concerns about the design of the study of Merolla et al.,[27] the data reported in this review indicate that intra-articular administered HA has a longer and better efficacy in patients with gleno-humeral osteoarthritis than CS. Bannuru et al.[21] showed similar data in their systematic review about the efficacy of intra-articular administered HA and CS in the knee.

Several systematic reviews and meta-analysis regarding the efficacy of intra-articular treatment with HA in patients with knee osteoarthritis report similar results as we are showing in the shoulder, with small to moderate treatment effects compared with PBS.[18,19] Rutjes et al.[19] concluded that the treatment with intra-articular administered HA in patients with knee osteoarthritis showed only small and clinically irrelevant benefit compared to intra-articular administered saline and a risk for serious adverse events. Colen

et al.[18] showed a 40-50% pain reduction in patients treated with intra-articular HA at a follow-up of 3 months. When comparing the efficacy of intra-articular administered HA to saline (approximately 30% pain reduction) they determined a weighted mean difference of just 10.20 using the VAS for pain. Colen et al.[20] also studied the efficacy of intra-articular administered HA in other joints (the metatarsophalangeal-joint, the ankle, the hip, the sacroiliac joint, the facet joints, the carpometacarpal-joint and the shoulder). They concluded that there is a significant improvement in pain injecting intra-articular HA compared to baseline but comparing the efficacy of HA to placebo there is only limited evidence that HA is superior and that there is no evidence that intra-articular HA is better than CS or other conservative therapies.

Both HA and CS injections are well-tolerated. Local adverse effects in the shoulder are typical of those observed in the hip and knee joint (Table 3).[1,10,13,14,26–29,35,36] Serious adverse effects are not reported in the studies included in this review. CS infiltrations are frequently administered for the treatment of shoulder pain and have been effective in clinical trials.[37–40]

However, the indications in all these studies for the treatment with CS were rotator cuff tendinopathy and adhesive capsulitis. In addition, the potential damage to the collage matrix of tendons and ligaments suggests caution in the use of CS injections around the shoulder, especially with repeated infiltrations.[41–44] Several clinical studies have indicated that HA is also effective in managing pain associated with various other shoulder pathologies (adhesive capsulitis and rotator cuff tendinopathy).[45–49]

Although the difference in efficacy between intra-articular administered HA and PBS is small, the efficacy of intra-articular injection of HA at follow-up during the first 6 months is good in patients with gleno-humeral osteoarthritis (grade A of recommendations: Table 2). intra-articular treatment with HA is useful as a conservative treatment in patients with gleno-humeral osteoarthritis. Because the intra-articular treatment with CS is only reported in a single retrospective case control study showing a very low efficacy (grade B of recommendations: Table 2) and the fact that the above-mentioned risks of the use of intra-articular CS are serious, we agree with the guidelines of the American Academy of Orthopedic Surgeons that there are no clear recommendations for the use of intra-articular CS injections in patients with gleno-humeral osteoarthritis.[50] In future research we recommend to focus on sufficiently powered randomized trials to compare the efficacy of HA, CS, PBS and other intra-articular treatment options in patients with gleno-humeral osteoarthritis.







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# CHAPTER 3

## Shoulder arthroplasty for gleno-humeral osteoarthritis: results from a comprehensive survey in Belgium and the Netherlands

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**Introduction**
The purpose of this survey in Belgium and the Netherlands was to assess treatment variation in gleno-humeral osteoarthritis between experienced and less experienced orthopedic surgeons, and to investigate perioperative treatment after shoulder arthroplasty in a large group of orthopedic surgeons.

**Materials and Methods**
Orthopedic surgeons specialized in shoulder surgery were invited to complete a survey between November 2013 and February 2015.

**Results**
Seventy percent of the approached surgeons completed the survey. Less experienced surgeons (< 6 years) and surgeons from the Netherlands find patient characteristics (e.g. smoking $p$=0.01) more relevant than more experienced surgeons (≥ 6 years) and surgeons from Belgium.

Less experienced surgeons will less likely ($p$=0.001) perform resurfacing arthroplasty compare to experienced surgeons. The less and the experienced surgeons use similar indications for a reverse shoulder arthroplasty regarding age limit and cuff arthropathy without osteoarthritis.

Less experienced surgeon will more likely ($p$=0.003) prescribe a low molecular weight heparin during the hospital stay after a shoulder arthroplasty.

**Conclusion**
In this survey, we found a decrease in the use of resurfacing arthroplasty and a strong increase in the use of reverse shoulder arthroplasty. Besides, there is little consensus concerning pre-operative planning, patient characteristics, surgical technique, and patient reported outcome measures.

**Keywords: glenoid, arthroplasty, surgery, survey, osteoarthritis, shoulder.**
**Level of evidence: IV**





## INTRODUCTION

Gleno-humeral osteoarthritis is a common source of pain and disability with a prevalence of 17%.[1] Shoulder replacement yields satisfactory results by improving range of motion, patient reported outcome measures and decreasing pain sensation.[2] In 2014 the Dutch Arthroplasty Register (LROI) added the registration of shoulder arthroplasties to existing hip and knee arthroplasty registry.[3]

In the US, between 1990 and 2000 only a small increase in the number of shoulder arthroplasties was observed.[4] After the year 2000, the number of shoulder arthroplasties has been exponentially growing.[4]

In the Netherlands and Belgium the number of reverse shoulder arthroplasties increased and the number of anatomical arthroplasties decreased since 2014.[5,6] Commonly used indications for performing a specific type of shoulder implant differ across the world and in literature,[7–10] an online survey was initiated in our two neighboring countries. Registration of patient reported outcome measures are not yet standardized and differ throughout the world, including the Netherlands and Belgium.[11] The purpose of this survey is to present an overview of the pre-operative planning, preferred type of implants, preferred surgical technique and postoperative procedures that are commonly applied in shoulder arthroplasty and to compare in neighboring countries. To assess whether years of experience may influence perioperative strategy we compared the results of the survey between experienced (≥6 years) and less experienced (<6 years) orthopedic surgeons.

## MATERIALS AND METHODS

Only orthopedic surgeons with a special interest in shoulder surgery, and all members of the Dutch Shoulder and Elbow Society and Belgian Elbow and Shoulder Society, were invited to participate in current online survey. A total of 181 orthopedic surgeons received an email invitation to log onto the website to complete the survey. The survey was available at www.shoulderelbowplatform.com from January 2014 until February 2015. During this period, the orthopedic surgeons who did not complete the survey, were encouraged to do so every three months. The participants could fill out the survey at their own pace, in multiple instances and at various computers if necessary.

Besides demographic information, participants were asked to answer various questions regarding shoulder implants, including type and brand of implant, implant choice, supports a national implant register, surgical approach, biceps treatment, use of low molecular weight heparin (LMWH), patient reported measures, and post-operative restrictions regarding activities. Specifically, we assessed differences between experienced (≥6 years)

and less experienced (<6 years) orthopedic surgeons and differences between the orthopedic surgeons from the two neighboring countries.

*Statistics*

The chi square test was used to compare between observed frequencies in one or more categories. A $p$ -value of <0.05 was considered significant.

## RESULTS

**Participants**

Of the 181 invited orthopedic surgeons, 128 (71%) completed the survey. 105 of the 128 observers (82%) indicated to support a national shoulder arthroplasty registry.

Orthopedic surgeons with less than 6 years' experience were more ($p$ = 0.016) supporting a national shoulder arthroplasty registry, in contrast to more experienced (≥6 years) orthopedic surgeons. There are more proponents of a national shoulder arthroplasty registry under Dutch orthopedic surgeons ($p$ <0.0001) compared to the respondents from Belgium. The demographics of the observers are reported in table I.

**Pre-operative planning**

Seven out of the 121 observers (6%) use only plain radiographs before performing a reverse shoulder arthroplasty. Most surgeons (71%) use MRI or CT besides plain X-ray before performing a reverse arthroplasty or total shoulder arthroplasty. See table II for all observer's pre-operative planning diagnostics.

**Patient Characteristics and decision-making**

For responders with less than 6 years' experience, the presence of diabetes mellitus ($p$ =0.03) and smoking habits ($p$ =0.01) are more relevant compared to more experienced (≥6 years) orthopedic surgeon. For Dutch orthopedic surgeons, body mass index ($p$ =0.03) and smoking habits ($p$ =0.0004) are more relevant compared to the Belgian respondents. See table III for the evaluation of the patient characteristics in decision making.

**Table I** | Demographics of participating surgeons (n=128)

| | | Total | Belgium | Netherlands | $p$ | ≥ 6 years' experience | < 6 years' experience | $p$ |
|---|---|---|---|---|---|---|---|---|
| Number of participants | | 128 | 44 | 84 | | 87 | 41 | |
| Mean age in years (range) | | 46 (32-68) | 46 (33-62) | 45 (32-68) | | 49 (38-68) | 38 (32-45) | |
| Mean experience as an orthopedic surgeon in years (range) | | 12 (1-35) | 14 (1-35) | 10 (1-30) | | 15 (6-35) | 3 (0-5) | |
| Country in practice | Netherlands | 84 (66%) | | | | 50 (57%) | 34 (83%) | |
| | Belgium | 44 (34%) | | | | 37 (43%) | 7 (17%) | |
| Member of national shoulder elbow society | | 123 (96%) | 43 (98%) | 80 (95%) | | 84 (97%) | 39 (95%) | |
| Hospital of main practice | General | 100 (78%) | 38 (86%) | 62 (74%) | | 71 (82%) | 30 (73%) | |
| | University | 9 (7%) | 5 (11%) | 4 (5%) | | 6 (7%) | 3 (7%) | |
| | Private | 12 (9%) | 1 (2%) | 11 (13%) | | 8 (9%) | 4 (10%) | |
| | Other | 7 (5%) | 0 (0%) | 7 (8%) | | 3 (3%) | 4 (10%) | |
| Shoulder arthroplasty/year | < 20 | 48 (38%) | 12 (27%) | 36 (43%) | | 26 (30%) | 22 (54%) | |
| | 20-50 | 66 (52%) | 25 (57%) | 41 (49%) | | 49 (56%) | 18 (44%) | |
| | > 50 | 14 (11%) | 7 (16%) | 7 (8%) | | 13 (15%) | 1 (2%) | |
| Shoulder pathology in daily practice | < 30% | 13 (10%) | 2 (5%) | 11 (13%) | | 6 (7%) | 7 (17%) | |
| | 30-60% | 65 (51%) | 25 (57%) | 40 (48%) | | 43 (49%) | 22 (54%) | |
| | > 60% | 50 (39%) | 17 (39%) | 33 (39%) | | 38 (44%) | 12 (29%) | |

**Table I** | Continued

| | | Total | Belgium | Netherlands | *p* | ≥ 6 years' experience | < 6 years' experience | *p* |
|---|---|---|---|---|---|---|---|---|
| Performed | Resurfacing/Stemless shoulder arthroplasty | 53 (41%) | 24 (55%) | 29 (35%) | 0.046 | 45 (52%) | 8 (20%) | 0.001 |
| | Hemi Shoulder arthroplasty | 102 (80%) | 34 (77%) | 68 (81%) | 0.079 | 74 (85%) | 28 (68%) | 0.050 |
| | Total shoulder arthroplasty | 112 (88%) | 40 (91%) | 72 (86%) | 0.572 | 77 (89%) | 35 (85%) | 0.823 |
| | Reverse shoulder arthroplasty | 116 (91%) | 44 (100%) | 72 (86%) | 0.021 | 80 (92%) | 36 (88%) | 0.671 |
| supports national shoulder arthroplasty registry | | 105 (82%) | 23 (52%) | 82 (98%) | <0.0001 | 66 (76%) | 39 (95%) | 0.016 |

All amounts in n(%)

**Table II** | Pre-operative diagnostics (n=128)

| | X-ray | CT | MRI | X-ray and CT | X-ray, CT and MRI | X-ray and MRI | X-ray and US | X-ray, CT and US | NP |
|---|---|---|---|---|---|---|---|---|---|
| **Resurfacing shoulder (n=71)** | 8 (11%) | 4 (6%) | 3 (4%) | 20 (28%) | 2 (3%) | 19 (27%) | 1 (1%) | 9 (13%) | 57 (45%) |
| **Hemi shoulder (n=107)** | 7 (7%) | 7 (7%) | 2 (2%) | 39 (36%) | 7 (7%) | 27 (25%) | 6 (6%) | 10 (9%) | 21 (16%) |
| **Total shoulder (n=120)** | 4 (3%) | 5 (4%) | 3 (3%) | 39 (33%) | 15 (13%) | 31 (26%) | 4 (3%) | 13 (11%) | 8 (6%) |
| **Reverse shoulder (n=121)** | 7 (6%) | 5 (5%) | 4 (3%) | 53 (42%) | 9 (7%) | 24 (20%) | 4 (3%) | 13 (11%) | 7 (6%) |

All numbers in n(%)
US = Ultrasound, NP = not performing this type of arthroplasty

**Table III** | Patient characteristics and decision making (n=128)

| Important in deciding an arthroplasty | Yes | No | Belgium (n=44) Yes | Netherlands (n=84) Yes | *p* | ≥6 yr. (n=87) Yes | <6 yr. (n=41) Yes | *p* |
|---|---|---|---|---|---|---|---|---|
| **Diabetes** | 48 (38%) | 80 (63%) | 14 (32%) | 34 (40%) | 0.4424 | 27 (31%) | 21 (52%) | 0.0283 |
| **Body Mass Index (BMI)** | 37 (%) | 91 (71%) | 7 (16%) | 30 (36%) | 0.0322 | 22 (25%) | 15 (38%) | 0.1834 |
| **Smoking** | 56 (43%) | 72 (57%) | 9 (20%) | 46 (55%) | 0.0004 | 30 (34%) | 25 (60%) | 0.0106 |

All numbers n (%)

**Table IV** | Complications which poses the biggest problem after shoulder arthroplasty (n=128)

| | Infection | Fracture | Dislocation | Overstuffing |
|---|---|---|---|---|
| Resurfacing shoulder arthroplasty | 32 (25%) | 2 (2%) | 2 (2%) | 92 (72%) |
| Hemi shoulder arthroplasty | 85 (67%) | 14 (11%) | 29 (22%) | 0 (0%) |
| Total shoulder arthroplasty | 81 (64%) | 15 (12%) | 32 (25%) | 0 (0%) |
| Reverse shoulder arthroplasty | 76 (59%) | 23 (18%) | 29 (23%) | 0 (0%) |

All amounts in n (%)

**Table V** | Reverse shoulder arthroplasty (n=128)

| | Yes | No | Belgium Yes (n=44) | Netherlands Yes (n=84) | *p* | ≥6 yr. Yes (n=87) | <6 yr. Yes (n=41) | *p* |
|---|---|---|---|---|---|---|---|---|
| **RSA in patients younger than 70 years** | 95 (74%) | 33 (26%) | 39 (87%) | 56 (67%) | 0.013 | 65 (75%) | 30 (71%) | 0.863 |
| **Age under limit for RSA** | 50 (38%) | 78 (62%) | 11 (25%) | 39 (46%) | 0.030 | 32 (36%) | 18 (43%) | 0.442 |
| **RSA in case of irreparable RC without OA** | 76 (59%) | 52 (41%) | 32 (73%) | 44 (52%) | 0.042 | 53 (61%) | 23 (55%) | 0.603 |

All amounts in n(%)
RSA = reverse shoulder arthroplasty, RC = rotator cuff, OA = osteoarthritis

**Resurfacing/stemless hemi prosthesis**

Orthopedic surgeons with at least 6 years of experience are ($p$=0.001) more likely to perform a resurfacing/stemless shoulder arthroplasty compared to orthopedic surgeons with less experience (<6 years) (Table I). Seventy-two percent of the observers thinks overstuffing is the greatest risk for failure in resurfacing/stemless arthroplasty. (Table IV)

**Reverse Prosthesis**

More experienced surgeons will only slightly likely ($p$ =0.60) perform reverse shoulder arthroplasty in patients without osteoarthritis (61%) compared to surgeons with less experience (55%). Both groups will perform reverse shoulder arthroplasty in patients younger than 70 years.

Belgian surgeons were more likely to perform a reverse shoulder arthroplasty in younger patients (<70 years) ($p$ =0.013) and in cases with an irreparable rotator cuff rupture without gleno-humeral osteoarthritis ($p$ =0.042) compared to Dutch orthopedic surgeons. (Table V).

**Surgical Approach**

Most observers (60%) prefer a subscapularis tenotomy as an arthrotomy technique in case of an anatomical shoulder (resurfacing-, hemi- and total shoulder prosthesis) arthroplasty. In case of reverse arthroplasty, 39% of the observers use a subscapularis tenotomy as an arthrotomy technique. Seventy out of the 121 observers (58%) prefer to use a deltopectoral approach for reverse shoulder arthroplasties. All techniques of arthrotomies are reported in table VI.

**Long head Biceps tendon**

When performing a hemi-, total- or reverse shoulder arthroplasty, 54-66% of all surgeons will perform a long head biceps tenodesis. All preferred biceps interventions are reported in table VI.

**Table VI** | Arthrotomy technique in case of primary osteoarthritis and biceps intervention.

| | **Anatomic SA n=298** | **Reverse SA n=121** |
|---|---|---|
| **Arthrotomy** | | |
| SS tenotomy | 180 (60%) | 47 (39%) |
| Peel off SS of MT | 41 (14%) | 19 (16%) |
| Osteotomy of MT | 62 (21%) | 8 (7%) |
| Rotator interval | 10 (3%) | 28 (23%) |
| Other | 5 (2%) | 19 (16%) |





**Table VI** | Continued

| | **Anatomic SA n=298** | **Reverse SA n=121** |
|---|---|---|
| **Biceps** | | |
| Tenodesis | 200 (67%) | 65 (54%) |
| Tenotomy | 89 (30%) | 54 (45%) |
| None | 9 (3%) | 2 (2%) |
| NP | 86 (29%) | 7 (5%) |

All amounts in n (%)
SA = Shoulder arthroplasty, SS = subscapularis, MT = minor tubercle, NP = not performing this type of arthroplasty



**Thrombosis prophylaxis**

Eleven of the 44 responding Belgian orthopedic surgeons (25%) use a LMWH during hospitalization after a shoulder prosthesis operation, compared to 71% of the Dutch orthopedic surgeons that responded ($p$ <0.0001). Twenty-five of the 44 Belgian respondents (57%) do not use LMWH at all, compared to 12 of the 84 (14%) of the Dutch respondents ($p$ <0.0001).

Observers with less experience (76%) are more likely ($p$ =0.003) to use a LMWH during hospital stay compared to more experienced (≥6 years) orthopedic surgeon (46%). See table VII for all the observer's thrombosis prophylaxis.

**Table VII** | Low molecular weight heparins as thrombosis prophylaxis after shoulder implant surgery (n=128)

| | | **Belgium (n=44)** | **Netherlands (n=84)** | $p$ | **≥6 yr. experience (n=87)** | **<6 yr. experience (n=41)** | $p$ |
|---|---|---|---|---|---|---|---|
| **Only during hospital stay** | 71 (55%) | 11 (25%) | 60 (71%) | <0.0001 | 40 (46%) | 31 (76%) | 0.0031 |
| **2 weeks** | 6 (5%) | 4 (9%) | 2 (2%) | | 5 (6%) | 1 (2%) | |
| **4 weeks** | 3 (2%) | 2 (5%) | 1 (1%) | | 3 (3%) | 0 (0%) | |
| **6 weeks** | 11 (9%) | 2 (5%) | 9 (11%) | | 11 (13%) | 0 (0%) | |
| **None** | 37 (30%) | 25 (57%) | 12 (14%) | <0.0001 | 28 (32%) | 9 (22%) | 0.3247 |

All amounts in n (%)

**Post-operative restrictions**

After a hemi shoulder arthroplasty, 29 out of the 107 observers (27%), advise their patients to restrict activities to general daily living tasks and to do no sports, compared to 52% for non-impact sports (jogging and dancing) and light sports (swimming).

Twenty-nine out of the 120 observers (27%) advise to do only general daily living tasks and no sports, compared to 58% for non-impact sports (jogging and dancing) and light sports (swimming), after total shoulder arthroplasty.

After a reverse shoulder arthroplasty 42 out of the 121 observers (35%) advise to do only general daily living tasks and no sports, compared to 49% of the surgeons who advice to do only non-impact sports (jogging and dancing) and light sports (swimming).

After a total shoulder or reverse shoulder arthroplasty, 4% of the observers allow patients to lift heavy objects and allow high impact sports (weightlifting).

See table VIII for all post-operative restrictions after shoulder arthroplasty.

**Table VIII |** Restrictions after shoulder arthroplasty (n=128)

| | Resurfacing (n=71) | Hemi shoulder (n=107) | Total shoulder (n=120) | Reverse shoulder (n=121) |
|---|---|---|---|---|
| **Non-impact[a] and light sports[b]** | 25 (35%) | 56 (52%) | 70 (58%) | 59 (49%) |
| **Sports with risk of falling[c]** | 18 (25%) | 18 (17%) | 16 (13%) | 15 (12%) |
| **Lifting heavy objects and High impact sports[d]** | 3 (4%) | 4 (4%) | 5 (4%) | 5 (4%) |
| **No restrictions in daily living[e]/no sports[f]** | 22 (31%) | 29 (27%) | 29 (24%) | 42 (35%) |
| **Do not perform that kind of arthroplasty** | 57 (45%) | 21 (16%) | 8 (6%) | 7 (5%) |

All amounts in n (%)
[a] for example jogging and dancing
[b] for example swimming
[c] for example skiing and tennis
[d] for example weightlifting
[e] movement based and limited by pain
[f] only general daily living tasks

**Patient reported outcome measures**

Thirty-six percent of the surgeons (46 out of 128) do not no patient reported outcome measures. Eleven out of the 128 observers (9%) use only Constant scores to evaluate their surgical results after a shoulder arthroplasty. Two out of the 128 observers (2%) use only





the Oxford Shoulder Score (OSS) after a shoulder arthroplasty. Twenty-one out of 128 observers (16%) use the OSS in combination with another scoring method. See table IX for all the observer patient reported outcome measures.

**Table IX |** Patient reported outcome measures n=128

| post-operative questionnaires (n) | | This questionnaire alone n (%) |
|---|---|---|
| VAS | 57 | 8 (6%) |
| OSS | 20 | 2 (2%) |
| DASH | 27 | 1 (1%) |
| SST | 26 | 2 (2%) |
| Constant score | 41 | 11 (9%) |
| Other | 5 | 4 (3%) |
| None | 46 | 46 (36%) |
| **Combination of a mentioned questionnaires** | | |
| 2 | 24 (19%) | |
| 3 | 17 (13%) | |
| 4 | 6 (5%) | |
| 5 | 2 (2%) | |

n = every time this questionnaire is used, alone or in combination with another of multiple other questionnaires.
VAS = Visual Analogue Scale, OSS = Oxford Shoulder Score, DASH = Disabilities of the Arm, Shoulder and Hand, SST = Simple Shoulder Test

## DISCUSSION

This online survey reports several perioperative topics concerning shoulder arthroplasty for gleno-humeral arthritis in Belgium and the Netherlands, demonstrating a large variation in pre-operative planning, patient selection, type of implants, surgical techniques, thrombosis prophylaxis, outcome assessment with patient reported outcome measures and post-operative restrictions.

This study should be interpreted in the light of the following strengths and weaknesses. In literature, online surveys achieve an average response rate of 43%.[12] With 128 responses (71%) from all the invited surgeons (181), this is the largest and most complete survey on this topic in currently available literature. The large group allows subgroup analyses as well as comparisons between orthopedic surgeons from the two countries. There were some limitations that should be considered when interpreting the results and conclusions of this survey.

The overall conclusion of the present study is that there is a wide variation regarding the evaluated topics on performing shoulder arthroplasty. The 4 most interesting findings were:

First, in 2014, 834 anatomical shoulder arthroplasties were performed in the Netherlands. This number decreased to 797 (-4.4%) in 2015.[5] In Belgium a decrease of the anatomical prosthesis of 13.7% (350 to 302) was seen between 2015 and 2016.[6] This is in line with our study, we found a decrease in the use of anatomical arthroplasty, especially the resurfacing/stemless arthroplasty. The shoulder resurfacing/stemless arthroplasties are more likely performed by experienced (≥6 years) orthopedic surgeons. Less experienced (<6 years) orthopedic surgeons are likely to perform a total or reverse shoulder arthroplasty, instead of a hemi shoulder arthroplasty. This is in contrast with the study of Mann et al.[13] These authors concluded that hemi shoulder arthroplasty is a procedure commonly performed for primary gleno-humeral osteoarthritis among recent orthopedic graduates ($p$ <0.001). Shoulder fellowship trained surgeons were more likely to use a total shoulder arthroplasty for this indication.[13] The authors believe the resurfacing arthroplasties are less popular by less experienced orthopedic surgeons because of its less predictable outcome possibly due to less control of lateralisation and varus/valgus of the humeral component.

Second, the number of reverse shoulder arthroplasties strongly increased since 2011.[14] Criticasters of the increased use of reverse arthroplasty sometimes refer to this phenomenon as “reversomania”. This increase is also seen in in Belgium and the Netherlands. In the Netherlands, the number of reverse shoulder arthroplasties for example, increased from 1225 in 2014, to a total of 1501 in 2015 (+22.5%).[5] And in Belgium, the reverse shoulder prosthesis increased between 2015 and 2016 by 31.9% (1626 to 2144).[6]

More than 50% of the surgeons may perform a reverse shoulder arthroplasty for a symptomatic non-repairable massive cuff tear without radiographic degeneration of the gleno-humeral joint. This in line with the Food and Drug Administration (FDA), who approved the reverse shoulder arthroplasty in 2004. They stated it was indicated to treat cuff arthropathy in patients above 70 years.[8,15–19] Over time, the indications have expanded and it is currently being used for several diagnoses, including fracture sequelae[8,20–24], revision arthroplasty[8,20,25–27], instability[8,27], and tumors[8,27–30] as well. Literature also supports the use of reverse shoulder arthroplasty in patients with a massive rotator cuff tear with pseudo-paralysis in the absence of gleno-humeral arthritis when conservative treatment has failed.[8,20,27,31–36] Based on our survey, experienced orthopedic surgeons use the same indications for reverse shoulder arthroplasty as orthopedic surgeons with less experience. However, responders from Belgium will more likely perform a reverse shoulder arthroplasty in younger patients (<70 years) ($p$ =0.013) and will more likely perform a reverse shoulder arthroplasty in patients with an irreparable rotator cuff rupture without gleno-humeral osteoarthritis ($p$ =0.042) compared to Dutch orthopedic surgeons. We





believe because of more predictable outcome of the reverse shoulder arthroplasty and possible less surgical demanding procedure compared to the total shoulder arthroplasty, this might also be the reason of the increased number of the reverse shoulder arthroplasty and the “reversomania”.

Third, in literature, there is no consensus regarding either type or duration of thrombosis prophylaxis. The incidence of a venous thromboembolism (VTE) after shoulder arthroplasty is estimated between 0.2%-16%.[37–41] Arthroplasty for fractures, advanced age, female gender and previous diagnosis of malignancy were all associated with increased risk for VTE.[37–41] An aspirin based thrombosis prophylaxis protocol in the form of 325 mg enteric-coated tablets twice a day for 6 weeks was used in this study by Willis et al.[42] However, the efficacy of aspirin as prophylaxis in this study is debatable with a VTE prevalence of 16%.[40,42] Jameson et al.[43] suggested in their study that thrombosis prophylaxis might not be required, even in high-risk patients, and that it could be potentially harmful. Saleh et al.[40] did not find a higher incidence of VTE if bone cement was used in their study. Despite the absence of consistent evidence, the American Academy of Orthopaedic Surgeons suggests that perioperative mechanical and/or chemical prophylaxis should be used to prevent VTE in the treatment of shoulder arthroplasty.[44] In 2007, the National Institute for Health and Clinical Excellence (NICE) recommended that all orthopedic inpatients be offered low molecular weight heparins (LMWH) for the duration of their hospital stay.[45] In contrast to this, in 2010 the same institute (NICE) recommended that patients should not routinely be offered VTE prophylaxis undergoing upper limb surgery.[46]

In our survey, we found only 55% of the respondents to use LMWH during hospital stay after shoulder arthroplasty operations. However, the less experienced orthopedic surgeons will more likely ($p$ =0.003) use LWWH during hospital stay compared to the more experienced orthopedic surgeons.

