UiT Norges arktiske universitet

Faculty of Health Sciences

# Midterm outcomes for stemless hemiarthroplasty for glenohumeral osteoarthritis

A retrospective study

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Supervisor: Khaled Meknas, MD, PhD

# Preface

I have had a great fascination for the bones, joints and muscles of the human body since long before I started my medical education, and naturally developed an attraction towards orthopedics once I started university. That is why contacting the orthopedic department at the university hospital was the obvious choice for me when it came to choosing a subject for my thesis. I contacted Khaled Meknas, MD, PhD who agreed to be my supervisor. He presented the subject, and I agreed to take it on. The objective of the project is to assess the outcomes of stemless hemiarthroplasty in patients with osteoarthritis of the glenohumeral joint operated at the University Hospital of North Norway.

I would like to thank Khaled Meknas for a great oppurtunity and patience during the work process, and for providing good advice and relevant literature to the thesis. Meknas also spent three days in the outpatient clinic together with the author to conduct the follow up sessions. Thank you for brilliant supervision! I would also like to offer my thanks to Hilde Espnes for advice on statistical methods.

Tromsø, 29.05.21

# Table of contents

# Abstract

**Background:** Osteoarthritis is the most common form of arthritis and end stage treatment includes arthroplasty. The gold standard for treatment of shoulder osteoarthritis is total arthroplasty with stemmed prosthesis. The trend surrounding shoulder arthroplasty focuses on reducing stem-related complication, but mid- to long-term studies on stemless hemiarthroplasty are needed to evaluate durability. Our hypothesis was that stemless hemiarthroplasty is a good and reliable alternative for treatment of shoulder OA.

**Method:** 21 shoulders in 17 patients with glenohumeral osteoarthritis were treated with Eclipse stemless HSA from 2010 to 2016, and followed for four to eleven years. Functional outcomes were evaluated using VAS, ASES and CS, while superior caput migration, degree of glenoid erosion and radiolucency was assessed on radiographs.

**Results:** At last follow up time, there was significant improvement of VAS, ASES and CS from **(**7.5) to (1.8) $p< 0.05$, (36.4) to (84.1) $p<0.05$, and (33.5) to (79.6) $p<0.05$ respectively. In addition, there was no clinically significant radiological changes.

**Conclusion:** In this retrospective study, the clinical assessments revealed significant improvements in the VAS, ASES and CS seven years after intervention. There were minimal radiological changes without clinical significance.

# Abbreviations

OA – Osteoarthritis

RA – Rheumatoid arthritis

HSA – Hemiarthroplasty of the shoulder

TSA – Total shoulder arthroplasty

UNN – University Hospital of North Norway

ASES – American Shoulder and Elbow Surgeons

CS – Constant-Murley score

ADL – Activities of daily living

ROM – Range of motion

VAS – Visual analog scale

# 1 Introduction

## 1.1 Glenohumeral osteoarthritis

### 1.1.1 Definition and clinical picture

Arthritis is commonly used term to describe any disease affecting the joints of the body. Osteoarthritis (OA) and rheumatoid arthritis (RA) are the two most common forms of arthritis. While RA is an autoimmune disease OA is a degenerative one and does not involve the immune system. OA is a disease that can affect any synovial joint of the body. A synovial joint is an organ consisting of joint cartilage, subchondral bone and a joint capsule, covered by synovial membrane on the inside and reinforced by ligaments on the outside (1). OA is defined as a degenerative, non-inflammatory joint disease characterized by degeneration of articular cartilage and subchondral bone, with narrowing of the joint space as a result. It is a gradual and progressive process that through mechanical and biochemical breakdown of the joint components causes loss of joint function, pain and instability (2). Other types of arthritis include gout, lupus, fibromyalgia and septic arthritis (3).

The glenohumeral joint OA causes pain and disability. The diagnosis involves a certain set of symptoms, physical examination findings and radiological changes to the bone; the humeral head, the glenoid or both. Initially patients often suffer from activity related pain that is localized deep in the joint, mostly posteriorly. Progression of the disease makes nocturnal pain and resting pain more common, and sleep disturbance is reported more frequently (4;5). In advanced stages of OA physical examination demonstrates a loss of active and passive range of motion in the shoulder joint with bony crepitus i.e. significant loss of function (5). Radiological changes are an important part of diagnosing OA. Degree of radiological changes may be subtle in cases of mild to moderate disease, and might only be visible on MRIs at this initial stage (4). Radiologically glenohumeral OA is typically characterized by osteophyte formation, joint space narrowing, subchondral sclerosis and subchondral cyst formation. In OA, as opposed to for example rheumatoid arthritis, the joint space narrowing is predominantly posterior which results in eccentric posterior glenoid wear. Osteophyte formation is usually seen in proportion to the degree of joint space narrowing (6).

### 1.1.2 Epidemiology and risk factors

Musculoskeletal disorders in general have had and continue to have an immense impact on the population of the world (4). OA is as previously stated the most common form of arthritis

and OA in general is among the most common causes of severe pain and invalidity with studies indicating more than half of the adult population showing signs of the disease. In a study conducted by Garstang and Stitik 78% of persons aged 70 years and older were reported having symptomatic arthritis (7). At the time prevalence of OA was expected to increase by 50% by the year 2020 (1;7). According a Canadian study from 2019 OA affects 9.6% of men and 18.0% of women over 60 years of age worldwide (8). OA of the glenohumeral joint, however, is considered rare and far from as common as osteoarthritis of the larger weight-bearing joints, such as the hip and the knee. However, a study from 2011 found a 16,1% prevalence among the elderly population of South Korea (9).
Risk factors for developing OA include age, genetics, sex, weight, joint infection, history of shoulder dislocation and previous injury. The prevalence of OA increases with age and nearly 60% of those affected are older than 65 years. Additionally, people with certain occupations that require a heavy work load or overhead work have increased risk of later developing OA in the shoulder joint (4).

