Region Västra Götaland, HTA-centrum
Health Technology Assessment
Regional activity-based HTA
2013:63

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Nilsson A, Bergh C, Hjalmarsson Y, Ibsen-Sörensen A, Sollerman C, Wikberg U, Samuelsson O

VÄSTRA GÖTALANDSREGIONEN
SAHLGRENSKA UNIVERSITETSSJUKHUSET

HTA-centrum
Sahlgrenska Universitetssjukhuset

Metacarpophalangeal and proximal interphalangeal joint arthroplasty in patients with severe arthritis or osteoarthritis [Fingerledproteser hos patienter med svår artrit eller artros]

Nilsson A*[1], Bergh C[2], Hjalmarsson Y[3], Ibsen-Sörensen A[1], Sollerman C[1], Wikberg U[3], Samuelsson O[2],

[1]Department of Hand Surgery and Plastic Surgery, Sahlgrenska University Hospital, University of Göteborg, Sweden
[2]HTA-centrum of Region Västra Götaland, Sweden.
[3]Medical Library, Sahlgrenska University Hospital, Göteborg, Sweden

*Corresponding author

Published July 2013
2013:63

Suggested citation: Nilsson A, Bergh C,Hjalmarsson Y, Ibsen-Sörensen A, Sollerman C, Wikberg U, Samuelsson O. HTA- analysis of hand MCP and PIP-joint treatment in arthritis and osteoarthritis patients [[Fingerledproteser hos patienter med artrit och artros] Göteborg: Västra Götalandsregionen, Sahlgrenska Universitetssjukhuset, HTA-centrum; 2013. Regional activity-based HTA 2013:63

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Summary of the Health Technology Assessment

Method and patient group:
Patients with arthritis (rheumatoid arthritis; RA) or osteoarthritis (OA) with joint disabilities of the metacarpophalangeal (MCP) or proximal interphalangel (PIP) joints of the hand may be treated with anti-inflammatory drugs or surgery with prosthesis or joint fusion. Prostheses can be either silicone prostheses or prostheses made of other material. The silicone prostheses can be either the Swanson silicone prosthesis or other types of silicone prostheses. The main indication for prosthetic surgery is pain.

Questions at issue:

1: Are drugs or any other prosthesis more effective than the Swanson silicone prosthesis to reduce pain and to improve grip strength, range of motion (ROM), patient satisfaction, activities of daily living (ADL), and function (Disabilities of the Arm, Shoulder and Hand (DASH) score or Quick DASH score) in adults with arthritis or osteoarthritis involving the MCP joints?
What is the rate of complications?

2: Is any other prosthesis more effective than the Swanson silicone prosthesis to reduce pain and to improve grip strength, range of motion, satisfaction, activities of daily living, and function (DASH score or Quick DASH score) in adults with arthritis or osteoarthritis involving the PIP joints?
What is the rate of complications?

Studied risks and benefits for patients of the new health technologies

Arthritis in the metacarpophalangeal joint (PICO 1, PICO 3 and PICO 4)
Range of motion improved significantly within each study group (see below) when pre- and postoperative measurements were compared. Also pain was significantly reduced within each group when pre- and postoperative pain scores were evaluated.

Prosthesis of any material except silicone compared to a silicone prosthesis in patients with arthritis and deformities of the MCP joints
Two randomised, controlled trials (RCTs) were identified in the systematic literature search. There were no observed statistical differences in the effects on ROM, pain, strength or patient satisfaction (low quality of evidence, GRADE ⊕⊕OO).

Any type of silicone prosthesis except the Swanson silicone prosthesis compared to the Swanson prosthesis in patients with arthritis and deformities of the MCP joints
Five RCTs were identified in the systematic literature search. There were no observed statistical differences in the effects on ROM, pain, strength, patient satisfaction or function (low quality of evidence, GRADE ⊕⊕OO).

Pharmacological intervention compared to the Swanson silicone prosthesis in patients with arthritis and deformities of the MCP joints

One non-randomised, controlled study was identified in the systematic literature search. In comparison to the effects of pharmacological intervention ROM, function and patient satisfaction were significantly better in patients who received joint prostheses. The quality of evidence is very low (GRADE ⊕OOO). There were no observed statistical differences in the effects on pain or on strength (very low quality of evidence, GRADE ⊕OOO).

Osteoarthritis in the metacarpophalangeal joint (PICO 2)

No study was identified that compared different kinds of prostheses in patients with osteoarthritis in the MCP joint (PICO 2).

Osteoarthritis in the proximal interphalangeal joint (PICO 5 and PICO 6)

Prosthesis of any material except silicone compared to a silicone prosthesis in patients with osteoarthritis of the PIP joints

One RCT and one non-randomised, controlled study were identified in the systematic literature search. There were no observed statistical differences in the effects on ROM or on pain (very low quality of evidence, GRADE ⊕OOO). Hand grip strength and function improved in patients who received the Swanson silicone prosthesis. The quality of evidence is very low (GRADE ⊕OOO).

No study was identified that specifically compared the Swanson silicone prosthesis with another kind of prosthesis.

Complications

The most frequent complication was fracture of a prosthesis, which has been reported to occur between 0 - 20%. Two other important complications were sclerosis followed by bone resorption. The reported rate of surgical revision varied between 0 and 42% with the highest rates observed for non-silicone prosthesis in the PIP joints. The infection rate in relation to surgery varied between 0 and 5%.

Ethical aspects

Prosthetic arthroplasty of finger joints have positive effects on the patient's activities of daily living and most probably on his/her physical and personal integrity, as well as on the perception of himself/herself.

Economical aspects.

The reimbursement per patient for MCP or PIP joint replacement at the Sahlgrenska University Hospital was 41 000 SEK (4 600 €) during 2012. The reimbursement is presently the same regardless of the type of prosthesis that is used.

Thus, the annual cost for 30 patients will add up to 1.25 million SEK (142 000 €).

Concluding remarks

The main indication for prosthetic surgery of the MCP and PIP joints in patients with inflammatory arthritis or osteoarthritis is pain. The implantation of any one of all the available joint prostheses results in a substantial pain reduction after surgery. However, there is no documentation that suggests that any particular prosthesis is superior to another.

The working group

1a **Who lead the project?**
Anders Nilsson, MD, PhD, Department of Hand Surgery and Plastic Surgery, Sahlgrenska University Hospital, University of Göteborg, Sweden

1b **Who posed the question?**
Anna Elander MD, PhD. Head of Department of Hand Surgery and Plastic Surgery, Sahlgrenska University Hospital, University of Göteborg, Sweden.

Additional parties who posed the question?
Anders Nilsson MD, PhD, Department of Hand Surgery and Plastic Surgery, Sahlgrenska University Hospital, University of Göteborg, Sweden.

1c **Co-workers:**
Allan Ibsen-Sörensen, MD, and Christer Sollerman professor, MD, PhD. Both at the Department of Hand Surgery and Plastic Surgery, Sahlgrenska University Hospital, University of Göteborg, Sweden.

1d **Other participants, from the HTA centrum and external reviewers**
Ola Samuelsson MD, PhD and Christina Bergh, professor, MD, PhD. Both at HTA-centrum of Region Västra Götaland, Sweden.

Yommine Hjalmarsson, librarian, Medical Library, Sahlgrenska University Hospital, Göteborg, Sweden.
Ulla Wikberg Adania, librarian, Medical Library, Sahlgrenska University Hospital, Göteborg, Sweden.

External reviewers:
Juri Kartus, MD, PhD, Professor of Orthopedics, NU Hospital Group, Sweden
Susanne Bernhardsson, MSc, physiotherapist, Närhälsan, Region Västra Göteland, Sweden.

1e **Are there any conflicts of interest for the proposer or any of the participants in the work group?**
Christer Sollerman is one of the principal investigators and authors of one randomised, controlled trial included in the assessment of PICO 3 (see below 3d).
No other conflicts of interest were reported.

Disease of Interest and Present Treatment

2a Arthritis and osteoarthritis in the MCP and PIP joints

The metacarpophalangeal (MCP) and proximal interphalangeal (PIP) joints in the hand can be affected by inflammatory diseases as well as by degenerative disorders.

Inflammatory arthritis of the MCP and PIP joints is most commonly caused by rheumatoid arthritis (RA). It is considered to be an autoimmune disease. Usually it makes its debut around the age of 50 years with symmetric swollenness, pain and joint stiffness in finger-, toe- and/or wrist joints. The triggering cause is still unknown. It is shown that T-lymphocytes are activated and penetrate the joint capsule, and subsequently release cytokines. This results in a destruction of the joints and tendons.

In the early stage of the disease the main problem is pain. Later the grip functions are severely affected, and the joints become deformed. This negatively influences the activity of daily living (ADL), as well as the patient's social abilities.

Figure. Subluxation and ulnar deviation of the MCP-joints in a RA hand. Courtesy of A. Nilsson and C. Sollerman.

Osteoarthritis (OA) is the result of a partial or total reduction of joint cartilage. This results in pain, and subsequently, also in reduced strength and range of motion (ROM) of the affected joint and impaired ADL functions.

Arthritis and osteoarthritis in the finger joints can lead to:

☑ Risk of disability and reduced health-related quality of life

2b Prevalence and incidence of arthritis and osteoarthritis in the MCP and PIP joints

The prevalence of RA is about one percent in the adult Swedish population (Statens beredning för medicinsk utvärdering, HTA-report nr 136; 1997), and it increases with age (about 5% in patients over 75 years of age). It is three to four times more common in females. According to the HTA-report from The Swedish Council on Health

Technology Assessment the annual incidence of RA in Sweden is 2 000 – 4 000. This corresponds to 25 -50 new cases per 100 000 adult individuals per year. It is estimated that there are 16 000 patients with RA, of which 4 000 – 5 000 are males, in the Region Västra Götaland.

Osteoarthritis in any joint is a common disorder. This is exemplified by an annual incidence of 13.5 per 100 000 females in the age group 65 – 74 years, and an annual incidence of nine per 100 000 in males over 75 years of age. The exact prevalence of incidence of OA in a finger joint is unknown.

2c **Present treatment of inflammatory arthritis and osteoarthritis in the MCP and PIP joints in the outpatient and in-patient setting.**

Early stages of RA and OA are treated pharmacologically. In RA the initial treatment is normally a disease modifying anti-rheumatic drug, such as metotrexat or sulfasalazin, often combined with low dose steroid therapy. If the disease activity is not reduced adequately after a few months of treatment a biologically active drug, such as a TNF-alfa inhibitor is frequently added. At later stages when joint destruction with joint deformation and disability have developed, surgery may be indicated.

The main indication for surgery is severe pain. Surgery is also performed due to ulnar drift, subluxation, decreased ROM, reduced grip strength and impaired ADL functions. It may occasionally also be performed for cosmetic reasons. There are two surgical alternatives. A joint fusion (i.e. arthrodesis) may be performed, or a prosthesis can be implanted.

A prosthetic joint replacement allows early joint motion and stability. The Swanson silicone prosthesis was introduced in 1969. Until recently it has been the standard prosthesis used in patients with inflammatory arthritis or osteoarthritis. Today several other prostheses (silicone or of other materials) are available for the use in the MCP and the PIP joints.

