

## Prosthetic arthroplasty in primary shoulder osteoarthritis

Kärrholm J, Steen K, Hultenheim Klintberg I, Ekholm C,  
Svanberg T, Samuelsson O.

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Kärrholm J<sup>1\*</sup>, Steen K<sup>1</sup>, Hultenheim Klintberg I<sup>2</sup>, Ekholm C<sup>1</sup>,  
Svanberg T<sup>3</sup>, Samuelsson O<sup>3</sup>.

<sup>1</sup> Department of Orthopedic Surgery, Sahlgrenska University Hospital, Göteborg, Sweden.

<sup>2</sup> Department of Physiotherapy, Sahlgrenska University Hospital, Göteborg, Sweden.

<sup>3</sup> HTA-centrum of Region Västra Götaland, Sweden.

\*Corresponding author

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Statement from HTA-centre 2012-09-26

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### Method and patient group

Glennohumeral osteoarthritis is usually associated with chronic pain of various severities, as well as loss of motion and function. The disorder can be treated non-surgically or surgically. In severely affected patients the pain may be disabling, cause sleep disturbances, and can also aggravate the impaired motion. During recent years the design of shoulder implants has improved rapidly. Currently, two major types of shoulder implants are available; those that can replace the whole glennohumeral joint, so called total shoulder arthroplasty, and those that only replace either the glennoid surface or the humeral head, so called hemiarthroplasty.

### Questions at issue, PICO:

1. Does surgical implantation with shoulder prosthesis improve function and quality of life in patients with severe primary glennohumeral osteoarthritis in comparison with non-surgical interventions?
2. Does total shoulder arthroplasty improve function and quality of life in patients with severe primary glennohumeral osteoarthritis in comparison with hemiarthroplasty?

### **PICO 1**

P = patients with primary shoulder osteoarthritis and intact rotator cuff

I = any type of shoulder arthroplasty

C = non-surgical treatment, sham surgery

O = overall shoulder score, pain, quality of life, mobility, activity of daily life, surgical revision, complications

### **PICO 2**

P = patients with primary shoulder osteoarthritis and intact rotator cuff

I = total shoulder arthroplasty (TSA)

C = hemiarthroplasty (HA)

O = overall shoulder score, pain, quality of life, mobility, activity of daily life, surgical revision, complications

### Studied risks and benefits for patients of the new health technology

#### ***Any type of shoulder arthroplasty versus nonsurgical treatment***

The systematic literature search did not identify any publication that has reported the effects of prosthetic arthroplasty (of any type) in comparison with sham surgery or non-surgical treatment in patients with primary glennohumeral osteoarthritis. All the studies that have compared TSA and HA with one another (see below) have also reported the changes in outcome variables between the preoperative status and the postoperative status for each type of arthroplasty. All of them consistently reported marked improvements with regard to pain, mobility, activity of daily life and mobility after both TSA as well as HA in comparison to the preoperative status.

#### ***Total shoulder arthroplasty versus hemiarthroplasty***

There were no differences in outcome between the two types of shoulder implants with regard to overall shoulder score (low quality of evidence, GRADE ⊕⊕○○), pain (GRADE ⊕⊕○○), quality of life (GRADE ⊕⊕○○), mobility (GRADE ⊕⊕○○), activity of daily life (very low quality of evidence, GRADE ⊕○○○), and need for surgical revision (GRADE ⊕○○○).

### Complications

Any kind of early complication (i.e. within three weeks after TSA or HA) have been reported to occur with an incidence rate of 3 - 12 %, whereas late complications have been reported to occur with an annual rate of about 1-3 %. There are no published data on perioperative mortality.

### Ethical aspects

It may not be ethically acceptable to introduce shoulder arthroplasty in the clinical routine on a large scale before there is convincing documentation that it is more effective compared to other non-surgical interventions in reducing symptoms. On the other hand, based on the observed effects of shoulder replacement on pain, mobility and activity of daily life observed after surgery in comparison to the preoperative status in all the studies a major ethical question is whether it is acceptable to refrain from implantation of prosthesis in patients with severe symptoms?

### Economical aspects

The average total hospital cost for a shoulder arthroplasty was approximately 75 000 SEK in Region Västra Götaland in 2010. An increased use of shoulder arthroplasty with about 7-8 % more patients each year will lead to an annual increment in cost over the present budget of about 1 million SEK. The technological expansion of the implants might also imply slightly increased cost per surgical procedure.

### Conclusions

The reported beneficial effects of shoulder replacement in comparison to the patients' preoperative status with regard to pain, mobility and activity of daily life are large. However, this has only been analysed in uncontrolled patient series. There is no study that has compared prosthetic arthroplasty with a parallel control group receiving non-surgical intervention. There are no documented differences in the effects between the two different types of shoulder arthroplasty TSA and HA (low or very low levels of evidence GRADE ⊕⊕○○ or ⊕○○○).

**Which health technology or method will be assessed?**

**1a Who will lead the project?**

Johan Kärrholm, MD, PhD, Professor, Department of Orthopedic Surgery, Sahlgrenska University Hospital, Göteborg, Sweden.

**1b Who posed the question?**

Johan Kärrholm, MD, PhD, Professor, Department of Orthopedic Surgery, Sahlgrenska University Hospital, Göteborg, Sweden.

**1c Co-workers:**

Carl Ekholm, MD, PhD, Department of Orthopedic Surgery, Sahlgrenska University Hospital, Göteborg, Sweden.

Ingrid Hultenheim Klintberg, Physiotherapist, Sahlgrenska University Hospital, Göteborg, Sweden.

Karin Steen, MD, Sahlgrenska University Hospital, Göteborg, Sweden.

**1d Other participants, from the HTA centre and external reviewers**

Frida Jorstedt, librarian, Sahlgrenska University Hospital, Göteborg, Sweden.

Ola Samuelsson, MD, PhD, and Therese Svanberg, HTA-librarian; both at the HTA-centre of Region Västra Götaland, Sweden.

**External reviewers**

Maria Skogby RN, PhD, Frölunda Hospital, Göteborg, Sweden.

Magnus Rizell, MD, PhD, Department of Transplantation and Liver Surgery, Sahlgrenska University Hospital, Göteborg, Sweden.

**1e Are there any conflicts of interest for the proposer or any of the participants in the work group?**

No

## Disease/disorder of Interest and Present Treatment

### 2a **Disease/disorder of interest and its degree of severity**

Arthritis in the glenohumeral joint can be the result of a trauma or an inflammatory disorder, but can also occur as primary osteoarthritis. In primary osteoarthritis typical changes develop with a central wear of the humeral articular cartilage, flattening of the humeral head and marginal osteophytes. Also the glenoid develop typical changes with posterior wear and erosion. This disorder is usually associated with chronic pain of various severities, as well as loss of motion and function. In severely affected patients the pain may be disabling and cause sleep disturbances, and with impaired motion, predominately characterised by loss of elevation and external rotation.

- Risk of permanent illness or damage, or reduced quality of life
- Risk of disability and health-related quality of life

### 2b **Prevalence and incidence of the disease/disorder**

The prevalence and incidence of glenohumeral osteoarthritis in the Swedish adult population are unknown. The experience from prevalence studies of osteoarthritis in other joints in various populations indicates that it varies considerably in different ethnic groups (Zetterberg and Hansson, 1995).

According to the Swedish Shoulder and Elbow Register the annual number of shoulder prosthetic arthroplasties in Sweden increased from 343 in 1999 to 891 in 2009. This register has a completeness of about 86 % of all patients undergoing prosthetic arthroplasty of the shoulder. A similar increase of shoulder arthroplasties has been observed in the United States, with a predominance of total shoulder arthroplasty (TSA) over hemiarthroplasty (HA) with a ratio of about 3:2. In both Sweden and the United States the increase in prosthetic arthroplasties have escalated since 2004. Thus, the true number of shoulder replacements in Sweden during 2012 can be estimated to be approximately slightly over 1000.

In the U.S. about 53,000 people now have shoulder replacement surgery each year, according to the Agency for Healthcare Research and Quality (quoted from the AAOS homepage). Transferred to the Swedish population this would yield an estimated number of shoulder arthroplasties of about 1600 per year.

### 2c **Present treatment of the disease/disorder in the outpatient setting/ in-patient setting.**

A shoulder joint disorder is often combined with co-existing abnormalities of the peri-articular soft tissues. This leads to a complex interaction of potential pain generators surrounding the glenohumeral joint (Boselli et al., 2010; Gartsman and Taverna, 1997). Glenohumeral osteoarthritis is also frequently associated with intra- or extra-articular shoulder conditions that cause shoulder instability and an impingement syndrome.

Primary osteoarthritis can be treated non-surgically or surgically. Non-surgical treatment includes oral analgesic and non-steroid anti-inflammatory drugs, intra-articular injections (corticosteroids, hyaluronic acid), activity modification and physiotherapy with the aim to improve flexibility and strength as well as to maintain general fitness (Parsons et al., 2004).

### *Physiotherapy*

Physiotherapy is one of the first line interventions in management of painful musculoskeletal conditions of the shoulder (Green et al., 2003; Denard et al., 2011). The specific treatment modalities include therapeutic exercise, manual mobilization, acupuncture and TENS (Transcutaneous Electric Neuro Stimulation). Therapeutic exercises are well documented, and can restore function and reduce pain (van der Heijden et al., 1997; Marinko et al., 2011; Farr et al., 2010). Well-structured exercise programs have been shown to be more efficient than self-management in osteoarthritis of the knee joint (Farr), and it is most probably the case also for shoulder osteoarthritis (Marinko).

### *Surgery*

Patients who do not achieve an acceptable pain relief and/or function by nonsurgical interventions can be treated with arthroscopic debridement or with prosthetic arthroplasty. There are two major types of prosthetic surgery; total shoulder arthroplasty and hemiarthroplasty. In the former both the humeral head and the glenoid cavity is replaced by prosthesis, whereas in HA the humeral head is replaced by an implanted prosthesis.

#### **2d Number of patients per year who undergo current treatment regimen?**

During 2010 a total of 37 shoulder arthroplasties due to primary osteoarthritis were performed in Region Västra Götaland. The number of such patients had increased to 56 during 2011. The corresponding total numbers of shoulder arthroplasties due to any reason and including trauma diagnoses increased from 122 to 171. Of these 14 and 22 were revision procedures.

It is estimated that the need for shoulder arthroplasty in Region Västra Götaland is about 200 patients per year. This would imply an increase the next coming years of about 10 % per year, i.e. about 17 additional patients each year.

#### **2e The normal pathway of a patient through the health care system**

Patients with glenohumoral osteoarthritis are normally first treated by general practitioners in the out-patient setting. Most patients are evaluated by physical examination and a conventional radiographic examination of the shoulder.

Severe cases with therapy-resistant symptoms will be referred to an orthopedic surgeon. The normal wait time from referral to a first visit to the orthopedic surgeon is about three months.

The great majority of these severe cases will then be subject to about six months of well-structured exercises and manual manipulation. If there has not been a sufficient reduction of pain, restoration of range of motion and function, after this period the patient is reassessed for consideration of surgical treatment.

#### **2f Actual wait time in days for medical assessment /treatment**

Once the decision to perform arthroplasty has been made the wait time for surgery is less than three months.