### 1.1.3 Treatment

Treatment of OA depends on the severity of symptoms; degree of pain, work restriction and activity level. The main aim of treatment is pain relief and regaining a satisfactory range of motion for the patient to be able to resume “pre-OA” daily function (2).
Conservative treatment includes the use of NSAIDs/analgesics, physical therapy and steroid injections (10). At the moment there are no documented treatment options that reverse the disease and therefore aims become to relieve pain and restore function. Mild degenerative disease can be treated with physical therapy and medication. More advanced cases that prove refractory to these treatment options can be managed by corticosteroid injections. Surgery is indicated in severe cases where other treatment options have failed (4).

## 1.2 Shoulder arthroplasty

The first documented shoulder arthroplasty dates back to 1891, and Neer published his historical indications for total shoulder arthroplasty (TSA) in the 1970’s. Following this the debate about indications for TSA and HSA, stemmed or stemless, kicked off and is still going (11). Pfahler et al. stated in 2006 that most studies at the time reported better results of the TSA than those of the HSA, however risk of complications need to be taken into consideration (12). What keeps the debate going is the hypothesis that stemless designs are more adaptive to premorbid patient anatomy and cause fewer complications by preserving

bone stock and making for easier revisions (13). Concerning hemiarthroplasty of the shoulder more results including stemless alternatives are needed to assess the functionality and durability of these compared to TSA (14).

### 1.2.1 Arthroplasty choices

Meticulous clinical judgement is needed to select the appropriate prosthesis as there are several different approaches to arthroplasty surgery. The options include humeral head resurfacing (i.e. stemless hemiarthroplasty), stemmed hemiarthroplasty, anatomical total shoulder arthroplasty and reverse total shoulder arthroplasty. For the glenoid, options include leaving as is, using implants or non-implants resurfacing (11). The gold standard for surgical treatment of glenohumeral OA is conventional total shoulder arthroplasty with stemmed implants and documentation shows sufficient results related to pain reduction and regain of shoulder function (14).

### 1.2.2 Complications

Complications of shoulder arthroplasty include bone stock loss, intraoperative and postoperative periprosthetic fractures, rotator cuff deficiency, neural damage, glenoid erosion, mal-positioning of the humeral component and occasionally infections affecting the medullary canal, which can be difficult to eradicate. The main complication of shoulder arthroplasty is loosening of the implants (11;14).
Stem-related complication, along with the possibility of easier revisions and preservation of bone-stock lead to the introduction of stemless or short-stemmed humeral implants (15). This resulted in the first stemless alternative to humeral implants becoming available in Europe in 2004. There have been several studies showing promising results on short- to midterm follow up on stemless TSA, and in 2018 Beck et al. published one of the first studies on long term follow up on these kinds of shoulder replacement procedures (16). Stemless alternatives are being increasingly used but mid- and long term results, though firstly on total shoulder replacements (14).

## 1.3 Aims

The purpose of this thesis is to assess patient satisfaction, functional and radiological outcomes of stemless hemiarthroplasty with a single implant type on patients with glenohumeral OA operated at UNN from 2010 to 2016. Our hypothesis was that stemless hemiarthroplasty is a good and reliable alternative for treatment of shoulder OA.

# 2 Materials and methods

## 2.1 Study design and material

Since 2010 about 60-70 stemless hemiarthroplasty of the shoulder was performed at the Orthopedic department at the University Hospital of North Norway. 35 patients underwent surgery with OA as indication. Other indications were proximal humeral fractures and rotator cuff arthropathy. Inclusion criteria for this study were patients with glenohumeral osteoarthritis operated with stemless HSA using the Eclipse prosthesis (Arthrex, Naples, USA) between 2010 and 2016. Exclusion criteria include patients with severe organ failure, malignancy, reduced general state of health and revision surgery.

35 patients were invited to participate in the study. 14 patients were lost to follow up and among these, six declined participation, three died, two were excluded because of comorbidity and four underwent revision surgery because of rotator cuff tear. All in all, 21 shoulders belonging to 17 unique patients were assessed.

The follow up period was between four and eleven years. The evaluation includes both clinical and radiological outcome. Patients were also asked to report their actual pain levels (i.e. pain at the time of follow up). Furthermore, we included a single categorical question evaluating patient satisfaction, asking if they were satisfied having had the surgery (answer either ‘yes’ or ‘no’).

## 2.2 Clinical assessment

The clinical evaluation was conducted pre- and postoperatively using two shoulder scores, ASES and the Constant-Murley score, in addition Visual Analog Scale (VAS-score) was used to determine pain levels both pre- and postoperatively. A vast number of tools to help assess functionality and clinical outcomes of shoulder pathology and surgeries exist. Both CS and ASES are among those widely acknowledged in the scientific community, both scores have psychometric properties that make them acceptable for evaluation of glenohumeral OA (17). Few scoring systems are gold standards due to varying limitations and psychometric properties, however according to a review article by Angst et al. assessing different measurement methods of shoulder function ASES and CS are highly accepted in the clinical community for osteoarthritis and arthroplasty respectively (17). ASES consists of a patient-rated and a physician-rated part, but does not include physical examination and can be used for self-assessment by the patient. The maximum score is 100, and the final sum is 50% pain

and 50% function. The higher the score the better (17;18). The CS was first used in 1987, and though not validated at the time it was published several studies have later validated its use after, among other indications, shoulderarthroplasty. Though not strictly validated for many shoulder related conditions the book "The shoulder" reports it as the most used outcome score in the literature (11). The CS consists of four parts; pain level, ADL, mobility and strength. Pain and ADL are assessed by interview (35 points) and mobility and strength by physical examination (65 points). The maximum score is 100. The strength and mobility being such a considerable part of the final score might be of benefit when assessing shoulder arthritis (18).