Lastly, in our survey, we found 65% of the orthopedic surgeons assessed outcome using patient reported outcome measures. Furthermore, little consensus was found on which type or combination to assess outcome of shoulder arthroplasty. In literature, currently more than 20 different region-specific and condition-specific outcome instruments are being used to determine the functional outcomes, level of pain and quality of life, after shoulder surgery.[47–50] Because of the absence of a single set of universally accepted shoulder outcome measurements, many different outcome instruments for various shoulder conditions continue to be reported in the literature.[49] Oh et al.[49] concluded, that there is no single shoulder outcome instrument superior to the others in terms of measurement properties. The comparison of the surgical result is not possible due to the different outcome instruments focusing on different topics (pain, function, disability, independency). Lo et al.[48] pointed out that most outcome measures consist of physician generated questionnaires; therefore,

the items in the measurement tools are those that physicians deem to be important and not necessarily those that are important to patients. At the time of the start of the Dutch National Implant Registration of Shoulder Arthroplasties, a taskforce composed a set of outcome measures to assess the results of shoulder arthroplasties. To avoid overloading the patient with too many questions, careful consideration was made regarding the amount and type of questions. Adhering to the COSMIN principles the following tools were selected to assess pain, function and social well-being.[51] Pain is assessed with a numerical rating scale (NRS) in rest and during activities.[52] Social well-being is evaluated with EQ-5D.[53] Although the Western Ontario Osteoarthritis of the Shoulder (WOOS) has been adopted in most Scandinavian Registries.[54,55] The Oxford Shoulder Score (OSS) was selected as the primary outcome score to assess shoulder arthroplasties in the Dutch National Implant Registry. The authors suggest, the orthopedic community should use one or two patient reported outcome measures for shoulder arthroplasties. This would facilitate comparison between orthopedic surgeons, implants and hospitals.

Performing shoulder arthroplasty can be technically challenging and, therefore, have a greater potential for technical errors and complications than many of the other arthroplasty types.[56] With the increasing number of shoulders being surgically treated with an arthroplasty, we advocate including all types of artificial shoulder joints into a national database. Although the benefits of a shoulder arthroplasty registry are obvious,[57,58] the value of a joint registry is dependent on accuracy and completeness of the data entered.[3,59]

In conclusion, insight in perioperative management in end stage gleno-humeral osteoarthritis by orthopedic surgeons in Belgium and the Netherlands was provided. Also, a comparison between experienced and less experienced orthopedic surgeons was made. A decrease in the use of resurfacing arthroplasty and an increase in the use of reverse shoulder arthroplasty was found. Furthermore, there was little consensus concerning pre-operative planning, patient characteristics, type of implant, surgical technique, thrombosis prophylaxis, outcome assessment with patient reported outcome measures and post-operative restrictions for the patients. Further research is essential to gain additional information to support evidence-based guidelines concerning these topics.





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# CHAPTER 4

## Hemi or total shoulder arthroplasty for osteoarthritis of the shoulder, a systematic review of the literature

**Introduction**
The optimal surgical treatment of end-stage primary gleno-humeral osteoarthritis remains controversial. The objective of this article is to systematically review the current available literature to formulate evidence-based guidelines for treatment of this pathology with an arthroplasty.

**Material and methods**
A systematic literature search was performed to identify all articles from 1990 onward that presented data concerning treatment of osteoarthritis of the shoulder with a total shoulder arthroplasty or hemi shoulder arthroplasty with a minimal follow-up of 7 years. The most relevant electronic databases were searched.

**Results**
After applying the in- and exclusion criteria we identified 18 studies (of the initial 832 hits). The search included a total of 1958 patients (hemi shoulder arthroplasty: 316 and total shoulder arthroplasty: 1642) with 2111 shoulders (hemi shoulder arthroplasty: 328 + v: 1783). The revision rate for any reason in the hemi shoulder arthroplasty group (13%) was higher than in the total shoulder arthroplasty group (7%) ($p$ <0.001). There was a trend of a higher complication rate (of any kind) in the total shoulder arthroplasty group (12%) when compared to the hemi shoulder arthroplasty group (8%) ($p$ =0.065). The weighted mean improvement in anteflexion, exorotation and abduction were respectively 330, 150 and 310 in the hemi shoulder arthroplasty group and were respectively 560, 210 and 480 in the total shoulder arthroplasty group. Mean decrease in pain scores was 4.2 in the hemi shoulder arthroplasty and 5.5 in the total shoulder arthroplasty group.

**Discussion**
We conclude that total shoulder arthroplasty results in less need for revision surgery and has a trend to result in more complications. The conclusions of this review should be interpreted with caution as only level 4 studies could be included.

**Key words: systematic review, shoulder, osteoarthritis, arthroplasty, complication, revision rate, humerus, glenoid**
**Level of evidence: IV**





## INTRODUCTION

The total shoulder replacement is possibly the first documented replacement of a large joint in the human body. In 1893 Jules Emile Péan inserted a platinum cylinder with a rubber head in a 37-year-old patient with TB of the shoulder. The survival of the prosthesis was 2 years.[1] Since then both design and survival rates have improved significantly.

Modern shoulder replacement was introduced by Neer in the 1950s. The indication was mainly for the treatment of proximal humeral fractures.[2–4] Further development of the implants and the introduction of glenoid implants broadened the indications to other pathology of the shoulder, including gleno-humeral osteoarthritis.[4] If conservative treatment for gleno-humeral osteoarthritis fails, surgical treatment such as hemi-shoulder prosthesis (with or without stem) and total shoulder prosthesis is considered.[4] The best surgical treatment for gleno-humeral osteoarthritis remains debatable.

The advantages of a hemi shoulder prosthesis are a shorter operation time, less blood loss and the operation is technical less demanding.[4] However, there is concern about the progression of glenoid degeneration and the need for revision surgery to a total shoulder prosthesis.[4,5]

Total shoulder arthroplasty is characterized by a longer operation time and increased blood loss.[4] In addition, it is more technically demanding and it carries more risk of possible loosening and wear of the glenoid component.[4]

Radnay et al.[4] performed a systematic review and meta-analysis regarding the treatment of primary gleno-humeral osteoarthritis and concluded that in comparison with hemi shoulder arthroplasty, total shoulder arthroplasty significantly improves pain relief, range of motion, and satisfaction and has a significantly lower rate of revision surgery. However, this conclusion is not based on long term outcome studies.

When deciding to perform a hemi shoulder arthroplasty or a total shoulder arthroplasty two factors are very relevant, the possibility of glenoid loosening in total shoulder arthroplasty versus the possibility of glenoid erosion when performing a hemi shoulder arthroplasty. We searched the most common databases to compare the revision rates of both types of arthroplasty with long term follow-up. The objective of this article is to systematically review the current available literature to formulate evidence-based guidelines for clinical practice for treatment of osteoarthritis of the shoulder with an arthroplasty. Secondarily we will formulate guidelines and recommendations for future research.

## MATERIAL AND METHODS

**Inclusion and Exclusion Criteria**

We reviewed the titles and abstracts of related studies for all articles from 1990 to present and followed a predefined set of criteria to determine whether or not to include the material. Relevant data was referenced from articles written in English, German, and Dutch languages, in which arthroplasty was used as the form of treatment for shoulder osteoarthritis. All treatments comprised of a minimal follow-up of 7 years, and all types of shoulder osteoarthritis were included (idiopathic, rheumatic, post-traumatic, osteonecrosis, rotator cuff arthropathy). Osteoarthritis of the shoulder was defined as a joint disease and further characterized by several factors – loss of cartilage, subchondral sclerosis, cyst formation, deterioration of the joint, and the formation of new bone (osteophytes) around the joint. History, physical examination, and radiographs all were used to determine a diagnosis.

Articles concerned with arthroplasties performed after a proximal humeral or glenoid fracture, or with additional bone grafting and biologic resurfacing of the glenoid were not considered. Excluded from the review were articles reporting on the results of revision operations or articles dealing with biochemical studies as well as any article concentrating on the survival of the glenoid component or stem. Articles that did not report on new patient series, such as review articles and expert opinions were not used. In addition, abstracts of scientific meetings that were not published as full text articles were not considered and any case reports on 5 or less patients were excluded. Any article presenting data that was thought to be presented previously was included once.

**Identification of Studies**

A wide-ranging and comprehensive search was performed with the assistance of a clinical librarian. This search was limited to adult humans and included the following Mesh terms: shoulder, arthroplasty, revision, survival, complication, function, pain, outcome, humerus, and glenoid (Figure 1). The Pubmed/Medline, Cochrane Clinical Trial Register, and Embase databases were searched for studies performed from 1990 to October 2011. All resulting publications were additionally manually checked to verify that they met the inclusion criteria. A review of the title abstract was performed in order to identify the relevant articles for full review. The above-mentioned criteria were then applied to the full text to determine articles for inclusion in this review. The reviews were done independently by MB and PG with disagreements handled through a group discussion. Disagreements that remained unresolved were handled through arbitration by a third author, MS Studies were not blinded for author, affiliation, and source.





Shoulder arthroplasty OR shoulder arthroplasties OR total shoulder replacement OR total shoulder arthroplasty OR humeral head replacement OR shoulder hemiarthroplasty OR shoulder hemiarthroplasties OR shoulder hemi-arthroplasties OR shoulder hemi-arthroplasty) AND (osteoarthritis OR arthritis)

**Figure 1** | Pubmed/Medline search strategy

**Data Extraction**

Once the initial review of the articles was complete, several data points were collected from the articles meeting the inclusion criteria: number of patients, gender, age, type of arthroplasty, follow-up, function, pain, revision rate, and general complications. A further review was done to reassess the data and determine if any of the articles met the exclusion criteria. Several studies had differing reasons for inclusion which resulted in different outcome measures. This prohibited a proper meta-analysis and comparison. Several factors were compared between the different treatments, including pain scores, functional outcome, revision rate, complication rate and range of motion.

**Methodological quality**

In order to determine methodological quality, the studies were accessed and assigned a level of evidence defined by the Centre for Evidence Based Medicine (http://www.cebm.net). In general, the following levels are defined in studies on therapy or prognosis: Level I is attributed to well-designed and performed randomized controlled trials; Level II is attributed to cohort studies; Level III is attributed to case control studies; Level IV is attributed to case series; and Level V is attributed to expert opinion articles (Table 1). These evidence levels were assigned by the 2 authors, MB and PG, with disagreement resolved through consensus. Recommendations for clinical practice were formulated based on the level assigned, and a grade was added. Grade A meant treatment options were supported by strong evidence (consistent with level I or II studies); Grade B meant treatment options were supported by fair evidence (consistent with level III or IV studies); Grade C meant treatment options were supported by either conflicting or poor quality evidence (level IV studies); and Grade D was used when insufficient evidence existed to make a recommendation (Table 2).

**Table 1** | Level of evidence

| | |
|---|---|
| Level I: | high quality prospective randomized clinical trial |
| Level II: | prospective comparative study |
| Level III: | retrospective case control study |
| Level IV: | case series |
| Level V: | expert opinion |

**Table 2 |** Grades of Recommendation (given to various treatment options based on the Level of Evidence supporting that treatment)

| | |
|---|---|
| Grade A | treatment options are supported by strong evidence (consistent with level I or II studies) |
| Grade B | treatment options are supported by fair evidence (consistent with level III or IV studies) |
| Grade C | treatment options are supported by either conflicting or poor-quality evidence (level IV studies) |
| Grade D | when insufficient evidence exists to make a recommendation |

## RESULTS

The initial search resulted in 832 hits. After applying the in- and exclusion criteria we identified 18 studies that report on the results of total shoulder arthroplasty,[6–17] or hemi shoulder arthroplasty (Figure 2).[14,18–22]

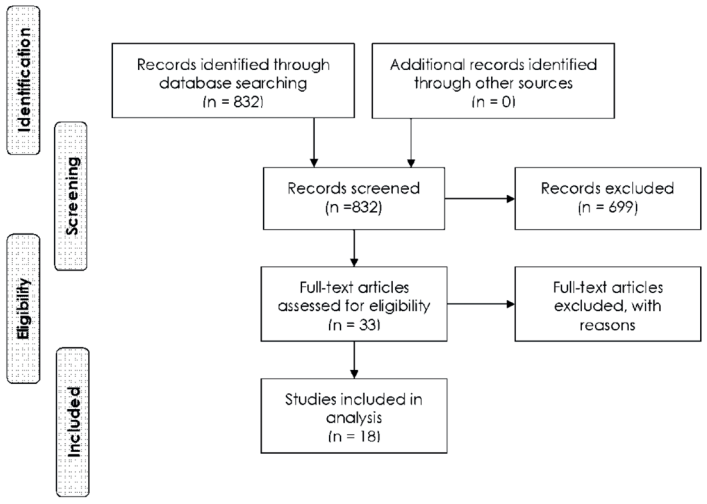


**Figure 2 |** Flowchart summarizing the selection procedure for the articles eligible for systematic reviewing

The included studies are summarized in table 3. All studies were case series (level of evidence IV). The first study was published in 1995[19] and the most recent in 2011.[8,18] Eleven studies were from the US and 7 were from Europe. The smallest study was from Betts et al.[6] and the largest from Walch et al.[8]. The search included a total of 1958 patients (hemi shoulder arthroplasty: 307 and total shoulder arthroplasty: 1642) with 2111 shoulders (hemi shoulder arthroplasty: 319 + total shoulder arthroplasty: 1783) in both groups. The mean age in the hemi shoulder arthroplasty group was 55 years and 64 years in the total shoulder arthroplasty group. The male/female ration in the hemi shoulder





arthroplasty group was 1/1.1 and 1/2.5 in the total shoulder arthroplasty group. The shoulder pathologies for which the arthroplasty was performed are summarized in table 4. Because many studies did report a mean for continuous outcome measures, but without a SD, we calculated a weighted mean, but no statistical comparison was possible due to the lack of reporting SD's. Pooling of functional outcome data and pain scores was not possible subsequent to a lack of data.

### Revisions

Revision rate was reported by all but one study.[13] The revision rate for any reason in the hemi shoulder arthroplasty group (13%) was higher than in the total shoulder arthroplasty group (7%) ($p$ <0.001). No difference was made between revisions of the humeral and of the glenoid component. This rate could be calculated over 1884 (328 hemi shoulder arthroplasty + 1556 total shoulder arthroplasty) shoulders. Five revisions in the hemi shoulder arthroplasty group were performed for reasons other than painful glenoid or glenoid arthritis. Almost all of the patients with glenoid erosion were revised to a total shoulder arthroplasty.

### Complications

Complication rate was reported by al studies, although the exact type of complication was not mentioned in all articles. There was a trend of a higher complication rate (of any kind) in the total shoulder arthroplasty group (12%) when compared to the hemi shoulder arthroplasty group (8%) ($p$=0.065). This rate could be calculated over 1746 (328 hemi shoulder arthroplasty + 1418 total shoulder arthroplasty) shoulders.

### Range of movement

Improvement in range of movement was reported by all studies in the hemi shoulder arthroplasty group[14,18–22] and by 10 studies in the total shoulder arthroplasty group.[8–17] The weighted mean improvement in anteflexion, exorotation and abduction were respectively 33°, 15° and 31° in the hemi shoulder arthroplasty group. The weighted mean improvement in anteflexion, exorotation and abduction were respectively 56°, 21° and 48° in the total shoulder arthroplasty group. A statistical comparison was not possible due to the missing SD's reported in the included articles.

### Pain decrease

Four studies concerning total shoulder arthroplasty[6,11,14,16] and four[14,18,21,22] reporting on the decrease in pain after hemi shoulder arthroplasty were included in this analysis. Mean decrease in pain scores was 4.2 in the hemi shoulder arthroplasty group and 5.5 in the total shoulder arthroplasty group. Scores reported on a 5-point scale were calculated to a 10-point scale and pain scores from constant scores were not included in this analysis.

**Table 3** | Characteristics of included studies

| Author | Year | Country | n = shoulder (patients) | Type of prosthesis |
|---|---|---|---|---|
| **Hemi shoulder arthroplasty** | | | | |
| Bartelt et al.[18] | 2011 | USA | 20 | 13 Cofield, 5 Bio-Modular, 1 Neer, 1 Howmedica (cemented) |
| Krishnan et al.[20] | 2007 | USA | 36 (34) | 10 cemented and 26 cementless |
| Rispoli et al.[21] | 2006 | USA | 51 | 29 Neer II, 18 Cofield, 4 bio-modular |
| Sperling et al.[14] | 2007 | USA | 95 | Only totals for hemi shoulder arthroplasty and total shoulder arthroplasty were reported |
| Cofield et al.[19] | 1995 | USA | 67 (64) | uncemented humeral head replacement and 1 cemented |
| Wirth et al.[22] | 2006 | USA | 50 (43) | DePuy Global Shoulder modular prosthesis |
| **Total shoulder arthroplasty** | | | | |
| Betts et al.[6] | 2009 | Scotland | 14 (12) | Neer II, glenoid cemented, humerus uncemented |
| Deshmukh et al.[7] | 2005 | USA | 320 (267) | Neer II (287), Kirschner II (16), Gristina (13), Dana (2), Cofield (1), Michael-Reese (1) |
| Kasten et al.[10] | 2010 | Germany | 96 (88) | Tornier cemented keeled glenoid and 93 cemented Tornier stem, 3 uncemented Tornier |
| Khan et al.[11] | 2009 | UK | 25 | Aequalis |
| Raiss et al.[12] | 2008 | Germany | 21 | Aequalis |
| Rosenberg et al.[13] | 2007 | UK | 90 | uncemented Biomodular |
| Rosenberg et al.[13] | 2007 | UK | 103 | initial Nottingham uncemented |
| Rosenberg et al.[13] | 2007 | UK | 34 | recent Nottingham |
| Sperling et al.[14] | 2007 | USA | 187 | Only totals for hemi shoulder arthroplasty and total shoulder arthroplasty were reported |
| Tammachote et al.[15] | 2009 | USA | 100 (94) | Neer II, metal backed glenoid or PE |
| Walch et al.[8] | 2011 | Europe | 333 (295) | Aequalis, cemented PE convex-back keeled glenoid component |
| Torchia et al.[17] | 1997 | USA | 114 (101) | Neer press-fit or cemented humeral component, glenoid cemented PE |
| Young et al.[9] | 2011 | France | 263 (247) | Aequalis, cemented 3rd gen, keeled flat back PE |
| Taunton et al.[16] | 2008 | USA | 83 (78) | uncemented humeral and metal backed glenoid component |





**Table 4** | Results

| Type arthroplasty | HSA | TSA |
|---|---|---|
| Articles | 6 | 12 |
| Patients | 307 | 1642 |
| Shoulders | 319 | 1783 |
| Mean age | 55 | 64 |
| Male / female | 1/1.1 | 1/2.5 |
| OA/AVN/RA/other or unknown * | 178/6/127/17 | 950/7/303/458 |
| Revisions (for any reason) ** | 42/328=13% | 109/1556=7%*** |
| Complications | 26/328=8% | 168/1418=12%**** |
| Improvement in anteflexion | 33° | 56° |
| Improvement in exorotation | 15° | 21° |
| Improvement in abduction | 31° | 48° |
| Pain decrease | 4.2 | 5.5 |

HA = hemi shoulder arthroplasty
TSA = total shoulder arthroplasty
* This ratio does not correspond with total included patients at baseline
**Not all articles report revision rate
*** Chi-square, $p<0.001$
**** Chi-square, $p=0.065$

## DISCUSSION

The objective of this systematic review was to collect evidence concerning the long-term outcome of hemi shoulder arthroplasty and total shoulder arthroplasty to compare the results of these two treatments. After including 18 articles we concluded that total shoulder arthroplasty results in less revision surgery but has a trend to result in more complications. This is the first review with a strict methodology based on a large sample size which compares the long term (mean follow-up was at least 7 years) outcome of hemi shoulder arthroplasty and total shoulder arthroplasty for osteoarthritis of the shoulder.

The conclusions of this review should be interpreted with caution due to the fact that only level 4 studies could be included; there are no randomized or controlled trials with a long term (> 7 years) follow-up.

There are differences in some baseline characteristics and duration of follow-up. An association between the underlying diagnosis and the risk of revision of a shoulder arthroplasty has been described.[23] There is also an association between gender and revision rates, with male gender having twice the risk of revision of shoulder arthroplasties.[24-26] Based on a series of patients with a total shoulder arthroplasty, Henn et al.[27] concluded

that younger patients have greater expectations of a total shoulder arthroplasty, which may have implications for outcome and implant longevity. Farng et al.[28] concluded that implant survival is largely driven by factors associated with increased activity and age. We did not evaluate BMI and comorbidities because these were not associated with an increased risk of revision.[26]

There are only 18 publications which report on the long-term results of total or hemi shoulder arthroplasty. This low number is astonishing when considering the increasing number of shoulder arthroplasties performed annually in the western world.[29] And that the first arthroplasty was performed in 1893, with the shoulder arthroplasty being popularized already in the fifties by Neer.[2,3]

Comparison of the continuous outcome measures (pain, range of movement) was not possible due to lack of reporting of SD's in the original articles. The differences between anteflexion, exorotation and abduction in favor of the total shoulder arthroplasty were respectively 23°, 6°, and 17°.

Many studies are performed by high volume and designer groups so the results will probably be better than in lower volume centers. Hammond et al.[30] conclude that patients of surgeons with higher average annual caseloads of total shoulder arthroplasty and hemi shoulder arthroplasty have decreased complication rates and hospital lengths of stay compared with the patients of surgeons who perform fewer of these procedures.

We included articles from 1990 (with minimal follow-up of 7 years) so all arthroplasties performed from 1983 and later will be included in our analysis. The design of the arthroplasties and especially of the glenoid components has improved in these years. Strauss et al.[29] reviewed the literature and concluded that no conclusions can be made with respect to an optimal design of the glenoid. Biomechanical studies and early clinical follow up found that a cemented pegged and curved glenoid implant in the correct version with a radial mismatch of between 4-7 mm is most likely to be a prolonged stable fixation.[29]

Current review and other recent other systematic reviews[4,23,31] conclude that total shoulder arthroplasty has some advantages over hemi shoulder arthroplasty. Despite these conclusions many hemi shoulder arthroplasties are still implanted these days.[32] We propose careful consideration of both options, but analysis of existing evidence shows a preference towards total shoulder arthroplasty. Some surgeons state that a hemi shoulder arthroplasty can always be converted to a total shoulder arthroplasty in cases of symptomatic glenoid erosion. Carroll et al.[5] however concluded that the results of a revision of a hemi shoulder arthroplasty to a total shoulder arthroplasty are inferior to those of primary total shoulder arthroplasty and this operation should be considered as a salvage procedure.





For future research projects it would be interesting to report the long-term results of previous reported RCT's or to initiate a large multicenter trial. Ideal long-term follow-up multicenter trial would have a sample size calculation, uses computer randomization, will focus on patient related outcome measures and will have blinding of the patients and outcome assessors.

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# CHAPTER 5

## Short term results of the uncemented Global CAP resurfacing shoulder prosthesis

**Introduction**
Cementless humeral resurfacing arthroplasty is a bone conserving arthroplasty option for patients with gleno-humeral arthritis. We report the two-year results of the Global CAP uncemented resurfacing shoulder prosthesis (DePuy/Synthes, Warsaw, IN, USA).

**Methods**
We analyzed prospectively collected clinical data of 48 patients with primary gleno-humeral osteoarthritis, who underwent a cementless humeral resurfacing arthroplasty between 2007 and 2009. The Constant Score, visual analogue pain scale, Dutch Simple Shoulder Test, SF-12 scores and physical examination were assessed both pre-operatively and two years post-operatively. All surgical complications and adverse experiences were documented. Radiographs were evaluated for implant loosening and (sub)luxation.

**Results**
We included 36 female and 12 male patients with a mean age of 69 years old (range 56-86 years). The Constant Score (corrected for gender and age), shoulder function, visual analogue pain scale, Dutch Simple Shoulder Test and physical SF-12 scores improved significantly ($p < 0.05$) from preoperatively to two years postoperatively. The mean mental SF-12 scores remained the same preoperatively and two years postoperatively. Complications included one traumatic lesser tuberosity avulsion fracture, one intra-articular loose body due a fractured osteophyte, and one case of a subscapularis tendon rupture. None of the patients required revision surgery for any reason.

**Conclusions**
Cementless humeral resurfacing arthroplasty is a viable treatment option for primary gleno-humeral arthritis. Two-year results indicate that the desired function and pain relief was achieved with an acceptable complication rate in this case series. Longer follow-up studies will be required to establish whether this outcome will endure.

**Key words: Shoulder, osteoarthritis, cementless, resurfacing, arthroplasty, humerus, glenoid**
**Level of evidence: Therapeutic Level IV**





## INTRODUCTION

Shoulder arthroplasty in the modern era was first performed in 1951 by Neer.[1] The Copeland cementless surface replacement arthroplasty, a surface replacement designed specifically for use in arthritic shoulders, was introduced in the early 1980's.[2,3] Since then shoulder resurfacing arthroplasty has gained popularity as an alternative to conventional shoulder arthroplasty for the treatment of gleno-humeral arthritis.

Shoulder arthroplasty has proven to be a reliable procedure to relieve pain and improve function in patients with osteoarthritis.[4–11] Results of total shoulder arthroplasty have been shown to last an average of at least ten years. Glenoid component loosening in up to 39% remains the most frequent indication for revision surgery.[5,12–17] The optimal surgical treatment for gleno-humeral osteoarthritis with intact rotator cuff is still under debate. To avoid this risk of glenoid loosening after long term follow-up at the cost of the risk of glenoid erosion, a shoulder hemi-arthroplasty can be performed. In a recent report from the Danish shoulder arthroplasty registry in which the clinical outcome and short term survival of 2137 primary arthroplasties were evaluated, 28% were resurfacing hemiarthroplasties.[18] In contrast to conventional shoulder hemi-arthroplasty, shoulder resurfacing replaces only the proximal part of the humeral head, with a metal-alloy cap fitted over the remainder of the humeral head.

The data reported by Copeland and Levy with the Mark 3 prosthesis are comparable in terms of pain relief and range of motion to those obtained with stemmed implants,[9,19] with the assumed advantage of restoration of the anatomy and preservation of bone stock.

This prospective study reports our 2-year results of the Global Conservative Anatomic Prosthesis (CAP) uncemented resurfacing shoulder prosthesis (DePuy/Synthes, Warsaw, IN, USA).

## PATIENTS AND METHODS

All patients above 18 years of age, with failed conservative treatment (physiotherapy, intra-articular injections with corticosteroids or arthroscopic debridement), a clinically sufficient rotator cuff, adequate bone stock of the proximal humerus (>60% estimated on radiographs), glenoid centric (assessed on plain radiographs) type A1, A2 or B1 (Walch classification[20], see Figure 1) and operated between January 2007 and December 2009 were included in this study. All shoulders were assessed with Magnetic Resonance Imaging (MRI). Rotator cuff tears larger than 1 cm were excluded.