**3a Name/description of the health technology at issue**

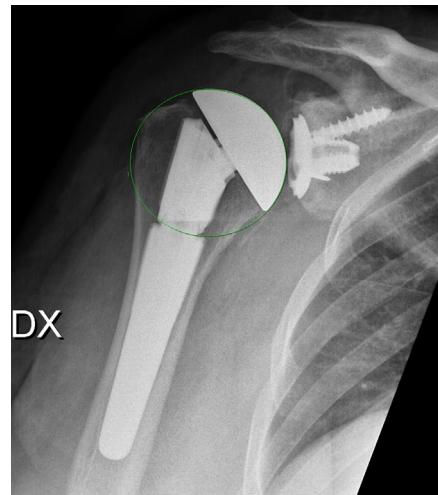
Presently, there is no curative treatment for glenohumeral osteoarthritis. There is no available technology that can restore joint cartilage or restore the deformation of the articulating surfaces. Furthermore, no treatment modality has convincingly been shown to curb the progress of the disease.

The aim of non-surgical treatment is to alleviate the symptoms well enough to defer shoulder arthroplasty (unless bone loss necessitates surgery). Intra-articular injections of hyaluronic acid have been reported to have some beneficial effects on symptomatic patients. However, this was reported in one uncontrolled patient series, i.e. comparison of pre- and post-intervention (Silverstein et al., 2007). Arthroscopic debridement has also been reported to both reduce pain and increase function in uncontrolled patient series (Weinstein DM et al, Arthroscopy 2000, Van Thiel et al., 2010).

Shoulder replacement surgery was initially performed in the 1950s to treat complicated shoulder fractures. Similar to hip replacement surgery the technology is now also used to treat other painful shoulder conditions such as osteoarthritis.

- **Hemiarthroplasties (HA)** may be stemmed or be of a surface replacement type. The latter means that they are bone sparing by no or minimum invasion of the humeral canal. These types of implants are used when the glenoid is more or less intact. Stemmed hemiarthroplasties are also used for fracture treatment or as salvage, when the glenoid is too severely destroyed to anchor a glenoid component.
- The typical **total shoulder arthroplasty (TSA)** involves the replacement of the arthritic joint surfaces with a highly polished metal ball attached to a stem, and a plastic socket. To achieve good function the rotator cuff has to be intact.

*Figure. Total shoulder arthroplasty with metal backed glenoid component*



If the rotators are completely torn, or if there is a destruction of the glenoid a, so called, reversed TSA may be used. This technique is frequently also used when revision surgery is needed. The reversed shoulder prosthesis stabilises the joint by use of a spherical glenoid component facing the joint. The glenoid articulates against a concave joint surface on the stemmed humeral component. The construction of the reversed shoulder arthroplasty allows other muscles (e.g. the deltoid) to elevate or abduct the arm.

Whether one should perform a replacement of the glenoid articulating surface in addition to the humeral arthroplasty, i.e. TSA instead of HA, is debated. The fixation of the glenoid component is less reliable, and may sometimes be impossible with existing bone loss. Although it is currently believed that glenoid resurfacing yields superior results, this surgical procedure is more demanding, and treatment of complications may be technically more challenging.

- 3b The work group's understanding of the potential value of the health technology**
- Osteoarthritis, primary or secondary, is a progressive condition that leads to pain and reduced shoulder function. As a consequence the patients quality of life is reduced, and may also limit the patients ability work or, in the elderly, to maintain independence. Indeed, recent studies on the consequences of well-treated proximal humeral fractures show that the impact on the patients' health related quality of life (HRQoL) is in the same magnitude as the consequences of hip fractures (Olerud et al., 2010). When non-surgical intervention no longer can relieve the patient of pain and improve function the alternative may be a surgical replacement of the joint with TSA or HA.

During recent years the design of shoulder implants has improved rapidly. Modern implants have a high degree of modularity to enable closer reproduction of the patient's individual anatomy. We may therefore expect improved outcome with future replacement surgery.

The actual need for shoulder arthroplasty is not established. Because the knowledge of the available technology is not widely spread one might speculate that patients who would benefit from shoulder arthroplasty have not been referred for surgery. Early surgery is to be preferred as late surgery may be considerably more difficult. It may even be impossible if the progression of the osteoarthritis has caused severe bone loss.

In a meta-analysis of the effect of TSA on health related quality on life, Carter et al reviewed 20 studies (1 576 total shoulders) (Carter 2012). Nearly all patients had been operated upon due to primary osteoarthritis. They concluded that TSA improved both function and pain to a large extent according to the SF-36 physical component, the Constant score and the American Shoulder and Elbow Surgeons score (see below 3d)

**3c The central questions for the current HTA project**

1. Does surgical implantation with shoulder prosthesis improve function and quality of life in patients with severe primary glenohumoral osteoarthritis in comparison with non-surgical interventions?
2. Does total shoulder arthroplasty improve function and quality of life in patients with severe primary glenohumoral osteoarthritis in comparison with hemiarthroplasty?

3d

**PICO**

P= Patients, I= Intervention, C= Comparison, O=Outcome

**PICO 1**

P = patients with primary shoulder osteoarthritis and intact rotator cuff  
I = any type of shoulder arthroplasty  
C = non-surgical treatment  
O = overall shoulder score\*, pain, quality of life, mobility, activity of daily life, surgical revision, complications

**PICO 2**

P = patients with primary shoulder osteoarthritis and intact rotator cuff  
I = total shoulder arthroplasty (TSA)  
C = hemiarthroplasty  
O = overall shoulder score\*, pain, quality of life, mobility, activity of daily life, surgical revision, complications

\* Overall shoulder score is a mean to weigh the patient's pain, activity, mobility and strength together in one total score. The most commonly used scores are the Constant score (Constant and Murley 1987), the American Shoulder and Elbow Surgeons Shoulder score (ASES) (Wright and Baumgarten 2010) and the University of California and Los Angeles Shoulder score (UCLAS) (Snyder et al., 1995), Ellman et al., 1986).

**Study design:**

Randomized and non-randomized controlled trials.

Case series > 25 patients.

**Limits:** publication date from 1995, English and Scandinavian languages.

3e

**Key words**

English: shoulder Joint; Osteoarthritis; Arthroplasty; total shoulder arthroplasty; hemiarthroplasty

Swedish: Skulderled; Artros; Artroplastik

### 4 Search strategy, study selection and references – appendix 3

During January, 2011, with an update in December 2011, the library performed searches in PubMed, EMBASE, the Cochrane Library, CINAHL, AMED and a number of HTA-databases. Reference lists of relevant articles were also scanned for additional references. A total of 740 articles were identified after removal of duplicates, of which 672 abstracts were excluded by the library. Another 25 articles were excluded by the librarians after having been read in full text. 43 articles were sent to the work group for assessment. 29 of these articles are included in the report; two of which were randomised controlled trials (RCT), and five were non-randomised controlled studies. These studies have been critically appraised. The appraisal of original articles is based on a checklist from SBU regarding randomized controlled trials, and another checklist for non-randomised controlled studies developed by Olle Nyrén, professor, Karolinska Institutet, Stockholm, Sweden.

Furthermore, two systematic reviews were identified. Both were of good quality according to the AMSTAR criteria.

Search strategies, eligibility criteria and a graphic presentation of the selection process are accounted for in appendix 3. The literature search and exclusion of abstracts were made by two librarians (TS, FJ) in consultation with the HTA-centre and the work group.

### 5a Describe briefly the present knowledge of the health technology

#### *Any type of shoulder arthroplasty versus other treatment (PICOI)*

Neither the systematic literature search of this HTA nor the Cochrane review of 2010 could identify any publication that has reported the effects of prosthetic arthroplasty (of any type) in comparison with sham surgery, arthroscopic debridement, or non-surgical treatment in patients with primary glenohumeral osteoarthritis.

All the seven studies that have compared TSA and HA with one another (see below) have also reported the changes in outcome variables between the preoperative status and the postoperative status for each type of arthroplasty. All of them consistently reported marked improvements with regard to pain, mobility, activity of daily life and mobility for both TSA and HA after implantation of the prosthesis in comparison to the preoperative status. The time of follow-up in these studies ranged from one year up to seven and half years.

The systematic review of Zumstein and co-workers summarised the experience of 21 uncontrolled follow-up studies of patients treated with reverse total shoulder arthroplasty (RSA). They concluded that complications, reoperations and revisions were all common after RSA.

### ***Total shoulder arthroplasty versus hemiarthroplasty (PICO2)***

The systematic literature search identified two randomised controlled trials (RCT), and five non-randomised controlled studies, in which TSA have been compared to HA in patients with primary glenohumeral osteoarthritis. Both RCTs were of moderate quality, and were the same two trials also included in the Cochrane review of 2010. One of the non-randomised controlled studies was of moderate and the remaining four studies were of low quality.

#### *Overall shoulder score*

Two RCTs and five non-randomised controlled studies compared TSA with HA, Appendix 1:1.

Conclusion: There were no differences between the study groups at end of follow-up. Low quality of evidence (GRADE ⊕⊕○○), Appendix 4.

#### *Pain*

Two RCTs and five non-randomised controlled studies compared TSA with HA, Appendix 1:2, Appendix 4.

Conclusion: There were no differences between the study groups at end of follow-up. Low quality of evidence (GRADE ⊕⊕○○), Appendix 4.

#### *Quality of Life*

One RCT and one non-randomised controlled study compared TSA with HA, Appendix 1:3.

Conclusion: There were no differences between the study groups at end of follow-up. Low quality of evidence (GRADE ⊕⊕○○), Appendix 4.

#### *Mobility*

Two RCTs and three non-randomised controlled studies compared TSA with HA, Appendix 1:4, Appendix 4.

Conclusion: There were no differences between the study groups at end of follow-up. Low quality of evidence (GRADE ⊕⊕○○), Appendix 4.

#### *Activity of daily life*

One RCT and four non-randomised controlled studies compared TSA with HA, Appendix 1:5.

Conclusion: There were no differences between the study groups at end of follow-up. Very low quality of evidence (GRADE ⊕○○○), Appendix 4.

#### *Surgical revision*

Two RCTs and two non-randomised controlled studies compared TSA with HA, Appendix 1:6.

Conclusion: The number of surgical revisions was very low, which made comparisons between the two arthroplasties not meaningful.

Very low quality of evidence (GRADE ⊕○○○), Appendix 4.

#### *Complications*

Complications can be divided into *early* complications that occur within three weeks after surgery, or *late* complications that occur after three weeks. Most of the studies have only reported the overall rate of complications that could be directly related to surgery. Thus, the rate of “any complication” presented in Appendix 1-7 will be identical with that of the rate of “complications directly related to surgery” for most studies.

The different kinds of specific complications that may occur after arthroplasty are humerus fracture, infection, nerve palsy, dislocation, rotator cuff or subscapular tear, subluxation, prosthetic wear, loosening of prosthesis and erosion. The complication rates, including fatal events, are presented in Appendix 1:7. No study report data on perioperative mortality. If the reported total mortality in the studies are recalculated to a yearly mortality rate it varies from 0.2 % to 1.5 % in a population with an average age of about 65 years at the time of surgery.

Early complications, i.e. within three weeks of surgery, regardless of TSA or HA, have been reported to occur at a rate of 3 - 12 %.

The time of follow-up in the studies vary from 1 – 20 years. This means that the incidence of late complications during follow-up differ substantially between studies. Four studies that have reported late complications have a follow-up of about 4 years. The incidence rate of late complications in these studies was 3 – 13 %. A simple recalculation yields an annual rate of late complications of about 1-3 % per year.