## 2.3 Radiological assessment

Radiographs in anterior-posterior and axillary plane were used to assess radiological changes. Evaluation of possible radiological changes were divided into three categories; radiolucent lines surrounding HSA-implant, migration of caput humeri, measured by difference in acromiohumeral distance (mm) from post-op control to last follow up; no migration = 0 mm, slight migration = 0.1-5.0 mm, moderate migration = 5.1-7.0 mm, severe migration >7.0 mm, and to what degree glenoid osteoarthritis occurred. Glenoid OA is measured on a numeric scale with 0 indicating no glenoid OA, 1 indicating low degree, 2 indicating moderate degree and 3 indicating high degree of OA. All patients except one presented with radiographs taken ahead of the clinical evaluation.

## 2.4 Statistics

Descriptive statistics are presented in table as median with range and SD in parentheses for continuous variables. The Shapiro-Wilks test was used to determine normality for all variables. Wilcoxon Signed Rank test was used to compare the pre- and post-operative means as most of the variables were tested as non-normal. A two-tailed p-value of $<0.05$ was considered significant. To analyze correlation between functional outcome and radiological changes Spearman's correlation was used. IBM SPSS 27.0 was used for statistical analyses.

## 2.5 Ethical considerations

Prior to collecting the study data through clinical sessions at UNN the study was approved by REK ("Regionale komiteer for medisinsk og helsefaglig forskningsetikk), case number REK Nord Ref 142110 (see enclosure 1 for full sanction).

## 2.6 Work process

The process of this thesis started in March/April 2020 when my supervisor presented this project and I agreed to take it on. I used a month from March to April writing the protocol with help from my supervisor. During the fall semester of 2020 we planned and carried out three days of clinical evaluation where patients had taken radiographs ahead of their appointment and were clinically and radiologically assessed by my supervisor and myself. The main part of the writing process and statistical analyses was conducted during spring 2021, after I had finished my clinical rotations on my fifth year.

# 3 Results

35 patients eligible for this study received stemless HSA during a time period of seven years. 21 shoulders in 17 patients were available for last follow up. Four patients had undergone bilateral stemless hemiarthroplasty with an interval of one to three years between operations. Three patients (four shoulders) were assessed through a telephone interview as they lived far away and did not wish to make the journey to Tromsø. One of these patients did not present with any radiographs and was unable to be evaluated radiologically.
Mean follow up time for this study was 7,2 years (range 4 to 11, SD ± 1,9) and mean age of patients at the time of follow up was 69,5 years (range 50 to 85, SD ± 8,9) (table 1).

**Table 1 Descriptive data**

| Variable | n | Mean (SD) | Range |
|---|---|---|---|
| **Years since surgery** | 21 | 7.19 (1.9) | 7 (4-11) |
| **Age at follow up** | 21 | 69.57 (8.9) | 35 (50-85) |
| **VAS pre** | 21 | 7.52 (0.87) | 3 (6-9) |
| **VAS post** | 21 | 1.81 (2.87) | 10 (0-10) |
| **CS pre** | 21 | 33.48 (8.36) | 34 (20-54) |
| **CS post** | 21 | 79.57 (18.3) | 67 (31-98) |
| **ASES pre** | 20 | 36.40 (7.27) | 32 (20-52) |
| **ASES post** | 21 | 84.10 (23.7) | 87 (13-100) |

- *SD: standard deviation*
- *Range: difference (interval)*

95,2% (n=20) of the patients stated they were satisfied with the decision of having surgery.

## 3.1 Functional outcomes

Comparing data from pre-operation to post-operation the VAS-score improved from 7.5 ± 0.9 to 1.8 ± 2.9 ($p<0.05$). The ASES score improved significantly 36.4 ± 7.2 to 84.10 ± 23.7 ($p<0.05$), as did the Constant-Murley score from 33.5 ± 8.4 to 79.6 ± 18.0 ($p<0.05$). The Wilcoxon signed-ranks test thus showed statistically significant improvement in all three matched pairs (pre- and post-op) measuring functional outcome. Functional outcome means and SD are presented in Table 2.

**Table 2 Pre- and postoperative values of stemless HSA**

| **Variable** | **Maximum** | **Pre-operative** mean ± SD | **Post-operative** mean ± SD | **p-value*** |
|---|---|---|---|---|
| **VAS** | 10 | 7.5 ± 0.9 | 1.8 ± 2.9 | < 0.05 |
| **Constant-Murley** | 100 | 33.5 ± 8.4 | 79.6 ± 18.0 | < 0.05 |
| **ASES** | 100 | 36.4 ± 7.2 | 84.10 ± 23.7 | <0.05 |

**analysed using Wilcoxon signed-rank test*

## 3.2 Radiological outcomes

20 shoulders were available for radiographic follow up. 20% (n=4) had no superior migration and 70% (n=14) showed slight superior displacement (range 0.1-5.0 mm). Moderate superior displacement of the humeral head was found in 10% (n=2) with a maximum migration of 5.3 mm. No severe migration was observed.

Radiolucent lines along the bone implant interface was observed in (n=3). For glenoid OA the mean was 1.3 ± 1.2. 35% of the patients (n=7) had low degree, 10% (n=2) had moderate degree and 25% (n=5) had high degree of OA on the glenoid surface. Radiological outcomes are listed in table 3 and figure 1.