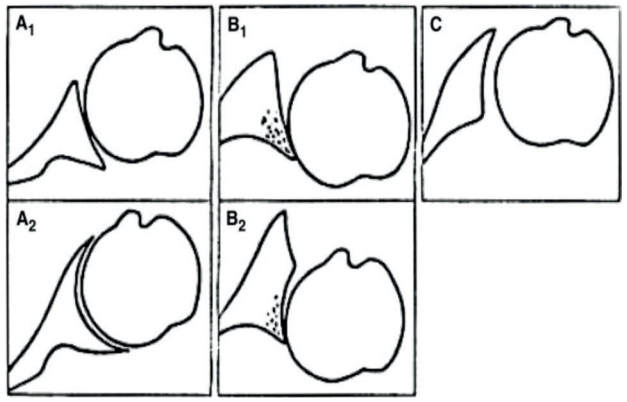


**Figure 1** | Walch Classification[20]

**Intervention**

All operations were performed by the senior authors in two separate clinics, Alrijne Hospital (Leiderdorp, the Netherlands) en Spaarne Hospital (Hoofddorp, the Netherlands). All patients were treated with a cementless humeral resurfacing prosthesis Global CAP (DePuy/Synthes, Warsaw, IN, USA) implant. A first-generation cephalosporin was administered intravenously 30 minutes prior the incision. General anesthesia in conjunction with a preoperative interscalene block was used. The patient was placed in beach chair position with the arm draped free.

A delto-pectoral approach was used, with preservation of the pectoralis major tendon and the circumflex humeral vessels. The subscapularis tendon was divided about one centimeter medial to its insertion, in line with the anatomic neck. Aggressive soft tissue release of the subscapularis tendon and the anterior and inferior aspects of the capsule were performed when necessary to improve tendon excursion. This included a 360-degree release of the subscapularis tendon. The anterior aspect of the capsule was left attached to the subscapularis to enhance suture fixation of the tendon back to its original fixation on the lesser tuberosity. Tenodesis or tenotomy of the long head of the biceps was not performed routinely. This was only performed when tendinopathy was diagnosed intra-operatively. Patients with a symptomatic acromion-clavicular joint arthritis had a lateral clavicle resection. The appropriately sized implant was placed with respect for anatomic (retro) version and inclination. The implant is available in five head sizes, and each size has two heights to match the anatomy of the shoulder. The glenoid was treated with a chondropick to enhance micro fracturing of the eroded articular surface. No glenoid implants were used, but micro-fracturing of the eroded glenoid was performed to stimulate the growth of fibrous cartilage





A standard sling was used for up to six weeks. Patients were stimulated to perform front-to-back pendulum exercises and were allowed to start with forward elevation and abduction (passively and actively assisted) direct post-operatively. External rotation was allowed within the maximum degree of that obtained during surgery after subscapularis tendon repair to minimize tension in the reattached tendon.

**Clinical and radiological assessment**

Baseline assessment, including demographic details, diagnosis (primary arthritis), radiographs and MRI was administered the outpatient clinic by one of the senior authors. Two physician's assistants (PS and MC), who did not participate in the peri-operative care and did not see the post-operative x-ray's, assessed the visual analogue pain scale (VAS[21,22]), assessed the patient's activities and daily living (SF-12[23–25]), the Dutch version of the Simple Shoulder Test (DSST[26]), and the range of motion and strength to derive a Constant score.[22,27–31]

The VAS was assessed by asking the amount of pain on a scale of 1-10, 1 no pain and 10 the most pain ever experienced. The Constant score is a scoring system which consists of four variables that are used to assess the function of the shoulder. The subject variables are pain and activities of daily living (sleep, work, recreation/ sport) which give a total of 35 points. The objective variables are range of motion and strength which give a total of 65 points. Maximum points scored on the Constant score are 100.

Antero-posterior views, and axillary views were taken postoperatively, at 3 months and every year postoperatively. An assessment of radiolucent lines and their evolution over time was made. Definite loosening was defined as a change in position of a component over time. Probable loosening was defined as unchanged position but progressive radiolucencies of > 2 milimeter wide of the component.[9] The changes of the glenoid were assessed by measuring the distance of the implant in relation to the coracoid. The distance between the lateral border of the coracoid and the medial side of the implant was measured on the first postoperative radiograph and compared with the distance on the radiographs 2 years post-operatively. This space might decrease due to degeneration and might increase in time due to the formation of fibrosis, because of the micro fracturing. Assessments were made for dislocation of the prosthesis and migration of the prosthesis outside the center of the glenoid.

**Statistics**

Preoperative and postoperative scores, Constant, shoulder function (internal, external rotation and strength), visual analogue pain scale, SF-12 and Dutch Simple Shoulder Test, were analyzed with the use of a Wilcoxon signed ranks test. We used this test because the sample data are not normally distributed, and they cannot be transformed to a normal

distribution by means of a logarithmic transformation. The preoperative and postoperative elevation and abduction results were analyzed with the use of paired t-test. A p value of < 0.05 was considered significant. We used the software of SPSS (SPSS Inc., Chicago, IL, USA) version 20.0.

## RESULTS

Forty-eight Global CAP resurfacing prosthesis humeral head surface replacement arthroplasty operations were performed in 46 patients (two bilateral). We included 36 female and 12 male patients with a mean age of 69 years old (range 56-86 years). One patient was lost to follow up because she was unable to attend at the follow up appointments. The length of follow up was two years in all patients.

Six patients had a lateral clavicle resection. Thirty-seven patients had a tenodesis of the biceps tendon. The mean Constant score (corrected for gender and age) improved from 49 ± 18 points (range, 19 to 100) preoperatively to 79 ± 23 points (range, 17 to 100) at follow-up ($p < 0.000000$).

The mean Dutch Simple Shoulder Test (DSST) improved from 22 ± 23 points (range, 0 to 92 points) preoperatively to 66 points ± 29 points (range, 29 to 100 points) at follow up ($p < 0.000000$).

All components of the range of motion (elevation, abduction, external and internal rotation and strength) improved significantly following resurfacing shoulder arthroplasty at follow up (table 1 and 2).

The pain score, according to the visual analogue scale (VAS), decreased from 65 ± 18 (range, 4 to 100) preoperatively to 35 ± 27 points (range, 0 to 90) at follow up ($p = 0.000006$).

The SF-12 was divided in mental score and physical score. The mean SF-12 mental score did not improve ($p = 0.773$). The mean SF-12 physical score improved from 35 ± 8 points (range, 22 to 50) preoperatively to 42 ± 10 points (range, 21 to 59) at follow up ($p = 0.000076$).

We found no correlation with glenoid centric type, according to Walch classification, with the clinical outcome in this short-term follow-up.[20]





**Table 1 |** Mean Range of motion

| Function | Pre-operative (SD) | Post-operative (SD) | *p* |
|---|---|---|---|
| Elevation (degree) | 99 ° (± 34) | 120 ° (± 36) | < .000042 |
| Abduction (degree) | 82 ° (± 28) | 113 ° (± 38) | < .000000 |
| External rotation (six-point scale, table 2) | 3 (± 1) | 4 (± 2) | < .000001 |
| Internal rotation (six-point scale table 2) | 3 (± 1) | 4 (± 1) | < .000050 |
| Strength (kg) | 8 kg (± 3) | 10 kg (± 3) | < .016026 |

**Table 2 |** Internal and external rotation was pre-operative and post-operative divided in a six-point scale

| External rotation |
|---|
| 1. Impossible |
| 2. Hand behind head with elbow forward |
| 3. Hand behind head with elbow behind |
| 4. Hand on head with elbow forward |
| 5. Hand on head with elbow behind |
| 6. Full elevation hand from head |

| Internal rotation |
|---|
| 1. Dorsum hand – lateral thigh |
| 2. Dorsum hand – pelvis |
| 3. Dorsum hand – lumbar-sacral |
| 4. Dorsum hand – middle (Lumbar 3) |
| 5. Dorsum hand – Thoracal 12 |
| 6. Dorsum hand – between the scapulae |

**Radiology**

Radiographs were available for 48 shoulders in 46 patients. None of these patients showed loosening around the prosthesis two years postoperatively. The distance between the lateral border of the coracoid and the medial side of the implant did not change during this short-term follow-up.

**Complications**

For this study we only report on implant and operation complications. Complications such as bladder infections and hospital acquired pneumonia were not reported for this study. There were no major peri-operative complications such as neurovascular injury, infection, humeral fracture or gross mal position of the implant. One patient suffered

from a subscapularis tendon rupture shortly after the operation. Two months after the first operation the tendon was re-attached during a second operation. One patient suffered from a loose body caused by a fractured osteophyte, from the posterior rim of the glenoid eight months after the first operation. The posterior rim of the glenoid was trimmed via a posterior joint approach and the loose body removed during a second operation. One patient suffered a lesser tuberosity avulsion fracture after intensive fitness exercise. The lesser tuberosity avulsion fracture was re-attached 15 months after the primary surgery.

**Revision surgery**
No revision surgery was necessary within two years follow-up.

## DISCUSSION

The most important finding of this study is that the outcome of the Global CAP shoulder resurfacing arthroplasty is good after short term follow-up. We report the results of cementless humeral resurfacing arthroplasty in 48 shoulders, which were placed between 2007 and 2009 and were followed prospectively for two years. We found substantial increase in patient satisfaction, a perceived return of function, and decreased pain with neither loosening nor radiolucent lines around the prosthesis. Our results are similar to the results reported with the Mark III prosthesis reported by Copeland and others.[19,32,33] Our early results are slightly better compared to other reported results with stemmed implants.[34–38] We tried to minimize selection bias in this study by only including patients with an intact cuff (< 1cm. rotator cuff tear) and gleno-humeral osteoarthritis. Measurement bias was minimized by having assessors who were not involved with the original operation. To our knowledge this is the first article which reports on the outcome with the Global CAP resurfacing shoulder prosthesis.

Although we realize that total shoulder arthroplasty is the golden standard for treatment of gleno-humeral osteoarthritis of the shoulder today, we think there is a place for resurfacing hemi prosthesis because of the unknown survival of the glenoid in total shoulder arthroplasty after long term follow-up. Glenoid loosening after unconstrained total shoulder arthroplasties has been reported to be between 0% and 20% at medium term follow-up and 39 % mid-term to long term follow-up,[5,12–17,40] with more than 5% rate of revision surgery at long term follow-up. Several factors such as rotator cuff tears, component malposition and glenoid instability can contribute to glenoid failure.[17,40,41]

Some advantages of hydroxyapatite coated surface replacement of the shoulder when compared to stemmed implants are: less bone resection, primary press-fit cementless fixation with bone in-growth into a hydroxyapatite coating, easier replication of the native





anatomy, reduced risk of intraoperative humeral shaft fracture and stem perforation, preservation of humeral bone stock, and easier revision surgery.[9,42,43]

Although there were some complications in our series, all have been reported in association with the standard surgical technique for any shoulder replacement and were not specific to this humeral resurfacing shoulder implant design. Although we report a short follow up, the complication rate with this implant in our series was equal with stemmed implants.[9,12] No revision surgery was performed and required, which is equal compared with low revision rates for stemmed prosthesis after short term follow-up.[9,44,45] We agree with Cofield et al.[41] that revision rate alone is not a synonym for a failed implant based on the subjective assessment of the surgeon. Failures should also be considered when patients reported pain is equal to or worse than their pre-operative situation.[46]

Glenoid changes after resurfacing prosthesis were assessed by measuring the joint space and determination of possible bone loss of the glenoid. This space might increase by the formation of fibrosis, because of the micro fracturing. Glenoid erosion in hemiarthroplasty is one of the major reasons of revision to total shoulder arthroplasty.[47–49] In our series we did not observe glenoid erosion, probably because of the short term follow up. Nevertheless, radiological glenoid deterioration is not correlated with pain or deterioration of clinical results.[34]

Periprosthetic fractures were not seen in our series. This is possibly because of the absence of stress shielding with resurfacing implants.[50–52] Stemmed prostheses create a stress riser effect at the tip of the stem in the midshaft of the humerus.[9] The absence of a stem means that there is no stress riser in the midshaft in the humerus. This is especially important with elderly patients, who have a greater tendency to fall. This situation can cause difficulties in the event of a humeral shaft fracture.[33,53–55] Periprosthetic fractures, which have a reported prevalence of 3%, account for approximately 20% of all complications associated with total shoulder arthroplasty during surgery and postoperatively. This can be avoided using this prosthesis.[33,53–57]

This study had some limitations. Although the patients were enrolled prospectively in a computerized database, there was no control group treated with a stemmed implant. Besides, the population reported is small but nonetheless comparable to other published studies of shoulder resurfacing.[9,13,33]

Nevertheless, small case numbers suggest caution in interpreting the incidence of uncommon complications. Performing a “new” type of surgery on a large scale would not be considered wise because of the recent lessons we have learned from for example the metal-on metal discussion in hip surgery. Long-term follow up is critical to determine

if the patients treated with this cementless resurfacing implant of end-stage osteoarthritis of the shoulder is viable. Despite of the promising two year follow up, with good pain relief and functional outcomes, we still have concerns over the longevity of this cementless resurfacing implant. We still have concern regarding progressive glenoid erosion and loosening of the component. We conclude that the short-term follow-up of the uncemented global CAP resurfacing prosthesis is encouraging.

We report the clinical and radiologic outcome for the uncemented global CAP resurfacing prosthesis for the treatment of primary osteoarthritis in patients with an intact rotator cuff at 2 years of follow-up. We conclude that the short-term follow-up of the uncemented global CAP resurfacing prosthesis is encouraging and comparable with modular stemmed hemiarthroplasty and the Mark III resurfacing prosthesis. We report no patients requiring revision surgery, no aseptic loosening, no periprosthetic fractures, and no glenoid erosion at short term follow-up. Long term follow-up is necessary to evaluate if these good results will endure.





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# CHAPTER 6

## Outcome and revision rate of uncemented gleno-humeral resurfacing (CAP) after 5-8 years

**Introduction**
Resurfacing of the gleno-humeral joint for patients with gleno-humeral arthritis has gained popularity since the first introduction. We report the mid- term results of the Global CAP uncemented resurfacing shoulder prosthesis (DePuy/Synthes, Warsaw, IN, USA).

**Methods**
From January 2007 until December 2009, 48 humeral cementless resurfacing prosthesis in 46 patients were performed. All patients were diagnosed with primary gleno-humeral osteoarthritis.

Patients were contacted for review, the Constant Score, visual analogue pain scale, Dutch Simple Shoulder Test, SF-12 scores and physical examination were assessed both pre-operatively and yearly postoperatively.

Complications and revision surgery were documented. Radiographs were evaluated for component size, offset, inclination, height, loosening and subluxation.

**Results**
Forty-six patients (12 males) with a mean age of 72 years old (range 59-89) were included. At a mean 6.4-year follow up (range 5-8), the Constant Score, visual analogue pain scale and the Dutch Simple Shoulder Test scores improved significantly ($p < 0.05$) from baseline.

Three patients were lost to follow up. One patient died, and two patients were not able to attend the follow-up appointments, due to other health-related issues. Eleven patients (23%) had a revision operation.

**Conclusions**
The most important findings of this study of the Global CAP shoulder resurfacing arthroplasty were an increase of range of motion, a reduction of pain complaints, but a concerning high rate of revision after mid-term follow-up.

**Key words: Shoulder, osteoarthritis, cementless, resurfacing, arthroplasty, humerus, glenoid**
**Level of evidence: Therapeutic Level IV**





## INTRODUCTION

Shoulder pathology is a common source of pain and disability affecting patients with a prevalence of 17%.[1] Shoulder replacement can provide satisfactory results through restoration of shoulder congruity that improves range of motion and decreases pain sensation.[2]

The optimal surgical treatment for gleno-humeral osteoarthritis with an intact rotator cuff is still under debate.[3–5] Good outcomes of total shoulder arthroplasty have been shown to last an average of at least ten years. Glenoid component loosening in up to 39% remains the most frequent indication for revision surgery.[6–12]

Resurfacing shoulder replacement of the proximal humerus is a viable alternative to conventional shoulder replacement in order to restore shoulder function in patients with osteoarthritis. The first surface replacement was designed by Copeland and was performed only in young and active patients in the mid-1980's.[13,14] After this initial period, surface replacement has been popularized and increasingly used in elderly patients and has also been described as a viable treatment option for many indications, such as osteoarthritis, avascular necrosis, rheumatoid arthritis, rotator cuff tear and post-traumatic arthritis.[6,15–22] Some of the advantages are the preservation of the humeral bone stock, which eases the conversion to a stemmed total or reversed shoulder prosthesis if a revision becomes necessary.[13,19,22,23] Other potential benefits include the shorter operation time, less risk of periprosthetic fractures and less per-operative blood loss. Studies report satisfactory results at short and mid-term follow-up.[18,23–27] The purpose of this study is to asses mid-term patient reported outcome measures, revision rate and radiographs of the Global Conservative Anatomic Prosthesis (CAP) uncemented resurfacing shoulder prosthesis (DePuy/Synthes, Warsaw, IN, USA). This study has been performed as an extension to the ongoing follow up study, short term results published in 2014.[26] The authors expect satisfactory patient reported outcome results and a revision rate lower or equal to literature.

## PATIENTS AND METHODS

This study was performed as an extension to the ongoing follow up study in patients treated with uncemented Global CAP resurfacing shoulder prosthesis, short term results published in 2014.[26] The study was approved by the Northern Dutch Review board (M1330348), and all patients had signed informed consent.

**Patient population**
Patients older than 18 years, with an intact and sufficient rotator cuff, adequate bone stock of the proximal humerus (>60% estimated on radiographs and Magnetic Resonance

Imaging (MRI)), with failed conservative treatment (physiotherapy, intra-articular injections with corticosteroids or arthroscopic debridement), glenoid centric type A1, A2 or B1 according of Walch classification assessed on MRI,[28] and treated with a resurfacing prosthesis between January 2007 until December 2009 were included in this study. In all patients' preoperative radiographs and MRI scans were assessed. To minimize selection bias only patients with an intact cuff and gleno-humeral osteoarthritis were included.

**Intervention**

The senior authors performed all operations in two clinics, Alrijne Hospital (Leiderdorp, the Netherlands) and Spaarne Hospital (Hoofddorp, the Netherlands). All shoulders were treated with a cementless humeral resurfacing implant (Global CAP, DePuy/ Synthes, Warsaw, IN, USA). Thirty minutes before the first incision a first-generation cephalosporin was administered intravenously. Preoperative interscalene block was used in combination with general anesthesia. Patients were placed in the beach chair position with their arm draped freely. In all shoulders a delto-pectoral approach was used. Care was taken with preservation of the tendon of the pectoralis major and the vessels of the humeral circumflex. Soft tissue releases of the tendon of the subscapularis and the anterior and posterior aspects of the capsule were performed to improve range of motion if necessary. This could also include a 360-degree release of the tendon of the subscapularis. The tendon of the subscapular muscle was cut close to its insertion at the minor tubercle, leaving a small part of the tendon attached. The reattachment could be done safely and strongly with multiple stiches. The construction was tested by external rotation of the arm before closure. Tenodesis or tenotomy of the long head of the biceps was only performed when tendinopathy was diagnosed intraoperatively by the senior authors. A lateral clavicle resection was performed in patients with a symptomatic acromion-clavicular joint diagnosed by the senior authors during physical examination prior the operation.

With respect for anatomic (retro) version and inclination the appropriate size implant was placed. Only the affected glenoid was treated with a chondropick to enhance micro fracturing of the eroded articular surface to stimulate the growth of fibrous tissue. No glenoid implants were used.

**Rehabilitation**

Postoperative patients used a standard sling for up to six weeks. Immediately postoperative patients were stimulated to start with forward elevation and abduction and to perform front-to-back pendulum exercises. To minimize the tension in the re-attached subscapularis tendon, external rotation was allowed within the maximum degree of that obtained during surgery. Patients followed a routine rehabilitation protocol after the resurfacing shoulder arthroplasty. This protocol consisted of supervised physiotherapy for three to six months and self exercises.





**Clinical and radiological assessment**

The senior authors did the baseline assessments in all patients, including demographic details, diagnosed primary osteoarthritis, radiographs and MRI in the outpatient clinic. Two physician's assistants (PS and MC), assessed the pain score according to the visual analog pain scale (VAS[29,30]), the Dutch version of the Simple Shoulder Test (DSST[31]), the range of motion and strength to derive a Constant score,[30,32–37] and the patient's activities and daily living (SF-12[38–40]). The physician assistants did not participate in the perioperative care and did not see the postoperative radiographs.

The first day postoperative and at 3 months and annually radiographs antero-posterior and axillary were taken. Signs of loosening, such as radiolucent lines, and their evolution over time were made. Definite loosening was defined as a change in position of the implant over time. Unchanged position but progressive radiolucencies of > 2 milimeter wide from the component were defined as probably loosening.[19] Analyses were made for luxation of the prosthesis and migration of the prosthesis outside the center of the glenoid and the length of gleno-humeral offset was assessed to measure overstuffing.[41]

**Statistics**

For analyzing the preoperative and postoperative scores we used of a Wilcoxon signed ranks test. The study data were not normally distributed, and they cannot be transformed to a normal distribution by means of a logarithmic transformation. A $p$ value of $<0.05$ was considered significant. The Constant score increased and the pain (VAS) score decreased after two year follow up. This can be explained by the patients with the poor scores had a revision surgery and were not included for further data analysis. To minimize selection bias only patients with an intact cuff and gleno-humeral osteoarthritis were included. Statistic software of SPSS (SPSS Inc., Chicago, IL, USA) version 20.0 was used.

## RESULTS

Forty-eight resurfacing humeral head surface replacement arthroplasty operations were performed in 46 patients. This cohort consists of 36 female and 12 male patients with a mean age of 72 years old (range 59-89 years). The short term results were described in a previous publication.[26]

Three patients (6 %) were lost to follow up. One patient died because of reasons not related to the prosthesis or operation. Two patients were not able to attend at the follow-up appointments due to health-related issues. The health issues were not related to the implant or operation. Eleven of 48 prosthesis (23%) had a revision operation.

Mean follow-up was 6.4 years (range 5.1 – 7.9). In six patients (13%) an additional lateral clavicle resection was performed. Thirty-eight patients (79%) had a biceps tenodesis and three patients (6%) had a biceps tenotomy.

The mean Constant score (corrected for gender and age[37]) improved from points 47 ± 18, preoperatively to 83 ± 22 points at follow-up ($p < 0.001$). The mean Dutch Simple Shoulder Test (DSST) improved from 20 ± 21 points, preoperatively to 67 ± 30 points at follow up ($p < 0.001$). The pain score, according to the visual analog scale (VAS), decreased from 66 ± 19, preoperatively to 29 ± 28 points at follow up ($p < 0.001$).

The SF-12, divided in a mental and a physical score, the mean SF-12 mental score improved from 49 ± 12 points preoperatively, to 51 ± 8 points at follow up ($p = 0.45$). The mean SF-12 physical score improved from 35 ± 8 points preoperatively, to 39 ± 11 points at follow up ($p = 0.05$). All pre-operative, short-term (two year) and mid-term follow up data are listed in table 1.

**Table 1** | pre- and post-operative scores, n=48

| | Pre-operative | Short-term (2yr) | Mid-term (mean 6.4yr) | *p* |
|---|---|---|---|---|
| Constant score | 39 | 65 | 72 | < 0.001 |
| Corrected Constant score | 47 | 76 | 83 | < 0.001 |
| DSST | 20 | 66 | 67 | < 0.001 |
| VAS | 66 | 35 | 29 | < 0.001 |
| SF-12 mental | 49 | 49 | 51 | 0.45 |
| SF-12 physical | 35 | 42 | 39 | 0.05 |

DSST = Dutch Simple Shoulder Test VAS = Visual Analog Scale

**Radiology**

For 36 shoulders radiographs were available. No loosening or dislocation were seen at mid-term follow-up. Some degree of superior migration, as an indication of rotator cuff failure or insufficiency, was noted in 15 of the 36 shoulders (42%). Six (17%) patients had severe migration and nine (25%) had mild superior migration, see table 2. Twenty-one (58%) shoulders showed no superior migration. Moderate-to-severe glenoid erosion was present in twelve (33%) of the shoulders at a mid-term follow-up, see table 3.





**Table 2** | Constant score and VAS in patients with Sign of rotator cuff failure

| | Sign of rotor cuff failure | Glenoid erosion | Constant score | VAS |
|---|---|---|---|---|
| 1 | Mild | Mild | 87 | 0 |
| 2 | Severe | Mild | 60 | 30 |
| 3 | Severe | Mild | 85 | 10 |
| 4 | Mild | Mild-Moderate | 29 | 80 |
| 5 | Severe | Mild | 86 | 20 |
| 6 | Mild | Moderate | 31 | 80 |
| 7 | Mild | None/Mild | 72 | 45 |
| 8 | Mild | Moderate | 39 | 20 |
| 9 | Mild | Severe | 25 | 50 |
| 10 | Severe | Mild | 78 | 35 |
| 11 | Severe | Severe | 17 | 60 |
| 12 | Mild | Mild | 90 | 0 |
| 13 | Mild | None | 78 | 25 |
| 14 | Mild | Mild/Moderate | 98 | 0 |
| 15 | Mild | None | 93 | 0 |

VAS = Visual Analog Scale

**Table 3** | Constant score and VAS in patients with glenoid erosion

| | Glenoid erosion | Sign of rotator cuff failure | Constant score | VAS |
|---|---|---|---|---|
| 1 | Moderate | None | 71 | 15 |
| 2 | Moderate/Severe | None | 72 | 20 |
| 3 | Moderate | None | 62 | 35 |
| 4 | Moderate/Severe | None | 76 | 10 |
| 5 | Moderate/Severe | None | 69 | 50 |
| 6 | Moderate | Slightly | 31 | 80 |
| 7 | Moderate | None | 66 | 53 |
| 8 | Severe | None | 25 | 50 |
| 9 | Moderate | Slightly | 39 | 20 |
| 10 | Moderate | None | 69 | 60 |
| 11 | Severe | Yes | 77 | 18 |
| 12 | Severe | Yes | 17 | 60 |

VAS = Visual Analog Scale

**Complications**

The early complications were described in the two year follow up. No revision surgery was performed or necessary within the short term follow up.[26]

**Revision surgery**

Eleven patients (23%), 5 male's and 6 females', had a revision operation to a reversed shoulder arthroplasty or total shoulder arthroplasty, see table 4. Mean time of revision 54 months (range 34 – 81 months). Mean constant score prior to revision 55 (range 28-85). Patients had a mean VAS of 59 (range 15-75) prior to revision.

All revision surgeries were a complete revision of the resurfacing prosthesis and glenoid. All cultures taken during revision surgery were negative in the all mentioned patients, except the low-grade infection. All revised patients had satisfactory results after revision surgery.

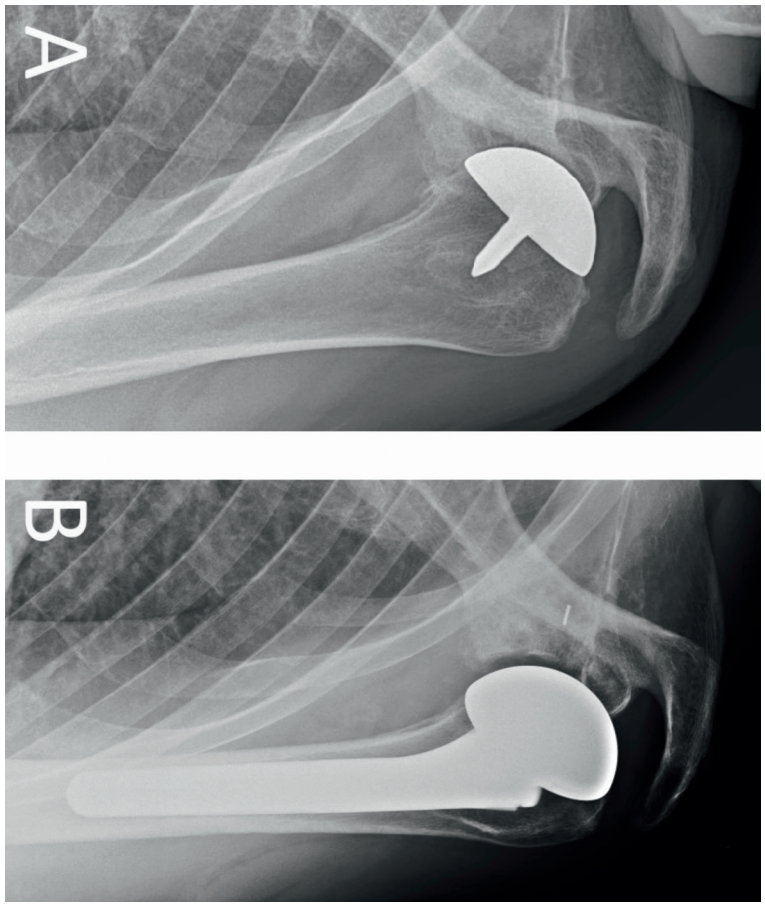


**Figure 1** | Anteroposterior radiographs of left shoulder with (A) Global CAP resurfacing prosthesis before revision and (B) total shoulder arthroplasty after revision.