2d **Number of patients per year who undergo finger joint arthroplasty**

The average number of patients who were treated with MCP joint surgery at the Department of Hand Surgery at Sahlgrenska University Hospital during the period between 2009 and 2012 was 30 patients per year. Of these patients two thirds had interventions of the first MCP joint and one third, i.e. 10 patients, had MCP-2-5 joint arthroplasties.

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

Hand surgery is predominately available at the university hospitals in Sweden. Patients with RA or OA of the MCP or PIP joints that may be considered for implantation of a joint prosthesis in the Region Västra Götaland are referred to the department of Hand Surgery at the Sahlgrenska University Hospital, Göteborg. Most referrals are from Orthopaedic and Rheumatology departments.

At the first out-patient visit the patient will be examined by a specialist in hand surgery with specific training in prosthesis surgery. After evaluation the physician and the patient will discuss the various alternative treatments, and the possible results that can be expected from different available techniques.

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

The average time between the decisions to perform the implantation of prosthesis to surgery is currently six months. However, this time varies considerably. Many of the patients also have other complications from their underlying disease, and may be on waiting list for other treatments. This is especially common in older patients with arthritis.

Present Health Technology

3a **Description of prosthetic surgery of the MCP and PIP joints**

The Swanson silicone prosthesis is commonly regarded as the gold standard in MCP- and PIP-joint replacement surgery. During the last 15 years new types of both silicone prostheses as well as prostheses of other materials have been developed. The surgical technique of implantation is similar for most types of prostheses.

The techniques for surgery of RA and OA are based on different principles. In OA the soft tissue, i.e. ligaments and capsule, is unaffected by the disease and the prosthesis is inserted in a stable joint, with or without cement (depending of the type of prosthesis). In RA the soft tissue has to be reconstructed to have a stable joint for the inserted prosthesis.

In the replacement of the MCP joint a transverse skin incision is commonly used. The extensor hood is then incised on the ulnar side of the extensor tendon to expose the joint. The metacarpal head is excised with an oscillating saw and the collateral ligaments, the volar plate, and the abductor digiti minimi tendon are transected if needed. The base of the proximal phalanx is penetrated by an awl and the metacarpal proximal phalanx medullar canals are reamed by hand. The prosthesis is fitted and the extensor tendons are balanced and centralized. Finally, the skin is sutured and the hand is rested in a plaster with fluffy dressing with the MCP joints in slight flexion and the PIP joints in extension.

Figure. A Swanson silicone prosthesis with grommets (upper left), a Neuflex prebent silicon prosthesis (upper right), a pyrocarbon prosthesis (lower left) and a SR™MCP prostesis (lower right). Courtesy of A. Nilsson and C. Sollerman.

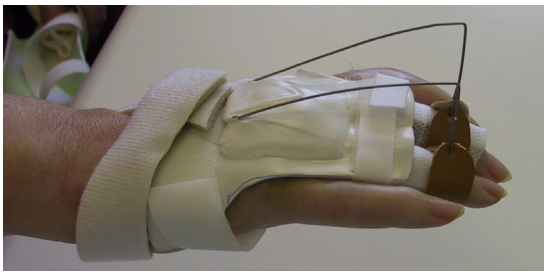
Figure. X-ray of a RA hand after flexible silicone prosthesiss in the MCP joints. The prosthesiss reduce the ulnar deviation of the joints. (left). X-ray of SR^{TM}MCP prosthesis in the long finger (right). Courtesy of A. Nilsson and C. Sollerman.

There are different surgical techniques to implant a prosthesis in the PIP joints. A midlateral, a palmar, or a dorsal approach may be used. The distal proximal and the proximal midphalangeal articular surfaces are removed with a transverse cut, using an oscillating saw, and the intramedullar cavities are prepared with an awl followed by sized broaches. The Swanson silicone prosthesis has been used for many decades, but nowadays there are also other alternative prostheses. Two of them are shown below.

Figure. The SR^{TM} PIP prosthesis (left and middle) and the pyrocarbon PIP prosthesis (right). Courtesy of A. Nilsson and C. Sollerman.

Following prosthetic surgery the hand is mobilized after seven to ten days without loading in a dynamic extension splint, aiming to achieve 45 º flexion. This is done under supervision of an occupational therapist. A static palmar splint is used at night with the MCP joints slightly flexed. At six weeks, slight loading is permitted and the dynamic splint is gradually abandoned. All splints are abandoned after 12 weeks and loading is permitted as allowed by pain.

Figure. Postoperative mobilisation with dynamic extension. Courtesy of A. Nilsson and C. Sollerman.



3b The working group's understanding of the potential value of prosthetic surgery of the MCP and PIP joints

It has been shown that prosthetic joint replacement yields better results than resection arthroplasty or finger fusion (Tupper 1989). However, early attempts to replace finger joints with metal prosthesis resulted in bone absorption and metal corrosion. Currently, the flexible silicone prosthesis are the most widely used prosthesis for MCP and PIP joints of the hand. They have been associated with less long-term complications, but there are still problems with sclerosis, bone resorption, and fractures in some patients. New prostheses such as the SR and the pyrocarbon prostheses are now available. Whether these different prostheses differ in their short- and long-term beneficial effects and complications needs to be evaluated.

3c The central questions for the current HTA project

1: Are drugs or any other prosthesis more effective than the Swanson silicone prosthesis to reduce pain and to improve grip strength, range of motion (ROM), patient satisfaction, activities of daily living (ADL), and function (Disabilities of the Arm, Shoulder and Hand (DASH) score or Quick DASH score) in adults with arthritis or osteoarthritis involving the MCP joints?
What is the rate of complications?

2: Is any other prosthesis more effective than the Swanson silicone prosthesis to reduce pain and to improve grip strength, range of motion, satisfaction, activities of daily living, and function (DASH score or Quick DASH score) in adults with arthritis or osteoarthritis involving the PIP joints?
What is the rate of complications?

3d PICO P= Patients, I= Intervention, C= Comparison, O=Outcome

PICO 1
P: patients (> 18 years) with severe arthritis of the MCP joints of the hand (MCP-I excluded)
I: a “non-silicone” prosthesis
C: a silicone prosthesis
O: ROM, pain, strength, satisfaction, ADL, DASH, quick-DASH, complications

PICO 2
P: patients (> 18 years) with severe osteoarthritis of the MCP joints of the hand (MCP-I excluded)
I: a “non-silicone” prosthesis
C: a silicone prosthesis
O: ROM, pain, strength, satisfaction, ADL, DASH, quick-DASH, complications

PICO 3
P: patients (> 18 years) with severe arthritis of the MCP joints of the hand (MCP-I excluded)
I: a silicone prosthesis (except Swanson)
C: a Swanson silicone prosthesis
O: ROM, pain, strength, satisfaction, ADL, DASH, quick-DASH, complications

PICO 4
P: patients (> 18 years) with severe arthritis of the MCP joints of the hand (MCP-I excluded)
I: pharmacological intervention
C: a Swanson silicone prosthesis
O: ROM, pain, strength, satisfaction, ADL, DASH, quick-DASH, complications

PICO 5
P: patients (> 18 years) with severe osteoarthritis or severe arthritis and prosthesis or fusion in the PIP-joints
I: a “non-silicone” prosthesis
C: a silicone prosthesis or joint fusion
O: ROM, pain, strength, satisfaction, ADL, DASH, quick-DASH, complications

PICO 6
P: patients (> 18 years) with sever osteoarthritis or severe arthritis and prosthesis or fusion in the PIP-joints
I: a “non-silicone” prosthesis
C: a Swanson silicone prosthesis
O: ROM, pain, strength, satisfaction, ADL, DASH, quick-DASH, complications

4 Search strategy, study selection and references – appendix 3

During September 2012 two librarians (YH, UWA) performed systematic searches in PubMed, Embase, the Cochrane Library, and a number of HTA-databases. Reference lists of relevant articles were also scrutinised for additional references. Search strategies, eligibility criteria and a graphic presentation of the selection process are accounted for in appendix 3. The librarians conducted the literature searches, selected studies and independently assessed the obtained abstracts, and a first selection of full-text articles for inclusion or exclusion. Any disagreements were resolved in consensus. The remaining articles were sent to the project group, who independently read the articles, and then decided in a consensus meeting which articles should be included in the final assessment.

The literature search identified a total of 602 articles (after removal of duplicates). The librarians then excluded 510 articles after reading abstracts. Another 40 articles were excluded by the librarians after reading the articles in full text. The remaining 52 articles were sent to the work group, and 33 of them were finally included in the report. Ten controlled studies (11 publications) were identified. They have been critically appraised independently by all participants in the work group using modified checklists from SBU (The Swedish Council on Health Technology Assessment).

5a The main findings of the assessment of prosthetic surgery of the MCP and PIP joints

The systematic literature search identified one systematic review from the Ontario Health Technology Assessment Series, Vol.4, No6, 2004.. It was an analysis with focus on pyrocarbon finger joint implants in MCP and PIP joints. Its main conclusion was that pyrocarbon prostheses are primarily indicated in patients with post-traumatic arthritis or osteoarthritis.

Arthritis in the metacarpophalangeal joint

The systematic literature search identified eight controlled studies in patients with severe arthritis in the MCP joint. Two randomised controlled trials (RCTs) compared any kind of silicone prosthesis with prostheses of another material (PICO 1), five RCTs (six publications) compared specifically the Swanson silicone prosthesis with another type of silicone prosthesis (PICO 3), and one non-randomised, controlled study compared the Swanson prosthesis with pharmacological treatment (PICO 4).

No study was identified that compared different kinds of prosthesis in patients with osteoarthritis in the MCP joint (PICO 2).

In nearly all studies regarding PICO 1, PICO 3 and PICO 4 the ROM variables, such as flexion, extension, and ulnar deviation, improved significantly within each study group when pre- and postoperative measurements were compared. Also pain was significantly reduced within each group when pre- and postoperative pain scores were evaluated.

Prosthesis of any material except silicone compared to a silicone prosthesis – PICO 1 (Appendix -1:1, Appendix 4)

In both prosthesis groups the various ROM variables improved after the implantation of prostheses in comparison with the preoperative status. The length of follow-up varied between one and five years. The effect was of the same magnitude in the

patients who received a silicone prosthesis as well as in those who received a prosthesis of another material. There were no statistically significant differences between the prostheses groups. The same was found regarding the other outcome variables pain, strength and patient satisfaction.
Conclusion: It is uncertain whether prostheses of any other material than silicone differ from silicone prostheses with regard to the effects on ROM, pain, strength and patient satisfaction (low quality of evidence, GRADE ⊕⊕OO).

Any type of silicone prosthesis except the Swanson silicone prosthesis compared to the Swanson prosthesis -PICO 3 (Appendix 1:3, Appendix 4)

In both prosthesis groups the various ROM variables improved after the implantation of prostheses in comparison with the preoperative status. The length of follow-up varied between one and five years. The effect was of the same magnitude in the patients who received a Swanson silicone prosthesis as well as in those who received another type of silicone prosthesis. There were no statistical differences between the prosthesis groups. The same was found regarding the other outcome variables pain, strength, patient satisfaction and function.
Conclusion: It is uncertain whether silicone prostheses of any other type than the Swanson silicone prosthesis differ from the Swanson prosthesis with regard to the effects on ROM, pain, strength and patient satisfaction (low quality of evidence, GRADE ⊕⊕OO).