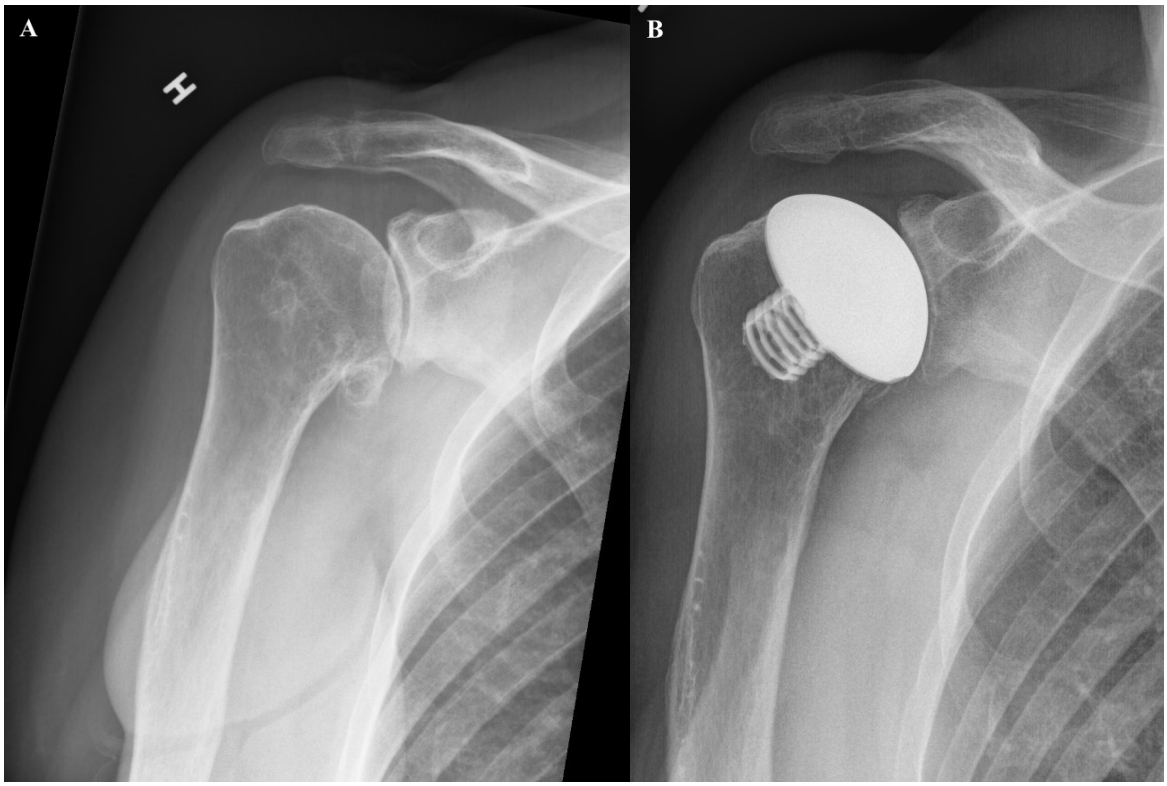


*Fig 1: Anteroposterior radiographs. Preoperative (A) and at last follow up 8 years after surgery (B). This patient had an improvement in ASES from 22 to 89, and in CS from 36 to 100, and VAS 0 at follow up. No caput migration, glenoid OA or radiolucency was observed.*

### 3.2.1 Influence of radiological changes on functionality and pain

To determine correlation between clinical variables and radiological changes a Spearman correlation test was used. There was no statistically significant correlation between radiological degree of OA or radiolucency and postoperative VAS, ASES or CS. There was a moderate, positive correlation between postop VAS and caput migration (Spearmans' rho = 0.471, two-tailed $p<0.05$).

**Tabell 3 Radiological outcomes at follow up**

| **Variable** | | | |
|---|---|---|---|
| **Radiolucency** | | Frequency (n) | Percent (%) |
| | Yes | 3 | 15 |
| | No | 17 | 85 |
| **Degree of glenoid OA** | | mean ± SD | |
| | | 1.3 ± 1.2 | |
| | | Frequency (n) | Percent (%) |
| | No OA (0) | 6 | 30 |
| | Low (1) | 7 | 35 |
| | Moderate (2) | 2 | 10 |
| | High (3) | 5 | 25 |
| **Caput migration, mm** | | mean ± SD | Range |
| | | 1.45 ± 1.7 | 5.3 (0-5.3) |
| | | Frequency (n) | Percent (%) |
| | No migration | 4 | 20 |
| | Slight migration | 14 | 70 |
| | Moderate migration | 2 | 10 |
| | Severe migration | - | - |

# 4 Discussion

The most important finding in this study of patients with shoulder joint OA is that at last follow up time there was still a significant improvement in the VAS, ASES and CS. The development of glenoid OA was only observed in five patients (25%) without influencing the clinical outcomes. As briefly mentioned the stemmed TSA has long been regarded as the gold standard of shoulder arthroplasty, but since the introduction of stemless alternatives in 2004 several short- to midterm studies on stemless humeral implants have been published. However, mid- to long term results are scarce. Technological progression is still being made, and fourth generation humeral implants are considered better than its forerunners, focusing on preventing stem-related complications such as bone loss and making revision easier (16;19).

Habermeyer et al. published the first midterm results on a stemless TSA in 2015. 78 patients were followed for a mean period of 72 months. 14 patients with OA were operated with HSA and 25 with TSA, using the Eclipse prosthesis. Both groups had significant improvement in CS and pain relief, and no significant difference in CS was observed between the hemiarthroplasty group when compared to total shoulder arthroplasty (20). In another study; Hawi et al. reported nine year outcomes after stemless arthroplasty, comparing TSA and HSA. The authors found significant improvement of CS in both groups and no significant difference between the HSA group and the TSA group (21). This is in line with the finding of this study presenting significant outcomes using stemless HSA. In another study, Brunner et al. reported a significant improvement in CS score for patients operated with the Eclipse prosthesis, both as HSA and TSA, after a two year follow period. The authors stated that patients with shoulder OA benefitted from the stemless arthroplasty, both HSA and TSA improved significantly, however the TSA group showed greater improvement in pain levels and functionality (22).