**Table 4** | Revision surgery

| | Reason | Follow-up prior to revision | Constant score prior to revision | VAS prior to revision | Over-stuffing | Revised to | Comment |
|---|---|---|---|---|---|---|---|
| 1 | Low grade infection and persistent pain | 40 months | 49 | 75 | No | TSA | Cultures: Pantoea Agglomerans, Staphylococcus Epidermidis, and Propionium Acnes, no sign of loosening[42] |
| 2 | Anterior subluxation | 54 months | 49 | 70 | No | RSA | earlier surgical subscapularis tendon repair |
| 3 | Arthrofibrosis | 42 months | 44 | 45 | No | TSA | pain and poor function |
| 4 | Glenoid erosion | 73 months | 75 | 50 | No | TSA | progressive pain |
| 5 | Pain and poor function | 58 months | 56* | 29* | No | TSA | patient is emigrated, revision surgery was abroad |
| 6 | Cuffarthropathy | 51 months | 28 | 75 | No | RSA | pain and poor function, traumatic rotator cuff tear, glenoid erosion |
| 7 | Pain after 1 year | 34 months | 85 | 60 | Yes | TSA | athlete, painful glenoid |
| 8 | Glenoid erosion | 81 months | 57 | 75 | No | TSA | progressive pain |
| 9 | Severe glenoid erosion | 47 months | 80 | 15 | Yes | TSA | progressive pain, (figure 1) |
| 10 | Pain and poor function | 54 months | 53 | 60 | No | TSA | progressive pain and loss of range of motion, no glenoid erosion. |
| 11 | Severe glenoid erosion | 63 months | 29 | 60 | No | RSA | progressive pain and loss of range of motion |

TSA = Total shoulder arthroplasty
RSA = Reversed shoulder arthroplasty
VAS = Visual Analog Scale
* = Last data before patient emigrated (3 months postoperative)

## DISCUSSION

The most important finding of this study of the Global CAP shoulder resurfacing arthroplasty were an increase of range of motion, a reduction of pain complaints, but an increased revision rate after mid-term follow-up in contrast of two year follow up.[26]

Outcome assessment bias was minimized by having assessors who were not involved with the initial operation.

Today, total shoulder arthroplasty is the first choice of treatment in patients with gleno-humeral osteoartrhritis.[3,26] We believe that resurfacing hemi shoulder prostheses are still a valid treatment option. Especially in young patients because of the high risk of glenoid failure after a total shoulder arthroplasty at long term follow-up.[26] Failure of the glenoid implant of 20% and 40% have been respectively reported at mid-term and long term follow up.[26] Possible factors of glenoid component failure; insufficient rotatorcuff, insufficient positioning and instability of the glenoid component.[8,26,42,43] The Global CAP uncemented resurfacing hemi shoulder prosthesis has a hydroxyapatite coating. This coating allows bone in growth and less bone resection is necessary compared to cemented implants. Advantages of a resurfacing shoulder replacement compared to stemmed prosthesis are shorter operation time, low risk of humeral shaft fractures, preservation of anatomic head-shaft angle and center of rotation and preservation of the humeral bone stock in case of a revision.[19,26,44–46]

In line with Cofield et al.[47] we think that the revision rate alone is not sensitive to a failed procedure due to the subjective assessment by the surgeon. This assessment by the surgeon should be used in combination with pain and satisfaction assessed by the patient. Especially, patients reporting pain equal or worse than their preoperative condition should also be considered as a failure.[19,48]

A resurfacing shoulder arthroplasty is less difficult to remove than a stemmed hemi arthroplasty. In contrast to Al-Hadithy et al.[24] and Alizadehkhaiyat et al.[25], our revision operations were achieved easily with the removal of the implant. During revision, significantly reduced bone density under the implant was observed. This observation is in line with the findings of Schmidutz et al.[5] However, the metaphyseal bone was adequate enough to make short stem prosthesis possible. No step cut of the glenoid and bone grafting of the glenoid was necessary in all revised patients.[49] All patients had no complications and satisfactory results after revision surgery.[49]





Glenoid erosion after a hemi shoulder implant was assessed by the decrease of joint space and medialization of the humeral implant. Due to the micro-fracture, this space can increase as a result of the formation of fibrosis. Revision to reverse or total shoulder prosthesis due to glenoid erosion after a hemi shoulder prosthesis is one of the main reasons.[26,50–53] As in our study and in the literature, we found no relationship with radiological glenoid erosion and the outcome of the patient reported outcomes.[26,41,54,55]

In our study we did not see any periprosthetic fractures. Probably because the resurfacing prosthesis does not have a tension shield in the humeral shaft.[26,56,57] A stemmed implant does not have this advantage and can cause a stress riser at the tip in the humeral shaft.[19,26] Periprosthetic fractures, which have a reported prevalence of 3%, account for approximately 20% of all complications associated with total shoulder arthroplasty. This can be reduced by using this prosthesis.[23,26,58–62]

The conclusions of this study have to be drawn in the light of some limitations. Although the patients were enrolled prospectively in a computerized database, there was no control group treated with a stemmed implant or a resurfacing prosthesis with a glenoid component as a TSP. The reported study group was small but nonetheless comparable to other published studies of shoulder resurfacing.[11,19,22,23] Our revision rate (23%) was higher compared to the rate reported by Levy at al., they reported a revision rate of 14% in the resurfacing shoulder replacement after ten years follow up.[22] In contrast to the serie reported by Streubel et al. our patients had satisfactory results after revision surgery.[63]

In the literature, high rates of survival are described after mid-term and long-term follow up. There is certainly a discrepancy in the literature with respect to revisions. Particularly recent literature from 2013 reported a significant high percentage of revisions due to glenoid erosion and pain.[13,18,22–27,57,64,65] Relevant studies and revisions are mentioned in table 5.

**Table 5** | Studies and revision rate

| Author | Year | No. | Type of prosthesis | Follow-up | Revisions |
|---|---|---|---|---|---|
| Levy et al.[13] | 2004 | 33 | CSRA | 6.5y | 1 (3%) |
| Levy et al.[23] | 2004 | 37 | CSRA | 4.4y | 0 |
| Thomas et al.[27] | 2005 | 48 | CSRA | <2y | 1 (2%) |
| Mullett et al.[18] | 2007 | 21 | Mark III | 4.7y | 1 (5%) |
| Pritchett et a.[57] | 2011 | 33 | DePuy/Synthes* | >20y | 4 (12%) |
| Al-Hadithy et al.[24] | 2012 | 50 | CSRA | 4.2y | 1 (2%) |
| Smith et al.[64] | 2013 | 50 | CAP | 2.5y | 11 (22%) |
| Alizadehkaiyat et al.[25] | 2013 | 102 | CSRA | 4y | 21 (21%) |
| Danish Registry et al.[65] | 2014 | 688 | Unknown | 1y | 7.5% |
| Geervliet et al.[26] | 2014 | 49 | CAP | 2y | 0 |
| Levy et al.[22] | 2015 | 37 | CSRA | 14.5y | 5 (14%) |
| Geervliet | | 48 | CAP | 6.4y | 11 (23%) |

No. = number of shoulders, CSRA = Copland Surface Replacement Arthroplasty (Biomet), Mark III = Copeland Mark III humeral resurfacing hemi-arthroplasty (Biomet), CAP = Conservative Anatomic Prosthesis (DePuy/Synthes), * type of prosthesis not specified.

Sperling et al.[53] reported similar revision rate in a stemmed hemi arthroplasty of 22%. A more recent study from Bartelt et al.[66] showed similar results at short term follow up with a high rate of revision of 30% at mid-term follow up.

Nevertheless, a small sample size suggests caution in interpreting the incidence of uncommon complications. Performing a "new" type of surgery on a large scale would not be considered wise because of the recent lessons we have learned from for example, the metal-on metal discussion in hip surgery. Long-term and precise follow up is essential to determine if treatment with this cementless resurfacing implant for end-stage osteoarthritis of the shoulder is viable.

In conclusion: we report the clinical and radiologic outcome for the uncemented global CAP resurfacing prosthesis for the treatment of primary osteoarthritis in patients with an intact rotator cuff with more than 6 years of follow up. The mid-term of the global CAP resurfacing prosthesis are in line with other studies with a concerning revision rate of 23%.





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# CHAPTER 7

## Long term results of hemi shoulder arthroplasty in patients with Rheumatoid Arthritis

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**Introduction**
Rheumatoid arthritis affecting the shoulder is typically associated with rotator cuff impairment and can result in severe glenoid erosion. Following hemi-arthroplasty severe glenoid erosion has also frequently been observed. Our aim was to retrospective evaluate the outcome of a cemented hemi shoulder arthroplasty in patients with rheumatoid arthritis.

**Methods**
We performed 45 cemented hemi-arthroplasties in 36 patients with rheumatoid arthritis involving the shoulder as well as associated rotator cuff compromise between 1995 and 2008. All patients were analyzed radiological and clinically using patient reported outcomes.

**Results**
The mean visual analogue pain score (VAS) score was 3 (SD 2). The mean Constant score was 55 (SD 16). The mean of the validated Dutch version of the Disabilities of the Arm Shoulder and Hand (DASH) was 42 (SD 19).

One patient needed an arthrotomy and capsulotomy because of persistent pain and limited range of motion. Tissue cultures taken during this second operation were negative for infection. No major revision surgery was necessary within this follow up period.

**Conclusion**
Cemented hemi-arthroplasty is a viable treatment option for gleno-humeral arthritis in patients with rheumatoid arthritis. Long term results show acceptable results and low complication rate in this case series. A randomized controlled trial comparing hemi-arthroplasty, total shoulder arthroplasty and reversed shoulder arthroplasty is necessary to draw definite conclusions in this specific patient population.

**Key words: Rheumatoid arthritis, hemi-arthroplasty, cemented, osteoarthritis, glenoid**
**Level of evidence: Retrospective Case Serie Level IV**





## INTRODUCTION

When the first modern shoulder replacement was performed in the 1950s, it was solely indicated for severe shoulder fractures.[1] Since then the indications have broadened and one of the indications is inflammatory destructive arthritis because of rheumatoid arthritis.[2–14]

Destruction of the gleno-humeral joint resulting from rheumatoid arthritis is typically associated with rotator cuff deficiency due of tearing or rotator cuff tendinopathy.[15–17] Secondary to rotator cuff failure superior migration of the proximal humerus is frequently observed following either total shoulder arthroplasty or hemi shoulder arthroplasty.[18,19] This can be associated with glenoid component loosening following total shoulder arthroplasty.[6,20–22]

Before the time of reverse shoulder arthroplasty this cuff deficiency could be a reason to perform hemi-arthroplasties in patients diagnosed with rheumatoid arthritis. The possible disadvantage of cemented hemi-arthroplasties is the severe glenoid erosion which has frequently been observed.[23–26] The purpose of this retrospective study was to evaluate the long-term results of hemi shoulder arthroplasty in patients with rheumatoid arthritis and to provide recommendations for clinical practice and future research.

## MATERIALS AND METHODS

All patients above 18 years of age, diagnosed with and medically treated for rheumatoid arthritis suffering clinical and radiographic gleno-humeral arthritis, and treated with a cemented hemi-arthroplasty (Aequalis hemi shoulder, Tornier, Montbonnot, France) between 1995 and 2008 were included in this study. All operations were performed by two senior staff orthopedic surgeons experienced in shoulder surgery in one hospital, (Slotervaart Hospital, Amsterdam, The Netherlands).

A first-generation cephalosporin was administered intravenously 30 minutes prior to the initiation of surgery. Surgery was performed under general anesthesia with or without an interscalenal block. The patient was placed in beach chair position and a delto-pectoral approach was used, with preservation of the tendon of the major pectoral muscle.

Tenotomy of the subscapular tendon was performed about one centimeter medial to the insertion. The appropriately sized implant was cemented with respect for height and retroversion.

Inspection of the rotator cuff was not meticulous since the hemi shoulder arthroplasty was placed regardless of the quality of the rotator cuff. At the time when this cohort was formed a reverse shoulder arthroplasty was not routinely used.

A sling was applied for up to six weeks. Patients were stimulated to perform front-to-back pendulum exercises and were allowed to start with forward elevation and abduction (passively and actively assisted) direct post-operatively. External rotation was allowed within the maximum degree of that was obtained during surgery after subscapular tendon repair to minimize tension in the re-attached tendon.

**Clinical and radiological assessment**

The visual analogue pain scale (VAS[27]), Constant score,[28,29] the Dutch validated version of Disabilities of the arm, shoulder and hand score (DASH[30,31]) and radiographs were assessed in the outpatient clinic by PG and MS. Complications such as neurovascular injury, infection, humeral fracture or gross malposition of the implant and revisions were also assessed.

Standard radiographs antero-posterior, and axillary views were taken annually. Assessment of radiolucent lines and their evolution over time was made. Loosening was defined as a change in position of the humeral component over time. Probable loosening was defined as unchanged position but progressive radiolucencies of more than two millimeters surrounding the component or the cement layer. The changes of the glenoid were assessed by measuring the joint space comparing the distance of the implant in relation of the coracoid. Assessment was made for dislocation of the implant and migration of the prosthesis medial and cranial in relation to the glenoid.

## RESULTS

Forty-five cemented hemi shoulder arthroplasties were performed in 34 patients (11 bilateral). We included 31 female and three male patients with a mean age of 64.5 years old (range 31-84 years).

Ten patients (12 shoulders) died of conditions that were not related to the shoulder arthroplasty, one patient could not be followed-up because of a paralysis of her operated arm due to a complication of cervical hernia surgery. Clinical assessment of one patient was not realistic because of Alzheimer disease.

The mean age of the deceased population was 67.7 years old (range 59-76). The mean survival of the implant of this group was 4.1 years (range 0-11 years). None of the patients in this group had complications related to the implant or operation. The radiographs in





this group showed consistently medialisation of the arthroplasty due to glenoid erosion and cranialisation due to rotator cuff insufficiency. There were no sign of implant loosening or fractures of the glenoid or acromion. This group will not be included in the following analysis.

The mean age of the follow-up group was 60.8 years old (range 31-84). The mean follow-up was 10.0 years (range 5-17 years). The mean Visual Analogue Pain (VAS) score was 3 (SD 2). The mean Constant score was 55 (SD 16). The Constant score, corrected for gender and age, was 64 (SD 20)29. The mean Dutch version of the Disabilities of the Arm Shoulder and Hand (DASH) score in 20 patients (two invalid forms) was 42 (SD 19). See table 1.

One patient had a VAS of 9 and DASH score of 68 and a Constant score of 29 because of a recent high energy trauma. This compromised the scores and function of the shoulder implant. No complications were seen on the radiographs in this specific patient.

**Table 1 |** Demographic characteristics and results

| | | | |
|---|---|---|---|
| Patients/shoulders | 22/31 | | |
| Male/Female | 3/19 | | |
| Mean age (yr) | 60 | SD ± 15 | Range 31-83 |
| VAS score | 3 | SD ± 2 | Range 1-9 |
| Constant score | 55 | SD ± 16 | Range 29-81 |
| Constant score corrected for age and sex | 64 | SD ± 20 | Range 34-100 |
| DASH score in 20 patients | 42 | SD ± 19 | Range 4-68 |
| Complications | 1/31 | Arthrotomy and capsulotomy because of persistent pain and limited range of motion | |

**Radiology**

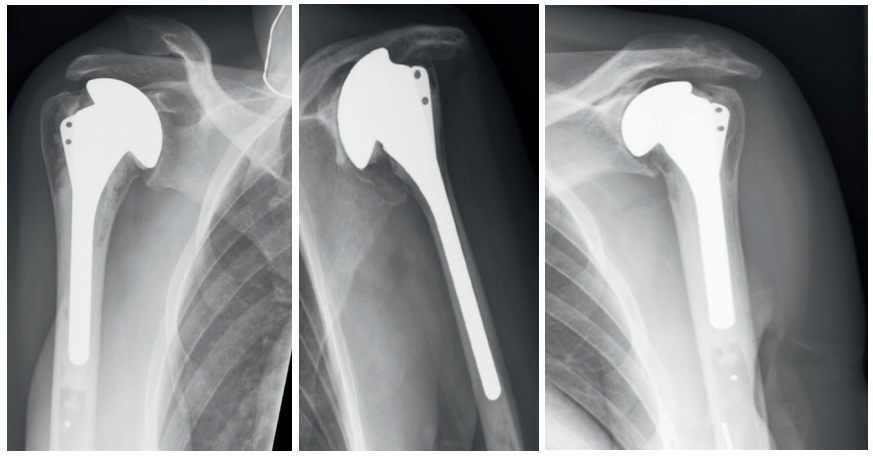
Radiographs were available of all shoulders. None of the patients showed definite or probable loosening of the stem at follow-up. All patients had medialisation of the arthroplasty due to glenoid erosion and cranialisation due to rotator cuff insufficiency (figure 1,2 and 3). No fractures of the glenoid or acromion were seen. No other radiographic complications were observed.

**Complications**

No major intra-operative complications, such as fractures or implant/instrument failure, were observed. One patient reported persistent pain and limited range of motion direct post-operatively. Two weeks after the initial operation an arthrotomy and capsulotomy was performed. Tissue cultures obtained during this operation were negative for infection. Finally, the pain subsided and the shoulder function improved.

**Revision Surgery**

No revision surgery was performed within this long-term follow-up period.



**From left to right:**

**Figure 1 |** Anteroposterior radiograph of a right shoulder with a cemented shoulder hemiarthroplasty showing severe medialization and cranialization

**Figure 2 |** Anteroposterior radiograph of a left shoulder with a cemented shoulder hemiarthroplasty showing severe medialization and cranialization

**Figure 3 |** Anteroposterior radiograph of a left shoulder with a cemented shoulder hemiarthroplasty showing moderate medialization and cranialization.

## DISCUSSION

We report the long term clinical and radiologic results of a cemented hemi shoulder arthroplasty in the treatment of osteoarthritis in patients with rheumatoid arthritis. We conclude that the long-term results are satisfying, without major complications and revision surgery in this specific patient population.

Strong points of this study are the long-term follow-up, the high percentage of patients available for clinical and radiological evaluation, and the evaluation with patient related outcome measures. Limitations of current study include those inherent to all retrospective studies. In addition, radiographic follow-up was done with conventional radiographs. CT scanning would be ideal to evaluate the glenoid (erosion and bone loss) and MRI would be ideal to evaluate the rotator cuff tendons. We did not use these scans because both will be disturbed by the arthroplasty and both scans are not part of the routine patient care and follow-up. Cranialisation of a hemi shoulder implant is consistent with rotator cuff





deficiency.[18,19] Koorevaar et al.[25] reported little pain after hemi shoulder arthroplasty in rheumatoid arthritis. The progressive glenoid erosion was seen in almost all their patients. This was not correlated with post-operative pain. In our current retrospective study patients reported little pain and all radiographs showed medialisation and cranialisation due to insufficient rotator cuff.

Although not evidence based, it is our opinion that total shoulder arthroplasty is not the first-choice treatment in patients with rheumatoid arthritis because of the potential development of cuff deficiency. This finally will result in a rocking horse phenomenon and eventually loosening of the glenoid component.[20–22]

At the time of the cohort analyzed in this study, reverse shoulder arthroplasty was not widely available, but this seems to be a good alternative for "older" patients these days. The most important finding of this study is that the long-term functional results of a cemented hemi shoulder arthroplasty in rheumatoid arthritis patients are good without major complications and without an indication for revision surgery. Although we did not include a second comparison group with patients having a total shoulder arthroplasty, we believe that hemi shoulder arthroplasty is a good option for treatment of patients with rheumatoid arthritis of the shoulder. This is in contrast with primary osteoarthritis of the shoulder with intact rotator cuff; in these patients is total shoulder arthroplasty the first option.[32–34]

A difference between rheumatoid arthritis of the shoulder and primary osteoarthritis relates to the effect on soft tissues, specifically the rotator cuff tendons. As the previous authors, we think that humerus resurfacing in patients with rheumatoid arthritis should be avoided due to concerns about overstuffing the rotator cuff.

Sperling et al.[2] concluded that among patients with shoulder joint destruction due to rheumatoid arthritis and an intact rotator cuff, improvement in pain and abduction was greater with total shoulder arthroplasty. They observed less patients with symptomatic glenoid component loosening compared to patients with painful glenoid arthritis requiring revision surgery.

In our current retrospective study less intra-operative and long-term complications were observed than by Sperling et al.[2] Hambright et al.[10] found that the perioperative complications of a shoulder replacement are low and similar for patients with and without rheumatoid arthritis. The cranialization of the humeral head in relation to the scapula that was observed on the radiographs is a result of a secondary rotator cuff deficiency. This was also observed in the current reported series. Another possible long-term complication of a hemi shoulder arthroplasty is an increase in glenoid erosion. This complication has been reported to be the most common reason for conversion of a hemi shoulder arthroplasty to a total shoulder arthroplasty or nowadays to a reverse shoulder arthroplasty.[24] Previous

authors found progressive glenoid erosions after hemi shoulder arthroplasty in patients with rheumatoid arthritis.[25,26] We observed some degree of erosion of the glenoid in all patients, but this did not lead to altered functional outcomes revision surgery.





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# CHAPTER 8

## Septic failure is not a septic loosening: A case report of a failed shoulder prosthesis

Septic failure of a shoulder arthroplasty due to a low-grade infection is generally called septic loosening. However, it is often not investigated if a prosthesis is genuinely loose. We present a case of a failed resurfacing prosthesis in a 70-year-old woman. This prosthesis failed due to a low-grade infection and a revision procedure was mandatory. All intraoperative cultures were positive and revealed a combination of bacteria. Nevertheless, histology revealed a macroscopic and a microscopic stable prosthesis with full osseointegration beneath the prosthesis. The general conception is that an infection leads to interface formation (with neutrophils) and loosening of the prosthesis. We debate this with the presentation of this case of a failed shoulder prosthesis and we think that periprosthetic infection and septic prosthetic loosening are two different entities.

**Key words: Infection, loosening, osseointegration, prosthesis, shoulder**
**Level of evidence: Case report**





## INTRODUCTION

Infectious failure of a shoulder arthroplasty is a devastating complication requiring revision surgery. In orthopedic literature, a differentiation between septic and aseptic prosthetic loosening is often made.[1–4] It is thought that cellular processes of the periprosthetic membrane with mobility of the implant lead to disintegration, osteolysis, and bone defectscausing (septic) prosthetic loosening.[1,2,4] We present a case of a patient with a failed uncemented resurfacing shoulder arthroplasty due to a low-grade infection. Nevertheless, histology revealed a fully osseointegrated prosthesis. To our knowledge, a prosthetic failure due to low-grade infection with a histological proven stable prosthesis has never been reported.

## CASE REPORT

A 70-year-old woman presented at our outpatient department with primary gleno-humeral osteoarthritis at the right side [Figure 1]. She had osteoarthritis in multiple joints and underwent previously a bilateral total knee replacement. General medical history revealed diverticulitis, mild chronic obstructive pulmonary disease (COPD), and atrial fibrillation. Because of her persisting pain non-responding to conservative treatment, she was scheduled for a resurfacing shoulder prosthesis on the right side. Standard antibiotic prophylaxis of three gifts of 1-gram cefazoline for 24 hours was used. A deltopectoral approach was used during surgery and the rotator cuff was intact. The osteophytes were removed and the 44mm uncemented resurfacing shoulder prosthesis (DePuy/Synthes, Warsaw, IN, USA) was placed (Figure 2). The glenoid was sclerotic without any bone loss and microfracturing was performed with the chondropick.

No wound problems occurred, and the patient was discharged 2 days after surgery. The physiotherapist accompanied a standard rehabilitation program with initial restricted passive range of motion. During the first 4 months, the patient was very satisfied with painless shoulder and full range of motion. Since this initial period, she suffered progressive shoulder pain. At examination, there was a painful arc and the supraspinatus resistance test was painful, but there were no clinical signs of a cuff rupture. It was thought that rotator cuff tendinitis caused this pain and an arthroscopic subacromial decompression was performed. Preoperative 1 gram of cefazoline was given. During surgery the rotator cuff was intact. At this time, an infection was not considered and therefore the gleno-humoral joint was neither inspected nor aspirated. However, the subacromial decompression did not relieve the complaints and the range of motion gradually decreased. At 2 years after the arthroplasty, the patient had pain on the anterior side of the shoulder, mild rest pain, increased pain whilst lifting, and a restricted forward flexion of 90° and external rotation of 50°. No clinical infectious signs were present, and the cuff seemed intact.

Her erythrocyte sedimentation rate (ESR) was slightly elevated since the first operation (between 30 and 45) with a normal C-reactive protein (CRP). However, the biochemical markers are not completely reliable for an infection due to her diverticulitis. The X-rays showed a well-positioned prosthesis without signs of loosening and some progression in glenoid erosion (Figure 3). To exclude an infection, a culture of intra-articular fluid (obtained by fine-needle aspiration) was done, which was negative. Because of the persisting pain and signs of progressive of glenoid erosion on plain radiographs, a conversion from hemi to total shoulder prosthesis was performed (Figure 4). Three times cefozline was given perioperative. Intraoperative inspection of the joint showed induration of the synovium and a sclerotic glenoid with irregular erosions. The prosthesis was macroscopically solidly incorporated in the bone. Routine swabs and tissue samples from the bone and synovium were taken for cultures. The peri- and postoperative course was uneventful with normal wound healing. However, after 10 days, all intraoperative cultures revealed a combination of micro-organisms and antibiotic therapy was started. The Pantoea agglomerans, Staphylococcus epidermidis, and Propionium acnes were found in all four operative cultures.