Pharmacological intervention compared to the Swanson silicone prosthesis – PICO 4 (Appendix1: 4, Appendix 4)

One non-randomised, controlled study compared the effect of a Swanson silicone prosthesis of the MCP joints with non-surgical intervention, i.e, with standard pharmacological management. The study groups were not adequately balanced at baseline with more patients having more severe arthritis in the prosthesis group. The length of follow-up was 3 years. The ROM and function variables, and patient satisfaction improved significantly (adjusted for baseline differences) in the group of patients who received a silicone prosthesis in comparison to patients who were treated pharmacologically. No significant differences were observed between the study groups with regard to pain ($p = 0.06$) or strength.
Conclusion: Range of motion and patient satisfaction improved in patients who received Swanson silicone prostheses in comparison to pharmacological intervention. The quality of evidence is very low (GRADE ⊕OOO). It is uncertain whether pharmacological intervention differs in its effects compared to the Swanson silicone prosthesis with regard to pain and on strength (very low quality of evidence, GRADE ⊕OOO).

Osteoarthritis in the proximal interphalangeal joint

The systematic literature search identified two controlled studies in patients with severe arthritis in the PIP joint. One RCT and one non-randomised, controlled study compared any kind of silicone prosthesis with prostheses of another material (PICO 5). Both studies included only patients with osteoarthritis.

No study was identified that compared specifically the Swanson silicone prosthesis with another kind of prosthesis (PICO 6).

Prostheses of any material except silicone compared to a silicone prosthesis - PICO 5 (Appendix 1:5, Appendix 4)

No changes in the various ROM variables were observed in any of the prosthesis groups in the pre- and postoperative comparisons. The length of follow-up was 1.6 – 3 years. Pain was reduced in all prosthesis groups compared with the preoperative status., but there were no differences between the different kinds of prostheses for pain at rest. For pain at exercise, there was a significant difference at follow-up in favour of the Swanson prosthesis compared with the titanium-polyethylene prosthesis. In the RCT the function variable (DASH score) improved in the patients who received the Swanson silicone prosthesis in comparison to two other types of prostheses.

Conclusion: It is uncertain whether prostheses of any material except silicon differ from a silicone prosthesis with regard to the effects on ROM (very low quality of evidence, GRADE ⊕OOO) or pain at rest (GRADE ⊕OOO). Hand grip strength and patient satisfaction improved in patients who received the Swanson silicone prosthesis. The quality of evidence is very low (GRADE ⊕OOO).

Complications

Metacarpophalangeal prostheses *(Appendix 1-6)*

The systematic literature search identified six RCT and eight case series that reported complications after MCP arthroplasty.

The most frequent complication was a fracture of a joint prosthesis, which has been reported to occur between 0 - 20%. Two other important complications were sclerosis followed by bone resorption. The reported rate of surgical revision varied between 0 and 22%.

Infection in relation to surgery occurred in 0 and 4% of the patients.

Proximal interphalangeal prostheses

The systematic literature search identified one RCT and thirteen case series that reported complications after PIP arthroplasty.

The most frequently reported complication was a fracture of a joint prosthesis which occurred at a rate of between 2 -1%. Surgical revision was needed for silicone prostheses in 3 -16%, SR prosthesis in 8 – 42% and for PY prosthesis in 0 -39% of performed surgery.

The infection rate in relation to surgery varied between 0 and 5%.

5b Outcome tables – appendix 1

5c Excluded articles – appendix 2

5d Ongoing research

A search in the ClinicalTrials database (www.clinicaltrials.gov) (2012-12-07) using the search terms (metacarpophalangeal OR MCP) AND (arthritis OR osteoarthritis) identified 15 trials with regard to the MCP joints. Only two studies were relevant for the present questions at issue. One was a completed RCT in which the NeuFlex prosthesis was compared to the Swanson silicone prosthesis. It has not yet been published. The other one was an ongoing non-randomised controlled study that compares the implantation of the Swanson prosthesis with non-surgical pharmacological treatment.

A search in the ClinicalTrials database (www.clinicaltrials.gov) (2012-12-07) using the search terms (PIP OR "proximal interphalangeal") AND (arthritis OR osteoarthritis) identified 3 trials with regard to the PIP joints. None of them were relevant the present questions at issue.

6 **Which medical societies or health authorities recommend prosthetic surgery of the MCP and PIP joints?**

There are no formal recommendations from any official health authority.

The Swedish Society for Surgery of the Hand, Scandinavian Society for Surgery of the Hand, the Swedish Orthopaedic Association and the Swedish Society of Surgery in Rheumatoid Arthritis all favour implantation of prostheses in painful affected joints, although there are no clearly stated recommendations.

Ethical aspects

7 **Ethical aspects**

See Appendix 5.

Organisation

8a **When can prosthetic surgery of the MCP and PIP joints be put into practice?**

Implantations of various MCP- and PIP-prostheses are already performed at the Department of Hand Surgery, Sahlgrenska University Hospital, Göteborg Sweden.

8b **Is prosthetic surgery of the MCP and PIP joints used in other hospitals in Region Västra Götaland of Sweden?**

Yes. Arthroplasty with finger joint prostheses is occasionally performed at the departments of Orthopedic Surgery at all the hospitals in the region.

The great majority of these arthroplasties is performed at the Department of Hand Surgery, Sahlgrenska University Hospital, Göteborg.

8c **According to the work group, will there be any consequences of prosthetic surgery of the MCP and PIP joints for personnel?**

The number of patients that have been subjected to joint arthroplasty surgery have been relatively constant the last years (see above 2d). It is not expected that the number of patients in need of surgery will increase in the near future

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

Not at the present time.

Economy

9a Present costs of prosthetic surgery of the MCP and PIP joints

The cost for the different available prosthesis in Sweden 2013-04-09 were:

Type of prosthesis	Cost for one prosthesis
Swanson silicone MCP or PIP	3 100 SEK (334 €)
Avanta Sutter silicone MCP	3 795 SEK (426 €).
Neuflex prebent silicone MCP	3 795 SEK (426 €).
SR MCP or PIP	8 450 SEK (948 €)
Pyrocarbon	9 800 SEK (1100 €)

The actual costs for each operation performed during 2012 and 2103 have not been calculated. The reimbursement per patient for MCP or PIP joint replacement at the Sahlgrenska University Hospital was 41 000 SEK (4 600 €) during 2012. This reimbursement was the same for every operation regardless of the type of prosthesis that has been used.

This means that the annual cost for 30 patients presently is 1.25 million SEK (142 000 €).

9b Expected costs of prosthetic surgery of the MCP and PIP joints

See above, 9a.

9c Total change of cost

See above, 9a.

9d Can prosthetic surgery of the MCP and PIP joints be adopted and used within the present budget (clinic budget/hospital budget)?

Presently, the costs of MCP- and PIP joint prostheses are not reimbursed per patient by the health care system. All costs must be dealt with within the present clinic budget. Thus, if the number of patients in need of prosthetic surgery of the MCP or PIP joints will increase the demand cannot be handled within the present budget.

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

No health economy assessment that has particularly been focused on MCP- and PIP-joint replacement was identified in the literature search. According to a report published in 1997 by the Swedish Council on Technology Assessment in Health Care (Statens beredning för medicinsk utvärdering Rapport nr 136/1, 1997) the direct costs for RA treatment was 800 million SEK. The indirect costs (sick leave) were 472 million SEK. The loss of production due to early retirement were 1 750 million SEK. However, this analysis was made before new biological active drugs for inflammatory diseases became available. Thus, the costs for, and the cost-effectivenss of, treatments for RA today are not known.

Unanswered Questions

10a **Important gaps in scientific knowledge**

There is still a lack of RCTs in which the Swanson silicone prosthesis has been compared to pharmacological treatment in either patients with arthritis or in patients with osteoarthritis. Also, there is a lack of RCTs in which the Swanson silicone prosthesis have been evaluated in ”head-to-head”- comparisons with prostheses of other types or material. Thus, it is still not clarified whether newly developed prostheses offer any advantages or have important disadvantages over the well established Swanson prosthesis.

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

Yes.

Statement from HTA-centrum of Region Västra Götaland, Sweden

Metacarpophalangeal and proximal interphalangeal joint arthroplasty in patients with severe arthritis or osteoarthritis

Questions at issue

1: Are drugs or any other prosthesis more effective than the Swanson silicone prosthesis to reduce pain and to improve grip strength, range of motion (ROM), patient satisfaction, activities of daily living (ADL), and function (Disabilities of the Arm, Shoulder and Hand (DASH) score or Quick DASH score) in adults with arthritis or osteoarthritis involving the MCP joints?
What is the rate of complications?

2: Is any other prosthesis more effective than the Swanson silicone prosthesis to reduce pain and to improve grip strength, range of motion, satisfaction, activities of daily living, and function (DASH score or Quick DASH score) in adults with arthritis or osteoarthritis involving the PIP joints?
What is the rate of complications?

Method and patient category

The metacarpophalangeal (MCP) and proximal interphalangeal (PIP) joints in the hand can be affected by inflammatory diseases as well as by degenerative disorders. Patients with severe arthritis (rheumatoid arthritis; RA) or osteoarthritis (OA) with joint disabilities of the MCP or PIP joints may be treated with anti-inflammatory drugs and surgery with prosthesis or joint fusion. Prostheses can be either silicone prostheses or prostheses made of other material. The silicone prostheses can be either the Swanson silicone prosthesis or other types of silicone prostheses. The main indication for prosthetic surgery is pain.

Results and quality of evidence

Arthritis in the metacarpophalangeal joint

Range of motion improved significantly within each study group (see below) when pre- and postoperative measurements were compared. Also pain was significantly reduced within each group when pre- and postoperative pain scores were evaluated.

Prosthesis of any material except silicone compared to a silicone prosthesis (PICO 1)
Two randomised, controlled trials (RCTs) were identified in the systematic literature search.
Conclusion: It is uncertain whether prostheses of any other material than silicone differ from silicone prostheses with regard to the effects on ROM, pain, strength and patient satisfaction (low quality of evidence, GRADE ⊕⊕OO).

Any type of silicone prosthesis except the Swanson silicone prosthesis compared to the Swanson prosthesis (PICO 3
Five RCTs were identified in the systematic literature search.
Conclusion: It is uncertain whether silicone prostheses of any other type than the Swanson silicone prosthesis differ from the Swanson prosthesis with regard to the effects on ROM, pain, strength and patient satisfaction (low quality of evidence, GRADE ⊕⊕OO).

Pharmacological intervention compared to he Swanson silicone prosthesis (PICO 4)
One non-randomised, controlled study was were identified in the systematic literature search.
Conclusion: Range of motion and patient satisfaction improved in patients who received Swanson silicone prostheses in comparison to pharmacological intervention. The quality of evidence is very low (GRADE ⊕OOO). It is uncertain whether pharmacological intervention differs in its effects compared to the Swanson silicone prosthesis with regard to pain and on strength (very low quality of evidence, GRADE ⊕OOO).

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Osteoarthritis in the metacarpophalangeal joint

No study was identified that compared different kinds of prosthesis in patients with osteoarthritis in the MCP joint (PICO 2).

Osteoarthritis in the proximal interphalangeal joint

Prosthesis of any material except silicone compared to a silicone prosthesis (PICO 5)
One RCT and one non-randomised, controlled study were identified in the systematic literature search.
Conclusion: It is uncertain whether prostheses of any material except silicon differ from a silicone prosthesis with regard to the effects on ROM (very low quality of evidence, GRADE ⊕OOO) or pain at rest (GRADE ⊕OOO). Hand grip strength and patient satisfaction improved in patients who received the Swanson silicone prosthesis. The quality of evidence is very low (GRADE ⊕OOO).