A recent study published in march 2021 by Singh et al. addresses stemless shoulder arthroplasty, and functional and radiological outcomes of stemless TSA using the Eclipse prosthesis (19). This study follows 30 elderly patients from India with primary osteoarthritis for a short and midterm evaluation where preoperative CS and ASES improved from respectively 27.3 and 29.7 to 68 and 71.4 respectively. Functional scores are compared to our study lower both pre- and postoperatively, though the improvement is comparable to ours. Similar to our study where we found no gross complications; Singh et al. mention no specific complication rates. These low scores might be a consequence of patients seeking surgical intervention at a later stage than in western countries (19). Maier et al. conducted a study comparing outcomes between stemless and stemmed TSA for glenohumeral OA in 2015. In this study 12 patients were operated with the TESS implant, a stemless alternative TSA, and a control group with comparable demographics received a standard stemmed TSA. This was a short-term follow up, however they found no statistically significant differences in either postoperative proprioception or CS between the two groups (14).

In the present study, there was no loosening of any prosthesis and there was a relatively low rate of radiolucency around the humeral implant. Additionally, we did not find significant correlation between radiolucency nor OA of glenoid and functional outcomes, as well as pain levels. None of our patients were considered for revision based on this mild to moderate

degree of radiolucency. This indicates decent survival rates of the Eclipse HSA in mid- to long-term perspective. Beck et al. and Heuberer et al. agrees that radiolucent lines are not uncommon and may appear postoperatively without it being an isolated indication for revision surgery (16;23). These finding are also in line with the present study of stemless HSA. The present study reveals outcome results with significant improvement on all variables, a strength considering the shortage of articles on mid- to long-term perspective on stemless HSA. The clinical relevance of the present study is that stemless HSA is a simple, safe and reliable method for treating shoulder OA.

## 4.1 Strengths and limitations

In the present study, the treatment options were not mixed and one group received only stemless HSA, making the results more coherent. The length of follow up and specific indication (glenohumeral OA) should be considered a strength as there are few studies on hemiarthroplasty evaluating this problem specifically. In addition, the fact that both clinical and radiological outcomes are studied. No severe complications reported is another strength. The limitations of the study include the relatively small number of participants as well as the lack of control group. Furthermore, four shoulders were evaluated using telephone interview and may affect the grading of ASES and CS. A further weakness is that it lacks a second reviewer for radiological evaluation and has not undergone a test-retest procedure. For future studies, a larger cohort is recommended.

# 5 Conclusion

The present study reveals predictably better function with the stemless hemiarthroplasty at midterm follow up. We found statistically significant improvement in VAS, ASES and CS from pre-operative to post-operative evaluation. Radiological findings had low correlation rate with functional outcomes, particularly radiolucency and glenoid OA. 95% (n=20) of the patients were satisfied with having the surgery.

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American Shoulder and Elbow Surgeons (ASES) Society Standardized Shoulder Assessment Form, Constant (Murley) Score (CS), Simple Shoulder Test (SST), Oxford Shoulder Score (OSS), Shoulder Disability Questionnaire (SDQ), and Western Ontario Shoulder Instability Index (WOSI). Arthritis Care Res (Hoboken) 2011;63(S11):S174-S88.
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# 7 Enclosure

| Region: | Saksbehandler: | Telefon: | Vår dato: | Vår referanse: |
|---|---|---|---|---|
| REK nord | Maren Melsbø | 77620748 | 14.05.2020 | 142110 |
| | | | Deres referanse: | |

Mohamed Khaled Meknas

**142110 Medium-term results after stemless hemiarthroplasty of osteoarthritis in shoulder**

**Forskningsansvarlig**: UiT Norges arktiske universitet

**Søker**: Mohamed Khaled Meknas

**Søkers beskrivelse av formål:**

*Master oppgave for 5e års medisin student (Marit Katarina Robertsen)*
*Since 2010 the orthopedic department at the University Hospital of Northern Norway has performed hemiarthroplasty operation in several patients. The one-year follow-up on these patients showed good results. We plan to perform new evaluation now several years after surgery, there will also be clinical evaluation and an evaluation of glenoid status using X-ray to determine any new lesions or osteoarthrosis to the glenoid.*

**REKs vurdering**

Vi viser til innsendt framleggingsvurderingsskjema datert 05.05.2020 med vedlegg. Henvendelsen er behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK nord) ved sekretariatsleder, etter fullmakt gitt av komiteen med hjemmel i forskningsetikkforskriften § 7, første ledd, tredje punktum.

Veiledning vedrørende framleggingsplikt

De prosjekter som skal framlegges for REK er prosjekter som dreier seg om "*medisinsk og helsefaglig forskning på mennesker, humant biologisk materiale eller helseopplysninger*", jf. helseforskningsloven § 2. *«Medisinsk og helsefaglig forskning»* er i § 4 a), definert som *«virksomhet som utføres med vitenskapelig metodikk for å skaffe til veie ny kunnskap om helse og sykdom»*. Det er altså formålet med studien som avgjør om et prosjekt skal anses som framleggelsespliktig for REK eller ikke.