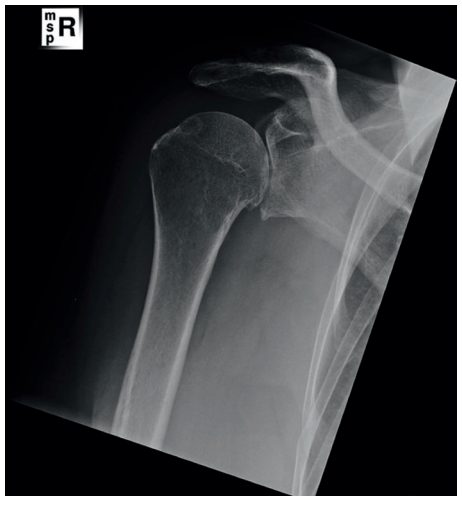


**Figure 1 |** AP radiograph of the right shoulder showing osteoarthritis of the gleno-humeral joint.





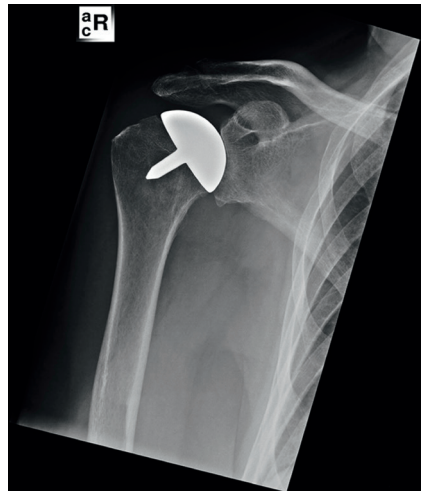


**Figure 2 |** Immediate postoperative radiograph of the resurfacing hemi shoulder prosthesis

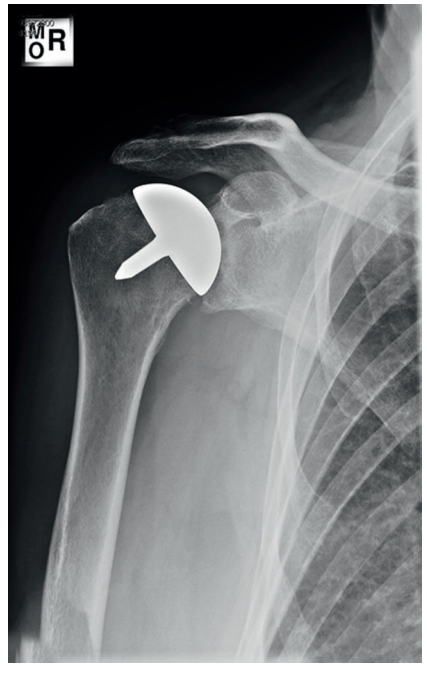


**Figure 3 |** Two years postoperative, the radiograph shows progressive glenoid erosion with a well-positioned prosthesis

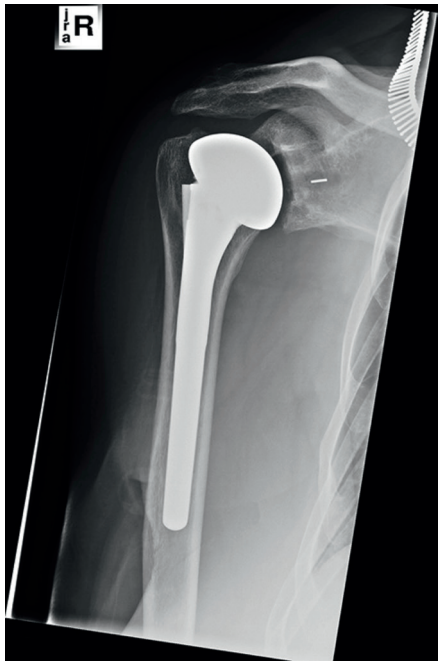


**Figure 4 |** Postoperative situation after conversion to a total shoulder prosthesis

The resected resurfacing prosthesis was sent to a specialized bone lab. It was fixated in buffered formalin at 4°C and the prosthesis was cut along the central stem. After embedding of the halves in polymethyl methacrylate (PMMA), the surfaces were polished, sputter coated with cold, and examined by scanning electron microscope (SEM). Then, surfaces were polished again, acid etched to partially remove the PMMA, and then stained with basic fuchsin and photographed. A microscopic stable prosthesis with full osseointegration was seen. The bone was intact, generally osteoporotic, and in good contact with the coating of the prosthesis. There were no signs of soft tissue interface formation due to loosening or microfractures of the bone trabeculae (Figures 5-8).





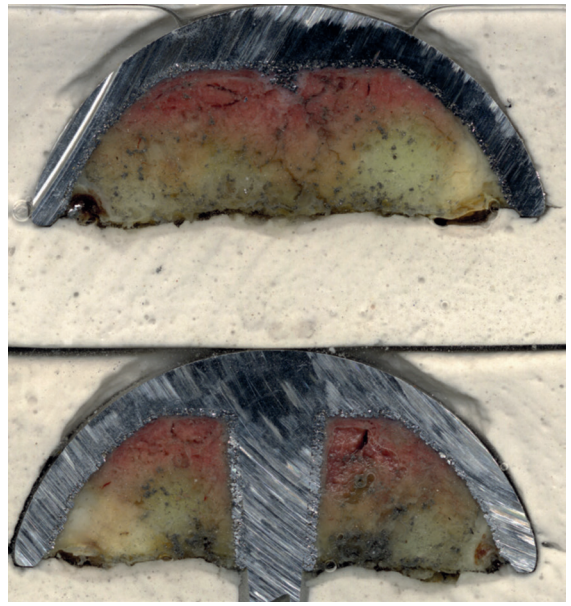

**Figure 5 |** Cross-sections of the uncemented resurfacing shoulder prosthesis (DePuy; Global CAP). Most tissue under the cup is fatty marrow with some scarce and thin bone trabeculae

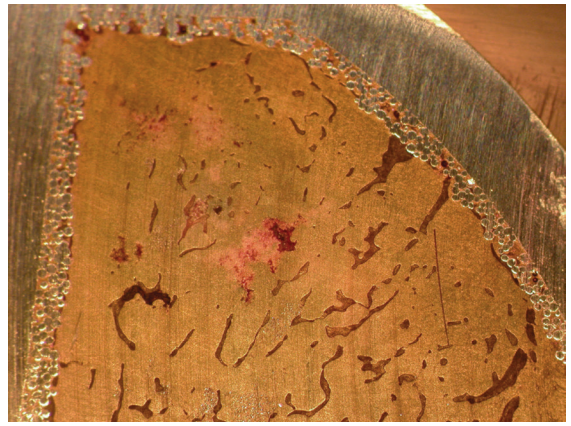

**Figure 6 |** Enlargement of area directly under the cup. Notice bone trabeculae running in the direction of the porous coating of the cup

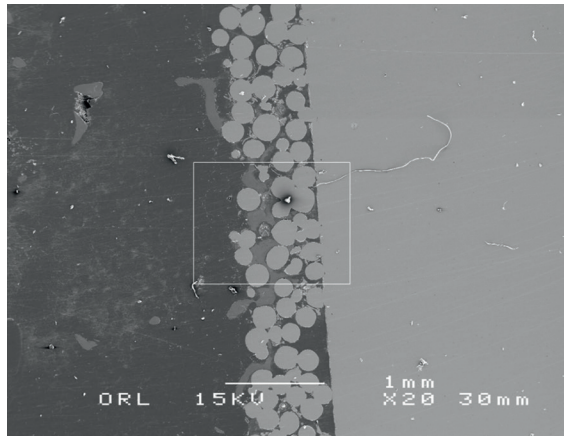


**Figure 7** | Low magnification of plastic embedded and polished surface of area directly under the porous coating

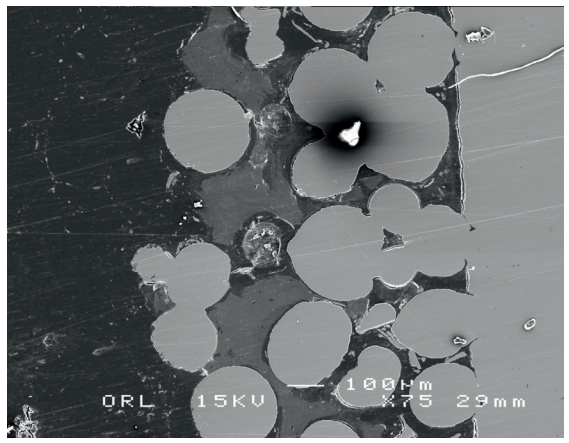


**Figure 8** | Higher magnification of boxed area in Figure 7 showing bone trabeculae in close contact with the porous coating

These findings led to the conclusion that the resurfacing prosthesis failed due to a painful low-grade infection, without loosening of the prosthesis. According to the advice of the microbiologist, prolonged antibiotic regiment was started until the ESR and CRP normalized after 3 months. The rehabilitation period was longer than after the first operation, but uneventful and no wound problems occurred. At the last follow-up, 24 months postoperative, she was satisfied with her shoulder. She had a pain-free active forward flexion of 140°, endorotation of 70°, and exorotation of 30°. There were no clinical or biochemical signs of infection and the radiograph showed a correct position of the prosthesis with no signs of loosening (Figure 9).





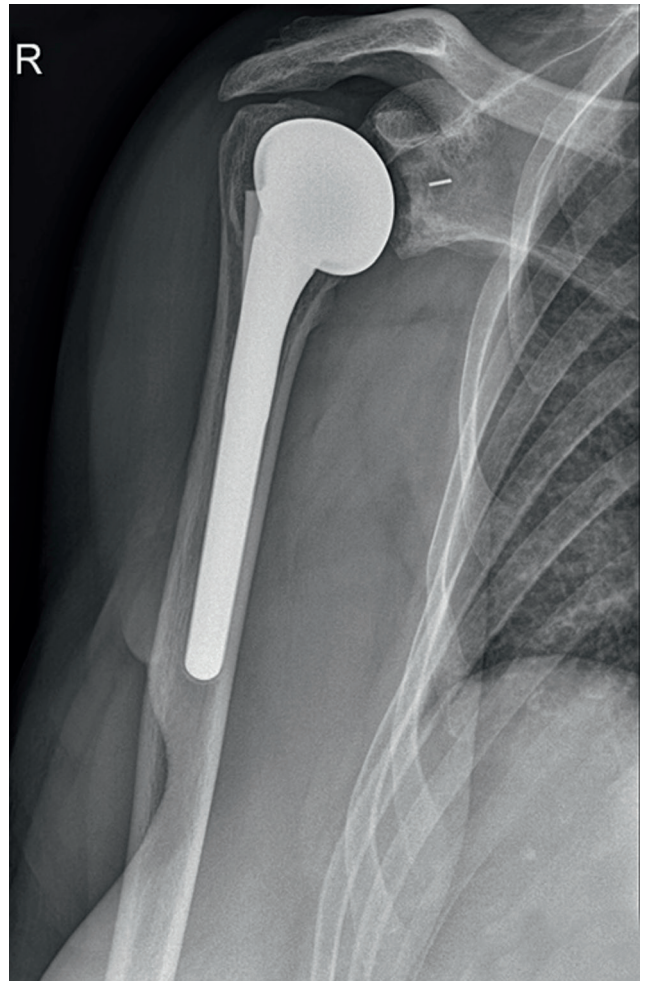


**Figure 9** | Radiograph 2 years postoperative after total shoulder arthroplasty

## DISCUSSION

The results of shoulder arthroplasty are generally good; however, failures do occur due to prosthesis malalignment, infection, fracture, and prosthesis loosening due to various causes.[5–7] Infection is a devastating complication requiring revision surgery, with reported rates between 0% and 4% in primary shoulder arthroplasties.[5–8] The diagnosis of infection is often classified as high (acute) or low grade (chronic). It is based on a combination of symptoms, laboratory tests, findings in physical and radiological examinations, and confirmed by positive intraoperative cultures.[1,4,8,9] While high-grade infections are easily recognizable from clinical signs, chronic or low-grade infection can be a serious diagnostic challenge.[4] In these cases, most of the pre-operative investigations prove not to be extremely

useful and positive culture rates can be as high as 25% in presumably uninfected shoulders during revision arthroplasty.[1,6,7,9]

Patients with a failed shoulder prosthesis often present with pain and stiffness, whatever the cause is, as illustrated in our case.[6] Although the preoperative analysis (including intra-articular fluid culture) did not reveal a septic cause of the failure, the intraoperative culture revealed a combination of bacteria, including Propionium acnes. The ideal antibiotic regimen is disputable, and we followed the advice of our microbiologist with a prolonged antibiotic treatment of 3 months.

**Septic loosening and osseointegration**

The development of the definition of a periprosthetic infection is still ongoing; the results of microbiology cultures of the periprosthetic tissues are considered to be gold standard.[10] Confusingly, a periprosthetic infection is often called septic loosening and debate has even been raised concerning whether living (proliferating) microorganisms are indeed necessary for septic loosening.[2] The earliest and probably clinically the most important step in periprosthetic infections is the competition between tissue cell integration and bacterial adhesion to the same surface. When an implant is surgically placed in bone, there are numerous biological, physical, chemical, thermal, and other factors that determine whether or not osseointegration will occur.[2,11]

Surgical intervention causes an acute inflammatory reaction in bone and the surrounding soft tissues.[2] If this reaction disappears, a lace-like trabecular bony layer is formed which surrounds the prosthesis.[2] This will lead to osseointegration of the prosthesis. The inflammatory response can also continue and lead to a chronic inflammation which will lead to loosening.[2] Factors related to a chronic inflammatory response and loosening of the implant include infection, allergic reaction, insufficient blood supply and trauma.[2,11]

It is known that a well-fixed and stable implant is a necessity for long-term pain-free function of a joint replacement. In successfully osseointegrated implants, the junction between implant and host bone ought to be a tight or bony union.[2,11] On the other hand, it has been described that a layer of connective tissue develops between the bone and prosthesis in both septic and aseptic loosening.[3,12–14] And even well-fixed implants may have these membranes, even though they are considerably thinner.[11,12] Several pathological mechanisms that may lead to loosening have been described and have been summarized in a histological classification which defines four types of periprosthetic membranes.[3,12,15] The histological feature that suggests the pathological diagnosis of septic loosening is the presence of numerous inflammatory cells, particularly neutrophil polymorphonuclear leukocytes (neutrophils) in the periprosthetic membrane. Although the reliability of this investigation is questionable, it is agreed that the presence of numerous neutrophils in the





periprosthetic tissue strongly correlates with septic loosening.[12,15] However, whether or not failure of an infected prosthesis is due to loosening with interface formation remains unclear.

In our case, the histological analysis of the shoulder prosthesis did not fit the standardized histological classification. This was due to the fact that we did not find a periprosthetic interface as the bone was fully integrated onto the hydroxyapatite-coated undersurface of the prosthesis. This is in contrast to the theory that an infection leads to interface formation and subsequently loosening of the prosthesis.

In conclusion, we present a case of a failed hemi-shoulder prosthesis due to a periprosthetic infection, which was histologically fully osseointegrated. The general conception is that an infection leads to interface formation (with neutrophils) and loosening of the prosthesis. We debate this with the presentation of this case, and we think that periprosthetic infection and septic prosthetic loosening are two different entities.

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# CHAPTER 9

## Overstuffing in hemi resurfacing arthroplasty is a potential risk for failure

*Acknowledgements*

*The authors are very grateful to* ***B van der Heijden MSc*** *(statistician) for his statistical assistance and to* ***SM Bollen MD*** *and* ***BWK de Wit MD*** *(musculoskeletal radiologists) for their valuable contribution to the measurements.*

**Purpose**
Literature describes the concern of an overstuffed shoulder joint after a resurfacing shoulder hemi arthroplasty. The purpose of this study was to evaluate inter-observer variability of (1) the critical shoulder angle (CSA) (2) the length of the gleno-humeral offset (LGHO) and (3) the anatomic center of rotation (COR) in a patient population operated with a Gobal Conservative Anatomic Prosthesis (CAP) resurfacing shoulder hemi arthroplasty. The measurements were compared between the revision and non-revision groups to find predictive indicators for failure.

**Methods**
Pre- and post-operative radiographs were retrieved from 48 patients who underwent resurfacing shoulder hemi arthroplasty from 2007 to 2009 using a Gobal CAP hemiarthroplasty for end stage osteoarthritis. This cohort consisted of 36 females (12 men) with a mean age of 77 years (SD 7.5). Two musculoskeletal radiologist and two specialized shoulder orthopedic surgeons measured the CSA, LGHO and COR of all patients.

**Results**
The inter-observer reliability showed excellent reliability for the CSA, LGHO and the COR, varying between 0.91 and 0.98. The mean COR of the non-revision group was 4.9mm (SD 2.5) compared to mean COR of the revision group, 8mm (SD 2.2) ($p$<0.01). The COR is the predictor of failure (OR 1.90 (95%Cl 1.19-3.02)) with a cut of point of 5.8mm. The mean CSA was 29.8 degrees (SD 3.9) There was no significant difference between the revision and non-revision groups ($p$=0.34). The mean LGHO was 2.6mm (SD 3.3) post-surgery. The mean LGHO of the revision group was 3.9 (SD 1.7) ($p$=0.04) post-surgery. Despite the difference in mean LGHO, this is not a predictor for failure.

**Conclusion**
The CSA, LGHO and COR can be used on radiographs and have a high inter-observer agreement. In contrast with the CSA and LGHO we found a correlation between clinical failure and revision surgery in case of a deviation of the COR greater of 5mm.

**Keywords: Resurfacing Humeral Head Implant, Overstuffing, Shoulder, Radiographs, Revision**





## INTRODUCTION

The resurfacing shoulder hemi arthroplasty provides good clinical results for patients with gleno-humeral osteoarthritis.[1–7] The purpose of a resurfacing shoulder hemi arthroplasty is to restore the patient's individual anatomy and the lateral offset of the proximal humerus while preserving the bone stock of the humeral head.[8–10]

Sizing of the proximal humerus is generally preoperative estimated on the radiograph and definitely measured during surgery. Because of a deformed proximal humerus, surgeons often have difficulty to accurate assess the correct size of the implant and restoring the anatomy compared with stemmed arthroplasty.[8,10] In literature, high rate of revision of the resurfacing shoulder hemi arthroplasty is a concern.[11–13] Alolabi et al.[8] found a possible relation with overstuffing, however in literature there is no definite correlation reported between overstuffing and revision.

This study was performed as an extension to an ongoing follow-up study in patients treated with uncemented Global Conservative Anatomic Prosthesis (CAP) (DePuy/Synthes, Warsaw, IN, USA) hemi resurfacing shoulder prosthesis from 2007 until 2009.[13–16] At the 5-8 years follow-up, our results are in line with other studies of a concerning high rate of revision.[13,16]

The aim of this current radiographic study was to evaluate the ability to restore humeral head anatomy and to determine the inter-observer reliability of the critical shoulder angle (CSA), length of the gleno-humoral offset (LGHO) and deviation of the center of rotation (COR) in a resurfacing shoulder hemi arthroplasty.

Furthermore, with these measurements to find prognostic tools to predict poor functional outcome and the necessary of revision. First, we used the pre-operative CSA which assesses the possible association of implant failure due to rotator cuff failure or progressive glenoid erosion. Second, we measured the LGHO before and after surgery. Finally, with best-fit circle technique to measure the deviation COR of the prosthetic humeral head from native anatomy after resurfacing humeral head arthroplasty.

All measurements were performed on shoulders of patients operated for primary, end stage gleno-humeral osteoarthritis with a Global CAP resurfacing hemiarthroplasty. The group consisted of patients who underwent a revision arthroplasty and patients with good patient reported outcome measures.

## MATERIALS AND METHODS

**Patient selection**

Between 2007 and 2009, 48 shoulders were operated using a Global CAP uncemented resurfacing shoulder hemiarthroplasty at two regional Hospitals in the Netherlands (Alrijne Hospital and Spaarne Hospital). This cohort consisted of 12 males and 36 females. All patients were operated on by two senior orthopedic surgeons (AvN or CV) specialized in shoulder pathology. The included 48 shoulders with only primary gleno-humeral osteoarthritis had intact rotator cuff, sufficient bone stock (>60%) of the proximal humerus and type A1, A2 or B1 glenoid (Walch Classification[17]) as assessed on radiographs and Magnetic Resonance Imaging (MRI) scans. Patients with severe fatty infiltration (Goutallier[18] grade 4), paresis of rotator cuff muscles, wound healing problems, neuromuscular pathologies or active infections were excluded for this study.

**Surgical protocol**

The orthopedic surgeons did not use radiological planning prior to surgery. All operations were performed via deltopectoral approach. Osteophytes present were removed, and the cartilage of the head was reamed guided by the anatomical neck of the humerus. Appropriately sized prosthesis was placed in patient own (retro)version and inclination. The prosthesis is available in five sizes, and each size has two heights to match the anatomy of the proximal humerus. No glenoid implants were used. Due to a hydroxyapatite coating, no cement was used for fixation. Digital pre- and post-operative radiographs were retrieved from the 48 shoulders. The post-operative treatment protocol was immobilization with an arm sling on the first day. Hereafter, active and passive movement supervised by a physiotherapist was allowed. After six weeks, free and active movement, respecting the patient's pain threshold, was encouraged and supervised by a physiotherapist.

**Radiographic measurements**

Radiographic measurements were performed to assess the critical shoulder angle (CSA), length of gleno-humeral offset (LGHO), and the center of rotation (COR). For reliable assessments, four independent observers performed the measurements: two senior musculoskeletal radiologists (SB and BdW), and two orthopedic surgeons (PG and JW) specialized in shoulder pathology and shoulder arthroplasty performed the measurements. All measurements were taken electronically on radiographs displayed on a PACS workstation (Cerner Corp. Kansas City, Missouri, USA). Patient characteristics and patient reported outcomes and revisions were unknown to the assessors. The X-ray technique of the two hospitals was standardized; the patients were positioned standing with their 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 the cranial caudal direction and was centered toward the shoulder joint.

This "true" antero-posterior radiographs were used to perform the measurements. The assessors used the pre-operative radiographs and the 6 weeks post-operative radiographs. If the 6 weeks radiographs were insufficient for assessment, the 1-year post-operative radiographs were used instead.

**Critical Shoulder Angle**

The critical shoulder angle (CSA) was assessed on all pre-operative "true" antero-posterior (AP) shoulder radiographs. The angle was formed by a line connecting the superior and inferior bony margins of the glenoid and a line drawn from the inferior bony margin of the glenoid to the most lateral border of the acromion (fig 1.).[19] The CSA angle is defined by three grades (table 1).

**Table 1 |** Critical Shoulder Angle[19]

| | **Angle in degrees** | |
|---|---|---|
| **Grade I** | < 30° | Osteoarthritis |
| **Grade II** | 30° - 35° | Normal |
| **Grade III** | > 35° | Rotator Cuff tear |

**Length of the Gleno-Humeral Offset**

The modified length of the gleno-humeral offset (LGHO) of the 48 shoulders was assessed on both pre- and postoperative "true" AP radiographs.[10,20,21] First, a line from the top to the bottom of the glenoid cavity was drawn. Second, a parallel line was drawn from the center axis of the humeral bone until the most lateral part of the greater tubercle was touched. 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). The length of gleno-humeral offset is important in shoulder function, since it affects soft tissue tension and joint balancing. Normal LGHO averages from 54 to 57mm (range 43-68mm).[22] As a result of gleno-humeral osteoarthritis, with narrowing of the joint space, the soft tissue will adapt to the changed morphology. The LGHO should not increase after surgery.[10]

**Center of Rotation**

The center of rotation (COR) was measured.[8] A best-fit circle was placed on the "true" AP radiograph using three preserved bone landmarks: the lateral cortex of the greater tubercle, medial calcar at the inflection point where calcar meets the articular surface, and the medial edge of the greater tubercle medial of the footprint of the supraspinatus tendon. A second circle, the implant matched circle, was placed to fit the curvature of the prosthetic humeral head. The COR was identified from each circle, and the distance

between the CORs was calculated in millimeter (fig 3.1). A coordinate system was then generated from the anatomic COR, with the y-axis aligned parallel to the intramedullary axis and the x-axis defined as perpendicular to this line. This created four regions in which the location of the decimation of COR could be defined; superior medial, inferior medial, superior lateral and inferior lateral (fig 3.2). By use of the COR, we measured the overstuffing of the shoulder joint after resurfacing shoulder prosthesis. Medial deviation of the COR was defined as overstuffing.[8]

**Revision**

At the 9-year follow-up (range 5-12 years) 12 shoulders (25%) had a revision to a total shoulder arthroplasty. One patient had a revision for pain and loss of range of motion. On the radiographs, there was progressive glenoid erosion. At revision to total shoulder arthroplasty, the tissue samples retained per-operatively were tested positive on Pantoea Agglomerans, Staphylococcus Epidermidis, and Propionium Acnes. We excluded this patient from data analysis for infection reason. The eleven revision patients used in data analysis are mentioned in table 2. All other revisions had negative per-operative cultures.

**Table 2 |** Revision of 11 patients

| Reason | Revision | Comment |
|---|---|---|
| Glenoid erosion | TSA | progressive pain |
| Arthrofibrosis | TSA | pain and poor function |
| Severe glenoid erosion | TSA | progressive pain |
| Rotator cuff arthropathy | RSA | pain and poor function, traumatic rotator cuff tear, glenoid erosion |
| Rotator cuff arthropathy | RSA | earlier surgical subscapularis tendon repair |
| Pain and poor function | TSA | progressive pain and loss of range of motion, minimal glenoid erosion |
| Pain and poor function | TSA | patient is emigrated, revision surgery was abroad |
| Severe glenoid erosion | RSA | progressive pain |
| Glenoid erosion | TSA | progressive pain |
| Glenoid erosion | TSA | progressive pain |
| Severe glenoid erosion | RSA | progressive pain and loss of range of motion |

TSA: Total Shoulder Arthroplasty
RSA: Reverse Shoulder Arthroplasty

**Statistical analysis**

Statistical analysis was performed by use of Statistical Package for the Social Sciences (SPSS) (IBM, Armonk, NY, USA, version 26.0). After confirmation of normal distribution, continuous variables are presented as means with standard deviations (SD). Categorical





data are described as frequencies with accompanying proportions. Differences between the revision and non-revision group were assessed using Student's t-tests or Chi$^2$-tests, where appropriate.

Inter-observer reliability was assessed by calculating of the intra class coefficient (ICC agreement, two-way random effect model).[23] An ICC >0.7 was considered as sufficient.[24,25] Additionally, the standard error of measurement (SEM) was calculated as the square root of the within-subject variance (i.e. sum of the between measures variance and the residual variance) with accompanying smallest detectable difference (SDD) as 1.96*2*SEM.[26]

To identify predictors for revision, univariate logistic regression was performed for potential predictors, such as age, gender, CSA, LGHO and COR. In the case of significant association (adjusted significance level of 0.10), the factors were entered in a multivariate logistic regression analysis. For all analyses, odds ratios (OR) with 95% confidence interval (95%CI) were calculated and presented.

To calculate an optimal cut-off value of the measurement that was significantly associated with revision in the final model, a receiver operating characteristic (ROC) curve analysis was performed. A bootstrapping procedure, drawing 1000 bootstrap samples, was used to estimate a standard error to provide a 95%CI around the cut-off value. As a measure of accuracy, the area under the curve (AUC) was calculated.

## RESULTS

**Population**

The average age of the patient population was 77 years (SD 7.5), and 36 patients out 47 were female (77%). The demographics and measurements of the revision and non-revision group for the CSA, LGHO and COR are outlined in table 3.

**Table 3 |** demographics and measurements.

| | Total (n=47) | Revision (n=11) | Non-revision (n=36) | *p*-value |
|---|---|---|---|---|
| Age, years, mean (SD) | 76.6 (7.5) | 74.8 (6.4) | 77.1 (7.9) | 0.39 |
| Gender, n (%) | | | | |
| Male | 11 (23) | 4 (36) | 7 (19) | 0.25 |
| Female | 36 (77) | 7 (64) | 29 (81) | |
| CSA, mean (SD) | 29.8 (3.9) | 30.8 (3.0) | 29.5 (4.2) | 0.34 |
| CSA, n (%) | | | | |
| < 30 | 26 (55) | 5 (46) | 21 (58) | 0.66 |
| 30-35 | 16 (34) | 5 (46) | 11 (31) | |
| > 30 | 5 (11) | 1 (8) | 4 (11) | |
| LGHO pre-operative, mean (SD) | 49.6 (5.0) | 51.1 (4.0) | 49.1 (5.3) | 0.26 |
| LGHO post-operative, mean (SD) | 52.1 (4.9) | 54.9 (4.4) | 51.3 (4.8) | 0.03 |
| LGHO CFB (SD) | 2.6 (3.3) | 3.9 (1.7) | 2.2 (3.6) | 0.04 |
| COR, mean (SD) | 5.6 (2.7) | 8.0 (2.2) | 4.9 (2.5) | <0.01 |

CSA: Critical shoulder angle (degrees)
LGHO: Length of the gleno-humeral offset (mm)
COR: Center of Rotation (mm)
CFB: Change from baseline

**Reliability and measurement error**

The inter observer reliability showed excellent reliability for the CSA, LGHO pre- and postoperative and the COR, varying between 0.91 and 0.98 (table 4).

**Table 4 |** Inter observer reliability

| | CSA | LGHO pre | LGHO post | COR |
|---|---|---|---|---|
| ICC (95%CI) | 0.97 (0.95-0.98) | 0.96 (0.93-0.97) | 0.91 (0.85-0.95) | 0.98 (0.96-0.99) |
| SEM | 0.69 | 1.13 | 1.52 | 0.43 |
| SDD | 1.91 | 3.12 | 4.22 | 1.2 |

CSA: Critical shoulder angle (degrees)
LGHO: Length of the gleno-humeral offset (mm) – pre- and postoperative
COR: Center of Rotation (mm)
ICC: Inter observer reliability
SEM: Standard Error of Measurement
SDD: Smallest Detectable Difference





**Critical Shoulder Angle**

Based on the study by Moor et all.[19], CSA values were classified into three grades; Grade I. CSA < 30°, Grade II. CSA 30-35° and Grade III. CSA > 35° (table 1). The mean CSA of 47 shoulders is 29.8° (SD 3.9). We found no significant difference in CSA between the revision group and non-revision group ($p$ =0.34) (table 3).