**5b Outcome tables – appendix 1**

**5c Excluded articles – appendix 2**

**5d Ongoing research**

A search in [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (2012-03-06) with the keywords (osteoarthritis AND shoulder AND arthroplasty) identified 15 trials. However, only one of the trials is relevant for the question at issue. NCT01288066 is an RCT in which the effectiveness of HA versus TSA using implants of the “Epoca” system will be compared. It will evaluate the effectiveness with regard to pain and function after 6 months, 1, 3 and 5 years. It has not yet started the recruitment of patients. There were no ongoing or planned studies listed in [www.clinicaltrials.gov](http://www.clinicaltrials.gov) with the aim to compare arthroplasty with intra-articular injections, arthroscopic debridement or physiotherapy.

**6 Which medical societies or health authorities recommend the new health technology?**

- The National Board of Health and Welfare
- Medical societies
- Other health authority

**Which medical society or health authority?**

The Swedish Association of Shoulder and Elbow

## Ethical aspects

### 7 Ethical consequences

Shoulder arthroplasty needs to be compared with other interventions in well-designed controlled studies before it is introduced as a clinical routine on a large scale. However, in individual patients with severe pain or disability it may well be ethical to offer such surgical intervention. For detailed analysis see Appendix 5.

## Organisation

### 8a When can this new health technology be put into practice?

Shoulder arthroplasty is today performed at 3 hospitals in VGR, (see 8b).

### 8b Is this technology used in other hospitals in Western Region of Sweden?

In VGR elective shoulder arthroplasties are performed at the Departments of Orthopaedics at the Sahlgrenska University Hospital Mölndal, the Södra Älvsborg Hospital, Borås, and the Norra Älvsborgs County Hospital, Uddevalla, Sweden.

### 8c According to the work group, will there be any consequences of the new health technology for personnel?

The expected increased use of shoulder arthroplasty will require more resources in terms of personnel, education, and accessibility to operating theaters, as well as for equipment and implants.

### 8d Will there be any consequences for other clinics or supporting functions at the hospital or in the whole Western Region of Sweden?

The documented increase in prosthetic arthroplasties in patients with primary shoulder osteoarthritis (see 2b) will cause an increased need of resources in terms of surgical procedures and in- and outpatient care.

If the ongoing expansion of shoulder arthroplasty will not be reimbursed, the production of other types of elective orthopaedic surgery including total hip and knee arthroplasty will have to be reduced.

## Economy

**9a Present costs of currently used technologies**

During 2010 the average hospital cost for a shoulder arthroplasty in Region Västra Götaland was approximately 75 000 SEK.

**9b Expected costs of the new health technology?**

Based on the observed increase in the use of HA and TSA in Sweden up until 2009 (The Swedish Shoulder and Elbow Register) it is estimated that the need of shoulder arthroplasties will be 100-200 implants per year in Region Västra Götaland when patients with fractures (trauma) are excluded. This corresponds to a total annual cost of 7 500 000 – 15 million SEK.

**9c Total change of cost**

In Region Västra Götaland about 170 shoulder arthroplasties were performed in 2011. Based on an increase per year of about 10 %, i.e. an annual increase of about 17 patients, the increment in cost each year will be about 1 million SEK (17 x 75 000 SEK) for the total population of patients subjected to shoulder arthroplasty. Patients with primary glenohumeral osteoarthritis will account for half of this cost.

**9d Can the new technology be adopted and used within the present budget (clinic budget/hospital budget)?**

No.

The use of shoulder arthroplasty for primary glenohumeral osteoarthritis has increased. This increase will most probably continue for several years due to an aging population and the functional results and pain reduction observed after shoulder arthroplasty when these effects will become better known by general practitioners.

**9e Are there any available analyses of health economy? Cost advantages or disadvantages?**

Mather et al. reported the cost effectiveness of HA and TSA in a study based on the US Medicare system (Mather et al., 2010). They based their calculations on the national average Medicare reimbursement (2008). This probably means that the total cost including patient visits, the impact of the disease on disability, handicap aids, medications and sick-leave was not totally covered. With these shortcomings the cost effectiveness ratio for TSA was estimated to be 957 US dollars per QALY and for HA 1194 US dollars per QALY. This would imply that these procedures are at least as cost effective as a total hip arthroplasty.

## Unanswered Questions

### 10a **Important gaps in scientific knowledge?**

It is still not clarified to what extent a shoulder arthroplasty may improve function and reduce pain in comparison to nonsurgical intervention in patients with primary osteoarthritis and intact rotator cuff.

It is not known which of the presently available prosthetic devices that is most effective in improving function and reducing pain in this patient category.

### 10b **Is there any interest in your own clinic/research group/organisation to start studies/trials within the research field at issue?**

Yes.

1. One of our primary interests is to study shoulder function and patient satisfaction related to choice of implant and diagnosis. We have recently installed a new radiologic laboratory designed for radiostereometric analysis. This technique enables dynamic studies of shoulder function and kinematics.
2. Another subject of interest is to evaluate the efficacy of non-surgical versus surgical treatment, and in more detail study the effects of these treatments on muscle activation, pattern of shoulder motion and pain.

Presently we do not have any funding for these projects.

## Statement from HTA-centrum, Region Västra Götaland

**Prosthetic arthroplasty in primary shoulder osteoarthritis**Questions at issue:

1. Does surgical implantation with shoulder prosthesis improve function and quality of life in patients with severe primary glenohumeral osteoarthritis in comparison with non-surgical interventions?
2. Does total shoulder arthroplasty improve function and quality of life in patients with severe primary glenohumeral osteoarthritis in comparison with hemiarthroplasty?

PICO**PICO 1**

- P = patients with primary shoulder osteoarthritis and intact rotator cuff  
 I = any type of shoulder arthroplasty  
 C = non-surgical treatment  
 O = overall shoulder score, pain, quality of life, mobility, activity of daily life, surgical revision, complications

**PICO 2**

- P = patients with primary shoulder osteoarthritis and intact rotator cuff  
 I = total shoulder arthroplasty (TSA)  
 C = hemiarthroplasty (HA)  
 O = overall shoulder score, pain, quality of life, mobility, activity of daily life, surgical revision, complications

**Summary of the health technology assessment:**Method and patient category:

Glenohumeral osteoarthritis is usually associated with chronic pain of various severities, as well as loss of motion and function. The disorder can be treated non-surgically or surgically. During recent years the design of shoulder implants has improved rapidly. Currently, two major types of shoulder implants are available; those that can replace the whole glenohumeral joint, so called total shoulder arthroplasty (TSA), and those that only replace either the glenoid surface or the humeral head, so called hemiarthroplasty (HA).

Level of evidence:***Any type of shoulder arthroplasty versus nonsurgical treatment***

The systematic literature search did not identify any publication that has reported the effects of prosthetic arthroplasty (of any type) in comparison with sham surgery, non-surgical treatment or placebo in patients with primary glenohumeral osteoarthritis. All the studies that compare TSA and HA with one another report marked improvements with regard to pain, mobility, activity of daily life and mobility for both arthroplasties after surgical intervention in comparison to the preoperative status.

***Total shoulder arthroplasty versus hemiarthroplasty***

There were no differences in outcome between the two types of shoulder implants with regard to overall shoulder score (low quality of evidence, GRADE ⊕⊕○○), pain (GRADE ⊕⊕○○), quality of life (GRADE ⊕⊕○○), mobility (GRADE ⊕⊕○○), activity of daily life (very low quality of evidence, GRADE ⊕○○○), and need for surgical revision (GRADE ⊕○○○).

Side effects and complications:

Early complications within three weeks after arthroplasty, TSA or HA, have been reported to occur with an incidence rate of 3 - 12 %, whereas late complications occur with an annual rate of about 1-3 % per year.

Ethical aspects:

It may not be ethically acceptable to introduce shoulder arthroplasty in the clinical routine on a large scale before there is convincing documentation that it is more effective compared to other non-surgical interventions in reducing symptoms. On the other hand, based on the observed effects of shoulder replacement on pain, mobility and activity of daily life, after surgery in comparison to the preoperative status in all the studies a major ethical question is whether it is acceptable to refrain from implantation of prosthesis in patients with severe symptoms?

Economical aspects

An increased use of shoulder arthroplasty will lead to an increased cost that is estimated to be about 1 000 000 SEK per year for Region Västragötaland.

**Concluding remarks**

The reported beneficial effects of shoulder replacement in patients with primary osteoarthritis in comparison to their preoperative status with regard to pain, mobility and activity of daily life are large. However, this has only been analysed in uncontrolled patient series, and there is no study that has compared prosthetic arthroplasty with a parallel control group receiving non-surgical intervention. There are no documented differences in the effects between the two different types of shoulder arthroplasty TSA and HA (low or very low levels of evidence GRADE ⊕⊕○○ or ⊕○○○).

The Regional Health Technology Assessment Centre (HTA-centrum) of Region Västra Götaland, Sweden (VGR) has the task to make statements on HTA reports carried out in VGR. The statement should summarise the question at issue, level of evidence, efficacy, risks, and economical and ethical aspects of the particular health technology that has been assessed in the report.

HTA was accomplished during the period of  
2011-01-19 – 2012-09-26. Last search updated in October 2011

On behalf of the HTA quality assurance group, in Region Västra Götaland, Sweden  
Göteborg, Sweden, 2012-09-26

Christina Bergh, Professor, MD  
Head of HTA-centrum of Region Västra Götaland, Sweden

HTA quality assurance group, Region Västra Götaland, Sweden

Christina Bergh  
MD, Professor  
Thomas Franzén  
Head of hospital library  
Magnus Hakeberg  
OD, Professor  
Lennart Jivegård  
MD, Senior university lecturer  
Peter Johansson  
MD, PhD

Anders Larsson  
MD, PhD  
Christian Rylander  
MD, PhD  
Ola Samuelsson  
MD, Associate professor  
Henrik Sjövall  
MD, Professor  
Petteri Sjögren  
DDS, PhD

Maria Skogby  
RN, PhD  
Annika Strandell  
MD, Associate professor  
Therese Svanberg  
HTA-librarian  
Margareta Warrén Stomberg  
Senior university lecturer  
Kjell-Arne Ung  
MD, Associate professor

## Utlåtande och sammanfattande bedömning från Kvalitetssäkringsgruppen

### Skulderledsprotos vid artros

#### Frågeställning:

1. Förbättras funktionen och livskvaliteten hos patienter med skulderledsartros av efter operation med insättning av en skulderledsprotos jämfört med icke-kirurgiska behandlingsåtgärder?
2. Förbättras funktionen och livskvaliteten hos patienter med skulderledsartros om de opereras med en total skulderledsprotos jämfört med om de erhåller en halvprotos?