Av prosjektbesrkivelsen følger at: "*Since 2010 the orthopedic department at the University Hospital of Northern Norway has performed hemiarthroplasty operation in several patients. The one-year follow-up on these patients showed good results. We plan to perform new evaluation now several years after surgery, there will also be clinical evaluation and an evaluation of glenoid status using X-ray to determine any new lesions or osteoarthrosis to the glenoid.*"

Videre presiseres i skjemaet: "*Vi har rutiner for å kontrollere pasienter som fikk innoperert protese i et ledd etter 3 måneder, et år, 3, 5, og 10 år. Pga redusert kapasitet*

*generellt i vårt sykehus ble pasientene kontrollert bare et år etter operasjon. Vi ønsker å kontrollere pasienter som ble operert med hemiprotese i skulder minst 5 år etter operasjon for å vurdere resultater."*

Slik prosjektet er beskrevet skal man se på hvordan det har gått med de aktuelle pasientene etter 5 år og se på resultatene av å gjennomføre proteseoperasjon. Dette vil ikke fremskaffe ny kunnskap om sykdom og helse, særlig også sett hen til at det her dreier seg om en rutine som ikke er blitt gjennomført grunnet kapasitetsproblemer.

Prosjektet faller ikke inn under helseforskningslovens virkeområde.

Prosjekter som faller utenfor helseforskningslovens virkeområde kan gjennomføres uten godkjenning fra REK. Det er institusjonens ansvar å sørge for at prosjektet gjennomføres på en forsvarlig måte med hensyn til for eksempel regler om taushetsplikt og personvern.

**Vedtak**

Ikke fremleggspliktig

Prosjektet er ikke framleggingspliktig.

Vi gjør oppmerksom på at vurderingen og konklusjonen er å anse som veiledende jf. forvaltningsloven § 11.

Med vennlig hilsen

May Britt Rossvoll
sekretariatsleder

Maren Johannessen Melsbø
rådgiver

*Enclosure 1.*

# 8 GRADE

| **Referanse:** Heuberer PR, Brandl G, Pauzenberger L, Laky B, Kriegleder B, Anderl W. Radiological changes do not influence clinical mid-term outcome in stemless humeral head replacements with hollow screw fixation: a prospective radiological and clinical evaluation. BMC Musculoskelet Disord. 2018;19(1):28-. | | | **Study design: Case series**<br>**Grade - kvalitet** 2 |
|---|---|---|---|
| **Aims** | **Materials and methods** | **Results** | **Diskusjon/kommentarer/sjekkliste** |
| To evaluate whether or not clinical results in a midterm follow up after stemless shoulder arthroplasty was influenced by radiological changes<br>**Conclusion**<br>Clinical outcomes after this treatment were not influence by radiological changes.<br>**Country**<br>Austria<br>**Year of data collection**<br>2012 | **Study design and population**: A prospective single-center study evaluating short- and midterm outcomes on 73 shoulders with primarily idiopathic and posttraumatic osteoarthritis. 40 shoulders were treated with HSA and 33 were treated with TSA. **Inclusion**: Age 40-85 at the time of surgery, primary anatomical shoulder replacement, diagnosis of degenerative, rheumatic, posttraumatic osteoarthritis and fracture sequelae. **Exclusion**: Death or withdrawal before midterm follow up. **Outcome**: Functional and radiological outcomes based on Constant scores and **Statistical methods**: Descriptive statistics used to present patient characteristics. Data distribution evaluated by visual analysis of histograms and Kolmogorov-Smirnov-test. Fisher's exact tests (categorical), independent t-test, paired t-test. Kappa statistic to determine consistency. | 48 females and 24 males (1 bilateral) with mean age of 67.6 years at the time of surgery. Mean follow up time was 58 months. Demographics of the two groups (HSA vs TSA) were comparable. Comparison of operation times showed significantly shorter duration (minutes) for HSA (stemless 73.2, stemmed 95.1) than TSA (stemless 95.7, stemmed 120.7), $p<0.001$ for both groups. Radiological changes were detected in 37%, however where not found to influence clinical outcome. Constant scores significantly improved to midterm follow up, $p<0.001$. 92.2 percent of the patients where reported to be satisfied with the procedure. | Sjekkliste:<br>• Er formålet klart formulert? Yes.<br>• Var studien basert på et tilfeldig utvalg fra en egnet pasientgruppe? Yes.<br>• Var inklusjonskriteriene klart definert? Yes.<br>• Var alle pasientene i samme stadium av sykdommen? No.<br>• Ble det brukt objektive kriterier for å vurdere/validere endepunktene? Yes.<br>• Ved sammenligninger av pasientserier, er seriene tilstrekkelig beskrevet? Yes.<br>• Er prognostiske/konfunderende faktorer beskrevet7tatt hensyn til i design/anal?<br>• Var registreringen prospektiv? No, it was retrospective.<br>• Var oppfølgningen lang nok? Yes.<br>• Var oppfølgningen tilstrekkelig for å nå endepunktene? Yes, for a short to midterm follow up, but longer follow up time is also desirable<br>• Stoler du på resultatene? Yes.<br>• Kan resultatene overføres til praksis? Yes.<br>• Annen litteratur som støtter resultatene? Yes.<br><br>• Styrke: The authors list their results as an an outweighing strength<br>• Svakhet: In depth subjective assessmenets are missing. Bone mineral density analyses prior to operation |