No study was identified that specifically compared the Swanson silicone prosthesis with another kind of prosthesis (PICO 6).

Complications

The most frequent complication was fracture of an implant, which has been reported to occur between 0 - 20%. Two other important complications were sclerosis followed by bone resorption. The reported rate of surgical revision varied between 0 and 42 % with the highest rates observed for non-silicone prosthesis in the PIP joints. The infection rate in relation to surgery varied between 0 and 5 %.

Ethical aspects

Prosthetic arthroplasty of finger joints have positive effects on the patient's activities of daily living and most probably on his/her physical and personal integrity, as well as on the perception of himself/herself.

Economical aspects.

The reimbursement per patient for MCP or PIP joint replacement at the Sahlgrenska University Hospital was 41 000 SEK (4 600 €) during 2012.
Thus, the annual cost for 30 patients is 1.25 million SEK (142 000).

Concluding remarks

The main indication for prosthetic surgery of the MCP and PIP joints in patients with severe arthritis or osteoarthritis is pain. The implantation of any one of all the available joint prostheses results in a substantial pain reduction. However, there is no documentation that suggests that any particular prosthesis is superior to another.

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, results and quality of evidence regarding efficacy and 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
2012-09-19 – 2013-04-24. Last search updated in November 2012

On behalf of the HTA quality assurance group, in Region Västra Götaland, Sweden
Göteborg, Sweden, 2013-06-07

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
Associate professor
Kjell-Arne Ung
MD, Associate professor

Utlåtande och sammanfattande bedömning från Kvalitetssäkringsgruppen

Fingerproteser hos patienter med svår artrit eller artros

Frågeställning

1: Är läkemedelsbehandling eller någon protestyp som inte är en Swansons silikonprotes effektivare än Swanson-protesen när det gäller att minska smärta och förbättra handgreppsstyrka, rörelseomfång, patienttillfredsställelse, ADL och funktionsförmåga hos vuxna patienter med svår artrit eller artros i metakarpofalangelleder?
Hur vanligt är det med komplikationer?

2: Är någon annan protestyp som inte är en Swansons silikonprotes effektivare än Swanson-protesen när det gäller att minska smärta och förbättra handgreppsstyrka, rörelseomfång, patienttillfredsställelse, ADL och funktionsförmåga hos vuxna patienter med svår artrit eller artros i proximala interfalangealleder?
Hur vanligt är det med komplikationer?

Metod och målgrupp

Inflammatoriska ledsjukdomar och artros kan drabba handens metakarpofalangealleder (MCP) och proximala interfalangealleder (PIP). Patienter med svår artrit eller artros i dessa leder kan behandlas med anti-inflammatoriska läkemedel, insättning av fingerledsprotes eller med steloperation. Fingerproteser kan vara gjorda av silikon eller av andra material. Silikonproteser är antingen en Swansons silikonprotes eller kan vara någon annan typ av silikonprotes.

Kunskapsläge och evidensgradering

Artrit i metakarpofalangealleder

Rörelseomfånget förbättrades och smärta minskade signifikant efter protesoperation i varje studiegrupp (se nedan) då det postoperativa resultatet jämfördes med situationen före operation.

Fingerprotes av någon annan typ än Swansons silikonprotes jämfört med Swanson-protesen (PICO 1)
Den systematiska litteratursökningen identifierade två randomiserade kontrollerade studier.
Slutsats: Det är osäkert om annan typ av fingerprotes än Swansons silikonprotes är mer effektiv än Swanson-protesen att förbättra handgreppsstyrka, rörelseomfång, patienttillfredsställelse, ADL och funktionsförmåga samt minska smärta (Begränsat vetenskapligt underlag GRADE ⊕⊕OO).

Silikonprotes av någon annan typ än Swansons silikonprotes jämfört med Swanson-protesen (PICO 3)
Den systematiska litteratursökningen identifierade fem randomiserade kontrollerade studier.
Slutsats: Det är osäkert om annan typ av silikonprotes än Swansons silikon protes är mer effektiv än Swanson-protesen att förbättra handgreppsstyrka, rörelseomfång, och patienttillfredsställelse samt minska smärta (Begränsat vetenskapligt underlag GRADE ⊕⊕OO).

Läkemedelsbehandling jämfört med Swansons silikonprotes (PICO 4)
Den systematiska litteratursökningen identifierade en icke-randomiserad kontrollerad studie.
Slutsats: Såväl rörelseomfång som patienttillfreställelse var bättre hos patienter som erhållit fingerprotes jämfört med de som endast läkemedelbehandlats (Otillräckligt vetenskapligt underlag GRADE ⊕OOO).
Det är osäkert om läkemedelsbehandling skiljer sig i effekt jämfört med Swanson-protesennär det gäller handgreppsstyrka och smärta (Otillräckligt vetenskapligt underlag GRADE ⊕OOO).

Artos i metakarpofalangealleder

Den systematiska litteratursökningen identifierade ingen studie som jämfört olika proteser hos patienter med svår artros i MCP-leder.

Artros i proximala interfalangealleder

Fingerprotes av annat material än silikon jämfört med en silikonprotes (PICO 5)
Den systematiska litteratursökningen identifierade en randomiserad kontrollerad och en icke-randomiserad kontrollerad studie..
Slutsats: Det är osäkert om en fingerprotes av annat material än silikon är mer effektiv än en silikonprotes att förbättra rörelseomfång eller minska vilosmärtor (Otillräckligt vetenskapligt underlag GRADE ⊕OOO). Handgreppsstyrka och patienttillfredställelse förbättrades hos patienter som erhållit Swanson-protes (Begränsat vetenskapligt underlag GRADE ⊕⊕OO).

Den systematiska litteratursökningen identifierade ingen studie som specifikt jämfört Swansons silikonprotes med någon annan typ av finger proteser hos patienter med svår artros i PIP-leder (PICO 6).

Komplikationer

Fraktur av själva fingerprotesen är en relativt vanlig komplikation och kan förekomma i en frekvens mellan 0 – 20 %. Skleros och benresorption i anslutning till protesen är två andra viktiga komplikationer som kan uppträda på längre sikt. Behovet av kirurgisk revision har rapporterats i varierande frekvens mellan 0 – 42 % i olika patientmaterial, med högst frekvens hos patienter med en ”icke-silikonprotes” i en PIP-led. Infektioner i direkt anslutning till operation förekommer i 0 – 5 %.

Etiska aspekter

Välfungerade fingerledsproteser har en positiv effekt på patientens vardagliga liv och har därmed sannolikt en positiv effekt på hans/hennes personliga integritet och på patientens självuppfattning.

Ekonomiska aspekter

Ersättningen till kliniken 2012 för en fingerledsprotes i en MCP eller en PIP led var 41 000 kronor (oavsett vilken protes som användes).

Avslutande kommentar och slutsats

Den primära indikationen för operation med insättning av fingerledsprotes hos patienter med svår artrit eller artros är smärta. Oavsett vilken typ av protes som användes minskas smärtan markant efter proteskirurgin. Det finns ingen dokumentation som stöder att någon särskild typ av fingerledsprotes är bättre än övriga protestyper.

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

Projektet har pågått under perioden 2012-09-19 – 2013-04-24
Sista uppdatering av artikelsökning november 2012

För HTA-kvalitetssäkringsgruppen 2013-06-07

Christina Bergh
Ordförande

HTA-kvalitetssäkringsgruppen:

Christina Bergh	Anders Larsson	Maria Skogby
Professor, överläkare	Med dr, överläkare	Med dr, vårdenhetschef
Thomas Franzén	Christian Rylander	Annika Strandell
Bibliotekschef	Med dr, överläkare	Docent, överläkare
Magnus Hakeberg	Ola Samuelson	Therese Svanberg
Professor, övertandläkare	Docent, överläkare	HTA-bibliotekarie
Lennart Jivegård	Petteri Sjögren	Kjell-Arne Ung
Universitetslektor, överläkare	Med dr, tandläkare	Docent, överläkare
Peter Johansson	Henrik Sjövall	Margareta Warrén Stomberg
Med dr, överläkare	Professor, överläkare	Docent, Universitetslektor

Appendix 1:1 - PICO 1.
Silicone prosthesis versus other type of prosthesis in patients with arthritis in the MCP-joint.
a) **Outcome variable:** Range of motion (ROM). ROM is the summation of flexion and extension expressed in degrees. (NR = Not reported; NS = non-significant).

Author, year	Country	Study design	Number of patients Follow-up (FU)	With-drawals/ Dropouts	Results		Comments	Study limitations *	Directness *	Precision *
					Swanson sialistic prosthesis	Prosthesis of other material				
Honkanen, 2010	Finland	Randomised controlled trial	n = 80 1 year	28	26 hands, 91 joints <u>ROM</u> Baseline: 51 ° (sd NR) FU: 53 ° (sd NR) *NS between groups* <u>Palmar subluxation/dislocation</u> Baseline: 69/91 joints FU: 10/91 joints *$p < 0.05$ between groups* Ulnar deviation Baseline: 12-34 ° (MCP II-V) FU: 3 – 6 ° (MCP II-V) *NS between groups* <u>Extension lag</u> Baseline: 25-33 ° (MCP II-V) FU: 14-17 ° (MCP II-V) *NS between groups*	27 hands, 84 joints <u>ROM</u> Baseline: 41 ° (sd NR) FU: 51 ° (sd NR) <u>Palmar subluxation/dislocation</u> Baseline: 69/84 joints FU: 44/84 joints <u>Ulnar deviation</u> Baseline: 13-41 ° (MCP II-V) FU: 2 – 10 ° (MCP II-V) <u>Extension lag</u> Baseline: 27-40 ° (MCP II-V) FU: 8-22 ° (MCP II-V)	Material in “other prosthesis was stemless poly-L/D-lactide copolymer (PLDLA) Only patients with rheumatoid arthritis Improved palmar alignment in Swanson Flexion, extension, and ulnar deviation all improved significantly within each group when pre- and postoperative values were compared.	?	?	?
Sollerman, 1996	Sweden	Randomised controlled trial	n = 12 2.8 – 5 years	1	21 joints <u>ROM</u> Baseline: NR FU: 42 ° (range 20-70°) *NS between groups* <u>Ulnar deviation</u> Baseline: NR FU: 10 ° (MCP II-V) *NS between groups* <u>Extension lag</u> Baseline: NR FU: 11 ° (MCP II-V)	23 joints <u>ROM</u> Baseline: NR FU: 41 ° (range 20-70°) <u>Ulnar deviation</u> Baseline: NR FU: 6 ° (MCP II-V) <u>Extension lag</u> Baseline: NR FU: 6 ° (MCP II-V)	Material in “other prosthesis was polyurethane (Pellethane) Only patients with rheumatoid arthritis “Extension lag was more pronounced in the silicone joints” – no p-value was reported	?	-	?

b) **Outcome variable:** Pain. Visual analogue scale , VAS (0 -100). (IQR = InterQuartile Range)