#### PICO

##### PICO 1

P = patienter med primär artros i skulderleden och med intakt rotator cuff  
 I = någon typ av skulderledsprotos  
 C = icke-kirurgisk behandling  
 O = totalt skulder-score, smärta, livskvalitet, mobilitet, ADL, kirurgisk revision, komplikationer

#### PICO 2

P = patienter med primär artros i skulderleden och med intakt rotator cuff  
 I = total skulderledsprotos (TSA)  
 C = halvprotos (HA)  
 O = totalt skulder-score, smärta, livskvalitet, mobilitet, ADL, kirurgisk revision, komplikationer

### Resultat av HTA-processen:

#### Metod och målgrupp:

Artros i skulderleden är ofta förenat med såväl kronisk smärta av varierande svårighetsgrad som med inskränkning i rörlighet och funktion. Det kan behandlas med icke-kirurgiska eller ortopedkirurgiska åtgärder. Under de senaste åren har designen av olika skulderledsprotoser snabbt förbättrats. Idag finns två huvudtyper av protoser. Antingen kan hela leden ersättas med en total skulderledsprotos då såväl humerusdelen som glenoiddelen av leden ersätts med en protos (TSA). Den andra typen av protos är en så kallad halvprotos (HA) då antingen den humerala delen eller den glenoidala delen av leden byts ut med en protos.

#### Evidensläge:

#### *Skulderledsprotos jämfört med icke-kirurgiska åtgärder*

Den systematiska litteratursökningen fann ingen publicerad studie som har rapporterat effekterna av operativ ersättning av leden med en skulderledsprotos jämfört med sham-kirurgi, icke-kirurgisk åtgärd eller placebo hos patienter med primär artros i skulderleden. Alla studier som jämfört effekterna av TSA med de av HA har emellertid rapporterat uttalade förbättringar avseende smärta, rörlighet, ADL och funktion för båda huvudtyperna av protoser efter patienterna fått sin protos vid jämförelser med situationen före protosoperationen.

#### *Total skulderledsprotos jämfört med halvprotos*

Inga skillnader kunde observeras mellan de två huvudtyperna av protoser avseende effekter på totalt skulder-score (begränsad evidens, GRADE ⊕⊕○○), smärta (GRADE ⊕⊕○○), livskvalitet (GRADE ⊕⊕○○), mobilitet (GRADE ⊕⊕○○), ADL (otillräcklig evidens, GRADE ⊕○○○), och behov av kirurgisk revision (GRADE ⊕○○○).

### Komplikationer och biverkningar:

Tidiga komplikationer inom tre veckor efter proteskirurgi rapporteras uppkomma med en incidens av 3 - 12 %. Sena komplikationer har rapporteras med en årlig incidens på 1-3 % per år.

### Etiska aspekter och frågeställningar:

Det är tveksamt att införa skulderproteskirurgi i klinisk rutin innan det finns övertygande vetenskaplig dokumentation att det leder till bättre resultat än andra icke-kirurgiska åtgärder. Å andra sidan är det acceptabelt att avstå från att utföra protesoperationer hos patienter med uttalade besvär då erfarenheterna av okontrollerade studier ändå visar så påtagligt stora positiva effekter avseende smärta, rörlighet och ADL hos dessa patienter?

### Ekonomiska aspekter

Ett ökat användande av skulderledsproteser uppskattas leda till en årligen ökande kostnad på cirka 1 miljon kronor för Region Västragötaland.

### Sammanfattning och slutsats

De positiva effekterna avseende smärta, rörlighet och ADL som rapporterats efter proteskirurgi hos patienter med primär artros i skulderleden är stora. Dessa resultat har emellertid inte konfirmerats i kontrollerade studier där opererade patienter jämförts med icke-kirurgiska behandlingsåtgärder. I studier som jämfört effekterna av totalprotes och halvprotes har inga skillnader observerats (begränsad eller otillräcklig evidens GRADE ⊕⊕○○ eller ⊕○○○).

HTA-kvalitetssäkringsgruppen har ett uppdrag att yttra sig över genomförda HTA i Västra Götalandsregionen. Ytrandet skall innefatta sammanfattning av frågeställning, samlat evidensläge, patientnytta, risker samt ekonomiska och etiska aspekter för den studerande teknologin.

Projektet har pågått under perioden 2011-01-19 – 2012-09-26  
Sista uppdatering av artikelsökning oktober 2011

För HTA-kvalitetssäkringsgruppen 2012-09-26

Christina Bergh, professor  
Ordförande

HTA-kvalitetssäkringsgruppen:

Christina Bergh  
Professor, överläkare  
Thomas Franzén  
Bibliotekschef  
Magnus Hakeberg  
Professor, övertandläkare  
Lennart Jivegård  
Universitetslektor, överläkare  
Peter Johansson  
Med dr, överläkare

Anders Larsson  
Med dr, överläkare  
Christian Rylander  
Med dr, överläkare  
Ola Samuelson  
Docent, överläkare  
Petteri Sjögren  
Med dr, tandläkare  
Henrik Sjövall  
Professor, överläkare

Maria Skogby  
Med dr, vårdenhetschef  
Annika Strandell  
Docent, överläkare  
Therese Svanberg  
HTA-bibliotekarie  
Kjell-Arne Ung  
Docent, överläkare  
Margareta Warrén Stomberg  
Universitetslektor

## Comparison between total shoulder arthroplasty and hemiarthroplasty in patients with primary osteoarthritis with regard to the outcome variable Shoulder score -total

Author, year	Country	Study design	Number of patients (n)	With drawsals - dropouts	Result		Comments	Quality (may vary according to outcome)
					Total shoulder arthroplasty	Hemiarthroplasty		
Gartsman, 2000	USA	Randomised, controlled trial	TSA: 27 HA: 24	4	<u>ASES score - total<sup>ii</sup></u> 22.7 ( sd 14.4 ) ↓ 77.3 / sd 18.2 )  No statistical difference between groups  <u>UCLAS score - total<sup>iii</sup></u> 8.1 ( sd 2.8 ) ↓ 27.4 ( sd 4.9 )  No statistical difference between groups	<u>ASES score - total:</u> 22.6 ( sd 15.1 ) ↓ 65.2 ( sd 24.9 )  <u>UCLAS score - total:</u> 8.2 ( sd 3.5 ) ↓ 23.2 ( sd 5.9 )	<u>Follow up:</u> mean 34 months  Only patients with intact rotator cuff were included  For both TSA and HA the differences in ASES score and in UCLAS score between preoperative and follow-up status were statistically significant (p < 0.001)	Moderate
Lo, 2005	United Kingdom /Canada	Randomised, controlled trial	TSA: 21 HA: 21	1	<u>Constant score - total:</u> 28.7 ( sd 16.4 ) ↓ 70.8 ( sd 17.2 )  No statistical difference between groups	<u>Constant score - total:</u> 30.7 ( sd 14.2 ) ↓ 67.1 ( sd 19.6 )	<u>Follow up:</u> 2 years  Only patients with intact rotator cuff included  For both TSA and HA the difference in Constant score between preoperative and follow-up status was statistically significant (p < 0.001)	Moderate
Buchner, 2008	Germany	Retrospective observational study. Matched controls	TSA: 22 HA: 22	0	<u>Constant score - total<sup>i</sup></u> 25.9 ( sd 11.7 ) ↓ 67.2 ( sd 11.7 )  No statistical difference between groups in absolute values (p = 0.056) Δ baseline – end: TSA significantly better (p < 0.05)	<u>Constant score - total:</u> 33.1 ( sd 5.7 ) ↓ 59.3 ( sd 14.5 )	<u>Follow-up:</u> 12 months  The HA-group had a significantly better total Constant score preoperatively compared to the TSA-group ( p<0.05)  Patients with glenoid type A1, A2 and B1 included ( according to Walch et al. 1999)	Low

## Comparison between total shoulder arthroplasty and hemiarthroplasty in patients with primary osteoarthritis with regard to the outcome variable Shoulder score -total

Author, year	Country	Study design	Number of patients (n)	With drawsals - dropouts	Result		Comments	Quality (may vary according to outcome)
					Total shoulder arthroplasty	Hemiarthroplasty		
Edwards, 2003	France	Retrospective observational study	TSA: 601 HA: 89	0	<u>Constant score - total:</u> 31.1 ↓ 70.3  p < 0.001 between groups *	<u>Constant score - total:</u> 33.5 ↓ 64.1	<u>Follow up:</u> mean 43.3 months (24-110 months)  * comparison made of 80 age-, gender- and follow-up matched HA and TSA patients  For both TSA and HA the difference in Constant score between preoperative and follow-up status was statistically significant (p < 0.001)	Moderate
Iannotti, 2003 Norris 2002	USA	Prospective observational study	TSA: 95 HA: 33	36	<u>ASES score - total:</u> 33 (sd 18) ↓ 86 (sd 17)  No statistical difference between groups	<u>ASES score - total:</u> 35 (sd 15) ↓ 79 (sd 21)	<u>Follow-up:</u> mean 46 months (24-87 months)  For both TSA and HA the difference in ASES score between preoperative and follow-up status was statistically significant (p < 0.001)	Low
Levy, 2004	United Kingdom	Retrospective observational study	TSA: 42 HA: 37	5	<u>Constant score - total:</u> 20.0 ↓ 61.9  No statistical difference between groups	<u>Constant score - total:</u> 25.3 ↓ 58.1	<u>Follow up:</u> TSA mean 7.6 years HA mean 4.4 years  For both TSA and HA the difference in Constant score between preoperative and follow-up status was statistically significant (p < 0.05)	Low

Comparison between total shoulder arthroplasty and hemiarthroplasty in patients with primary osteoarthritis with regard to the outcome variable Shoulder score -total

Author, year	Country	Study design	Number of patients (n)	With drawals - dropouts	Result		Comments	Quality (may vary according to outcome)
					Total shoulder arthroplasty	Hemiarthroplasty		
Orfaly, 2003	USA	Prospective observational study	TSA: 37 HA: 28	19	<u>ASES score - total:</u> 37 ↓ 91  p < 0.05 between groups	<u>ASES score - total:</u> 42 ↓ 84	<u>Follow up:</u> mean 4.3 years (2-8 years)  For both TSA and HA the difference in ASES score between preoperative and follow-up status was statistically significant (p < 0.001)	Low

Footnotes:

- i. Constant score total: 0-100, the higher score the better result
- ii. ASES American Shoulder and Elbow Surgeons Shoulder Index - total: 0-100, the higher score the better result
- iii. UCLAS University of California and Los Angeles Shoulder – total: 0-35, the higher score the better result

## Comparison between total shoulder arthroplasty and hemiarthroplasty in patients with primary osteoarthritis with regard to the outcome variable Pain

Author, year	Country	Study design	Number of patients/shoulders (n)	With drawsals - dropouts	Result		Comments	Quality (may vary according to outcome)
					Total shoulder arthroplasty (TSA)	Hemiarthroplasty ( HA)		
Gartsman, 2000	USA	Randomised controlled trial	TSA: 27 HA: 24	4	<u>ASES score-pain<sup>ii</sup></u> 9.6 ↓ 41.1 p < 0.01 between groups  <u>UCLAS score-pain<sup>iii</sup></u> 1.5 ↓ 8.2 p < 0.01 between groups	<u>ASES score-pain</u> 9.4 ↓ 30.2  <u>UCLAS score-pain</u> 1.5 ↓ 6.0	<u>Follow up:</u> mean 34 months  Only patients with intact rotator cuff were included  For both TSA and HA the differences in ASES score and in UCLAS score between preoperative and follow-up status were statistically significant (p < 0.001 or p < 0.01)	Moderate
Lo, 2005	United Kingdom/ Canada	Randomised controlled trial	TSA: 20 HA: 21	1	<u>Mc Gill pain questionnaire<sup>iv</sup>:</u> 12.5 (sd 9.4) ↓ 0.9 (sd 1.4)  No statistical difference between groups  <u>Mc Gill pain visual analogue scale<sup>v</sup>:</u> 65(sd 20.9) ↓ 6.1 (sd 13.5)  No statistical difference between groups	<u>Mc Gill pain questionnaire:</u> 16 (sd 10.6) ↓ 2.7 (sd 6.8)  <u>Mc Gill pain visual analogue scale:</u> 65.2 (sd 20.9) ↓ 13.9 (sd 27.4)	<u>Follow up:</u> 2 years Only patients with intact rotator cuff included  For both TSA and HA the differences in Mc Gill pain questionnaire and visual analogue scale between preoperative and follow-up status were statistically significant (p < 0.001)	Moderate