**Length of Gleno-Humeral Offset**

The mean LGHO increased from 49.6mm (range 37.6-60.4) before surgery to 52.1mm (range 37.2-61.7) after surgery. The increase of the LGHO was significantly higher in the revision group compared to the non-revision group ($p$ =0.04). The preoperative LGHO was not significantly different between the two groups ($p$ =0.26). However, the postoperative LGHO of the revision group was significantly different compared to the non-revision group ($p$ =0.03), see table 3.

**Center of Rotation**

The mean deviation of the postoperative resurfacing head COR from the anatomic COR for all 47 cases was 5.6mm (2.7 SD).

The mean COR in the non-revision and the revision group was 4.9mm (2.5SD) and 8.0mm (SD2.2) respectively. This difference was significant ($p$ <0.01). Of the 47 shoulders, five implants (12%) had the COR shifted to medial inferior. The remaining 43 shoulders had the COR shifted to medial superior. All shoulders in the revision group (n=11) had the COR shift to medial superior, meaning overstuffing of the joint.

**Predictors of Revision**

Univariate analysis revealed that post-operative LGHO and the COR were both significantly associated with revision. However, in the final model only the COR remained as a predictor for revision with an OR of 1.90 (95%Cl 1.19-3.02), See table 5.

ROC analysis of the COR revealed a cut-off point for revision of 5.8mm (95%Cl of 4.0-8.4) with a corresponding AUC of 0.82 (95%CI: 0.68-0.95).

**Table 5** | Predictors of revision

| Univariate | OR (95%CI) | *p*-value |
|---|---|---|
| Age | 0.96 (0.87-1.05) | 0.38 |
| Gender | 2.37 (0.54-10.40) | 0.25 |
| CSA | 1.09 (0.92-1.30) | 0.33 |
| LGHO preoperative | 1.09 (0.94-1.25) | 0.26 |
| LGHO postoperative | 1.19 (1.01-1.41) | 0.04 |
| LGHO change from baseline | 1.19 (0.94-1.49) | 0.15 |
| COR | 1.90 (1.19-3.02) | 0.01 |
| Multivariate | OR (95%CI) | *p*-value |
| LGHO postoperative | 1.16 (0.95-1.43) | 0.15 |
| COR | 1.91 (1.14-3.20) | 0.02 |
| Final Model | OR (95%CI) | *p*-value |
| COR | 1.90 (1.19-3.02) | 0.01 |

CSA: Critical Shoulder Angle
LGHO: Length of the gleno-humeral offset
COR: Center of Rotation
OR: Odds Ratio

## DISCUSSION

Inaccurate sizing or positioning of a prosthetic humeral head can lead to overstuffing the joint and poor outcomes, including glenoid erosion, rotator cuff tearing, and in the case of a glenoid component wear and loosening.[27–32]

We assessed the CSA, LGHO and COR in a selected cohort of patients operated on with a Global CAP, an uncemented resurfacing shoulder hemiarthroplasty for primary end-stage osteoarthritis.

The aim of this study was to measure inter-observer reliability of the CSA, LGHO and COR and to define parameters to predict failure. The purpose of the Global CAP, like many other resurfacing shoulder hemi arthroplasty, is to recreate the normal anatomical gleno-humeral relationship of the shoulder. As considered by Mechlenburg et al.[10] and Alolabi et al.[8] the resurfacing shoulder hemi arthroplasty might potentially overstuff the gleno-humeral joint.

We found a high inter-observer reliability for the CSA, this is in line with other studies on CSA measurements.[33] Moor et al.[19] classified a CSA angle < 30° as gleno-humeral osteoarthritis and a CSA > 35° as rotator cuff tear. In our series, with the observed minimal





detectable difference of 1.9°, this classification should be interpreted with caution. Viehöfer et al.[34] showed that a higher CSA requires more rotator cuff activity to preserve joint stability. This leads to higher risk of rotator cuff failure.[35–37] Additionally, Watling et al.[38], found a high CSA being associated with glenoid component loosening and failure. In our series, however, we did not find a significant association between CSA angles and revision.

Originally, the measurements of the LGHO is performed using the distance from the base of the coracoid process to greater tubercle.[31,39] But this measure shows systematic errors in inter-tester reliability because it is difficult to locate the base of the coracoid process.[31] Due to the reported problems with inter-tester reliability of the standard LGHO measurements we used the modified LGHO.[10,20,21] Because, it is possible that factors like direct post-operative intra-articular fluid or releases related capsular laxity might falsely increase the LGHO measurements we used the 6 weeks or 1-year post-operative radiographs.

In theory, LGHO after surgery should be identical to LGHO before the shoulder morphology changed caused by arthritis without structural changes of the soft tissue. But as osteoarthritis progresses with narrowing of the joint space, destruction of the joint cartilage and capsule tightening, the soft tissue adapts to the changed morphology by losing elasticity and the LGHO should not be increased after surgery.[10,20,21] This in contrast with current study where the mean change of baseline of the LGHO increased by 2.6mm, and 3.9mm in the non-revision group and revision group, respectively.

Like Mechlenburg et al.[10] in our study the LGHO is not reproduced. Additionally, the difference between the postoperative LGHO between the revision and non-revision is significant ($p$=0.03). Nonetheless, we found that the postoperative LGHO is not a predictor of revision. Conform the study by Stilling et al.[21] we found high inter-observer agreement.

Alolabi et al.[8] found in their study that 65.1% of the resurfacing hemi shoulder arthroplasty demonstrated an inadequate reaming of the humeral head, resulting in overstuffing of the gleno-humeral joint. In our study we found 88% overstuffing in all shoulders, and 100% overstuffing in the revision group.

Multiple studies use different cut of points to define overstuffing of the gleno-humeral joint.[8,27–30,32]

In these studies, they assessed no relation to an increase of COR to patient reported outcomes or revision. As Pearl et al.[40,41] already showed in their computer simulation studies that the COR in resurfacing hemi shoulder arthroplasty have great difficulty matching the geometric dimensions of the native gleno-humeral anatomy. However, these measurements were done on cadaveric humerus, without relation to patient reported

outcomes or revision. And computer studies may not be directly comparable to the results of radiographic studies. Our results regarding resurfacing hemi shoulder arthroplasty are in line with Alolabi et al.[8], the normal gleno-humeral anatomy, regarding the COR, is not reproduced. We found a significant increase in COR in the revision group compared to the non-revision group. In other words, the probability of revision increases significantly with an increased COR. Overstuffing has always been a suspect for failure[8]. However, this has not been demonstrated in the literature before. in this current study we have shown a relation between failure and overstuffing

The main limitation of this study is the small study group. Because of the fact that this concerns to an ongoing study of the Global CAP, it provides valuable information of this uncemented resurfacing hemi shoulder arthroplasty. The rate of revision (25%) at 9 years follow-up in our cohort is high. We excluded the patient with low grade infection for data analysis because the authors believe it is difficult to distinguish between pain caused by glenoid erosion or pain caused by low grade infection.

Three questions arise why the rate of revision was higher compared by studies by Levy et al.[1,2,42,43] First, a number of revisions can happen when inexperienced surgeons perform few procedures. However, the surgeons in this cohort are specialized shoulder surgeons, in high volume shoulder hospitals, with experience in shoulder replacement/revision, shoulder arthroscopic procedures and fracture osteosynthesis.

Second, in this current study, the resurfacing hemi shoulder arthroplasty was positioned freehand based on anatomic landmarks, advised by the implant manufacturer, without a digital pre-operative planning. The authors agree with Alolabi et al.[8], intra-operative fluoroscopy may provide additional valuable information to confirm offset and varus/valgus of the implant. Finally, explanation could be patient selection, as some patients may have benefited more with a total shoulder arthroplasty.

Another limitation to this cohort study is the use of the “true” antero-posterior radiograph of the shoulder. Theoretically, the measurements could vary according the position of the arm or the scapula. Therefore, we only used the best 6-months or 1-year radiographs for post-operative measurements, which had better quality compared to direct post-operative radiographs. Moreover, Spiegl et al.[44] and Bouaicha et al.[45] showed that the CSA assessed on radiographs is equally to a Computer Tomogram (CT) scan and superior to a MRI scan.

The modified LGHO was assessed in multiple studies on radiographs,[10,20,21] in literature there is no study which compared the (modified) LGHO on radiographs compared to CT or MRI scan.





Many studies use the COR for hemi- and total shoulder arthroplasty on patient radiographs.[8,46–48] Other studies used CT on cadaveric shoulders to assess the COR.[40,49,50] In literature we found no superior evidence for CT or radiographs.

In this study we demonstrated that the CSA, LGHO and COR are reliable radiologic measurement methods with high inter-observer agreement. The Global CAP resurfacing shoulder hemi arthroplasty will lead to overstuffing of the gleno-humeral joint in almost all shoulders. In contrast with the CSA and LGHO we found a correlation between clinical failure and revision surgery in case of a deviation of the COR greater of 5mm.

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# CHAPTER 10

## Revision of failed resurfacing hemiarthroplasty: midterm results, survival and group comparison

**Introduction**
Shoulder arthroplasty is a valuable option in treating gleno-humeral osteoarthritis. Revision surgery for a failed shoulder arthroplasty is associated with difficult procedures, complications and worse outcomes. Resurfacing prosthesis compared to a total joint arthroplasty have the supposed advantage of limited perioperative complications and little bone loss during revision. The aim of this study was to describe patient reported outcome measures of revision surgery from failed uncemented Global CAP resurfacing hemi arthroplasty to total shoulder or reverse shoulder arthroplasty.

**Method**
Eleven patients in two collaborating institutes had a failed resurfacing prosthesis. Revision surgery was performed to total shoulder prosthesis in seven and reverse shoulder prosthesis in three patients. Data of one patient was missing. Outcome was monitored by use of Constant Score, Dutch Simple Shoulder Test, Short-Form 12, Visual Analogue Scale for pain and physical examination.

**Results**
Mean time to revision was 54 (SD 15.6) months. No perioperative complications occurred. At 42 (SD 15.9) months of follow-up clinical and patient reported outcome was excellent. Constant score improved a significant 29 points ($p$ <0.01), VAS pain score decreased from 55 to 5 points ($p$ <0.01) and Dutch Simple Shoulder Test and Short-Form 12 improved significantly ($p \leq 0.02$). 5-year survival was 82.6 (95% Confidence Interval 71.6% – 93.6%).

**Conclusion**
At 3.5 years' follow-up after revision from Global CAP resurfacing hemi arthroplasty, clinical and patient reported outcome measures results are satisfying.

**Key words: osteoarthritis, shoulder, arthroplasty, resurfacing, revision, surgery.**
**Level of evidence: retrospective cohort Level IV.**





## INTRODUCTION

Shoulder arthroplasty has been proven to be clinically useful in patients with gleno-humeral osteoarthritis during the past 6 decades.[1] Over time, many designs of prosthesis have been used. Copeland popularized the resurfacing prosthesis in the 1980's,[2,3] which required metal caps to be secured in place by a short central peg. The suggested advantages of this prosthesis are the preservation of the native head-shaft angle and center of rotation. Additionally, minimal resection of the humeral head is required to fit the prosthesis, which results in shorter operative time. Low prevalence of periprosthetic fractures is seen without the stress riser effect of a stem.[4,5] Nevertheless, anatomical restoration turned out to be difficult since the humeral head is easily oversized and the design of the prosthesis may not replicate the native humeral head.[6–8] Follow-up studies show positive functional and patient reported results.[4,5,9–13] Compared to conventional hemi shoulder arthroplasty, the results of the resurfacing prosthesis are equal, however the revision rate is higher.[14–17]

Revision of conventional hemi shoulder arthroplasty is a time consuming and difficult procedure, in which extraction of the stem is prone to perioperative complications.[18,19] Additionally, results are disappointing; up to 57% of the patients report unsatisfied patient reported outcome measures and up to 27% need re-revision in 10 years.[19,20] In case of revision of a resurfacing prosthesis however, the removal of the implant is easily facilitated. Perioperative complications are rare, bone graft to compensate lost humeral bone stock is seldom required and less surgical time is needed.[18,20] However, there is limited data published about the results of this revision, and to our knowledge follow-up is described in only three series of patients with conflicting results.[18,20–22]

The aim of this study was therefore to report the clinical and functional outcome of revision from the uncemented Global Conservative Anatomic Prosthesis (CAP) resurfacing prosthesis (DePuy/Synthes, Warsaw, IN, USA) to total shoulder prosthesis or reverse shoulder prosthesis. In addition, we performed a survivorship analysis and compared the baseline characteristics of the Global CAP revision and non-revision groups to determine factors predictive of revision.

## MATERIALS AND METHODS

**Patient population**
This study was performed as an extension to the ongoing follow-up study in patients treated with uncemented Global CAP resurfacing shoulder prosthesis.[10,17,23] The study received institutional review board approval, and all patients provided informed consent.

Adult patients suffering from osteoarthritis with failed conservative treatment were enrolled in this study and treated with uncemented Global CAP resurfacing hemi arthroplasty between January 2007 until December 2009. This cohort consists of 36 females and 12 male patients with a mean age of 66 years old (range 54-84 years). The 48 shoulders (46 patients) that were included had intact rotator cuff, sufficient (>60%) bone stock of the proximal humerus and type A1, A2 or B1 glenoid (Walch Classification[24]) as assessed on radiographs and MRI scans. Excluded patients had severe fatty infiltration (Goutallier grade 4[25])- or paresis of rotator cuff muscles, wound healing or neuromuscular pathologies, or active infections.[10,17]

At a mean follow-up of 4.5 years, 11 patients (23%) had undergone revision surgery. Pain and poor function were caused by glenoid erosion in four patients (36%), undefined pain and loss of function was found in two (18%). Cuff arthropathy was found in two patients (18%), with one of that prosthesis having anterior subluxations after a failed subscapularis tendon repair. Arthrofibrosis and painful glenoid without erosion were reasons for revision in two other patients. One patient (9%) had low grade infection without loosening of the prosthesis, cultures showed Pantoea Agglomerans, Staphylococcus Epidermidis and Propionium Acnes.[23] Total shoulder arthroplasty was used in eight patients. Three patients received a reverse shoulder arthroplasty, of which two patients had an insufficient rotator cuff and one had excessive glenoid erosion (Figure 1 and Table 1).

During the revision procedures, the prostheses were easily removed from the proximal humerus. The bone density underneath the prosthesis was significantly decreased in all cases, although none of the prostheses was loosened. All revisions did not require any humeral osteotomy or humeral bone allograft. No perioperative complications occurred.

Rehabilitation consisted of pendulum exercises of the arm during the first two weeks. A period of 4 weeks with active assisted and passive motion within 90 degrees' anteflexion and abduction and maximum of 30 degrees' external rotation was advised for total shoulder arthroplasty patients. A sling was given for support during the first 6 weeks. Restricted range of motion and usage of the supportive sling in reverse shoulder arthroplasty rehabilitation took two weeks. Additional physiotherapy was advised for 3 to 6 months for both total shoulder arthroplasty and reverse shoulder arthroplasty.





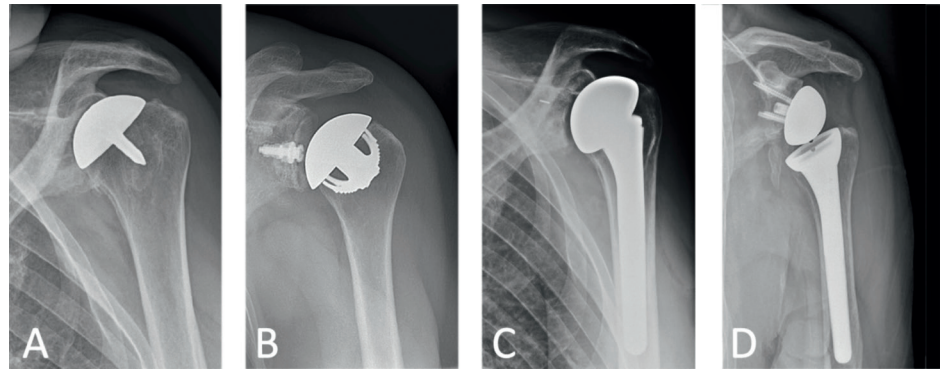


**Figure 1 |** Anteroposterior radiographs of left shoulders

Anteroposterior radiographs of left shoulders with;
(A) Global CAP resurfacing prosthesis before revision,
(B) T.E.S.S. Total Shoulder Arthroplasty (Biomet, Valence, France),
(C) Global AP Total Shoulder Arthroplasty (DePuy/Synthes, Warsaw, IN, USA) and,
(D) Delta Xtend Reverse Shoulder Arthroplasty (DePuy/Synthes) postoperative.

**Table 1 |** Revision patient population (n=11)

| | |
|---|---|
| Age at revision; years, SD | 69 ± 6.2 |
| Survival; months, SD | 54 ± 15.6 |
| Gender; % male (m/f) | 45% (5/6) |
| Side | |
| Dominant; % right (r/l) | 81% (9/2) |
| Operation; % right (r/l) | 45% (5/6) |
| Reason revision | 4 |
| Glenoid erosion; n | 2 |
| Pain and rROM; n | 2 |
| Cuff arthropathy; n | 2 |
| Arthrofibrosis; n | 1 |
| Infection; n | |
| Revision prosthesis | 3 |
| Global AP; n | 4 |
| T.E.S.S.; n | 3 |
| Delta Xtend; n | 1 |
| Unknown; n* | |

*SD*, standard deviation; *m/f*, male/female; *r/l*, right/left; *rROM*, restricted range of motion.
* Patient was emigrated and had revision abroad, data is missing.

**Study design**

Pre- and post-revision assessments were performed at the outpatient clinic. Constant-Murley Score was used as a guideline for shoulder function and was adjusted for sex and age.[26] Secondary outcomes included; pain measured by visual analogue scale of pain (VAS[27]), the Short-Form 12 (SF-12[28]) and shoulder function measured by the Dutch Simple Shoulder Test (DSST[29]). Initial pre-resurfacing data were retrieved from our study database. Baseline measurements of successful and revised CAP's was compared. The last orthopedic follow-up and date of death or revision were collected from all patient files to analyze the survival.

**Statistics**

Statistical analysis was performed with SPSS statistics software (IBM, Armonk, NY, USA, version 20.0). Nominal and ordinal outcome are presented with frequencies and corresponding percentages. Continuous variables are presented as means and standard deviations (SD) or 95% Confidence Intervals (CI). Pre- and postoperative pain, Constant Score score, SF-12 and DSST, as well as Range of Motion (ROM) and strength were compared by use of paired t-tests. Baseline characteristics of the patients with and without revision surgery were compared. For categorical variables chi-squared tests were performed; continuous variables were analyzed by use of t-tests or Mann Whitney U tests in case of non-normality. Kaplan Meier curves were used for survival analysis and a Log Rank test was performed to compare survival of the prosthesis between male and female patients. Revision was defined as endpoint and date of death or last follow-up were used as censuring dates. Differences are statistically significant at $p < 0.05$.

## RESULTS

Post-revision assessments were achieved in ten of the eleven revision patients. The one missing patient emigrated and had revision surgery abroad. This patient did not reply to our survey. Assessments were made at a mean of 42 months (minimum follow-up was 21 months, maximum 74; SD 15.9) and showed good clinical and patient reported outcome measures. The Constant Score improved significantly with a mean of 26 points (95% CI 9.6 – 43.0) and all patients scored above 80 points. Out of 10 patients, eight (80%) had no pain according to VAS score. The partial Constant-Murley score for internal rotation resulted in a significant improvement from a median score of 4 (reach to lumbosacral, IQR [4-4]) to 7 (reach between L3 and T12, IQR [5.5-8]) ($p$ =0.03). However, no significant improvement was observed for external rotation ($p$ =0.07). Both DSST and SF-12 were significantly improved (Table 2).





**Table 2** | Pre- and post-operative assessments

| Variable | Pre-revision | Post-revision | *p*-value |
|---|---|---|---|
| Elevation; mean, SD | 111° ± 34° | 143° ± 24° | 0.04 |
| Abduction; mean, SD | 92° ± 34° | 113° ± 29° | 0.09 |
| Force; mean, SD | 22.3 ± 3.5 | 22.0 ± 3.4 | 0.92 |
| CM; mean, SD | 67.1 ± 26.0 | 96.1 ± 7.2 | <0.01 |
| VAS; mean, SD | 54.3 ± 24.4 | 5.0 ± 10.8 | <0.01 |
| DSST; mean, SD | 43.9 ± 28.9 | 84.2 ± 13.3 | <0.01 |
| PCS; mean, SD | 36.7 ± 9.1 | 43.9 ± 12.3 | 0.02 |
| MCS; mean, SD | 42.6 ± 9.9 | 55.5 ± 10.6 | <0.01 |

*SD,* standard deviation; *Force,* pounds of abduction; *CM,* Constant Score; *VAS,* Visual Analogue Scale for pain; *DSST,* Dutch Simple Shoulder Score; *PCS,* Short Form 12 Physical Component Score; *MCS,* Short Form 12 Mental Component Score.

Baseline characteristics of patients with and without revision are listed in Table 3 and 4. Goutallier[25] grade fattening of the supraspinatus muscle was assessed on MRI and was significant higher in the non-revision CAP group ($p$ <0.01). No other significant pre-operative differences were found between the two groups. Regression analyses showed a significant correlation between Constant Score and gender ($p$ <0.01), therefore the comparison between the revision and non-revision group was corrected for gender.

**Table 3** | Baseline comparison

| Variable | Non-revision (n=37) | Revision (n=11) | *p*-value | Sig. cor.* |
|---|---|---|---|---|
| Gender; % male (m/f) | 18.9 % (7/30) | 45.5 % (5/6) | 0.11[a] | - |
| Age; mean, SD | 66.6 ± 7.8 | 62.9 ± 6.2 | 0.16 | - |
| AF; mean, SD | 99.2 ± 35.6 | 97.0 ± 29.3 | 0.85 | 0.61 |
| Abd; mean, SD | 81.9 ± 27.5 | 81.9 ± 32.2 | 0.99 | 0.64 |
| Force; mean, SD | 8.2 ± 2.8 | 9.5 ± 2.2 | 0.16 | 0.53 |
| CM; mean, SD | 46.8 ± 16.9 | 46.3 ± 18.5 | 0.93 | 0.42 |
| VAS; mean, SD | 65.2 ± 18.2 | 62.0 ± 15.1 | 0.60 | 0.73 |
| MCS; mean, SD | 48.1 ± 12.3 | 51.7 ± 10.8 | 0.39 | 0.58 |
| PCS; mean, SD | 35.5 ± 7.9 | 32.2 ± 6.5 | 0.22 | 0.20 |
| DSST; mean, SD | 20.0 ± 21.3 | 27.6 ± 27.5 | 0.34 | 0.57 |

* Significance by linear regression analysis corrected for gender. [a] Fisher's exact test. *SD,* standard deviation; *AF,* elevation; *Abd,* Abduction; *Force,* pounds of abduction; *CM,* Constant Score; *VAS,* Visual Analogue Scale for pain; *PCS,* Short Form 12 Physical Component Score; *MCS,* Short Form 12 Mental Component Score; *DSST,* Dutch Simple Shoulder Score.

**Table 4 |** Radiological assessment at baseline

| Variable | Non-revision n=37 | Revision n=11 | *p* -value |
|---|---|---|---|
| Goutallier fattening[25] | | | |
| None | 4 (11%) | 9 (82%) | |
| Grade 1 | 26 (70%) | 2 (18%) | 0.0003 |
| Grade 2 | 6 (16%) | 0 (0%) | |
| Grade 3 | 1 (3%) | 0 (0%) | |
| Glenoid[24] | | | |
| A1 | 17 (46%) | 9 (82%) | 0.14 |
| A2 | 14 (38%) | 1 (9%) | |
| B1 | 6 (16%) | 1 (9%) | |
| Osteophytes | | | |
| None | 1 (3%) | 1 (9%) | |
| Little | 14 (38%) | 6 (55%) | 0.39 |
| Moderate | 19 (51%) | 4 (36%) | |
| Severe | 3 (8%) | 0 (0%) | |
| Cuff rupture | | | |
| Yes (<1cm) | 4 (11%) | 0 (0%) | 0.60 |
| No | 33 (89%) | 11 (100%) | |
| Cuff calcifications | | | |
| Yes | 6 (16%) | 5 (45%) | 0.11 |
| No | 31 (84%) | 6 (55%) | |

Assessment by radiographs and MRI.

**Survival analysis**

In total the 5-year survival of the Global CAP resurfacing prosthesis was 82.6% (95% CI; 71.6 – 93.6). No significant difference was found between male and female patients (p=0.40). For women 5-year survival was 85.3% (95% CI; 73.3 – 97.3), for men 75% (95% CI; 50.5 – 99.5). The Kaplan Meier curves for all patients and gender specific are shown in Figure 2.

**Re-revision**

There were no re-revisions.





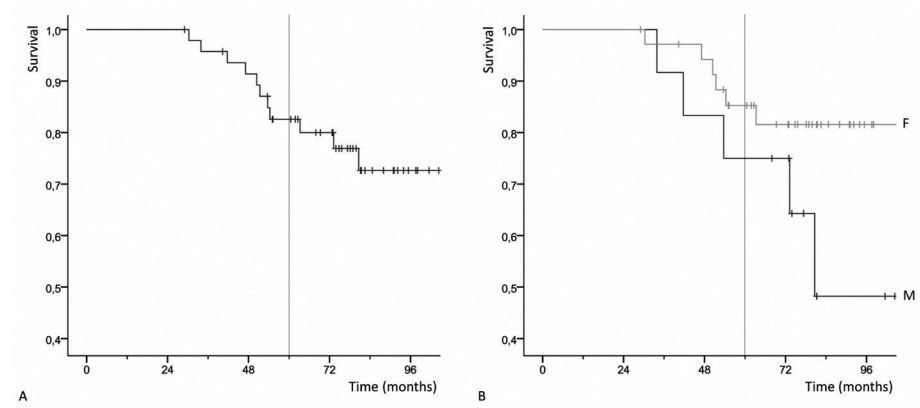


**Figure 2 |** Kaplan Meier survival analysis.

Five year cut of time marked with vertical line. (A) Total group, (B) gender specific, (M) male; (F) female.

## DISCUSSION

The main result of this study is the good outcome of shoulder arthroplasty after revision from the uncemented Global CAP resurfacing prosthesis at midterm follow-up. Comparable, good clinical outcome were reported by Natera et al.[20] in 18 revisions of the resurfacing Copeland prosthesis. In contrast, Streubel et al.[21] found that only four out of 11 (36%) patients had satisfied results based on the modified Neer score. One re-revision (9%) had to be performed in their series. In the latest report of Rasmussen et al.[22] non-satisfied outcome was reported by 41% of 80 shoulder resurfacing revision patients from the Danish national register.

These various results could be explained by the presence of confounding variables such as the experience of the surgeon, age, prior surgery, differences between implants used and underlying original pathology.[21] Surgical volume has proven to be related to the outcome of shoulder prosthesis.[30] The implantation rate of total shoulder arthroplasty and reverse shoulder arthroplasty are rising,[1,31] and therefore surgical skill and experience should increase proportionately.

High-volume orthopedic surgeons (i.e. more than eight shoulder arthroplasties/year[30]) performed the revisions in our institutes. We used three different prostheses designs to revise the failed CAP resurfacing prostheses (Table 1). The surgeons have extensive experience with these designs; the same prostheses used for primary stemmed total shoulder arthroplasty and reverse shoulder arthroplasty were used for the revision of the CAP during this study. In contrast, Natera et al.[20] successfully used one specific type of reverse shoulder arthroplasty and report that reverse shoulder arthroplasty is the best

option in revision situations. The role of surgeon experience and prostheses design in the outcome of revision surgery has limited evidence in literature. The best prosthesis design used for revision is yet to be determined. In our opinion, surgeon experience with the specific prosthesis design is most valuable.