Author, year	Country	Study design	Number of patients Follow-up (FU)	With-drawals/ Dropouts	Results		Comments	Study limitations *	Directness *	Precision *
					Swanson sialistic prosthesis	Prosthesis of other material				
Honkanen, 2010	Finland	Randomised controlled trial	n = 80 1 year	28	26 hands, 91 joints Baseline: 37 (IQR 9 – 53) FU: 5 (IQR 2 – 21) *NS between groups*	27 hands, 84 joints Baseline: 40 (IQR 7 – 58) FU: 6 (IQR 0 – 24)	Material in "other prosthesis was stemless poly-L/D-lactide copolymer (PLDLA) Only patients with rheumatoid arthritis. Pain was significantly reduced within each group when pre- and postoperative VAS scores were compared.	?	?	?

c) **Outcome variable:** Strength (percentage of total number of patients)

Author, year	Country	Study design	Number of patients Follow-up (FU)	With-drawals/ Dropouts	Results		Comments	Study limitations *	Directness *	Precision *
					Swanson sialistic prosthesis	Prosthesis of other material				
Honkanen, 2010	Finland	Randomised controlled trial	n = 80 1 year	28	26 hands, 91 joints <u>Tip pinch-index finger</u> Baseline: 13 % normal FU: 91 % normal *NS between groups* <u>Precision grip</u> Baseline: 8 % normal FU: 29 % normal *NS between groups* <u>Cylinder grip</u> Baseline: 13 % normal FU: 65 % normal *NS between groups* <u>Transverse volar grip</u> Baseline: 8 % normal FU: 42 % normal *NS between groups*	27 hands, 84 joints <u>Tip pinch-index finger</u> Baseline: 33 % normal FU: 57 % normal <u>Precision grip</u> Baseline: 20 % normal FU: 28 % normal <u>Cylinder grip</u> Baseline: 16 % normal FU: 68 % normal <u>Transverse volar grip</u> Baseline: 12 % normal FU: 28 % normal	Material in "other prosthesis was stemless poly-L/D-lactide copolymer (PLDLA). Only patients with rheumatoid arthritis. Strength was significantly increased in all four functional grips within the Swanson prosthesis group when pre- and postoperative strength were compared. In the PLDLA prosthesis group the cylinder grip was significantly increased postoperatively.	?	?	?

d) **Outcome variable:** Patient satisfaction at follow-up (number of patients and percentages in parenthesis)

Author, year	Country	Study design	Number of patients Follow-up (FU)	With-drawals/ Dropouts	Results		Comments	Study limitations *	Directness *	Precision *
					Swanson sialistic prosthesis	Prosthesis of other material				
Honkanen, 2010	Finland	Randomised controlled trial Only patients with rheumatoid arthritis	n = 80 1 year	28	Excellent and good: 17 (71 %) Satisfactory: 6 (25 %) Poor: 1 (4 %) *NS between groups*	Excellent and good: 20 (74 %) Satisfactory: 7 (26 %) Poor: 0 (0 %)	Material in "other prosthesis was stemless poly-L/D-lactide copolymer (PLDLA) Only patients with rheumatoid arthritis	?	?	?
Sollerman, 1996	Sweden	Randomised controlled trial	n = 12 2.8 – 5 years	1	"All patients were satisfied in both groups".		Material in "other prosthesis was polyurethane (Pellethane).	?	-	?

Appendix 1-3 . PICO 3.

Swanson silicone prosthesis versus other type of silicon prosthesis in patients with rheumatoid arthritis (RA) or psoriatric arthritis (PA) in the MCP-joint.

a) **Outcome variable:** Range of motion (ROM) degrees. ROM is the summation of flexion and extension expressed in degrees. (NR = Not reported; NS = non-significant).

Author, year	Country	Study design	Number of patients Follow-up (FU)	With-drawals/-dropouts	Results - ROM		Comments	Study limitations *	Directnes *	Precision *
					Swanson sialistic prosthesis	Other type of silicone prosthesis				
Delaney, 2005	UK	Randomised controlled trial	n = 22 2 years	n = 0	10 patients, 37 joints <u>Flexion</u> Baseline: 80 ° (sd 17) FU: 59 ° (sd 15) *P = 0.03 between groups* <u>Ulnar deviation</u> Baseline: 24 ° (sd 13) FU: 7 ° (sd 6) *NS between groups* <u>Extension lag</u> Baseline: 51 ° (sd 31) FU: 19 ° (sd 15) *NS between groups*	12 patients, 40 joints <u>Flexion</u> Baseline: 79 ° (sd 16) FU: 72 ° (sd 12) <u>Ulnar deviation</u> Baseline: 26 ° (sd 18) FU: 9 ° (sd 4) <u>Extension lag</u> Baseline: 47 ° (sd 30) FU: 16 ° (sd 19)	Other type of prosthesis: NeuFlex All patients had RA. Extension, and ulnar deviation improved within each group when pre- and postoperative values were compared, but no formal inference tests were reported.	?	?	?

Author, year	Country	Study design	Number of patients Follow-up (FU)	With-drawals /dropouts	Results - ROM		Comments	Study limitations *	Directness *	Precision *
					Swanson sialistic prosthesis	Other type of silicone prosthesis				
Escott, 2010	Canada	Randomised controlled trial	n = 33 1 year	n = 0	20 hands <u>ROM</u> Baseline: 26 ° (sd 13) FU: 42 ° (sd 24) *NS between groups* <u>Flexion</u> Baseline: 91 ° (sd 12) FU: 56 ° (sd 21) *$p < 0.01$ between groups* <u>Ulnar deviation</u> Δ pre-post = - 37 ° (sd 26) *NS between groups* <u>Extension</u> Baseline: 65 ° (sd 18) FU: 14 ° (sd 18) *NS between groups*	20 hands <u>ROM</u> Baseline: 28 ° (sd 19) FU: 54 ° (sd 18) <u>Flexion</u> Baseline: 89 ° (sd 18) FU: 75 ° (sd 19) <u>Ulnar deviation</u> Δ pre-post = - 34 ° (sd 19) <u>Extension</u> Baseline: 61 ° (sd 27) FU: 21 ° (sd 21)	Other type of prosthesis: NeuFlex All patients had RA. ROM, Flexion, extension, ulnar deviation, and extension all improved significantly within each group when pre- and postoperative values were compared.	+	?	?

Author, year	Country	Study design	Number of patients Follow-up (FU)	With-drawals/ dropouts	Results - ROM		Comments	Study limitations *	Directness *	Precision *
					Swanson sialistic prosthesis	Other type of silicone prosthesis				
McArthur, 1998	UK	Randomised controlled trial	n = 15 1 year	n = 0	31 joints <u>ROM</u> Baseline: 29 ° (sd 20) FU: 37° (sd 15) *NS between groups* <u>Flexion</u> Baseline: 75 ° (sd 13) FU: 59 ° (sd 15) *NS between groups* <u>Extension lag</u> Baseline: 47 ° (sd 26) FU: 23° (sd 12) *NS between groups*	41 joints <u>ROM</u> Baseline: 32 ° (sd 19) FU: 30° (sd 16) <u>Flexion</u> Baseline: 64 ° (sd 26) FU: 48 ° (sd 19) <u>Extension lg</u> Baseline: 33 ° (sd 21) FU: 17 ° (sd 14)	Other type of prosthesis: Sutter All patients had RA. Except for ROM in the Sutter prosthesis group, all range of motion variables improved significantly within each group when pre- and postoperative values were compared.	-	?	-
Möller, 2005	Sweden	Randomised controlled trial	n = 31 2.1 years (range 1.2–3.5))	n = 1	<u>Active ROM</u> Baseline: 28 ° (range 8-49 °) FU: 31 ° (range 9-52 °) *NS between groups* <u>Ulnar deviation</u> Baseline: 33 ° (range 18-52 °) FU: 10 ° (range 0 - 28 °) *NS between groups* <u>Extension lag</u> Baseline: 42 ° (range 26-74 °) FU: 16 ° (range 1 - 35 °) *NS between groups*	<u>Active ROM</u> Baseline: 32 ° (range 8-58 °) FU: 42 ° (range 20-60 °) <u>Ulnar deviation</u> Baseline: 29 ° (range 4 - 62 °) FU: 13 ° (range 0 - 28 °) <u>Extension lag</u> Baseline: 47 ° (range 2-86 °) FU: 19 ° (range -1-43 °) NS between groups	Other type of prosthesis: Avanta The patients had either RA or PA.	?	?	?

Author, year	Country	Study design	Number of patients Follow-up (FU)	With-drawals/ dropouts	Results - ROM		Comments	Study limitations *	Directness *	Precision *
					Swanson sialistic prosthesis	Other type of silicone prosthesis				
Tägil, 2009	Sweden	Randomised controlled trial	n = 18 5 years	n = 1	<u>Active ROM</u> Baseline: 23 ° (range 8-45 °) FU: 27 ° (range 10-45 °) *NS between groups* <u>Ulnar deviation</u> Baseline: 30 ° (range 18-42 °) FU: 7 ° (range 0 - 28 °) *NS between groups* <u>Extension lag</u> Baseline: 43 ° (range 26-74 °) FU: 14 ° (range 2 - 38 °) *NS between groups*	<u>Active ROM</u> Baseline: 25 ° (range 8-58 °) FU: 42 ° (range 20-60 °) <u>Ulnar deviation</u> Baseline: 28 ° (range 4 - 51 °) FU: 12 ° (range 3 - 22 °) <u>Extension lag</u> Baseline: 48 ° (range 1-86 °) FU: 17 ° (range 0-35 °)	Substudy of Möller et al. 2005 (see above) with longer follow-up. Other type of prosthesis: Avanta All patients had RA. Ulnar deviation and extension improved significantly within each group when pre- and postoperative values were compared.	?	?	?

Author, year	Country	Study design	Number of patients Follow-up (FU)	With-drawals/ dropouts	Results – ROM		Comments	Study limitations *	Directness *	Precision *
					Swanson sialistic prosthesis	Other type of silicone prosthesis				
Parkkila, 2005	Finland	Randomised controlled trial	n = 58 4.8 year (range 3.1–6.7)	9 hands	22 hands, 75 joints <u>ROM</u> Baseline: 56 ° (sd 22) FU: Δ = -14 ° *NS between groups* <u>Flexion</u> Baseline:82 ° (sd 13) FU: Δ= -28 ° *NS between groups* <u>Ulnar deviation</u> Baseline: 24 ° (sd 21 °) FU: Δ= 19 ° *NS between groups* <u>Extension lag</u> Baseline: 29 ° (sd 26) FU: Δ = 17 ° *NS between groups*	27 hands, 99 joints <u>ROM</u> Baseline: 52 ° (sd 18) FU: Δ = -4 ° <u>Flexion</u> Baseline:75 ° (sd 12) FU: Δ= -12 ° <u>Ulnar deviation</u> Baseline: 18 ° (sd 14 °) FU: Δ= 11 ° <u>Extension lag</u> Baseline: 24 ° (sd 21) FU: Δ = 8 °	Other type of prosthesis: Sutter. All patients had RA. ROM, flexion, ulnar deviation, and extension all improved significantly within each group when pre- and postoperative values were compared	+	?	?

b) **Outcome variable:** Pain. (NR = Not reported; NS = non-significant).