| **Referanse:** Beck S, Beck V, Wegner A, Dudda M, Patsalis T, Jäger M. Long-term survivorship of stemless anatomical shoulder replacement. Int Orthop 2018;42(6):1327-30. | | | **Study design: Case series**<br>**Grade - kvalitet** 3 |
|---|---|---|---|
| **Aims** | **Materials and methods** | **Results** | **Diskusjon** |
| To assess long term results of stemless anatomical TSA.<br><br>**Conclusion**<br>The authors found the results of arthroplasty with the said kind of implant to be comparable to long stemmed implants.<br><br>**Country**<br>Germany<br><br>**Year of data collection**<br>2017 | **Study design and population**: Retrospective single center study evaluating outcome of 46 patients (51 shoulders) treated with stemless anatomical shoulder arthroplasty using TESS implant. **Exclusion**: Not reported. **Outcome**: Clinical outcome and patient satisfaction was assessed by the use of VAS, Quick-DASH and Constant Score. Radiographs in AP, axillary and lateral views were used to assess radiological outcome. **Statistical methods**: The Shapiro Wilks test was used to test for normal distribution. Paired student's t-test used to compare means with normal distribution preop and postop and Wilcoxon signed rank test for the non-normal variable means. P-values<0.05 were considered significant. | Mean follow up time was 94.7 months. 20 patients were lost for follow up, and 26 patients (31 shoulders) were available for follow up. Survival rate of TESS implant at 93.5% after eight years. Revision rate of TESS implant 9.7%. Radiolucent lines found at bone implant interface of the glenoid component in 90.9 % of the cases. Radiolucency was mostly present in patients with rheumatoid arthritis. Loosening of the glenoid component was only seen in one shoulder. Loosening of the humeral component was not observed | Sjekkliste:<br>• Er formålet klart formulert? Yes.<br>• Var studien basert på et tilfeldig utvalg fra en egnet pasientgruppe? Yes.<br>• Var inklusjonskriteriene klart definert? Yes.<br>• Var alle pasientene i samme stadium av sykdommen? No.<br>• Ble det brukt objektive kriterier for å vurdere/validere endepunktene? Yes.<br>• Ved sammenligninger av pasientserier, er seriene tilstrekkelig beskrevet? Not relevant.<br>• Var registreringen prospektiv? No, it was retrospective.<br>• Var oppfølgningen lang nok? Yes.<br>• Var oppfølgningen tilstrekkelig for å nå endepunktene? Yes, but longer follow up time is also desirable.<br>• Stoler du på resultatene? Yes.<br>• Kan resultatene overføres til praksis? Yes.<br>• Annen litteratur som støtter resultatene? Yes.<br><br>• Styrke: Not specifically listed.<br>• Svakhet: Single center retrospective study. Some degree of telephone interview. |

| **Referanse:** Maier MW, Lauer S, Klotz MC, Bülhoff M, Spranz D, Zeifang F. Are there differences between stemless and conventional stemmed shoulder prostheses in the treatment of glenohumeral osteoarthritis? BMC musculoskeletal disorders 2015;16(1):1-7. | | | **Studiedesign: Retrospective cohort**<br>Grade - kvalitet 3 |
|---|---|---|---|
| **Aims** | **Materials and methods** | **Results** | **Discussion** |
| To evaluate early functional outcome and postoperative proprioception of stemless prosthesis compared to standard stemmed anatomic shoulder arthroplasty.<br>**Conclusion**<br>Functional and proprioceptive early outcomes are comparable between stemless and standard stemmed total shoulder arthroplasty.<br>**Country**<br>Germany<br>**Year of data collection**<br>2012 | **Population:** Cohorts: twelve patients with primary osteoarthritis of the glenohumeral joint received total shoulder arthroplasty with stemless implant (TESS). In the control group twelve patients received total shoulder arthroplasty with standard stemmed implant (Aequalis). **Outcomes:** Patients were evaluated one day before surgery and six months after surgery. Constant Score was evaluated preop and postop and proprioception was measured using active angle-reproduction (AAR) test. **Statistical methods:** Shapiro-Wilks test was used for testing normality and Levene test for homogeneity of variance. Wilcoxon test was used for comparing preop and postop shoulder joint angles, as well as CS and subscores. Differences between groups was evaluated by using a Mann-Whitney U test. | No intraoperative complications occurred, no revision was needed after a mean time of six months. CS improved significantly in both groups from preop to postop. There was no significant difference in CS between the two groups at follow up, p = 0.792. In both groups proprioception was not found significantly different from preop to postop. By trend postop proprioception was better in the stemless group. | **Sjekkliste:**<br>• Formålet klart formulert? Yes.<br>• Er gruppene rekruttert fra samme populasjon/befolkningsgruppe? Yes.<br>• Var gruppene sammenliknbare i forhold til viktige bakgrunnsfaktorer? Yes.<br>• Var de eksponerte individene representative for en definert befolkningsgruppe/populasjon? Yes.<br>• Ble eksposisjon og utfall målt likt og pålitelig (validert) i de to gruppene? Yes.<br>• Er den som vurderte resultatene (endepunkt- ene) blindet for gruppetilhørighet? Not reported, but presumably not.<br>• Var studien prospektiv? No, it was retrospective.<br>• Ble mange nok personer i kohorten fulgt opp? Yes, all patients were followed.<br>• Var oppfølgingstiden lang nok til å påvise positive og/eller negative utfall? No, further evaluation is needed.<br>• Er det tatt hensyn til viktige konfunderende faktorer i design/ gjennomføring/analyser? Not reported.<br>• Tror du på resultatene?<br>• Kan resultatene overføres til den generelle befolkningen? Longer follow up is required to tell.<br>• Styrke: The first six months after surgery are important in terms of complications and rehabilitation.<br>• Svakhet: Relatively short follow up period. No randomization and matching of patients according to age, height, weight, BMI or gender. |