Comparison between total shoulder arthroplasty and hemiarthroplasty in patients with primary osteoarthritis with regard to the outcome variable Pain

Author, year	Country	Study design	Number of patients/shoulders (n)	With drawals - dropouts	Result		Comments	Quality (may vary according to outcome)
					Total shoulder arthroplasty (TSA)	Hemiarthroplasty ( HA)		
Buchner, 2008	Germany	Retrospective observational study. Matched controls	TSA: 22 HA: 22	0	<u>Constant score-pain</u> <sup>i</sup> 4.1 (sd 2.2) ↓ 12.6 (sd 2.9)  No statistical difference between groups	<u>Constant score-pain</u> 3.9 (sd 2.5) ↓ 12.0 (sd 3.1)	<u>Follow-up:</u> 12 months  Patients with glenoid type A1, A2 and B1 included (according to Walch et al. 1999)	Low
Edwards, 2003	France	Retrospective observational study	TSA: 601 HA: 89	0	<u>Constant score-pain</u> 4.2 ↓ 12.9  No statistical difference between groups	<u>Constant score-pain</u> 4.4 ↓ 12.5	<u>Follow up:</u> mean 43.3 months (24-110 months)  For both TSA and HA the difference in Constant score between preoperative and follow-up status was statistically significant (p < 0.05)	Moderate
Iannotti, 2003 Norris, 2002	USA	Prospective observational study	TSA: 95 HA: 33	36	<u>ASES score-pain</u> n=95  74 (sd 23) ↓ 14 (sd 20)  No statistical difference between groups	<u>ASES score-pain</u> n=33  73 (sd 20) ↓ 20 (sd 24)	<u>Follow-up:</u> mean 46 months (24-87 months)  For both TSA and HA the difference in ASES score between preoperative and follow-up status was statistically significant (p < 0.001)	Low

Comparison between total shoulder arthroplasty and hemiarthroplasty in patients with primary osteoarthritis with regard to the outcome variable Pain

Author, year	Country	Study design	Number of patients/shoulders (n)	With drawals - dropouts	Result		Comments	Quality (may vary according to outcome)
					Total shoulder arthroplasty (TSA)	Hemiarthroplasty ( HA)		
Levy, 2004	United Kingdom	Retrospective observational study	TSA: 42 HA: 37	5	<u>Constant score-pain</u> 2.1 ↓ 14  No statistical difference between groups	<u>Constant score-pain</u> 3.9 ↓ 12	<u>Follow up:</u> TSA mean 7.6 years HA mean 4.4 years  For both TSA and HA the difference in Constant score between preoperative and follow-up status was statistically significant (p < 0.05)	Low
Orfaly, 2003	USA	Prospective observational study	TSA: 37 HA: 28	19	<u>ASES score-pain</u> 69 ↓ 9  No statistical difference between groups	<u>ASES score-pain:</u> 56 ↓ 17	<u>Follow up:</u> mean 4.3 years (2-8 years)  For both TSA and HA the difference in ASES score between preoperative and follow-up status was statistically significant (p < 0.001)	Low

Footnotes i. Constant score-subcategory pain: 15=no pain, 0=worst pain ii. ASES: American Shoulder and Elbow Surgeons Shoulder Index-subcategory pain: 0-100, the higher score the more pain.  
 iii. UCLAS: University of California and Los Angeles Shoulder-subcategory pain: 0-10 the higher score the less pain iv. Mc Gill pain questionnaire, 0-45!!!! the higher score the more pain  
 v. Mc Gill pain visual analogue scale, 0-78 the higher score the more pain

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result		Comments	Quality (may vary according to outcome)
					Total shoulder arthroplasty	Hemiarthroplasty		
Lo, 2005	United Kingdom Canada	Randomised, controlled trial	TSA: 20 HA: 21	1	<u>WOOS</u> <sup>ii</sup> After two years: 90.6 (sd 13.2)  No statistical difference between groups.	<u>WOOS</u> : After two years 81.5 (sd 24.1)	<u>Follow-up</u> : 2 years  Only patients with intact rotator cuff included. Significant improvement within group.  For both TSA and HA the difference in WOOS between preoperative and follow-up status was statistically significant (p < 0.001)	Moderate
Iannotti, 2003 Norris 2002	USA	Prospective observational study	TSA: 95 HA: 33	36	<u>ASES score-QoL</u> <sup>i</sup> 65(sd 26) ↓ 12 (sd 19)  No statistical difference between groups	<u>ASES score-QoL</u> 61 (sd 28) ↓ 17 (sd 27)	<u>Follow-up</u> : mean 46 months (24-87 months)  For both TSA and HA the difference in ASES score between preoperative and follow-up status was statistically significant (p < 0.05)	Low

## Footnotes:

- i. ASES score-subcategory Quality of Life: 0 = best possible; 100 = worst possible  
 ii. WOOS = Western Ontario Osteoarthritis of the Shoulder Index (Quality of life)

## Comparison between total shoulder arthroplasty and hemiarthroplasty in patients with primary osteoarthritis with regard to the outcome variable Mobility

Author, year	Country	Study design	Number of patients (n)	With drawals - dropouts	Result		Comments	Quality (may vary according to outcome)
					Total shoulder arthroplasty (TSA)	Hemiarthroplasty (HA)		
Gartsman, 2000	USA	Randomised, controlled trial	TSA: 27 HA: 24	4	<u>Active elevation:</u> Baseline: 86° Follow-up: 128°  No statistical difference between groups  <u>Active external rotation:</u> Baseline: 36° Follow-up: 61°  No statistical difference between groups  <u>UCLAS-score <sup>ii</sup>:</u> Baseline: 2.6 Follow-up: 4.2  No statistical difference between groups	<u>Active forward flexion:</u> Baseline: 89° Follow-up: 127°   <u>Active external rotation:</u> Baseline: 34° Follow-up: 61°   <u>UCLAS-score:</u> Baseline: 2.4 Follow-up: 4.1	<u>Follow-up:</u> mean 34 months  Only patients with intact rotator cuff were included   For both TSA and HA the difference in UCLAS-score between preoperative and follow-up status was statistically significant (p < 0.001)	Moderate

## Comparison between total shoulder arthroplasty and hemiarthroplasty in patients with primary osteoarthritis with regard to the outcome variable Mobility

Author, year	Country	Study design	Number of patients (n)	With drawsals - dropouts	Result		Comments	Quality (may vary according to outcome)
					Total shoulder arthroplasty (TSA)	Hemiarthroplasty (HA)		

Lo, 2005	United Kingdom/ Canada	Randomised, controlled trial	TSA: 20 HA: 21	1	<u>Constant score – domain:</u> <u>range of motion:</u> Baseline: 13.4 (sd 9.5) Follow-up: 29.2 (sd 8.3)  No statistical difference between groups	<u>Constant score – domain:</u> <u>range of motion:</u> Baseline: 13.7 (sd 7.2) Follow-up: 26.8 (sd 9.3)	<u>Follow-up:</u> 2 years  Only patients with intact rotator cuff included	Moderate
Buchner, 2008	Germany	Retrospective observational study. Matched controls	TSA: 22 HA: 22	0	<u>Flexion:</u> Baseline: 74.6° (sd 27.2°) Follow-up: 144.1° (sd 31.7°)  No statistical difference between groups  <u>Abduction:</u> Baseline: 62.7° (sd 19.3°) Follow-up: 132.7° (sd 33.0°)  p < 0.001 between groups  <u>External rotation:</u> Baseline: 2.8° (sd 2.9°) Follow-up: 7.2° (sd 2.0°)  No statistical difference between groups  <u>Constant score-mobility</u> Baseline: 11.7 (sd 5.7) Follow-up: 29.8 (sd 6.1)  p < 0.05 between group	<u>Flexion:</u> Baseline: 88.6° (sd 21.7°) Follow-up: 132.5° (sd 36.3°)  <u>Abduction:</u> Baseline: 75.9° (sd 16.5°) Follow-up: 105.0° (sd 36.7°)  <u>External rotation:</u> Baseline: 3.1° (sd 1.8°) Follow-up: 7.1° (sd 2.6°)  <u>Constant score-mobility</u> Baseline: 14.5 (sd 4.1) Follow-up: 24.7 (sd 7.6)	<u>Follow up:</u> 12 months  Patients with glenoid type A1, A2 and B1 included ( according to Walch et al. 1999)  For both TSA and HA the difference in flexion, abduction and Constant score between preoperative and follow-up status was statistically significant (p < 0.05 or p > 0.01 or p < 0.001)	Low

## Comparison between total shoulder arthroplasty and hemiarthroplasty in patients with primary osteoarthritis with regard to the outcome variable Mobility

Author, year	Country	Study design	Number of patients (n)	With drawals - dropouts	Result		Comments	Quality (may vary according to outcome)
					Total shoulder arthroplasty (TSA)	Hemiarthroplasty (HA)		
Edwards, 2003	France	Retrospective observational study	TSA:601 HA: 89	0	<u>Active forward flexion:</u> Baseline: 91.2° Follow-up: 144.5°  No statistical difference between groups  <u>Active external rotation:</u> Baseline: 7.2° Follow-up: 41.5°  Δ (baseline –end): p <0.05 between groups  <u>Constant score-mobility<sup>1</sup>:</u> Baseline: 15.1 Follow-up: 31.3  p <0.05 between groups*	<u>Active forward flexion:</u> Baseline: 95.7° Follow-up: 129.6°  <u>Active external rotation:</u> Baseline: 12.2° Follow-up: 35.5°  <u>Constant score-mobility:</u> Baseline: 15.5 Follow-up: 27.3	<u>Follow up:</u> mean 43.3 months (24-110 months)  For both TSA and HA the difference in flexion, external rotation and Constant score between preoperative and follow-up status was statistically significant (p < 0.001)  * comparison made of 80 age-, gender- and follow-up matched HA and TSA patients	Moderate

Comparison between total shoulder arthroplasty and hemiarthroplasty in patients with primary osteoarthritis with regard to the outcome variable Mobility

Author, year	Country	Study design	Number of patients (n)	With drawals - dropouts	Result		Comments	Quality (may vary according to outcome)
					Total shoulder arthroplasty (TSA)	Hemiarthroplasty (HA)		

Levy, 2004	United Kingdom	Retrospective observational study	TSA: 42 HA: 37	5	<u>Active forward flexion:</u> Baseline: 62° Follow-up: 128°  <u>Active abduction:</u> Baseline: 49° Follow-up: 107°  <u>External rotation:</u> Baseline: 13° Follow-up: 55°  <u>Internal rotation:</u> Buttock Follow-up: L2	<u>Active forward flexion:</u> Baseline: 72° Follow-up: 124°  <u>Active abduction:</u> Baseline: 52° Follow-up: 111°  <u>External rotation:</u> Baseline: 12° Follow-up: 54°  <u>Internal rotation:</u> Buttock Follow-up: L2	<u>Follow-up:</u> TSA mean 7.6 years HA mean 4.4 years  No statistical analyses are presented in the publication.	Low
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Footnotes

- i. Constant score-subcategory mobility: 30=good mobility, 0=no mobility
- ii. UCLAS: University of California and Los Angeles Shoulder-subcategory motion: 0-5 the higher score the better mobility
- iii. Constant score internal rotation 0:dorsum of hand to lateral of thigh. 2:dorsum of hand to buttock. 4:dorum of hand to lumbosacral junction. 6:dorsum of hand to waist (L3). 8:dorsum of hand to Th12. 10:dorsum of hand to interscapular region.