Author, year	Country	Study design	Number of patients Follow-up (FU)	With-drawals/ dropouts	Results - Pain		Comments	dy limitations *	Directness *	Precision *
					Swanson sialistic prosthesis	Other type of silicone prosthesis				
Escott, 2010	Canada	Randomised controlled trial	n = 33 1 year	n = 0	<u>Michigan Hand Outcomes Questionnaire MHQ – domain pain</u> Δpre-post = - 37 (sd 27) *NS between groups*	<u>Michigan Hand Outcomes Questionnaire MHQ – domain pain</u> Δpre-post = - 20 (sd 20)	Other type of prosthesis: NeuFlex All patients had RA. MHQ; 0-100; the lower score the less pain Pain was significantly reduced within both prosthesis groups when pre- and postoperative scores were compared.	+	?	?
Möller, 2005	Sweden	Randomised controlled trial	n = 31 2.1 years (range 1.2–3.5)	n = 1	<u>VAS (score) at rest</u> Baseline: 2.5 (range 0 – 6.8) FU: 1.7 (range 0 – 4.7) *NS between groups*	<u>VAS (score) at rest</u> Baseline: 2.2 (range 0 – 6.6) FU: 1.4 (range 0 – 6.4)	Other type of prosthesis: Avanta The patients had either RA or PA. VAS; 0-10; the lower score the less pain. Pain was significantly reduced within both prosthesis groups when pre- and postoperative scores were compared.	?	?	?
Tägil, 2009	Sweden	Randomised controlled trial	n = 18 5 years	n = 1	<u>VAS (mm) at rest</u> Baseline: 27 (range NR) FU: 17 (range NR) *NS between groups*	<u>VAS (mm) at rest</u> Baseline: 21 (range NR) FU: 5 (range NR)	Substudy of Möller et al. 2005 (see above) with longer follow-up. Other type of prosthesis: Avanta All patients had RA. VAS; 0-100 mm; the lower the less pain. Pain was significantly reduced within both prosthesis groups when pre- and postoperative scores were compared.	?	?	?

c) **Outcome variable:** Strength

Author, year	Country	Study design	Number of patients Follow-up (FU)	With-drawals/ dropouts	Results - Strength		Comments	Study limitations *	Directness *	Precision *
					Swanson sialistic prosthesis	Other type of silicone prosthesis				
Delaney, 2005	UK	Randomised controlled trial	n = 22 2 years	n = 0	Hand grip strength Baseline: 3.5 kg (sd 3.2) FU: 5.4 kg (sd 3.4) *NS between groups*	Hand grip strength Baseline: 4.6 kg (sd 3.1) FU: 6.9 kg (sd 3.4)	Other type of prosthesis: NeuFlex All patients had RA.	?	?	?
Escott, 2010	Canada	Randomised controlled trial	n = 33 1 year	n = 0	Jamar 2-7/8" grip strength Δpre-post = 16 (sd 31) *NS between groups*	Jamar 2-7/8" grip strength Δpre-post = 21 (sd 40)	Other type of prosthesis: NeuFlex All patients had RA.	+	?	?
McArthur, 1998	UK	Randomised controlled trial	n = 15 1 year	n = 0	Hand grip strength Baseline: 3.0 kg (sd 1.9) FU: 6.0 kg (sd 3.5) *NS between groups*	Hand grip strength Baseline: 4.5 kg (sd 6.0) FU: 6.5 kg (sd 5.0)	Other type of prosthesis: Sutter All patients had RA.	-	?	-
Möller, 2005	Sweden	Randomised controlled trial	n = 31 2.1 years (range 1.2–3.5)	n = 1	Hand grip strength Baseline: 50 ***N*** (range16-124) FU: 51 ***N*** (range15-102) *NS between groups*	Hand grip strength Baseline: 58 ***N*** (range 0-114) FU: 60 ***N*** (range11-107)	Other type of prosthesis: Avanta The patients had either RA or PA.	?	?	?
Tägil, 2009	Sweden	Randomised controlled trial	n = 18 5 years	n = 1	Hand grip strength Baseline: 42 ***N*** (range NR) FU: 50 ***N*** (range NR) *NS between groups*	Hand grip strength Baseline: 34 ***N*** (range NR) FU: 50 ***N*** (range NR)	Substudy of Möller et al. 2005 (see above) with longer follow-up. Other type of prosthesis: Avanta All patients had RA.	?	?	?
Parkkila, 2005	Finland	Randomised controlled trial	n = 58 4.8 year (range 3.1–6.	9 hands	Hand grip strength (10 mm) Baseline: 7.1kg (sd 2.7) Δpre-post = 1.2 *NS between groups*	Hand grip strength (10 mm) Baseline: 7.0 kg (sd 2.8) Δpre-post = 1.0	Other type of prosthesis: Sutter. All patients had RA.	+	?	?

* + = No problem ? = Some problems - =Major problems

d) **Outcome variable:** Patient satisfaction at follow-up.

Author, year	Country	Study design	Number of patients Follow-up (FU)	With-drawals/ dropouts	Results – Patient satisfaction		Comments	Study limitations *	Directnes *	Precision *
					Swanson sialistic prosthesis	Other type of silicone prosthesis				
Escott, 2010	Canada	Randomised controlled trial	n = 33 1 year	n = 0	MHQ – domain Satisfaction Δpre-post = + 51 (sd 25) *NS between groups*	MHQ – domain satisfaction Δpre-post = + 37 (sd 20)	Other type of prosthesis: NeuFlex All patients had RA. MHQ = Michigan Hand Outcomes Questionnaire; score 0-100. The higher score the greater satisfaction	+	?	?
McArthur, 1998	UK	Randomised controlled trial	n = 15 1 year	n = 0	"Each group of patients were satisfied with the result."		Other type of prosthesis: Sutter All patients had RA.	-	?	-
Möller, 2005	Sweden	Randomised controlled trial	n = 31 2.1 years (range 1.2–3.5)	n = 1	" 80 % of the patients were satisfied with their results, and were equally distributed between the groups."		Other type of prosthesis: Avanta The patients had either RA or PA.	?	?	?
Parkkila, 2005	Finland	Randomised controlled trial	n = 58 4.8 year (range 3.1–6.7)	9 hands	VAS Baseline: NR FU: 76 (sd 27) *NS between groups*	VAS Baseline: NR FU: 73 (sd 27)	Other type of prosthesis: Sutter. All patients had RA. VAS; 0-100 mm; the higher the greater satisfaction.	+	?	?

d) **Outcome variable:** Function.

Author, year	Country	Study design	Number of patients Follow-up (FU)	With-drawals/ dropouts	Results - Function		Comments	S Study limitations *	Directnes *	Precision *
					Swanson sialistic prosthesis	Other type of silicone prosthesis				
Delaney, 2005	UK	Randomised controlled trial	n = 22 2 years	n = 0	SODA Baseline: 69 (sd 18) FU: 88 (sd 18) *NS between groups*	SODA Baseline: 62 (sd 19) FU: 86 (sd 18)	Other type of prosthesis: NeuFlex All patients had RA. SODA = Sequential Occupational Dexterity Assessment; score 0 – 108. The higher score the better dexterity.	?	?	?
Escott, 2010	Canada	Randomised controlled trial	n = 33 1 year	n = 0	MHQ – domain Function Δpre-post = + 38 (sd 18) *NS between groups* MHQ – domain ADL Δpre-post = + 41 (sd 24) *NS between groups* Sollerman score Δpre-post = + 13 (sd 11) *NS between groups*	MHQ – domain Function Δpre-post = + 22 (sd 15) MHQ – domain ADL Δpre-post = + 28 (sd 19) Sollerman score Δpre-post = + 13 (sd 1)	Other type of prosthesis: NeuFlex All patients had RA. MHQ = Michigan Hand Outcomes Questionnaire; score: 0-100. The higher score the better outcome. Sollerman score 0 -100. The higher score the better function. All functional variables were significantly imporved within both prosthesis groups when pre- and postoperative scores were compared.	+	?	?
Möller, 2005	Sweden	Randomised controlled trial	n = 31 2.1 years (range 1.2–3.5)	n = 1	Sollerman score Baseline: 67 (range 32-78) FU: 66 (range 47-79) *NS between groups* VAS hand function Baseline: 2.6 (range 1.0-10) FU: 5.4 (range 1.8-7.8) *NS between groups*	Sollerman score Baseline: 69 (range 47-78) FU: 68 (range 35-79) VAS hand function Baseline: 3.5 (range 0.7-7.0) FU: 4.8 (range 0.9-8.0)	Other type of prosthesis: Avanta The patients had either RA or PA. Sollerman score 0 -100. The higher score the better function. VAS score 0 -10. The higher score the better function.	?	?	?

* + = No problem ? = Some problems - =Major problems

Author, year	Country	Study design	Number of patients Follow-up (FU)	With-drawals/ dropouts	Results - ROM		Comments	S Study limitations *	Directnes *	Precision *
					Swanson sialistic prosthesis	Other type of silicone prosthesis				
Tägil, 2009	Sweden	Randomised controlled trial	n = 18 5 years	n = 1	<u>Sollerman score</u> Baseline: 60(range NR) FU: 61(range NR) *NS between groups* <u>VAS hand function</u> Baseline: 2.3 (range NR) FU: 5.6 (range NR8) *NS between groups*	<u>Sollerman score</u> Baseline: 64 (range NR) FU: 63 (range NR) <u>VAS hand function</u> Baseline: 4.1 (range NR) FU: 4.6 (range NR)	Substudy of Möller et al. 2005 (see above) with longer follow-up. Other type of prosthesis: Avanta All patients had RA.	?	?	?

Appendix 1-4 - PICO 4.

Pharmacological treatment versus silicone prosthesis in patients with arthritis in the MCP-joint.

a) **Outcome variable:** Range of motion (ROM; degrees). ROM is the summation of flexion and extension expressed in degrees. (NS = non-significant).

Author, year	Country	Study design	Number of patients Follow-up (FU)	With-drawals/ Dropouts	Results - ROM		Comments	Sudy limitations *	Directness *	Precision *
					Silicone prosthesis	Non-surgery				
Chung, 2012	USA	Non-randomised controlled trial	n = 162 3 years	n = 47	42 patients <u>ROM</u> Baseline: 20 ° (sd 15) FU: 30 ° (sd 14) *Adjusted effect size; p < 0.05 between groups* <u>Ulnar drift</u> Baseline: 37 ° (sd 15) FU: 14 ° (sd 11) *Adjusted effect size; p < 0.05 between groups* <u>Extension lag</u> Baseline: 65 ° (sd 23) FU: 29 ° (sd 15) *Adjusted effect size; p < 0.05 between groups*	73 patients <u>ROM</u> Baseline: 37 ° (sd 18) FU: 29 ° (sd 16) <u>Ulnar drift</u> Baseline: 35 ° (sd 15) FU: 34 ° (sd 17) <u>Extension lag</u> Baseline: 47 ° (sd 18) FU: 53 ° (sd 21)	All patients had rheumatoid arthritis. Unbalanced disease severity between study groups with more severe disease in the surgical group. Medical management in the non-surgery group was decided at the discretion of the responsible rheumatologist.			

b) **Outcome variable:** Pain. (NR = Not reported; NS = non-significant).