For the treatment of gleno-humeral osteoarthritis total shoulder arthroplasty is the gold standard.[32–35] However, the authors believe that a hemi prosthesis, such as resurfacing implants, is still a valid treatment option in selected patients. The limited survival of the glenoid component in total shoulder arthroplasty is troubling. At midterm follow-up glenoid loosening has been reported to be 39%.[4,36–43] Factors such as rotator cuff failure, glenoid component malposition and instability can aid to glenoid component loosening and failure.[38,42,44].

Young patients have been shown to have higher demands of their shoulder prostheses and optimal shoulder function is needed in labor and physical activities.[4,11] Patient reported outcome measures are likely to be related to the demands.[45] Hemi shoulder arthroplasties are prone to fail in young patients and the average age in our series was 66 years; this elderly age could have been favorable to our outcome.

Streubel et al.[21] stressed the importance of exposure in their revision surgeries when prior preservation of the rotator cuff was done. Due to excessive scarring a different approach was needed in four of their eleven cases. In our series only one patient had prior surgery (subscapularis tendon repair). Due to the low prevalence of prior surgeries in our series, soft tissue damage and scarring was minimal. The extraction of the failed CAP prosthesis was easy accomplished after exposing the gleno-humeral joint. During revision surgery, humeral osteotomy or humeral bone allograft was not necessary in all cases; this in contrast of studies by Al-Hadithy et al.[46] and Alizadehkhaiyat et al.[47]. The current study did not show perioperative complications as humeral fractures. With these advantages, Cisneros et al.[18] found over an hour of time spared compared to revision of stemmed hemi shoulder arthroplasty, which is likely to minimize the perioperative complication hazard.

In the current study, the authors found a 5-year survival of 82.6%. Lebon et al.[48] found only 41% survival of resurfacing prosthesis at 5.5 years' follow-up in 37 patients, which was significantly poorer than the 0 revisions in their stemmed hemi shoulder arthroplasty group. Levy et al.[11] reported a better 5-year survival rate of 97%. Clearly higher revision rates were reported after passing the 5 year follow-up.[11,31,48]

There is certainly a discrepancy in the literature regarding the percentage of revision due to glenoid erosion and pain in resurfacing prosthesis.[11,47,49–52] Levy et al.[49] and Mullett et al.[50] reported 3% and 5% revisions, respectively, at midterm follow-up. Alizadehkaiyat et al.[47]





and Smith et al.[52] reported 22% and 21% revisions at short-term and midterm follow-up, respectively. We found similar revision rates (23%) despite our careful indications criteria; gleno-humeral osteoarthritis, intact rotator cuff and glenoid type A1, A2 and B1.

From our initial series 42% of the males and 17% of the females had a revision. However, a non-significant p-value was found comparing the gender specific survival curves. Additionally, similar results were reported in the 2015 Annual Report of the Australian Orthopaedic Association. They did not show gender specific differences in revision rate in 92 patients.[16] A fall in the use of resurfacing prosthesis was observed since 2006,[31] with a probable decrease of surgical skill. Developments in resurfacing are therefore likely to diminish.

Although varying in results, the indications for revision were comparable in all revision series we reviewed.[17,18,20–22] Hartel et al.[53], Sajadi et al.[54] and Dines et al.[55] showed inferior outcome if revisions of hemi shoulder arthroplasty were due to soft tissue pathologies compared to glenoid erosion or component failure. Regarding resurfacing prostheses, the effect of indication for revision has not been investigated. However, glenoid erosion is a major concern in resurfacing hemiarthroplasty.[56] With respect to the numbers available in our baseline comparison, we conversely found significant lower Goutallier[25] grades in the revision group, suggesting that good muscle condition could be a risk factor for early revision. This in contrast to Herschell et al.[57], who showed fatty infiltration of the rotator cuff as a risk for glenoid erosion in hemi shoulder arthroplasty.

The CAP resurfacing prosthesis did not show signs of loosening on radiographs and no loose prosthesis were found during revision operation. However, perioperative observations showed significant reduced bone density underneath the C.A.P prosthesis. These findings are similar to those described earlier by Schmidutz et al.[58] who reported that despite clear signs of stress shielding, adequate ingrowth of bone was observed to secure good stability of the prosthesis. The bone quality of the proximal humerus was not affected. Even a stemless prosthesis such as the T.E.S.S. (Biomet, France) could be firmly secured after the removal of the humeral head resurfacing arthroplasty.

A limitation of this study was the small sample size. Although a CAP resurfacing replacement was implanted in 48 shoulders, only eleven were revised and therefore available for this study. Another downside to this study is the lack of a control group. A stemmed control group or primary total shoulder arthroplasty group like the studies of Natera et al.[20] and Rasmussen et al.[22] would give valuable information and opportunities for comparison. Unfortunately, such data were not available. Despite the low therapeutic level of this study, it was to our knowledge the only cohort of revisions of this specific prosthesis described in the literature and showed good results.

We conclude that patient reported outcome measures are satisfying after revision of the uncemented Global CAP resurfacing hemi prosthesis to total shoulder arthroplasty or reverse shoulder arthroplasty at midterm follow-up. Despite the limited, conflicting literature on this subject, the data of this study support the authors' opinion that total shoulder arthroplasty or reverse shoulder arthroplasty is a viable option when a resurfacing hemiarthroplasty has failed.





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# CHAPTER 11

## Discussion, answers and implications for future research

This thesis is designed to answer the following questions, the following paragraphs list which answers have been collected and which are still open for future research

***1. Can we postpone an arthroplasty of the shoulder with intra-articular infiltration in gleno-humeral osteoarthritis?***

The answer to this question should emerge from a systematic review that describes and evaluates the evidence regarding efficacy of the several intra-articular infiltration treatment options of patients with gleno-humeral osteoarthritis.
In the review we have found that intra-articular treatment with hyaluronate acid has a good efficacy at follow-up compared to baseline, this is in contrast with corticosteroid infiltrations. However, the difference in efficacy between hyaluronate acid and placebo never reaches the minimal clinically important difference at any of the follow-up points. From the evidence reported in this thesis, it is not feasible to give a clear recommendation regarding the use of intra-articular injections in patients with gleno-humeral osteoarthritis to postpone shoulder arthroplasty. This is also the recommendation which concurs with the American Academy of Orthopaedic Surgeons.[1]

**Future research**
In clinical practice, shoulder arthroplasty for gleno-humeral arthritis is advised if conservative therapy has failed. Patients with osteoarthritis of the shoulder are advised to use nonsteroidal anti-inflammatory drugs, intra-articular infiltrations and exercise therapy supervised by a physiotherapist, despite the lack of evidence in literature.
A randomized trial to assess the combination of different kinds of conservative therapies and new kinds of infiltration (such as stem cell therapies, platelet rich plasma) can possibly give insight in which combination is useful in the conservative treatment of gleno-humeral osteoarthritis.

***2. Do strategies differ between countries regarding the choice for using resurfacing hemiarthroplasty?***

In **chapter 3** orthopedic surgeons from Belgium and the Netherlands, specializing in shoulder pathology, have been interviewed about their indications and the pre-, per- and post-operative treatment in cases of hemi, total and reverse shoulder arthroplasty.
In the survey (conducted in 2014), we have concluded that orthopedic surgeons from Belgium are significantly more likely to perform resurfacing hemiarthroplasty compared to the colleagues from the Netherlands. A shoulder resurfacing arthroplasty procedure is also more likely to be performed by experienced (≥6 years) orthopedic surgeons. Less experienced (<6 years) orthopedic surgeons prefer total or reverse shoulder arthroplasty instead of hemi shoulder arthroplasty. This is in contrast with the study of Mann et al.[2]





These authors have concluded that the hemi shoulder arthroplasty procedure is commonly performed for primary gleno-humeral osteoarthritis among recent orthopedic graduates. However, shoulder fellowship trained surgeons prefer a total shoulder arthroplasty for this indication.[2]

There have been a shift in the use of anatomical prosthesis and hemi shoulder arthroplasty. In 2014, 459 hemi shoulder arthroplasties and 465 total shoulder arthroplasties have been performed in the Netherlands. The number of hemiarthroplasties have decreased to 257 in 2018. In the same year the amount of total shoulder arthroplasties have increased to 672. In 2014, the amount of hemi shoulder arthroplasty and total shoulder arthroplasty have been 22% of all primary shoulder arthroplasty. In 2018 the amount of hemi shoulder arthroplasty have declined to 9%, in contrast to the amount of total shoulder arthroplasty, which remains at 22%.[3]

It is remarkable that we have found very large difference in two neighboring countries with many similarities. However, the treatment of gleno-humeral osteoarthritis is very different. We could have done a survey which compared two countries with great differences between both cultural and health systems. We probably would have found even greater differences in the treatment of gleno-humeral osteoarthritis. The use of resurfacing hemiarthroplasty is declining in both countries, but a larger decrease is seen in the Netherlands compared to Belgium. Do the medical equipment companies play a dominant role in recommending certain types of shoulder prosthesis? Does orthopedic training play a role in the experiences received in their training hospital (confirmation bias, knowledge dissemination)? In the Netherlands the increase of the reverse shoulder arthroplasty at the expense of the hemiarthroplasty share is also likely to play a role. As mentioned above the share of total shoulder arthroplasty remains 22%.

**Future research**
A future study should address why the resurfacing arthroplasty is not as popular with inexperienced orthopedic surgeons. It could be due to their lack of knowledge about ongoing studies of surgical problems at the humeral site (varus/valgus, lateralization, overstuffing).

***3. Does the (resurfacing) shoulder hemiarthroplasty provide similar patient reported outcomes compared to the total shoulder arthroplasty?***

Based on the systematic review outlined in **chapter 4**, we conclude that long-term follow-up patient reported outcomes are superior after total shoulder arthroplasty compared to hemi shoulder arthroplasty. Total shoulder arthroplasty will result in less need for revision surgery but tends to result in more complications. These include glenoid component failure,

as a result of aseptic or septic loosening, wear, soft tissue insufficiently, fracture and instability. No definitive answer could be given, since the research modality is not fully satisfactory due to the heterogeneity of data and quality of included studies.

A report from the Danish Shoulder Arthroplasty Registry based on 1.209 shoulder arthroplasties and in a similar study from the Nordic Arthroplasty Register Association based on 5.159 shoulder arthroplasties, no differences in failure rates between stemmed and resurfacing shoulder arthroplasties have been found.[4,5]
The only difference is a significant younger population in the resurfacing arthroplasty group.[4] This in contrast with studies by Ödquist et al.[6] and Lebon et al.,[7] in which a higher revision rate is found in the resurfacing group as compared to the stemmed arthroplasty. Patient related outcomes are similar in both groups.

The hemi shoulder arthroplasty and resurfacing shoulder arthroplasty show inferior results when compared to total shoulder arthroplasty. But if we can provide a well-positioned resurfacing or non-stemmed hemi prothesis with patient-specific instruments or fluoroscopy, hemiarthroplasty is the preferred procedure in young and active patients. In this population strict radiographic follow-up should observe glenoid erosion. As long as we do not have total shoulder protheses for life and revision is required when the patient is aging, this is a relatively simple initial step with all options open for revision to more extensive and reliable procedures in the future.

**Future research**
In future research, a randomized long-term follow-up study should assess and compare the patient reported outcomes, revision rate, post revision patient reported outcomes and implant survival of a stemmed total shoulder arthroplasty to a stemless/resurfacing total shoulder arthroplasty.

***4. Does the Global CAP resurfacing hemiarthroplasty provide satisfactory patient reported outcomes in primary osteoarthritis and does a hemi shoulder arthroplasty provide satisfactory patient reported outcomes in secondary gleno-humeral osteoarthritis (Rheumatoid arthritis) in the long term?***

This question is a two-fold.
First, we describe in **chapter 5** and **6** the short and mid-term follow-up of Global Conservative Anatomic Prosthesis CAP resurfacing hemiarthroplasty. At the 2-year follow-up no revision was necessary. The radiographs show no loosening or glenoid erosion. Patient reported outcome measures improves significantly.





Our results at short term follow-up are in line with the results found by Thomas et al.,[8] Mullet et al.[9] and Levy et al.[10] However, high rates of revision are described by the Danish Arthroplasty Register,[11] Smith et al.[12] and Alizadehkhaiyat et al.[13] at short term follow-up.

Despite the clinical improvement at short term follow-up, at mid-term follow-up patient reported outcome measures have improved, but eleven of the 48 patients (23%) had a revision operation.
On the available radiographs no loosening or dislocation have been seen. Some degree of superior migration, as an indication of rotator cuff failure or insufficiency, have been was noted in 42% of the shoulders. Of all patients, 17% had severe migration and 25% had mild superior migration. In 58% of the operated patients, no superior migration was observed. Moderate-to-severe glenoid erosion have been was present in 33% of the shoulders at a mid-term follow-up.

At short term follow up, no revision has been necessary. Nevertheless, at mid-term follow up the revision rate has been raised to 23%, which is comparable with the studies by Smith et al.[12] and Alizadehkhaiyat et al.[13] Studies by Sperling et al.[14] and Bartelt et al.[15] also have showed high revision rates of 22% and 30% in a stemmed hemiarthroplasty.
Studies of Levy et al.[9,10,16,17] and the Copeland group have reported low rates of revision at mid-term and long-term follow-up. This is not found in our series nor in other series in literature.[11–13]

Possible explanations for the different rates of revisions:
A. In the study by Smith et al.[12] (describing the Global CAP resurfacing prosthesis) a 22% revision rate at the 2.5-year follow-up have been found. Ingoe et al.[18] have found a 62% survival rate at the 7-year follow-up. The Global CAP resurfacing shoulder prosthesis implant is comparable but not identical to the Copeland prothesis. Properties of the designs might explain the difference in revision rates. However, Alizadehkhaiyat et al.[13] describes the Copeland resurfacing shoulder arthroplasty and have reported a 21% revision rate at the 4-year follow-up.
B. It is well known that complications and failure are related to low-volume shoulder surgeons (5-8 shoulder arthroplasties per year).[19,20] However, the arthroplasties in our studies have been performed by two orthopedic surgeons who perform respectively 20-50 per year and > 50 per year (data 2014[21]).
C. In our two institutes the revision surgery have been performed by the same surgeon who performed the primary operation. Research shows that revision surgery is often performed by a surgeon other than the initial surgeon, causing the revision to be less likely to be reported.[22–24] This could be an explanation to the lower revision rates compared to our series and the series by Smith et al.[12] and Alizadehkhaiyat et al.[13]

Summarizing, the results of the Global CAP resurfacing hemi arthroplasty are similar to the results found in literature with respect of revision rates. The long-term results by the Copeland group are not achieved by others in literature and should be interpreted with care.

Secondly, in **chapter 7** we describe that cemented hemiarthroplasty is a viable treatment option for end stage gleno-humeral arthritis in patients with rheumatoid arthritis. Long term results show acceptable results and low complication and revision rates.

We should see this in light of current literature, patients with rheumatoid arthritis are likely to have better PROM's with a reverse shoulder arthroplasty compared to a hemiarthroplasty.[25–28] In the study presented in **chapter 7**, the patients have been operated on between 1995 and 2008. The use of a reverse shoulder arthroplasty has not been widely available, especially in the mid 90's. Alternatively, the use of a total shoulder arthroplasty is known for high rates of failure in patients with rheumatoid arthritis.[29–31]

Cuff tears in rheumatoid patients are extremely common (20%-100%).[32–34] Therefore progressive upward migration of the humeral head in the rheumatoid population has been described as inevitable.[25,34] Moderate to severe degenerative changes of the gleno-humeral joint have been seen in nearly 70% of rheumatoid arthritis patients.[25,35,36] Glenoid degeneration makes implant fixation more challenging. This can lead to premature failure of the glenoid component due to insufficient fixation and instability. In the literature, authors have justified a hemi shoulder prosthesis for young patients or patients with major glenoid damage, therefore avoiding problems with replacing the degenerative glenoid.[25,37–40] The functional outcome is unsatisfactory and decreases further due to progressive glenoid degeneration.[25,38,41]

This in line with our study. All patients had medialization of the arthroplasty due to glenoid erosion and cranialization due to rotator cuff insufficiency at long-term follow-up. Although we have to emphasize that patients with rheumatoid arthritis are more willing to accept their condition, such as a limited range of motion due to glenoid erosion.[42]

Long term results of hemiarthroplasty in selected population patients with rheumatoid arthritis show satisfactory results and low revision rates. A reverse shoulder could possibly provide superior results but may be result in more complications (technical more demanding) and possible higher revision rate. Besides, young patients with an active rheumatoid arthritis and degenerative rotator cuff might be better off with a hemiarthroplasty.





**Future research**

Revision after resurfacing hemiarthroplasty is less demanding than revision after stemmed arthroplasty.[43–47] In future research, a long, randomized follow-up study should assess the patient reported outcomes, revision rate, post revision patient reported outcomes and implant survival of a hemi- and total shoulder arthroplasty in young patients (<60 year).

Future research can compare patient reported outcomes after hemiarthroplasty or reverse shoulder arthroplasty in end stage rheumatoid arthritis in young patients (<50 year).

***5. Why does the Global CAP resurfacing hemiarthroplasty fail and how are the reported outcomes after revision?***

The resurfacing shoulder procedure has been proven to be more technically demanding than expected. The implant tends to be of a larger size than the anatomical head.[7,48] This leads to overstuffing which might lead to pain and decreased range of motion.[12,48] In **chapter 9**, we demonstrate an overstuffing of more than 5 millimeters will lead to failure and possible revision.

Progressive pain and poor function with glenoid erosion is the main reason of revision in our series. At mid-term follow-up, rotator cuff failure or insufficiency is noted with 42% of the shoulders. 17% of the patients had severe migration and 25% had mild superior migration. Moderate-to-severe glenoid erosion is present in 33% of the shoulders.

Symptomatic glenoid erosion is a main concern in shoulder hemiarthroplasty.[49,50] The condition of the glenoid may be critical in determining whether humeral head replacement alone will be successful. In particular, patients with concentric glenoid wear and primary osteoarthritis seem to have better outcomes than those with eccentric glenoid wear and secondary osteoarthritis.[51] However, patients with severe glenoid erosion after a hemi shoulder arthroplasty seem to have better patient reported outcomes compared to patients with mild glenoid erosion.[51]
Contributing conditions to prevent degeneration of the glenoid after shoulder hemiarthroplasty were intact cartilage and the absence of cysts in the glenoid, absence of fractures and an intact rotator cuff.[50] The version of the glenoid, size of the humeral component and age seem not to play a role in the degeneration of the glenoid.[50] The degradation of the glenoid in shoulder hemiarthroplasty appears to be related to female patients, patients with rheumatism and the position of the humeral component in valgus position.[50]

Glenoid erosion is the consequence of an overstuffed shoulder leading to failure. In joint overstuffing, the tension and traction on the rotator cuff and the capsular ligamentous

complex increase during arm elevation. An overstuffing of a joint by 9 millimeters will require a torch of almost 3 times compared to an anatomic shoulder.[52]

A possible explanation for the high rate of revision might be the relatively ease of revising a resurfacing hemiarthroplasty compared to a well-fixed stemmed prosthesis.[18] In literature, intra-operative complications of a stemmed arthroplasty at revision surgery have been reported to occur in up to 30% of the cases.[43–47]
In line with Cofield et al.[53] revision rate alone is not a synonym for a failed procedure based on the subjective assessment of the surgeon. Failures should also be considered when patients reported pain is equal to or worse than their pre-operative condition.

Despite positive early and mid-term results with hemi shoulder arthroplasty, the need for revision to total or reverse shoulder arthroplasty has been demonstrated after longer-term follow-up. In the studies of Streubel et al.,[54] Hartel et al.,[55], Sajadi et al.,[56] and Dines et al.,[57] revision of a resurfacing shoulder arthroplasty to a total shoulder arthroplasty provides unsatisfying results. This is in contrast to our study, **chapter 10**, which has showed favorable results after revision.
In line with Ingoe et al.[18] factors such as the ease of revision of a resurfacing hemiarthroplasty, the choice to revise to a total or reverse shoulder arthroplasty, and good patient reported outcomes after revision, may lower the threshold in case of a painful shoulder. When compared to a painful total shoulder arthroplasty, without signs of loosening or low-grade infection, the surgeon will not easily proceed to revision because of the limited choices of implant and high risk of complications and poor patient reported outcomes.[58]

Both hemiarthroplasty and total shoulder arthroplasty may achieve positive short-term and mid-term result. However, while total shoulder arthroplasty may provide superior and more reproducible pain relief, the technical difficulties of inserting a glenoid component, and the long-term durability of glenoid prostheses in terms of loosening and wear must be considered.[14,59,60]

Singh et al.[61] have shown in their study that young patients with shoulder osteoarthritis are a risk factor in total shoulder arthroplasty. In addition, in their study, they showed that this particular group has a significantly higher risk of failure and revision after a primary total shoulder prosthesis.[6,61] This age-related risk may affect the choice of primary implant type if future revision is a likely outcome.[6,51] The design of implant can make it unattractive for revision surgery or affect the indication if revision will be considered in the future. Resurfacing arthroplasty has been suggested to be a good alternative in the young and active patients who may be more at risk for future revision.[6,17]





The Global CAP resurfacing hemiarthroplasty is likely to fail as a result of an overstuffing of more than 5 millimeters. This will probably be the case in all resurfacing arthroplasties, also in the prothesis used by the Copeland group. In case of the need to revise the Global CAP resurfacing arthroplasty the results post revision to total shoulder or reverse shoulder the patient reported outcomes are satisfactory. In line with Alolabi et al.[62], intra-operative fluoroscopy or patient specific instruments may provide additional valuable information to confirm offset and varus/valgus of the implant and avoid overstuffing and failure in the future.

**Future research**
In future research, a randomized study should assess the patient reported outcomes and revision rates on patients with a resurfacing hemiarthroplasty with and without patient specific instruments or intra-operative fluoroscopy. Also, the difference in offset, varus/valgus alignment and progression of glenoid erosion should be determined

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# CHAPTER 12

## Summary

**Chapter 1** describes a general introduction in the non-operative, operative and revision treatment of patients with gleno-humeral osteoarthritis and raises a number of research questions that are addressed in the subsequent chapters.

**Chapter 2** describes a systematic review of the literature which investigates intra-articular infiltration therapy for patients with gleno-humeral osteoarthritis. In this systematic review, we evaluate the current evidence regarding the efficacy of intra-articular infiltration treatment options in patients with gleno-humeral osteoarthritis.

With a database search (Pubmed/Medline, Cochrane Clinical Trial Register and Embase databases), we initially have found 1.492 papers. After reading the title and abstract, 32 articles have been screened for eligibility. Eight studies have been included, two randomized trials, five prospective case studies and one retrospective study.

The included randomized controlled trials compare the efficacy of intra-articular administered hyaluronic acid with placebo. The prospective case series all use intra-articular administered hyaluronic acid injections. The retrospective study compares the efficacy of intra-articular hyaluronic acid and corticosteroids injections.

A total of 895 patients have been included in these 8 studies; 579 patients have received hyaluronic acid injections Hylan G-F 20 (Synvisc, Genzyme Corporation, Cambridge, MA, USA), Supartz (Smith & Nephew, Inc, Andover, MA, USA) or Hyalgan (Sanofi-Aventis, Bridgewater, NJ, USA and Fidia Farmaceutici, SpA, Abano Terme, Italy), 33 patients have received corticosteroid injections (6-methylprednisolone acetate, Depo-Medrol (Pfizer, Latina, Italy) and 283 patients phosphate-buffered saline injections.

In conclusion, the difference in efficacy between intra-articular administered hyaluronic acid and placebo is small, the efficacy of intra-articular injection of hyaluronic acid at follow-up during the first 6 months is good in patients with gleno-humeral osteoarthritis. However, the difference in efficacy between hyaluronic acid and placebo never reaches the minimal clinically important difference at any of the follow-up points.

**Chapter 3** covers an intercountry comprehensive survey in Belgium and the Netherlands starting in 2013 and ending 2015. The purpose of this survey is to gain insight in indication, pre-, per- and post- operative management in end stage gleno-humeral osteoarthritis by orthopedic surgeons for the two countries. Also, a comparison between experienced and less experienced orthopedic surgeons has been made.

Orthopedic surgeons with a special interest in shoulder surgery, and all members of the Dutch Shoulder and Elbow Society and the Belgian Elbow and Shoulder Society have





been invited to participate in an online survey. One hundred eighty-one orthopedic surgeons have been invited to complete the survey, with a 71% response rate. Orthopedic surgeons with at least 6 years of experience are more likely to perform a resurfacing/stemless shoulder arthroplasty in gleno-humeral osteoarthritis compared to orthopedic surgeons with less experience (<6 years). Seventy-two percent of the orthopedic surgeons think overstuffing is the greatest risk of complication after a resurfacing arthroplasty. A decrease in the use of resurfacing arthroplasty and an increase in the use of reverse shoulder arthroplasty has been found. In conclusion, there is little consensus concerning pre-operative planning, patient characteristics, type of implant, surgical technique, thrombosis prophylaxis, outcome assessment with patient reported outcomes measured and post-operative restrictions for the patients.

**Chapter 4** describes a systematic review of the literature between hemi shoulder arthroplasty and total shoulder arthroplasty in patients with gleno-humeral osteoarthritis. The objective of this review is to systematically review the current available literature to formulate evidence-based guidelines for treatment of this pathology with arthroplasty. After a database search (Pubmed/Medline, Cochrane Clinical Trial Register and Embase databases), we initially have found 832 papers. This includes 18 studies, all case studies, with a total of 1.958 patients (316 hemi arthroplasty patients and 1.642 total shoulder arthroplasty patients). The revision rate reported in the hemi arthroplasty group is 3% and 7% in the total shoulder arthroplasty group. The exact type of complication is not described in the articles, although the complication rate in the total shoulder arthroplasty group is higher compared to the hemi arthroplasty group, 12% versus 8%. Four studies in both groups report a decrease of pain. Improvement in range of motion and pain comparison between the two groups is not possible due to missing standard deviation in the included articles. It is concluded that total shoulder arthroplasty results in less revision surgery but has a trend to lead to more complications compared to hemi arthroplasty.

**Chapter 5** a prospective study of an uncemented shoulder resurfacing hemi arthroplasty in patients with primary gleno-humeral osteoarthritis is described. The aim of this short-term follow up study is to evaluate clinical and functional outcome and radiographs of a Global Conservative Anatomic Prosthesis (CAP) (DePuy-Synthes, Warsaw, Indiana, USA). 36 female and 12 male patients with a mean age of 69 years old (range 56-86 years) show a significant improvement in all patient reported outcome measures after surgery. The mean Constant score improves from 49 ± 18 points preoperatively to 79 ± 23 points at follow-up. The mean Dutch Simple Shoulder Test improves from 22 ± 23 points preoperatively to 66 points ± 29 points at follow up. The pain score, according to the visual analogue scale, decreases from 65 ± 18 preoperatively to 35 ± 27 points at follow up.

The SF-12 is divided into mental score and physical score. The mean SF-12 mental score did not improve. The mean SF-12 physical score improves from 35 ± 8 points preoperatively to 42 ± 10 points at follow up. At the two-year follow-up, no revision surgery has been necessary. Radiographs of the shoulders show no loosening and no glenoid erosion at the two-year follow-up. In conclusion, at short-term follow-up of the uncemented global CAP resurfacing hemi arthroplasty is encouraging and comparable with literature.