Comparison between total shoulder arthroplasty and hemiarthroplasty in patients with primary osteoarthritis with regard to the outcome variable Activity of Daily Living

Author, year	Country	Study design	Number of patients (n)	With drawsals - dropouts	Result		Comments	Quality (may vary according to outcome)
					Total shoulder arthroplasty	Hemiarthroplasty		
Gartsman, 2000	USA	Randomised, controlled trial	TSA: 27 HA: 24	4	<u>ASES-score</u> <sup>ii</sup> Baseline: 13.1 Follow-up: 36.1  No statistical difference between groups	<u>ASES-score:</u> Baseline: 13.2 Follow-up: 34.9	<u>Follow up:</u> mean 34 months  Only patients with intact rotator cuff were included  For both TSA and HA the difference in score between preoperative and follow-up status was statistically significant (p < 0.001)	Moderate
Buchner, 2008	Germany	Retrospective observational study. Matched controls	TSA: 22 HA: 22	0	<u>Constant score-activity</u> <sup>i</sup> Baseline: 7.5 (sd 3.3) Follow-up: 17.5 (sd 2.9)  No statistical difference between groups	<u>Constant score-activity:</u> Baseline: 9.5 (sd 2.1) Follow-up: 15.8 (sd 3.7)	<u>Follow-up:</u> 12 months  Patients with glenoid type A1, A2 and B1 included ( according to Walch et al. 1999)  For both TSA and HA the difference in score between preoperative and follow-up status was statistically significant (p < 0.05)	Low
Edwards, 2003	France	Retrospective observational study	TSA:601 HA: 89	0	<u>Constant score-activity</u> <sup>i</sup> Baseline: 7.7 17.3  $\Delta$ (baseline –end): p<0.01 between groups	<u>Constant score-activity:</u> Baseline: 8.2 Follow-up: 15.3	<u>Follow-up:</u> mean 43.3 months (24-110 months)  For both TSA and HA the difference in score between preoperative and follow-up status was statistically significant (p < 0.001)	Moderate

Comparison between total shoulder arthroplasty and hemiarthroplasty in patients with primary osteoarthritis with regard to the outcome variable Activity of Daily Living

Author, year	Country	Study design	Number of patients (n)	With drawsals - dropouts	Result		Comments	Quality (may vary according to outcome)
					Total shoulder arthroplasty	Hemiarthroplasty		

Iannotti, 2003 Norris 2002	USA	Prospective observational study	TSA: 95 HA: 33	36	<u>Ability to use arm</u> <sup>iii</sup> Baseline: 77.4 (sd 2.1) Follow-up: 15.9 (sd 2.5)  No statistical difference between groups	<u>Ability to use arm:</u> Baseline: 69.7 (sd 5.1) Follow-up: 19.0 (sd 4.6)	<u>Follow-up:</u> mean 46 months (24-87 months)  For both TSA and HA the difference in score between preoperative and follow-up status was statistically significant (p < 0.001)	Low
Mansat, 2002	France	Retrospective observational study	TSA: 43 HA: 8	0	Entire patient series  <u>Activity</u> <sup>iv</sup> Baseline: 7 Follow-up: 16.5		<u>Follow-up:</u> mean 60 months (24-124 months)	Low
Orfaly, 2003	USA	Prospective observational study	TSA: 37 HA: 28	19	<u>Function-score</u> <sup>v</sup> Baseline: 69 Follow-up: 6	<u>Function-score:</u> Baseline: 59 Follow-up: 13	<u>Follow-up:</u> mean 4.3 years (2-8 years)  Data extracted from Figure 5.	Low

## Footnotes:

- i. Constant score-subcategory: activity ADL: 0-20, the higher score the better function in ADL
- ii. ASES-score- subcategory ADL: 0-50, the higher score the better function in ADL
- iii. VAS -score: 0 = best possible; 100 = worst possible
- iv. 0-20; the higher score the better function
- v. VAS -score: 0 = all activities; 100 = unable to perform any normal tasks

between total shoulder arthroplasty and hemiarthroplasty in patients with primary osteoarthritis with regard to the outcome variable Surgical revision

Author, year	Country	Study design	Number of patients (n)	With drawals - dropouts	Result		Comments	Quality (may vary according to outcome)
					Total shoulder arthroplasty	Hemiarthroplasty		
Gartsman, 2000	USA	Randomised, controlled trial	TSA: 27 HA: 24			3 HA (resurfacing of the glenoid - 19, 39 and 48 months postoperatively)	<u>Follow up:</u> mean 34 months  Only patients with intact rotator cuff were included.  The indication for revision was increasing pain and decreasing space between the humeral head and the glenoid.	Moderate
Lo, 2005	United Kingdom /Canada	Randomised, controlled trial	TSA: 20 HA: 21	1	1 (due to infection)	2 (due to progressive glenoid arthrosis and pain -16 and 19 months postoperatively) ↓ TSA	<u>Follow up:</u> 2 years  Only patients with intact rotator cuff included	Moderate
Buchner, 2008	Germany	Retrospective observational study Matched controls	TSA: 22 HA: 22	0	0	2 HA (7 and 9 months postoperatively) ↓ TSA	<u>Follow-up:</u> 12 months  The two HA who needed revision surgery had preoperatively been classified as type B1  Patients with glenoid type A1, A2 and B1 included ( according to Walch et al. 1999)	Low

between total shoulder arthroplasty and hemiarthroplasty in patients with primary osteoarthritis with regard to the outcome variable Surgical revision

Author, year	Country	Study design	Number of patients (n)	With drawals - dropouts	Result		Comments	Quality (may vary according to outcome)
					Total shoulder arthroplasty	Hemiarthroplasty		
Edwards, 2003	France	Retrospective observational study	TSA: 601 HA: 89	0	Entire patient series 96		Only shoulders with the original prosthesis in place were included for follow-up, other prosthetic revisions were excluded. Shoulders converted from HA to TSA were not excluded, provided the original humeral stem was in place.  <u>Follow up:</u> mean 43.3 months (24-110 months)	Moderate
Iannotti, 2003 Norris 2002	USA	Prospective observational study	TSA: 95 HA: 33	36	Entire patient series 6		<u>Follow-up:</u> mean 46 months (24-87 months)	Low
Levy, 2004	United Kingdom	Retrospective observational study	TSA: 42 HA: 37	5	4	0	<u>Follow up:</u> TSA mean 7.6 years HA mean 4.4 years	Low
Lo, 2005	United Kingdom /Canada	Randomised, controlled trial	TSA: 20 HA: 21	1	1 (due to infection)	2 (due to progressive glenoid arthrosis and pain -16 and 19 months postoperatively) ↓ TSA	<u>Follow up:</u> 2 years  Only patients with intact rotator cuff included	Moderate

between total shoulder arthroplasty and hemiarthroplasty in patients with primary osteoarthritis with regard to the outcome variable Surgical revision

Author, year	Country	Study design	Number of patients (n)	With drawals - dropouts	Result		Comments	Quality (may vary according to outcome)
					Total shoulder arthroplasty	Hemiarthroplasty		

Orfaly, 2003	USA	Prospective observational study	TSA: 37 HA: 28	19	Entire patient series 3  (due to hematoma; due to trauma 1 yr postop.; due to glenoid loosening 7 yr postop.)		<u>Follow up:</u> mean 4.3 years (2-8 years)  One patient developed a hematoma and a detachment of the suscapularis tendon in the early postoperative period. One patient developed a separation of the anterior deltoid origin due to trauma 1 year after surgery. One patient developed symptomatic glenoid loosening 7 years after surgery.	Low
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## Mortality, early and late complications after shoulder arthroplasty in studies comparing total shoulder arthroplasty (TSA) and hemiarthroplasty (HA)

Author, year	Country	Study design	Number of shoulders /patients n=  Age (years)	Follow-up	Total mortality during follow-up	Complications directly related to surgery	Early complications (within 3 weeks after surgery)	Late complications	Any complication
Buchner, 2008	Germany	Retrospective observational study. Matched controls.	TSA: 22 HA: 22  Age (years)	1 year	No Data	TSA: 0 % HA: 9 % (n=2)	No Data	No Data	TSA: 0 % HA: 9 % (n=2)
Edwards, 2003	France	Retrospective observational study	TSA: 601 HA: 89  67.2	Mean 3.7 yrs (24-110 months)	No Data	19 % (n=132)  "No difference between TSA and HA groups"	6 % (n=41)	13 % (n=91)	19 % (n=132)
Gartsman, 2000	USA	Randomised controlled trial	TSA: 27 HA: 24  65.0	Mean 2.8 yrs (24-72 months)	No Data	12 % (n=6)	No Data	No Data	12 % (n=6)
Levy, 2004	United Kingdom	Retrospective observational study	TSA: 39 HA: 30  72.3	TSA Mean 7.6 yrs HA Mean 4.4 yrs	6 % (n=4)  Time and cause of death not reported	18 % (n=12)	No Data	No Data	18 % (n=12)
Lo, 2005	United Kingdom/ Canada	Randomised controlled trial	TSA: 20 HA: 21  70.3	2 years	2 % (n=1)  2 days postoperatively Cause of death thromboembolism	22 % (n=9)	12 % (n=5)	10 % (n=4)	22 % (n=9)

Mortality, early and late complications after shoulder arthroplasty in studies comparing total shoulder arthroplasty (TSA) and hemiarthroplasty (HA)

Author, year	Country	Study design	Number of shoulders /patients n=  Age (years)	Follow-up	Total mortality during follow-up	Complications directly related to surgery	Early complications (within 3 weeks after surgery)	Late complications	Any complication
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Orfaly, 2003	USA	Prospective observational study	TSA: 37 HA: 28  63.0	Mean 4.3 yrs (2-8 years)	6 % (n=4)  Death "within two years of surgery". Causes of death "unrelated to surgery"	5 % (n=3)	2 % (n=1)	3 % (n=2)	5 % (n=3)
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## Mortality, early and late complications after shoulder arthroplasty in case series of total shoulder arthroplasty (TSA) and hemiarthroplasty (HA)

Author, year	Country	Study design	Number of shoulders /patients n=  Age (years)	Follow-up	Total mortality during follow-up	Complications directly related to surgery	Early complications (within 3 weeks after surgery)	Late complications	Any complication
Aldinger, 2010	Germany	Case series	485 (6 different implants)  67	Mean 3.5 years (1-10 years)	2 % (n=11)  Time of death not reported. Cause of death "unrelated to surgery"	10 % (n=50)	No data	No data	12 % (n=56)
Chin, 2006	USA	Case series	TSA: 431  65	Mean 4.2 years	No data	12 % (n=53)	7 % (n=32)	5 % (n=21)	12 % (n=53)
Churchill, 2005	USA	Case series	TSA: 128  64	2.5 – 5 yrs	No Data	5 % (n= 6)	No Data	No Data	5 % (n= 6)
Edwards, 2002	France	Case series	TSA: 478 HA: 77  67.6	Mean 3.6 yrs	2 % (n=12)  Time of death not reported. Cause of death "unrelated to surgery"	16 % (n=87)	4 % (n=24)	12 % (n=66)	16 % (n=90)
Farmer, 2007	USA	Case series	TSA: 625 HA: 369  67.7	0-6 years	0	No Data	No Data	No Data	8 % (n=75) Only in-hospital complications reported.