Author, year	Country	Study design	Number of patients Follow-up (FU)	With-drawals/ Dropouts	Results - Pain		Comments	Sudy limitations *	Directness *	Precision *
					Silicone prosthesis	Non-surgery				
Chung, 2012	USA	Non-randomised controlled trial	n = 162 3 years	n = 47	42 patients <u>MHQ-domain Pain</u> Baseline: 49 (sd 26) FU: 38 (sd 26) *Adjusted effect size; NS (p = 0.06) between groups*	73 patients <u>MHQ-domain Pain</u> Baseline: 36 (sd 25) FU: 31 (sd 24)	All patients had rheumatoid arthritis. Unbalanced disease severity between study groups with more severe disease in the surgical group. Medical management in the non-surgery group was decided at the discretion of the responsible rheumatologist. MHQ = Michigan Hand Outcomes Questionnaire. Score 0 – 100. The lower score the less pain.	?	?	?

c) **Outcome variable:** Strength (expressed as percentage of preoperative value or as the absolute value).

Author, year	Country	Study design	Number of patients Follow-up (FU)	With-drawals/ Dropouts	Results - Strength		Comments	Sudy limitations *	Directness *	Precision *
					Silicone prosthesis	Non-surgery				
Chung, 2012	USA	Non-randomised controlled trial	n = 162 3 years	n = 47	42 patients <u>Hand grip strength</u> Baseline: 5.4 kg (sd 5.2) FU: 6.0 kg (sd 4.2) *Adjusted effect size; NS between groups*	73 patients <u>Hand grip strength</u> Baseline: 8.6 kg (sd 7.4) FU: 9.7(kg (sd 5.9)	All patients had rheumatoid arthritis. Unbalanced disease severity between study groups with more severe disease in the surgical group. Medical management in the non-surgery group was decided at the discretion of the responsible rheumatologist. .	?	?	?

* + = No problem ? = Some problems - =Major problems

d) **Outcome variable:** Patient satisfaction.

Author, year	Country	Study design	Number of patients Follow-up (FU)	With-drawals/ Dropouts	Results- Satisfaction		Comments	Sudy limitations *	Directness *	Precision *
					Silicone prosthesis	Non-surgery				
Chung, 2012	USA	Non-randomised controlled trial	n = 162 3 years	n = 47	42 patients <u>MHQ-domain Satisfaction</u> Baseline: 27 (sd 20) FU: 55 (sd 25) *Adjusted effect size; p < 0.001 between groups*	73 patients <u>MHQ-domain Satisfaction</u> Baseline: 47 (sd 25) FU: 53 (sd 25)	All patients had rheumatoid arthritis. Unbalanced disease severity between study groups with more severe disease in the surgical group. Medical management in the non-surgery group was decided at the discretion of the responsible rheumatologist. MHQ = Michigan Hand Outcomes Questionnaire. Score 0 – 100. The higher score the greater satisfaction.	?	?	?

e) **Outcome variable:** Function.

Author, year	Country	Study design	Number of patients Follow-up (FU)	With-drawals/ Dropouts	Results - Function		Comments	Sudy limitations *	Directness *	Precision *
					Silicone prosthesis	Non-surgery				
Chung, 2009	USA	Non-randomised controlled trial	n = 117 1 year	n = 0	45 patients <u>MHQ-domain Function</u> Baseline: 37 (sd 22) FU: 59 (sd 19) *Adjusted effect size; p = 0.001 between groups* <u>MHQ-domain ADL</u> Baseline: 34 (sd 26) FU: 55 (sd 27) *Adjusted effect size; p = 0.001 between groups*	72 patients <u>MHQ-domain Function</u> Baseline: 58 (sd 19) FU: 58 (sd 21) <u>MHQ-domain ADL</u> Baseline: 59 (sd 24) FU: 61 (sd 27)	All patients had rheumatoid arthritis. Unbalanced disease severity between study groups with more severe disease in the surgical group. Medical management in the non-surgery group was decided at the discretion of the responsible rheumatologist. MHQ = Michigan Hand Outcomes Questionnaire. Score 0 – 100. The higher score the better Function/ADL.	?	?	?

Appendix 1-5 PICO 5.
Silicon prosthesis versus other type of prosthesis in patients with osteoarthritis in the PIP-joint.
a) **Outcome variable:** Range of motion (ROM; degrees). ROM is the summation of flexion and extension expressed in degrees. (NR = Not reported; NS = non-significant).

Author, year	Country	Study design	Number of patients Follow-up (FU)	With-drawals/ Dropouts	Results			Comments	Study limitations *	Directness *	Precision *
					Swanson Sialistic prosthesis	Prosthesis of other material # 1	Prosthesis of other material # 2				
Daecke, 2012	Germany	Randomised controlled trial	n = 43 3 years	n = 9 at 3 yr FU	18 joints <u>ROM</u> Baseline: 47 °(sd 19) FU: 55 °(sd 21) *NS between groups*	26 joints <u>ROM</u> Baseline: 38 °(sd 20) FU: 35 °(sd 32)	18 joints <u>ROM</u> Baseline: 40 °(sd 21) FU: 45 °(sd 34)	Material in "other prostheses were titanium polyethylene (1) and pyrocarbon (2). No significant changes within each group when pre- and postoperative values were compared.	?	-	-
Branam, 2007	USA	Non-randomised controlled trial	n = 22 Silicon prosthesis group: mean 3.8 years Pyrolytic carbon prosthesis group: mean 1.6 years		22 joints <u>Extension/flexion</u> Baseline: 11 °/ 64 ° FU: 13 °/ 62 ° *NS between groups*		19 joints <u>Extension/flexion</u> Baseline: 11 °/ 63 ° FU: 13 °/ 66 °	Material in "other prostehsies was pyrolytic carbon (2).	-	-	-

b) **Outcome variable:** Pain (visual analogue scale; VAS 0 – 10).

Author, year	Country	Study design	Number of patients Follow-up (FU)	With-drawals/ Dropouts	Results			Comments	Study limitations *	Directness *	Precision *
					Swanson Sialistic prosthesis	Prosthesis of other material # 1	Prosthesis of other material # 2				
Daecke, 2012	Germany	Randomised controlled trial	n = 43 3 years	n = 9	Baseline: 3.9 (sd 3.6) FU: 0.3 (sd 1.0) *NS between groups*	Baseline: 4.7 (sd 3.0) FU: 0.5 (sd 1.1)	Baseline: 6.0 (sd 2.8) FU: 0.2 (sd 0.4)	Material in "other prostheses were titanium polyethylene (1) and pyrocarbon (2). Pain was significantly reduced within each group when pre- and postoperative VAS scores were compared.	?	-	-

c) **Outcome variable:** Strength (expressed as percentage of preoperative value or as the absolute value).

Author, year	Country	Study design	Number of patients Follow-up (FU)	With-drawals/ Dropouts	Results			Comments	Study limitations *	Directness *	Precision *
					Swanson Sialistic prosthesis	Prosthesis of other material # 1	Prosthesis of other material # 2				
Daecke, 2012	Germany	Randomised controlled trial	n = 43 3 years	n = 9	<u>Hand grip strength</u> Δ + 65 % *NS between groups* <u>Tip pinch strength</u> Δ + 50 % *NS between groups*	<u>Hand grip strength</u> Δ - 25 % <u>Tip pinch strength</u> Δ + 20 %	<u>Hand grip strength</u> Δ + 60 % <u>Tip pinch strength</u> Δ + 65 %	Material in "other prostheses were titanium polyethylene (1) and pyrocarbon (2). Hand grip strength was significantly improved in the Swanson prosthesis group when pre- and postoperative values were compared. For all other functional grip tests the changes were not statistically significant within each prosthesis group.	?	-	-
Branam, 2007	USA	Non-randomised controlled trial	n = 22 FU of silicon prosthesis group: mean 3.8 years FU of pyrolytic carbon prosthesis group: mean 1.6 years		<u>Hand grip strength</u> (n = 6) Baseline: 18 kg FU: 19 kg *NS between groups*		<u>Hand grip strength</u> (n = 5) Baseline: 9 kg FU: 14 kg	Material in "other prostehsies was pyrolytic carbon (2).	-	-	-

d) **Outcome variable:** Disability of the Arm, Shoulder and Hand (DASH; 0 - 100). The lower the score the better function.

Author, year	Country	Study design	Number of patients Follow-up (FU)	With-drawals/ Dropouts	Results			Comments	Study limitations *	Directness *	Precision *
					Swanson sialistic prosthesis	Prosthesis of other material # 1	Prosthesis of other material # 2				
Daecke, 2012	Germany	Randomised controlled trial	n = 43 3 years	n = 9	Baseline: 57 (sd 16) FU: 19 (sd 21) *p < 0.01 compared to #2 (PY)*	Baseline: 65 (sd 17) FU: 42 (sd 19)	Baseline: 68 (sd 18) FU: 48 (sd 19)	Material in "other prostheses were titanium polyethylene (1) and pyrocarbon , PY(2).	?	-	-

Appendix 1-6.
Complications after MCP arthroplasty in case series of Swanson silicone prosthesis in patients with arthritis, or in studies comparing Swanson silicone prosthesis (SSP) with a prosthesis of other material than silicone, in studies comparing Swanson silicone prosthesis with another type of silicone material prosthesis (SMP) and in studies comparing Swanson silicone prosthesis with non-surgical treatment.

Author, year	Country	Study design	Number of patients/ joints	Follow-up	Fracture of implant	Sclerosis	Bone resorption	Synovitis	Surgical revision	Infection
Beckenbaugh 1976	USA	Case series	Swanson: 85/403 Niebauer: 34/127	Mean: 2.5 years	9 %	*No data*	55 %	*No data*	2 %	1 %
Chung 2012	USA	Case series	Swanson: 67/NR	3 years	10 %	*No data*	*No Data*	*No Data*	3 %	1 %
Delaney 2005	UK	Randomised controlled trial	Swanson: 10/37 SMP (NeuFlex): 12/40	2 years	Swanson: 0 % SMP: 0 %	*No data*	*No data*	Swanson: 0 % SMP: 0 %	Swanson: 0 % SMP: 0 %	Swanson: 0 % SMP: 0 %
Escott 2010	Canada	Randomised controlled trial	Swanson: NR/80 SMP (NeuFlex): NR/80	1 year	*No data*	*No data*	*No data*	*No data*	Swanson: 0 % SMP: 0 %	*No data*
Gellman 1997	USA	Case series	Swanson: 264/901	Mean: 8 years	14 %	*No data*	*No Data*	*No Data*	*No Data*	4 %
Hansraj 1997	USA	Case series	Swanson: 71/348	Mean: 5.2 years	3 %	84 %	8 %			0 %

Appendix 1-6.
Complications after MCP arthroplasty in case series of Swanson silicone prosthesis in patients with arthritis, or in studies comparing Swanson silicone prosthesis (SSP) with a prosthesis of other material than silicone, in studies comparing Swanson silicone prosthesis with another type of silicone material prosthesis (SMP) and in studies comparing Swanson silicone prosthesis with non-surgical treatment.