| **Referanse:** Hawi NMD, Magosch PMD, Tauber MMD, Lichtenberg SMD, Habermeyer PMD. Nine-year outcome after anatomic stemless shoulder prosthesis: clinical and radiologic results. J Shoulder Elbow Surg 2016;26(9):1609-15. | | | **Studiedesign: Prospective cohort**<br>Grade - kvalitet 3 |
|---|---|---|---|
| **Aims** | **Materials and methods** | **Results** | **Discussion** |
| To report mid- to long-term results nine years after use of stemless arthroplasty using the Eclipse prosthesis.<br>**Conclusion**<br>The study showed good results after nine years by using stemless humeral implant. Clinical results were comparable to third and fourth generation stemmed implants.<br>**Country**<br>Germany<br>**Year of data collection**<br>2016 | **Population:** 49 shoulder were operated with anatomic stemless shoulder arthroplasty by using Eclipse implant. Cohorts: 17 shoulders underwent total shoulder arthroplasty, 32 underwent hemiarthroplasty. **Outcomes:** Patients were monitored clinically by using Constant Score and abduction strength was measured by use of ISOBEX dynamometer. Radiographs in three planes were used to evaluate radiological changes; bone density, radiolucency, secondary glenoid wear and superior caput migration. **Exclusion:** Patients with rheumatoid arthritis, osteoporosis and large subchondral cysts. **Statistical methods:** Shapiro-Wilks test was used for testing normality and Levene test for homogeneity of variance. Wilcoxon test was used for comparing preop and postop shoulder joint angles, as well as CS and subscores. Differences between groups was evaluated by using a Mann-Whitney U test. | Mean follow up time was nine years, follow up rate was 88%. Overall results showed significant improvement in Constant Score, pain, ADL and range of motion ($p<0.001$). There was no significant difference in CS between HSA group and TSA group. Upward migration of caput humeri appeared in 14.7% of patients. Incomplete radiolucency was seen in 2.3%. No patient showed loosening of the humeral implant. Lowering of bone density was observed on AP radiographs of 29.4% of patients, however these results did not influence Constant Score or active range of motion. | **Sjekkliste:**<br>• Formålet klart formulert? Yes.<br>• Er gruppene rekruttert fra samme populasjon/befolkningsgruppe? Yes.<br>• Var gruppene sammenliknbare i forhold til viktige bakgrunnsfaktorer? Yes.<br>• Var de eksponerte individene representative for en definert befolkningsgruppe/populasjon? Yes.<br>• Ble eksposisjon og utfall målt likt og pålitelig (validert) i de to gruppene? Yes.<br>• Er den som vurderte resultatene (endepunkt- ene) blindet for gruppetilhørighet? No.<br>• Var studien prospektiv? Yes.<br>• Ble mange nok personer i kohorten fulgt opp? 88% follow up rate.<br>• Var oppfølgingstiden lang nok til å påvise positive og/eller negative utfall? Yes, nine years is considered mid- to long-term.<br>• Tror du på resultatene? Yes.<br>• Kan resultatene overføres til den generelle befolkningen? Yes.<br>• Styrke: Longterm follow up.<br>• Svakhet: Different indications for shoulder arthroplasty. No control group for comparing outcomes. |

| **Referanse:** Habermeyer P, Lichtenberg S, Tauber M, Magosch P. Midterm results of stemless shoulder arthroplasty: a prospective study. J Shoulder Elbow Surg 2015;24(9):1463-72. | | | **Study design: Case series**<br>**Grade - kvalitet** 2 |
|---|---|---|---|
| **Aims** | **Materials and methods** | **Results** | **Diskusjon** |
| To evaluate functional and radiological results of shoulder arthroplasty using a single type of stemless humeral implant, Eclipse.<br><br>**Conclusion**<br>Stemless shoulder arthroplasty showed comparable midterm results to standard stemmed arthroplasty of the third and fourth generation.<br><br>**Country**<br>Germany<br><br>**Year of data collection**<br>2015 | **Study design and population**: Stemless shoulder arthroplasty in 78 patients with primary osteoarthritis and post traumatic osteoarthritis at mean age of 58 years of age were evaluated prospectively at a mean follow up time of 72 months. **Outcome**: Functional outcomes were assessed using sex- and age-adjusted Constant Score with subcategories and radiological evaluation was conducted using standard radiographs. An ISOBEX dynamometer was used to measure abduction strength. **Statistical methods**: Level of significance: $p < 0.05$. Wilcoxon signed rank test used to analyze differences between preop and postop nonparametric data. Analyses between groups conducted using Mann-Whitney U test. | 14 patients received HSA and 25 patients received TSA. Functional results did not differ significantly between the two groups. Patients with primary osteoarthritis showed significantly improved active abduction compared to post-traumatic arthritis, $p = 0.035$. Humeral head migration was observed in 39.1% of the patients, incomplete radiolucent lines under the humeral implant was seen in one patient (1.3%). 3 patients presented with partial osteolysis (3.8%) and two of these in combination with glenoid loosening. Secondary glenoid wear was seen in 71.9% of the cases. Lowering of bone density did not influence functional outcome (CS and active range of motion). | Sjekkliste:<br>• Er formålet klart formulert? Yes.<br>• Var studien basert på et tilfeldig utvalg fra en egnet pasientgruppe? Yes.<br>• Var inklusjonskriteriene klart definert? No.<br>• Var alle pasientene i samme stadium av sykdommen? No.<br>• Ble det brukt objektive kriterier for å vurdere/validere endepunktene? Yes.<br>• Ved sammenligninger av pasientserier, er seriene tilstrekkelig beskrevet? Yes.<br>• Var registreringen prospektiv? Yes.<br>• Var oppfølgningen lang nok? Yes.<br>• Var oppfølgningen tilstrekkelig for å nå endepunktene? Longer follow up time is desirable to assess further.<br>• Stoler du på resultatene? Yes.<br>• Kan resultatene overføres til praksis? Yes.<br>• Annen litteratur som støtter resultatene? Yes.<br><br>• Styrke: Not reported.<br>• Svakhet: Not reported. |