## Mortality, early and late complications after shoulder arthroplasty in case series of total shoulder arthroplasty (TSA) and hemiarthroplasty (HA)

Author, year	Country	Study design	Number of shoulders /patients n=  Age (years)	Follow-up	Total mortality during follow-up	Complications directly related to surgery	Early complications (within 3 weeks after surgery)	Late complications	Any complication
Godenèche, 2002	France	Case series	TSA: 251 HA: 17	Mean 2.5 yrs	0.4% (n=1)  Only patients who survived 12 months after surgery included. Cause of death "unrelated to surgery"	9 % (n=23)	No Data	No Data	9 % (n=23)
Litchfield, 2011	Canada	Case series	TSA: 154  68.9	2 yrs	2 % (n=3)  2 days postoperatively Cause of death pulmonary embolism (n=1)  At 3 and 12 months. Causes of death "unrelated to surgery" (n=2)	9 % (n=14)	3 % (n=5)	6 % (n=9)	11 % (n=17) Including pulmonary embolism (n=1), stroke (n=1) and brain tumour (n=1)
Lynch, 1996	USA	Case series	TSA: 368  62	2 years	0.3 % (n=1)  Time of death not reported. Cause of death "unrelated to surgery"	5 % (n=17)  Only neurological deficits/lesions reported.	4 % (n=15)  Only neurological deficits/lesions reported	0.5 % (n=2)  Only neurological deficits/lesions reported	

## Mortality, early and late complications after shoulder arthroplasty in case series of total shoulder arthroplasty (TSA) and hemiarthroplasty (HA)

Author, year	Country	Study design	Number of shoulders /patients n=  Age (years)	Follow-up	Total mortality during follow-up	Complications directly related to surgery	Early complications (within 3 weeks after surgery)	Late complications	Any complication
Lädemann, 2011	France	Case series (TSA reverse primary arthroplasty vs anatomic primary arthroplasty)	TSA: 41 72.9	Mean 1yr	No Data	5 % (n=2) Only neurological deficits/lesions.	5 % (n=2) Only neurological deficits/lesions.	No Data	
Middernacht, 2008	Belgium, France	Case series	Reverse TSA: 419  Age not reported	Mean 2.1 yrs (1-6 yrs)	0.5 % (n=2)  Causer of death were cancer	No Data	No Data	No Data	3 % (n=16)
Rosenberg, 2007	United Kingdom	Case series	TSA: 227 60.0	1-11 yrs	No Data	1 % (n=2)	No Data	No Data	19 % (n=43)
Schmidt-Wiethoff, 2002	Germany	Case series	TSA: 63 HA: 118 56.5	Mean 2 yrs	No Data	No Data	No Data	No Data	9 % (n=16)
Singh, 2011	USA	Case series	TSA: 2588 65.0	20 yrs	No Data	No Data	No Data	No Data	8 % (n=212)

## Mortality, early and late complications after shoulder arthroplasty in case series of total shoulder arthroplasty (TSA) and hemiarthroplasty (HA)

Author, year	Country	Study design	Number of shoulders /patients n= Age (years)	Follow-up	Total mortality during follow-up	Complications directly related to surgery	Early complications (within 3 weeks after surgery)	Late complications	Any complication
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Trockmorton, 2010	USA	Case series	TSA: 100 68.6	Mean 4 yrs (1-8.2 yrs)	No Data	No Data	No Data	No Data	6 % (n=6)
Walch, 2011	France	Case series	TSA: 333 69.3	Mean 7.5 yrs	No Data	No Data	No Data	No Data	8 % (n=27)
Walch, 2002	France	Case series	TSA: 319 66.4	Mean 4.5 yrs (2-9.2 yrs)	No Data	No Data	No Data	No Data	3 % (n=11)
Young, 2011	France	Case series	TSA: 226 66.9	Mean: 10 yrs (5-18.2 yrs)	No Data	No Data	No Data	No Data	27 % (n=62)

Study (author, publication year)	Reason for exclusion
Bartelt, 2011	Does not fulfil PICO criteria.
Bryant, 2005	Three of four included RCTs were only presented as abstracts and not full publication.
Clinton, 2007	Does not fulfil PICO criteria.
Fama, 2004	Data presented in the included article by Edwards et al. 2003.
Fevang, 2009	Does not fulfil PICO criteria.
Kasten, 2009	Does not fulfil PICO criteria.
Lazarus, 2002	Does not fulfil PICO criteria.
Mather, 2010	Does not fulfil PICO criteria. The results will be commented on in the health economy part of the report.
Nho, 2010	Does not fulfil PICO criteria.
Pape, 2010	Does not fulfil PICO criteria.
Radnay, 2007	A systematic review with inclusion of studies published before the decided cut-off limit for the literature search in the present HTA report.
Sperling, 2005	Does not fulfil PICO criteria.
Laderman 2011	Does not fulfil PICO criteria
Singh, 2011	Does not fulfil PICO criteria

## Appendix 3, Search strategy, study selection and references

### Question(s) at issue:

1. Does surgical implantation with a shoulder prosthesis improve the function and quality of life in patients with severe primary glenohumeral osteoarthritis in comparison with non-surgical interventions?
2. Does total shoulder arthroplasty improve the function and quality of life in patients with severe primary glenohumeral osteoarthritis in comparison with hemiarthroplasty?

### PICO:

#### PICO 1

- P = patients with primary shoulder osteoarthritis and intact rotator cuff  
I = any type of shoulder arthroplasty  
C = non-surgical treatment  
O = overall shoulder score\*, pain, quality of life, mobility, activity of daily life, surgical revision, complications

#### PICO 2

- P = patients with primary shoulder osteoarthritis and intact rotator cuff  
I = total shoulder arthroplasty (TSA)  
C = hemiarthroplasty  
O = overall shoulder score\*, pain, quality of life, mobility, activity of daily life, surgical revision, complications

### Eligibility criteria

#### Study design:

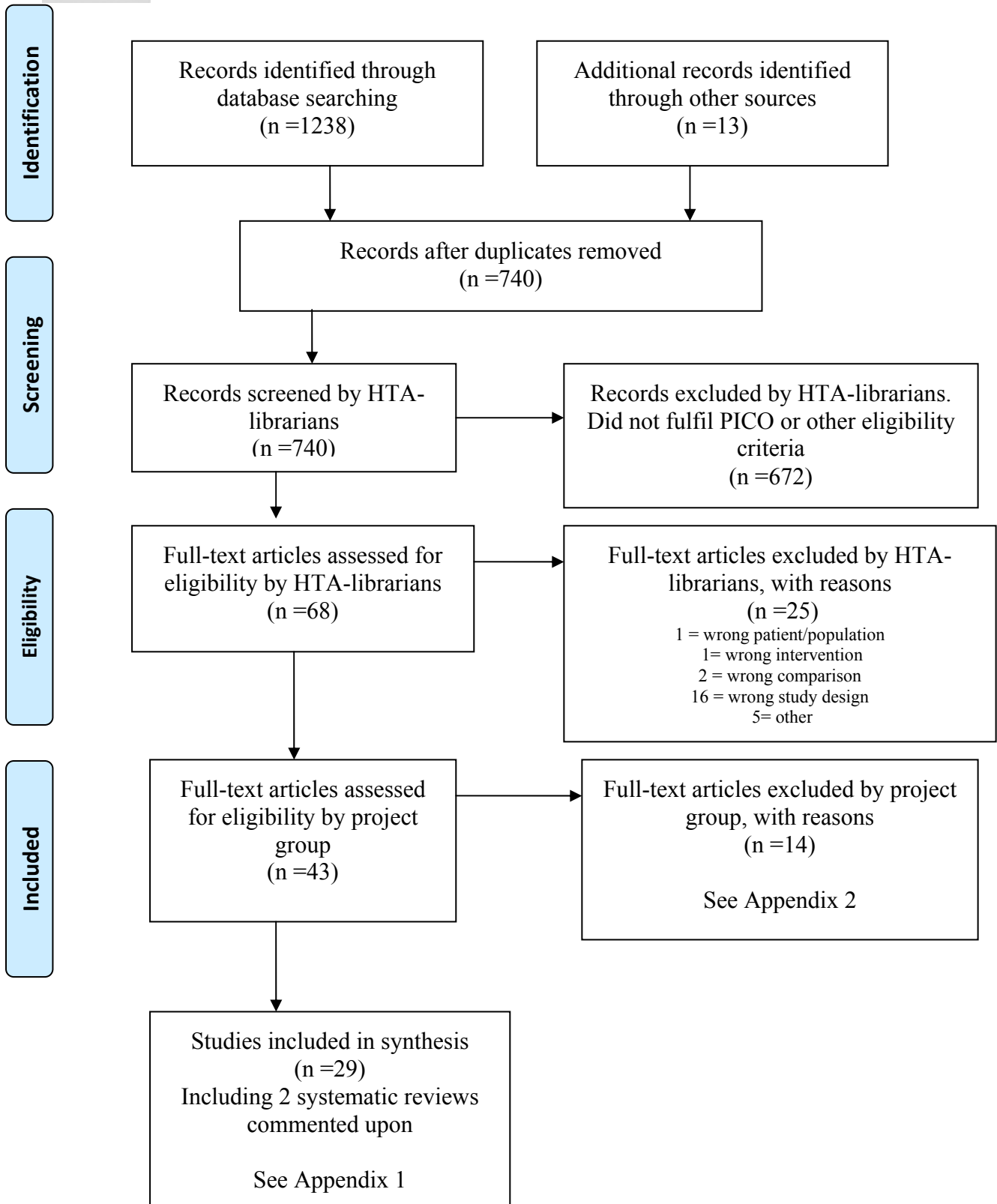
- Studies with some kind of control group
- Case series etc. if  $\geq 100$  patients
- No case reports or review articles

#### Language:

English, German, French, Swedish, Norwegian, Danish

**Publication date:** 1995-

## Selection process – flow diagram



## Search strategies

**Database:** PubMed

**Date:** 2011-01-24

**No of results:** 411

**Search updated:** 2011-12-20, 62 results

Search	Most Recent Queries	Result
#28	Search #10 AND #20 AND #26 Limits: Publication Date from 1995/01/01	411
#27	Search #10 AND #20 AND #26	489
#26	Search osteo-arthrosis[tw] OR osteoarthrosis[tw] OR osteoarthritis OR arthrosis[tw]	46368
#20	Search arthroplasty OR replacement[tw] OR hemiarthroplasty OR joint prosthesis	196264
#10	Search shoulder	42112

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**Database:** EMBASE (OVID SP)