**Chapter 6** is an extension of **Chapter 5**. The aim of this study is to evaluate patient reported outcomes and radiographs at mid-term follow up. At the mean follow-up of 6.4 years (range 5.1 – 7.9), patient reported outcomes show a significant improvement after surgery. The mean Constant score improves significantly from points 47 ± 18 preoperatively to 83 ± 22 points at follow-up. The mean Dutch Simple Shoulder Test improves significantly from 20 ± 21 points, preoperatively to 67 ± 30 points at follow up. The pain score, according to the visual analog scale, decreases significantly from 66 ± 19, preoperatively to 29 ± 28 points at follow up. The SF-12, divided in a mental and a physical score, the mean SF-12 mental score improves from 49 ± 12 points preoperatively, to 51 ± 8 points at follow up. The mean SF-12 physical score improves from 35 ± 8 points preoperatively, to 39 ± 11 points at follow up.

For 36 of the shoulders, radiographs are available, and show no loosening or dislocation at mid-term follow-up. Some degree of superior migration, as an indication of rotator cuff failure or insufficiency, is noted in 15 of the 36 shoulders (42%). Six (17%) patients have severe migration and nine (25%) have mild superior migration. Twenty-one (58%) shoulders show no superior migration. Moderate-to-severe glenoid erosion is present in 12 (33%) of the shoulders at a mid-term follow-up.

11 Patients (23%), 5 males and 6 females, have had a revision operation to total shoulder arthroplasty or reverse shoulder arthroplasty. One patient has had positive cultures during revision surgery. In conclusion, the mid-term results of the global CAP resurfacing hemi arthroplasty are in line with other studies with a concerning revision rate of 23%.

**Chapter 7**, in line with **Chapter 5** and **6,** concern a retrospective study of 35 patients with rheumatoid arthritis of the shoulder and associated rotator cuff pathology. The aim of this long-term follow-up is to evaluate patient reported outcomes and radiographs. 45 cemented hemiarthroplasties have been performed in 34 patients (11 bilateral). Included are 31 female and three male patients with a mean age of 65 years old (range 31-84 years).

Ten patients (12 shoulders) have died of conditions unrelated to shoulder arthroplasty. One patient has been lost to follow up, due to paralyses of her affected arm, related to a





complication of a cervical hernia surgery. Clinical assessment of one patient has not been possible related to the patient having Alzheimer's disease.

Mean age of the deceased population is 68 years old (range 59-76) and mean survival of the implant of this group is 4.1 years (range 0-11 years). None of the patients in this group has had complications related to the implant or operation. The radiographs in this group show consistent medialization of the arthroplasty due to glenoid erosion, and cranialization due to rotator cuff insufficiency. There are no signs of implant loosening, fractures of the glenoid or acromion. This group was not included in the data analysis.

The mean age for the follow-up group is 61 years old (range 31-84) and the mean follow-up period is 10.0 years (range 5-17 years). The mean visual analogue pain score is 3 (SD 2). The mean Constant score is 55 (SD 16). The mean Dutch version of the Disabilities of the Arm Shoulder and Hand score in 20 patients (two invalid forms) is 42 (SD 19). Radiographs available of all shoulders show no loosening of the stem at follow-up. All patients have had medialization of the arthroplasty due to glenoid erosion and cranialization due to rotator cuff insufficiency. No radiographic complications, such as fractures or implant/instrument failure, have been observed.

One patient has reported persistent pain and limited range of motion direct post-operatively. Two weeks post the operation date, arthrotomy and capsulotomy has been performed. Tissue cultures obtained per operatively are negative for infection. Ultimately, pain has decreased, and shoulder function has improved. No revision surgery is performed within this long-term follow-up period.

In conclusion, cemented hemi-arthroplasty is a treatment option for gleno-humeral arthritis in patients with rheumatoid arthritis. Long term results show acceptable results and low complication and revision rate.

**Chapter 8** is a case report of a patient (one of the included patients from the Global CAP study) who has presented with a failed resurfacing shoulder hemi arthroplasty due to a periprosthetic infection, which had been histologically fully osseointegrated. The general conception is that an infection lead to interface formation (with neutrophils) and loosening of the prosthesis. We have discussed this at the presentation of the case and believe that periprosthetic infection and septic prosthetic loosening are two different diagnoses.

**Chapter 9** is an extension of **Chapter 5 and 6**. The aim of this radiographic study is to evaluate the ability to restore humeral head anatomy and to determine the inter-observer reliability of the critical shoulder angle (CSA), length of the gleno-humoral offset (LGHO) and deviation of the center of rotation (COR) in a resurfacing shoulder hemi arthroplasty.

Furthermore, with these measurements we try to find prognostic tools to predict poor functional outcomes and the necessity of revision. For reliable assessments, four independent observers have performed the measurements. The assessors have used the pre-operative radiographs and the 6 weeks post-operative radiographs. At a median of 9-year follow-up (range 5-12 years) 12 shoulders (25%) have had a revision to total shoulder arthroplasty. One patient has been excluded for data analysis due to a low-grade infection.

The average age is 77 years (SD 7.5), with 36 patients of the 47 being female (77%). The inter observer reliability shows excellent reliability for the CSA, LGHO pre- and postoperative and the COR. A mean CSA of 47 shoulders is 29.8° (SD 3.9). We have found no significant difference in CSA between the revision group and non-revision group. The mean LGHO increases from 49.6mm (range 37.6-60.4) before surgery to 52.1mm (range 37.2-61.7) after surgery. The increase of the LGHO has been significantly higher in the revision group compared to the non-revision group. The preoperative LGHO is not significantly different between the two groups. However, the postoperative LGHO of the revision group is significantly different compared to the non-revision group. The mean deviation of the postoperative resurfacing head COR from the anatomic COR for all 47 cases is 5.6mm (2.7 SD). The mean COR in the non-revision and the revision group is 4.9mm (2.5SD) and 8.0mm (SD2.2) respectively. This difference is significant. Of the 47 shoulders, five implants (12%) had the COR shifted to medial inferior. The rest of the 43 shoulders have had the COR shifted to medial superior. In the revision group (n=11) all shoulders have had the COR shift to medial superior, meaning overstuffing of the joint. Univariate analysis has revealed that post-operative LGHO and the COR have both been significantly associated with revision. However, in the final model only the COR remains as a predictor for revision with an OR of 1.90 (95%Cl 1.19-3.02). ROC analysis of the COR has revealed a cut-off point for revision of 5.8mm (95%Cl of 4.0-8.4) with a corresponding AUC of 0.82 (95%CI: 0.68-0.95). In conclusion, performing hemi arthroplasty with the Global CAP resurfacing shoulder prosthesis will lead to overstuffing of the gleno-humeral joint in almost all shoulders. In contrast, with the CSA and LGHO we did find a correlation between clinical failure and revision surgery in case of a deviation of the COR greater of 5mm.

**Chapter 10** describes the patient reported outcome measures after revision of the uncemented Global CAP resurfacing hemi shoulder arthroplasty. The aim of this prospective study is to report the clinical and functional outcome of revision from the uncemented Global Conservative Anatomic Prosthesis (CAP) resurfacing prosthesis to total shoulder prosthesis or reverse shoulder prosthesis. In addition, we have performed a survivorship analysis and compare the baseline characteristics of the Global CAP revision and non-revision groups to determine factors predictive of revision.





At a mean follow-up of 4.5 years, 11 patients (23%) have undergone revision surgery. Pain and poor function have been caused by glenoid erosion in four patients (36%), undefined pain and loss of function have been found in two (18%). Cuff arthropathy have been found in two patients (18%). One of the patients, has experienced an anterior subluxation after a failed subscapularis tendon repair. Arthrofibrosis and painful range of motion without glenoid erosion have been reasons for revision in two other patients. One patient (9%) has had a low-grade infection.

Total shoulder arthroplasty is used in eight patients and three patients have received a reverse shoulder arthroplasty. Post-revision assessments have been achieved in 10 of the 11 revision patients. Assessments have been made at a mean of 42 months (minimum follow-up was 21 months, maximum 74; SD 15.9) and showed good clinical and patient reported outcomes measures. The Constant score did improve significantly with a mean of 26 points (95% CI 9.6 – 43.0) and all patients had a score of above 80 points. Out of 10 patients, eight (80%) have had no pain according to visual analogue scale. Both Dutch Simple Shoulder test and SF-12 are significantly improved. In total, the 5-year survival of the Global CAP resurfacing hemi arthroplasty is 82.6% (95% CI; 71.6 – 93.6). No significant difference has been found between male and female patients, and there have been no re-revisions. In conclusion, patient reported outcomes are satisfying after revision of the uncemented Global CAP resurfacing hemi shoulder arthroplasty to total or reverse shoulder arthroplasty at midterm follow-up.

# CHAPTER 13

## Nederlandse samenvatting

In **hoofdstuk 1** wordt een algemene inleiding gegeven in de conservatieve, operatieve en revisie behandeling van patiënten met gleno-humerale artrose en worden een aantal onderzoeksvragen gesteld die in de volgende hoofdstukken aan bod komen.

**Hoofdstuk 2** beschrijft een systematische review van de literatuur die intra-articulaire infiltratie therapieën onderzocht voor patiënten met gleno-humerale artrose. In deze systematische review hebben we het huidige bewijs geëvalueerd met betrekking tot de effectiviteit van intra-articulaire infiltraties bij patiënten met gleno-humerale artrose.

Na een databaseonderzoek (Pubmed/ Medline, Cochrane Clinical Trial Register en Embase-databases) hadden we aanvankelijk 1492 artikelen gevonden. Na het lezen van de titel en abstract werden 32 artikelen gescreend op geschiktheid. Uiteindelijk hadden we 8 studies, twee gerandomiseerde studies, vijf prospectieve casestudies en een retrospectieve studie, geschikt bevonden voor inclusie.

De twee gerandomiseerde onderzoeken vergeleken de werkzaamheid van intra-articulair toegediend hyaluronzuur met een placebo. De prospectieve studies gebruikten allemaal intra-articulair toegediend hyaluronzuur. De retrospectieve studie rapporteerde de werkzaamheid van hyaluronzuur en corticosteroïden infiltraties.

Een totaal van 895 patiënten waren geïncludeerd in deze 8 studies; 579 patiënten kregen een injectie met een hyaluronzuur, Hylan GF 20 (Synvisc, Genzyme Corporation, Cambridge, MA, VS), Supartz (Smith & Nephew, Inc, Andover, MA, VS) of Hyalgan (Sanofi-Avis, Bridgewater, NJ, VS) en Fidia Farmaceutici (SpA, Abano Terme, Italië), 33 patiënten een corticosteroïden injectie (6 methyl-prednisolonacetaat, Depo-Medrol (Pfizer, Latina, Italië) en 283 patiënten een injectie met een fosfaatgebufferde zoutoplossing.

Geconcludeerd werd dat het verschil in werkzaamheid tussen intra-articulair toegediende hyaluronzuur en placebo klein is. De werkzaamheid van een intra-articulaire injectie met hyaluronzuur bij follow-up gedurende de eerste 6 maanden was goed bij patiënten met gleno-humerale artrose. Het verschil in werkzaamheid tussen hyaluronzuur en placebo bereikten echter nooit het minimale klinisch belangrijke verschil op een van de follow-up momenten.

In **Hoofdstuk 3** wordt een interland onderzoek in België en Nederland van 2013 tot 2015 beschreven. Het doel van dit onderzoek was om inzicht te krijgen in indicatie, pre-, per- en postoperatieve behandeling bij gleno-humerale artrose door orthopedisch chirurgen in de twee landen. Ook werd een vergelijking gemaakt tussen ervaren en minder ervaren orthopedisch chirurgen.





Orthopedisch chirurgen met een interesse in schouderchirurgie en alle leden van de Werkgroep Schouder en Elleboog en de Belgian Elbow and Shoulder Society werden uitgenodigd om deel te nemen aan een onlinesurvey.

In totaal ontvingen 181 orthopedisch chirurgen een e-mail met een uitnodiging om de enquête in te vullen. De enquête werd door 128 (71%) deelnemers ingevuld. Orthopedisch chirurgen met ten minste 6 jaar ervaring plaatsten meer resurfacing schouderprotheses in vergelijking met orthopedisch chirurgen met minder ervaring (<6 jaar). Volgens de orthopedisch chirurgen (72%) was overstuffing het grootste risico voor falen bij resurfacing schouder prothese.

Er werd een afname in het gebruik van resurfacing hemi prothese en een toename in het gebruik van reverse schouder prothese gevonden.

Concluderend werd weinig consensus gevonden over preoperatieve planning, patiëntkenmerken, type implantaat, chirurgische techniek, tromboseprofylaxe, uitkomstbeoordeling met door de patient reported outcome measures (PROM's) en postoperatieve restricties.

**Hoofdstuk 4** beschrijft een systematische review van de literatuur tussen hemi-schouder prothese en totale schouder prothese voor patiënten met gleno-humerale artrose.

Het doel van deze review was om de huidige beschikbare literatuur te evalueren en om evidence based richtlijnen te formuleren voor de behandeling van gleno-humerale artrose met een prothese. Na een database onderzoek (Pubmed/ Medline, Cochrane Clinical Trial Register en Embase-databases) vonden we aanvankelijk 832 studies.

18 Studies werden geïncludeerd, alle caseseries, met in totaal 1958 patiënten (316 hemi schouder prothese en 1642 totale schouder prothese). Het revisiepercentage werd genoemd in alle artikelen (behalve één studie), voor de hemi schouder prothese was dit 13% en voor de totale schouder prothese 7%. Het exacte type complicatie werd niet vermeld in de artikelen, hoewel het percentage complicaties in de totale schouderprothese-groep hoger was in vergelijking met de hemi schouder prothese groep, 12% versus 8%. Vier studies in beide groepen rapporteerden een afname van pijn. Het vergelijken van beweging en pijn tussen de twee groepen was niet mogelijk vanwege het ontbreken van standaarddeviaties in de geïncludeerde artikelen.

Er werd geconcludeerd dat de totale schouderprothese leidde tot minder revisiechirurgie. Er bleek wel een trend te zijn dat het complicatierisico bij totale schouderprothesen hoger was dan bij hemi-prothesen.

**Hoofdstuk 5** beschrijft een prospectieve studie van een ongecementeerde hemi-schouder prothese bij patiënten met primaire gleno-humerale artrose.

Het doel van dit onderzoek was om de PROM's en röntgenopnames van de Global Conservative Anatomic Prosthesis (CAP) (DePuy-Synthes, Warschau, Indiana, VS) na twee jaar follow-up te evalueren. De geïncludeerde patiënten, 36 vrouwen en 12 mannen, met een gemiddelde leeftijd van 69 jaar oud (bereik 56-86 jaar) vertoonden een significante verbetering in alle PROM's. De gemiddelde Constante score verbeterde van 49 ± 18 punten preoperatief naar 79 ± 23 punten. De gemiddelde Dutch Simple Shoulder Test verbeterde van 22 ± 23 punten preoperatief naar 66 ± 29 punten. De pijnscore daalde van 65 ± 18 punten preoperatief naar 35 ± 27 punten.

Bij de SF-12, verdeeld in een mentale score en fysieke score, verbeterde de gemiddelde mentale score van SF-12 niet. De gemiddelde fysieke score van SF-12 verbeterde van 35 ± 8 punten preoperatief naar 42 ± 10 punten. Na twee jaar follow-up was geen revisiechirurgie nodig. Röntgenfoto's van de schouders vertoonden na twee jaar follow-up geen loslating en geen glenoid erosie.

Geconcludeerd werd dat de resultaten van de ongecementeerde Global CAP resurfacing hemi prothese na een follow-up van 2 jaar bemoedigend waren en vergelijkbaar met de literatuur.

**Hoofdstuk 6** is een uitbreiding van **Hoofdstuk 5**. Het doel van deze studie was om de PROM's en röntgenopnames op middellange termijn te evalueren. Bij een gemiddelde follow-up van 6,4 jaar (bereik 5,1 - 7,9) vertoonden de PROM's een significante verbetering na de operatie. De gemiddelde Constante score verbeterde significant van 47 ± 18 punten preoperatief naar 83 ± 22 punten. De gemiddelde Dutch Simple Shoulder Test verbeterde van 20 ± 21 punten preoperatief naar 67 ± 30 punten. De pijnscore daalde significant van 66 ± 19 punten preoperatief naar 29 ± 28 punten. Bij de SF-12, verdeeld in een mentale en een fysieke score, verbeterde de gemiddelde SF-12 mentale score van 49 ± 12 punten preoperatief naar 51 ± 8 punten; de gemiddelde fysieke score van SF-12 verbeterde van 35 ± 8 punten preoperatief naar 39 ± 11 punten.

Er waren röntgenfoto's van 36 schouders beschikbaar. Er werd geen loslating of dislocatie gezien tijdens de follow-up. Bij 15 van de 36 schouders (42%) werd enige mate van superieure migratie waargenomen, als een indicatie voor het falen van de rotatorcuff. Zes patiënten (17%) hadden een ernstige migratie en negen (25%) hadden een milde superieure migratie. Eenentwintig schouders (58%) vertoonden geen superieure migratie. Matige tot ernstige glenoïd erosie was aanwezig in twaalf van de schouders (33%) tijdens een de follow-up. Elf patiënten (23%), 5 mannen en 6 vrouwen, ondergingen een revisie naar een





totale schouder of reverse schouder prothese. Eén patiënt had tijdens de revisie operatie positieve kweken, duidend op een low grade infectie.

Concluderend: de tussentijdse resultaten van de Global CAP resurfacing hemi schouder prothese waren in lijn met andere studies met een verontrustend revisiepercentage van 23%.

**Hoofdstuk 7,** in lijn met **Hoofdstuk 5** en **6**, betreft een retrospectieve studie van 35 patiënten met reumatoïde artritis van de schouder en de bijbehorende pathologie van de rotator cuff.

Het doel van deze studie was om de PROM's en röntgenbeelden te evalueren na een lange termijn follow-up. Bij 34 patiënten (11 bilateraal) werden vijfenveertig gecementeerde hemi schouderprothesen uitgevoerd. Er werden 31 vrouwelijke en drie mannelijke patiënten met een gemiddelde leeftijd van 65 jaar (bereik 31-84 jaar) geïncludeerd.

Tien patiënten (12 schouders) overleden aan aandoeningen die geen verband hielden met de schouderprothese, één patiënt kon niet worden vervolgd vanwege een verlamming van haar geopereerde arm als gevolg van een complicatie van een cervicale hernia-operatie. Klinische beoordeling van één patiënt was niet realistisch vanwege de ziekte van Alzheimer.

De gemiddelde leeftijd van de overleden populatie was 68 jaar oud (bereik 59-76) en de gemiddelde overleving van het implantaat van deze groep was 4,1 jaar (bereik 0-11 jaar). Geen van de patiënten in deze groep had complicaties die verband hielden met het prothese of de operatie. De röntgenfoto's in deze groep vertoonden een consistente medialisatie van de prothese als gevolg van glenoïd erosie en cranialisatie als gevolg van rotator cuff-insufficiëntie. Er waren geen tekenen van loslating van de prothese of fracturen van het glenoïd of acromion. Deze groep werd niet meegenomen in de data-analyse.

De gemiddelde leeftijd van de follow-up groep was 61 jaar (bereik 31-84) en de gemiddelde follow-up was 10,0 jaar (bereik 5-17 jaar). De gemiddelde pijnscore was 3 (SD 2) en de gemiddelde constante score was 55 (SD 16). De gemiddelde Disabilities of the Arm, Shoulder and Hand (DASH) score bij 20 patiënten (twee ongeldige vormen) was 42 (SD 19). Röntgenfoto's van alle schouders vertoonden geen loslating van de prothese bij follow-up. Alle patiënten hadden medialisatie van de schouder prothese als gevolg van glenoïd erosie en cranialisatie als gevolg van insufficiëntie van de rotator cuff. Er werden geen radiografische complicaties zoals fracturen of implantaat falen waargenomen.

Eén patiënt hield persisterende pijn en een beperkte functie direct postoperatief. Twee weken na de eerste operatie werd arthrotomie en capsulotomie uitgevoerd. Peroperatief verkregen

weefselkweken waren negatief voor infectie. Uiteindelijk nam de pijn af en verbeterde de functie. Binnen deze langdurige follow-up periode werden geen revisieoperatie uitgevoerd.

Concluderend was een gecementeerde hemi schouder prothese een behandelingsoptie voor secundaire artrose bij patiënten met reumatoïde artritis. Resultaten op lange termijn lieten acceptabele resultaten en lage percentages complicatie en revisie zien.

In **hoofdstuk 8** werd een case report (één van de opgenomen patiënten uit de Global CAP-studie) van een patiënt gepresenteerd met een gefaalde resurfacing schouder hemi-prothese als gevolg van een periprothetische infectie, die histologisch volledig was ingegroeid.

De algemene opvatting is dat een infectie leidt tot interfacevorming (met neutrofielen) en loslating van de prothese. Met de presentatie van deze casus concluderen wij dat periprothetische infectie en septische loslating twee verschillende entiteiten zijn.

**Hoofdstuk 9** is een uitbreiding van **Hoofdstuk 5** en **6**. Het doel van deze radiografische studie was om te evalueren of het mogelijk is de anatomie van de humeruskop te herstellen door het plaatsen van een prothese. Ook werd de betrouwbaarheid tussen de waarnemers van de critical shoulder angle (CSA), lengte van de gleno- humorale offset (LGHO) en verandering van center of rotation (COR) in een resurfacing schouder hemi-prothese geanalyseerd. Bovendien probeerden we met deze metingen prognostische instrumenten te vinden om een slechte functionele uitkomst en de noodzaak tot revisie te voorspellen.

Voor betrouwbare beoordelingen voerden vier onafhankelijke waarnemers de metingen uit. De beoordelaars gebruikten de preoperatieve röntgenfoto's en de röntgenfoto's 6 weken postoperatief. Bij de 9-jarige follow-up (bereik 5-12 jaar) hadden 12 schouders (25%) een revisie naar een totale schouderprothese. Een patiënt was geïncludeerd voor data-analyse vanwege een low grade infectie.

De gemiddelde leeftijd was 77 jaar (SD 7,5) en 36 van de 47 patiënten waren vrouw (77%). De betrouwbaarheid van de waarnemer toonde een uitstekende betrouwbaarheid voor de CSA, pre- en postoperatieve LGHO, en voor de COR. De gemiddelde CSA van 47 schouders was 29,8 ° (SD 3,9). We vonden geen significant verschil in CSA tussen de revisie en de niet-revisiegroep. De gemiddelde LGHO nam toe van 49,6 mm (range 37,6-60,4) voor de operatie tot 52,1 mm (range 37,2-61,7) na de operatie. De toename van de LGHO was significant hoger in de revisiegroep in vergelijking met de niet-revisiegroep. De preoperatieve LGHO was niet significant verschillend tussen de twee groepen. De postoperatieve LGHO van de revisiegroep was significant toegenomen ten opzichte van de niet-revisiegroep. De gemiddelde afwijking van de postoperatieve COR voor alle 47 gevallen was 5,6 mm (2,7 SD). De gemiddelde COR in de niet-revisie- en de revisiegroep





was respectievelijk 4,9 mm (2,5 SD) en 8,0 mm (SD2,2). Dit verschil was significant. Van de 47 schouders, vijf implantaten (12%) was de COR verschoven naar mediaal inferieur. Bij de overige 43 schouders was de COR verschoven naar mediaal superieur. Alle schouders in de revisiegroep (n = 11) hadden de COR-verschuiving naar mediaal superieur, wat betekende dat het gewricht "overstuffed" was. Univariate analyse onthulde dat postoperatieve LGHO en de COR beide significant geassocieerd waren met revisie. In het uiteindelijke model bleef echter alleen de COR als voorspeller voor revisie met een odds ratio van 1,90 (95% Cl 1,19-3,02). ROC-analyse van de COR onthulde een afkappunt voor revisie van 5,8 mm (95% Cl van 4,0-8,4) met een overeenkomstige AUC van 0,82 (95% CI: 0,68-0,95).

Geconcludeerd werd dat de Global CAP resurfacing hemi schouderprothese leidde tot overstuffing van het gleno-humerale gewricht in bijna alle schouders. In tegenstelling tot de CSA en LGHO vonden we een verband tussen klinisch falen en revisie bij een afwijking van de COR groter dan 5 mm.

**Hoofdstuk 10** beschrijft de resultaten na revisie van de ongecementeerde Global CAP resurfacing hemi schouderprothese.

Het doel van deze prospectieve studie was om de klinische en functionele uitkomst van de revisie van de ongecementeerde Global CAP resurfacing-prothese tot totale schouder prothese of reverse schouderprothese te evalueren. Daarnaast hadden we een survivalanalyse uitgevoerd van de Global CAP-revisie en niet-revisie groepen om factoren te bepalen die voorspellend waren voor een revisie.

Bij een gemiddelde follow-up van 4,5 jaar hadden 11 patiënten (23%) een revisieoperatie ondergaan. Pijn en slechte functie werden veroorzaakt door glenoïd erosie bij vier patiënten (36%), bij twee patiënten werd ongedefinieerde pijn en functieverlies gevonden (18%). Cuffarthropathie werd gevonden bij twee patiënten (18%). Een patiënt had meerdere anterieure subluxaties na een mislukte operatieve subscapularispeesherstel. Artrofibrose en pijnlijke beweging zonder glenoïd erosie waren redenen voor revisie bij twee andere patiënten. Eén patiënt (9%) had een low grade infectie.

Bij acht patiënten werd een totale schouderprothese gebruikt en bij drie patiënten een reverse schouderprothese. Bij tien van de elf revisiepatiënten werden post-revisie evaluatie uitgevoerd. De gemiddeld follow-up was 42 maanden (minimale follow-up was 21 maanden, maximaal 74; SD 15,9). Er werd een goede klinische en door de patiënt gerapporteerde uitkomstmaten gevonden. De constante score verbeterde significant met een gemiddelde van 26 punten (95% BI 9,6 - 43,0) en alle patiënten scoorden boven de 80 punten. Van de 10 patiënten hadden er acht (80%) geen pijn volgens de visuele analoge schaal. Zowel de Dutch Simple Shoulder-test als de SF-12 waren aanzienlijk verbeterd. In totaal was de

5-jaars overleving van de Global CAP resurfacing hemi prothese was 82,6% (95% BI; 71,6 - 93,6). Er werd geen significant verschil gevonden tussen mannelijke en vrouwelijke patiënten. Er waren geen re-revisies.

Concluderend waren de door patiënten gerapporteerde resultaten na revisie van de ongecementeerde Global CAP resurfacing hemi-schouder prothese naar een totale of reverse schouderprothese bij tussentijdse follow-up bevredigend.

# CHAPTER 14

Dankwoord

Zo, dat is dat. 10 Jaar geleden ben ik met dit project begonnen (inderdaad bijna ¼ van mijn leven) niet wetende dat het met dit boekje zou eindigen. Ik ben het levende bewijs dat een niet-wetenschapper, wetenschappelijk onderzoek kan doen. Dit is echter alleen mogelijk door de juiste mensen om je heen te verzamelen en die heb ik gevonden. Zonder de betrokkenheid van onderstaande collega's, familie en vrienden was het eindresultaat niet zo mooi geworden.

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# CHAPTER 15

Curriculum vitae, List of Publications and Presentations

Pieter was born on 14 of January 1979 in Amsterdam. He grew up in Lelystad and after his HAVO he lived upstate New York, In 1997 he graduated from Stamford Central School, Stamford New York. In 1999 he graduated from the VWO in Zwolle and started studying medicine at the VUmc. During his study, he discovered an enthusiasm and interest for the musculoskeletal system.

In 2006 he started his orthopedic residency training at the department of general surgery of the Alrijne Hospital (dr. S.A. da Costa), followed by residency training at the orthopedic surgery departments of the Slotervaart Hospital (Prof. dr. R.G. Pöll), Spaarne Gasthuis (dr. P.A. Nolte) and Amsterdam Medical Center (Prof. dr. C.N. van Dijk).

During his residency in Spaarne Gasthuis he came in contact with Arthur van Noort and his enthusiasm for shoulder pathology was born. During the time in Spaarne Gasthuis he started a research which ended in this thesis.

In 2013 he started as orthopedic surgeon in Noordwest Clinics. Pieter lives together with his wife Cathelijne, daughter Philippine (2010) and Julius (2011) in Alkmaar.





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2005

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