**Date:** 2011-01-24

**No of results:** 491

**Search updated:** 2011-12-20, 53 results

#	Searches	Results
1	exp OSTEOARTHRITIS/	56507
2	(osteo-arthrosis or osteoarthrosis or osteoarthritis or arthrosis).ti,ab.	38635
3	(arthroplasty or replacement or hemiarthroplasty or joint prosthesis).ti,ab.	187286
4	exp SHOULDER ARTHROPLASTY/ or exp ARTHROPLASTY/ or exp REVERSE SHOULDER ARTHROPLASTY/	55278
5	exp REVERSE SHOULDER PROSTHESIS/ or exp SHOULDER PROSTHESIS/ or exp JOINT PROSTHESIS/	35612
6	exp SHOULDER/	16207
7	shoulder.ti,ab.	36978
8	1 or 2	65563
9	3 or 4 or 5	209093
10	6 or 7	42007
11	8 and 9 and 10	562
12	limit 11 to yr="1995 -Current"	491

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**Database:** CINAHL (EBSCO)

**Date:** 2011-01-24

**No of results:** 101

**Search updated:** 2011-12-20, 11 results

#	Searches	Results
<b>S12</b>	<b>S8 and S9 and S10</b> <b>Limiters - Published Date from: 19950101-20101231</b>	<b>101</b>
S11	S8 and S9 and S10	101
S10	S6 or S7	9198
S9	S3 or S4 or S5	22737
S8	S1 or S2	8460
S7	shoulder	9120
S6	(MH "Shoulder") OR (MH "Shoulder Joint+")	3818
S5	arthroplasty OR replacement OR hemiarthroplasty OR joint prosthesis	22737
S4	(MH "Joint Prosthesis")	1816
S3	(MH "Arthroplasty+") OR (MH "Arthroplasty, Replacement+")	8339
S2	osteo-arthritis OR osteoarthritis OR osteoarthritis OR arthrosis	8349
S1	(MH "Osteoarthritis+")	6962

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**Database:** AMED (EBSCO)

**Date:** 2011-01-24

**No of results:** 17

**Search updated:** 2011-12-20, no results

#	Searches	Results
S11	S8 and S9 and S10	17
S10	S6 or S7	3453
S9	S3 or S4 or S5	3386
S8	S1 or S2	2074
S7	shoulder	3453
S6	(DE "SHOULDER") OR (DE "SHOULDER JOINT")	1628
S5	arthroplasty OR replacement OR hemiarthroplasty OR joint prosthesis	2646
S4	(DE "JOINT PROSTHESIS") OR (DE "PROSTHESIS")	1129
S3	(DE "ARTHROPLASTY")	697
S2	osteo-arthritis OR osteoarthritis OR osteoarthritis OR arthrosis	2074
S1	(DE "OSTEOARTHRITIS")	1085

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**Database:** The Cochrane Library

**Date:** 2011-01-24

**No of results:** 72

*Cochrane reviews* 6

*Other reviews* 3

*Clinical trials* 56

*Technology assessments* 2

*Economic evaluations* 5

**Search updated:** 2011-12-20, 3 results in Clinical trials

#	Searches	Results
#1	(arthroplasty OR replacement OR hemiarthroplasty OR joint prosthesis):ti,ab,kw	12883
#2	(shoulder):ti,ab,kw	2543
#3	<b>(#1 AND #2), from 1995 to 2011</b>	<b>72</b>

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**Database:** CRD

**Date:** 2011-01-24

**No of results:** 17

*DARE* 9

*NHS EED* 6

*HTA* 2

#	Searches	Results
#1	arthroplasty OR replacement OR hemiarthroplasty OR joint prosthesis	
#2	shoulder	
#3	#1 AND #2	17

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The web-sites of **SBU, Kunnskapssenteret** and **Sundhedsstyrelsen** were visited  
2011-01-24

Nothing relevant to the question at issue was found

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**Reference lists**

13 results

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Appendix 4 SoF table. Total shoulder arthroplasty versus hemiarthroplasty

Number of studies	Design	Limitations	Consistency	Directness	Precision	Publication bias	Magnitude of effect	No. of pts with TSA	No. of pts with HA	Relative effect (95% CI)	Quality
<b>Shoulder score - total</b>											
7	2 RCT 5 Non-randomised studies	Some limitations (?)	No inconsistency	No indirectness	Serious imprecision (-1)	Unlikely	Not relevant	48 775	45 209	No difference between study groups	⊕⊕OO
<b>Pain</b>											
7	2 RCT 5 Non-randomised studies	Some limitations (?)	No inconsistency	No indirectness	Serious imprecision (-1)	Unlikely	Not relevant	48 775	45 209	No difference between study groups	⊕⊕OO
<b>Quality of life</b>											
2	1 RCT 1 Non-randomised study	No limitations	No inconsistency	No indirectness	Very serious imprecision (-2)	Unlikely	Not relevant	20 95	21 33	No difference between study groups	⊕⊕OO
<b>Mobility</b>											
5	2 RCT 3 Non-randomised studies	Some limitations (?)	No inconsistency	No indirectness	Serious imprecision (-1)	Unlikely	Not relevant	48 665	45 148	No difference between study groups	⊕⊕OO

Appendix 4 SoF table. Total shoulder arthroplasty versus hemiarthroplasty

Number of studies	Design	Limitations	Consistency	Directness	Precision	Publication bias	Magnitude of effect	No. of pts with TSA	No. of pts with HA	Relative effect (95% CI)	Quality
<b>Activity of daily living</b>											
6	1 RCT 5 Non-randomised studies	Some limitations (?)	No inconsistency	No indirectness	Very serious imprecision (-2)	Unlikely	Not relevant	20	21	No difference between study groups	⊕○○○
<b>Surgical revision</b>											
4	2 RCT 2 Non-randomised studies	Some limitations (?)	No inconsistency	o indirectness	Very serious imprecision (-2)	Unlikely	Not relevant	8 64	5 59	No difference between study groups	⊕○○○

## Appendix 5.

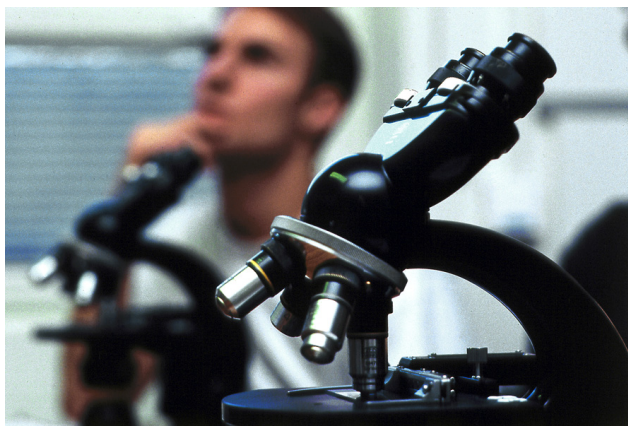
**ETHICAL ANALYSIS OF IMPLEMENTATION OF PROSTHETIC ATHROPLASTY IN PATIENTS  
WITH PRIMARY GLENOHUMERAL OSTEOARTHRITIS**

<b>Question</b>	<b>Answer/ comment</b>
1. From the patient's perspective, how does prosthetic arthroplasty affect the patient's quality of life and life expectancy?	Uncontrolled studies report marked reductions in pain, improved mobility and increased quality of life with rather few complications following prosthetic arthroplasty. However, also other, less costly and less invasive interventions, has also reported beneficial effects in uncontrolled studies. Based on the marked beneficial effects in uncontrolled studies an important question is whether it is ethically acceptable to refrain from implantation of prosthesis in patients with severe symptoms? On the other hand, it may not be acceptable to introduce shoulder arthroplasty in the clinical routine on a large scale without convincing documentation of its effects in comparison to other interventions.
2. How severe is the patient's need that the prosthetic arthroplasty must meet?	In individual patients the need of alleviating the shoulder symptoms of glenohumeral osteoarthritis is substantial.
3. Does prosthetic arthroplasty have any influence on how others view the patient (concerning humanity and human dignity), or on how the patient views himself or herself (concerning humanity and human dignity)?	No.
4. Can prosthetic arthroplasty affect the patient's ability and possibility to be independent?	No, most probably a patient's autonomy will not be negatively affected by prosthetic arthroplasty.
5. If implemented, does prosthetic arthroplasty require any special steps to not compromise the patient's autonomy?	No. All patients in need of any intervention for glenohumeral osteoarthritis must be fully informed of the procedures and be able to give their informed consent prior to any kind of treatment.
6. How does prosthetic arthroplasty affect the patient's physical, moral and personal integrity?	Since there are alternative interventions that are less invasive than the implantation of a prosthesis there is definitely some concern that prosthetic arthroplasty may affect the physical integrity of the patient to an unnecessary large extent. Most probably the moral and personal integrity of the patient will not be negatively affected by the surgical intervention.
7. Is prosthetic arthroplasty cost-effective?	It is presently unknown whether prosthetic arthroplasty is cost-effective or not.

8. How prosthetic arthroplasty affect resources?	An increase of shoulder arthroplasty will require more resources in terms of personnel, education, and accessibility to operating rooms, equipment and implants. Therefore, there will be an increasing need of economic resources.
9. Is prosthetic arthroplasty in conflict with professional values?	No.
10. Does prosthetic arthroplasty change the role of the professional in relation to the patient?	No.
11. Does prosthetic arthroplasty affect, or does it put any new demands on, a third party?	No.
12. Is there any legislation of relevance with regard to prosthetic arthroplasty?	No.
13. Is there any risk of conflict between the procedure of prosthetic arthroplasty and values of the society, or values of different groups?	No.
14. Is there a risk that an introduction of prosthetic arthroplasty will cause a conflict with particular interests?	Yes. The use of shoulder arthroplasty has not been convincingly documented to be superior to alternative interventions. The latter may be preferred by other care givers (both non-profit and profit organisations) within the health care sector.
15. Can an introduction prosthetic arthroplasty influence the trust of the health care system?	Most probably not.
<b>CONCLUSIONS</b>	Shoulder arthroplasty need to be compared with other interventions in well-designed controlled studies before it is introduced in the clinical routine on a large scale. However, in individual patients with severe pain or disability it may well be ethically acceptable to offer such surgical intervention.

# Region Västra Götaland, HTA-centrum

Health Technology Assessment  
Regional activity-based HTA



## HTA

Health technology assessment (HTA) is the systematic evaluation of properties, effects, and/or impacts of health care technologies, i.e. interventions that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policymaking in health care.

To evaluate the quality of evidence the Centre of Health Technology Assessment in Region Västra Götaland is currently using the GRADE system, which has been developed by a widely representative group of international guideline developers. According to GRADE the level of evidence is graded in four categories:

High quality of evidence	= (GRADE ⊕⊕⊕⊕ )
Moderate quality of evidence	= (GRADE ⊕⊕⊕○)
Low quality of evidence	= (GRADE ⊕⊕○○)
Very low quality of evidence	= (GRADE ⊕○○○)

In GRADE there is also a system to rate the strength of recommendation of a technology as either “strong” or “weak”. This is presently not used by the Centre of Health Technology Assessment in Region Västra Götaland. However, the assessments still offer some guidance to decision makers in the health care system. If the level of evidence of a positive effect of a technology is of high or moderate quality it most probably qualifies to be used in routine medical care. If the level of evidence is of low quality the use of the technology may be motivated provided there is an acceptable balance between benefits and risks, cost-effectiveness and ethical considerations. Promising technologies, but a very low quality of evidence, motivate further research but should not be used in everyday routine clinical work.

Christina Bergh, Professor, MD.  
Head of HTA-centrum