Author, year	Country	Study design	Number of patients/ joints	Follow-up	Fracture of implant	Sclerosis	Bone resorption	Synovitis	Surgical revision	Infection
Honkanen 2010	Finland	Randomised controlled trial	52 patients Swanson: NR/91 PLDLA: NR/84	1 year	Swanson: 10 % PLDLA: 0 %	*No data*	*No data*	*No data*	*No data*	*No data*
McArthur 1998	UK	Randomised controlled trial	15 patients Swanson: NR/31 SMP (Sutter): NR/44	1 year	Swanson: 0 % SMP: 0 %	*No data*	*No data*	*No data*	Swanson: 16 % SMP: 9 %	Swanson: 0 % SMP: 0 %
Möller 2005	Sweden	Randomised controlled trial	Swanson: 16/NR SMP (Avanta): 15/NR	1.2 – 3.5 years	Swanson: 13 % SMP: 20 %	*No data*	*No data*	*No data*	*No data*	*No data*
Parkkila 2005	Finland	Randomised controlled trial	Swanson: 21/75 SMP (Sutter): 24/99	3.1 – 6.7 years	*No data*	*No data*	*No data*	*No data*	*No data*	*No data*

Appendix 1-6.
Complications after MCP arthroplasty in case series of Swanson silicone prosthesis in patients with arthritis, or in studies comparing Swanson silicone prosthesis (SSP) with a prosthesis of other material than silicone, in studies comparing Swanson silicone prosthesis with another type of silicone material prosthesis (SMP) and in studies comparing Swanson silicone prosthesis with non-surgical treatment.

Author, year	Country	Study design	Number of patients/ joints	Follow-up	Fracture of implant	Sclerosis	Bone resorption	Synovitis	Surgical revision	Infection
Parkkila 2006	Finland	Case series	SMP (Sutter): 87/282	2.1 – 7.4 years	*No data*	59 %	50 %	*No data*	22 %	*No data*
Sollerman 1996	Sweden	Randomised controlled trial	12 patients Swanson: NR/21 Poly-urethane: NR/23	2.8 – 5.0 years	Swanson: 5 % PU: 4 %	Swanson: 29 % PU: 43 %	Swanson: 61 % PU: 22 %	Swanson: 9 % PU: 4 %	*No data*	*No data*
Swanson 1972	USA	Case series	Swanson: NR/3915	2 – 5 years	1 %	*No data*	*No Data*	*No Data*	*No Data*	0.5 %
Trail 2004	USA	Case series	Swanson: 381/1336	"..up to 17 years"	1 %	*No data*	*No Data*	*No Data*	6 %	*No Data*
Wilson 1993	UK	Case series	Swanson: 77/375	5 – 14 years	3 %	*No data*	*No Data*	*No Data*	3 %	1 %

Appendix 2 Excluded articles.

Study (author, publication year)	Reason for exclusion
Metacarphalangeal joint prosthesis	
Bogoch el al 2011	Post-hoc analysis of Escott 2010 with other outcome variables
Chung et al 2000	Review of studies already included in the HTA literature search
Chung et al 2006	Substudy of Chung et al 2012
Chung et al 2009 (J Hand Surg Am)	Substudy of Chung et al 2012
Chung et al 2009 (Palst Reconstr Surg)	Substudy of Chung et al 201. Case series without any data on complications
Clark et al 2001	Does not fullfill PICO
Goldner et al 1973	Mixed patient population (OA, RA and TOA), Combined MCP and PIP implants
Hagena et al 2005	Mixed patient population (OA and RA)
Ishikawa et al 2002	Does not fullfill PICO
Lester et al. 2012	Does not have any baseline data. Not standardised outcome variable.
Linscheid 1979	Prosthesis with both silicone and metallic material.
Neumann et al 1980	Does not fullfill PICO
Steffee et al 1981	Does not fullfill PICO
Weber et al 1986	Combined MCP and PIP implants, the number of patients unclear
Petterson et al 2006	Does not fullfill PICO

Appendix 2 Excluded articles.

Study (author, publication year)	Reason for exclusion
Proximal interphalangeal prosthesis	
Neumann 1980	Combined MCP and PIP implants
Pellegrini el al 1990	Too few patients
Stahlenbrecher and Hoch 2009	Mixed patient population (OA, RA and TOA),
Johnstone et al. 2008	Does not fullfill PICO

Appendix 3, Search strategy, study selection and references

Question(s) at issue:
1: Are drugs or any other prosthesis more effective than the Swanson silicone prosthesis to reduce pain and to improve grip strength, range of motion (ROM), patient satisfaction, activities of daily living (ADL), and function (Disabilities of the Arm, Shoulder and Hand (DASH) score or Quick DASH score) in adults with arthritis or osteoarthritis involving the MCP joints?
What is the rate of complications?

2: Is any other prosthesis more effective than the Swanson silicone prosthesis to reduce pain and to improve grip strength, range of motion, satisfaction, activities of daily living, and function (DASH score or Quick DASH score) in adults with arthritis or osteoarthritis involving the PIP joints?
What is the rate of complications?

PICO: (*P=Patient I=Intervention C=Comparison O=Outcome*)

PICO 1
P: patients (> 18 years) with severe arthritis of the MCP joints of the hand (MCP-I excluded)
I: a "non-silicone" prosthesis
C: a silicone prosthesis
O: ROM, pain, strength, satisfaction, ADL, DASH, quick-DASH, complications

PICO 2
P: patients (> 18 years) with severe osteoarthritis of the MCP joints of the hand (MCP-I excluded)
I: a "non-silicone" prosthesis
C: a silicone prosthesis
O: ROM, pain, strength, satisfaction, ADL, DASH, quick-DASH, complications

PICO 3
P: patients (> 18 years) with severe arthritis of the MCP joints of the hand (MCP-I excluded)
I: a silicone prosthesis (except Swanson)
C: a Swanson silicone prosthesis
O: ROM, pain, strength, satisfaction, ADL, DASH, quick-DASH, complications

PICO 4
P: patients (> 18 years) with severe arthritis of the MCP joints of the hand (MCP-I excluded)
I: pharmacological intervention
C: a Swanson silicone prosthesis
O: ROM, pain, strength, satisfaction, ADL, DASH, quick-DASH, complications

PICO 5
P: patients (> 18 years) with severe osteoarthritis or severe arthritis and prosthesis or fusion in the PIP-joints
I: a "non-silicone" prosthesis
C: a silicone prosthesis or joint fusion
O: ROM, pain, strength, satisfaction, ADL, DASH, quick-DASH, complications

PICO 6
P: patients (> 18 years) with severe osteoarthritis or severe arthritis and prosthesis or fusion in the PIP-joints
I: a "non-silicone" prosthesis
C: a Swanson silicone prosthesis
O: ROM, pain, strength, satisfaction, ADL, DASH, quick-DASH, complications

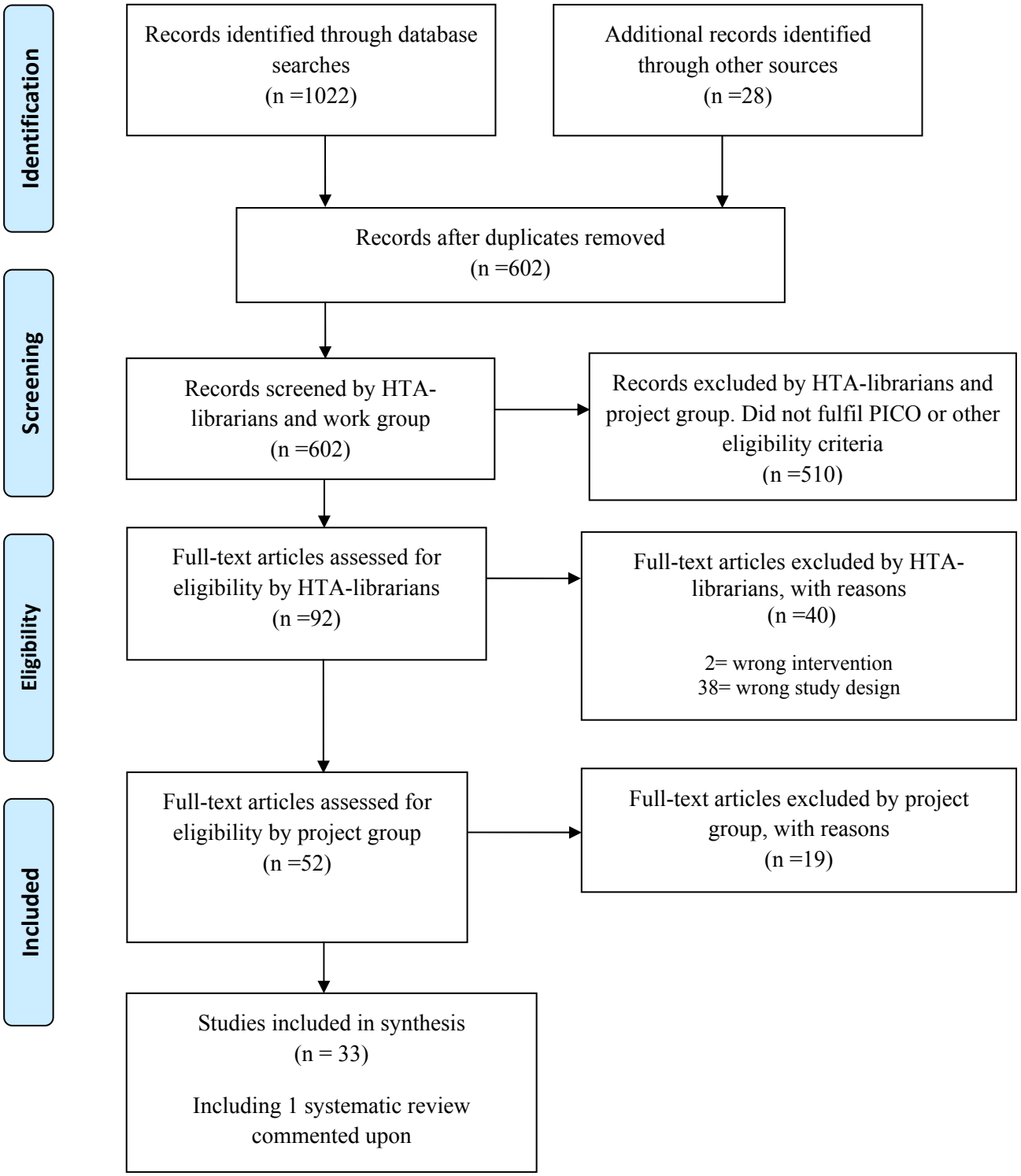
Eligibility criteria

Study design:
Studies with some kind of control group
Systematic reviews or meta-analyses
Case series etc. if ≥ 60 patients for MCP, if ≥ 40 patients for PIP

Language:
Danish, English, German, Norwegian, Swedish

Publication date:
No limits

Selection process – flow diagram



Search strategies

Database: EMBASE (OVID SP)
Date: 2012-09-26
No of results: 359 for MCP, 134 for PIP
Search strategies for MCP is shown below. A similar search for PIP where made with the words exp proximal interphalangeal joint/ OR (proximal interphalangeal OR PIP).ti,ab,kw

#	Searches	Results
1	exp arthritis/	292800
2	arthritis.ti,ab,kw.	145165
3	osteoarthritis/	48032
4	osteoarthritis.ti,ab,kw.	41743
5	1 or 2 or 3 or 4	317860
6	exp metacarpophalangeal joint/	3587
7	(metacarpophalangeal or MCP).ti,ab,kw.	20324
8	6 or 7	21737
9	exp finger arthroplasty/ or arthroplasty/	12518
10	(arthroplasty or arthroplasties).ti,ab,kw.	37633
11	exp silicone prosthesis/	3045
12	silicone.ti,ab,kw.	22965
13	joint prosthesis/ or exp prosthesis/	31912
14	prosthesis.ti,ab,kw.	50262
15	surface replacement.ti,ab,kw.	408
16	resurfacing.ti,ab,kw.	4806
17	9 or 10 or 11 or 12 or 13 or 14 or 15 or 16	129255
18	5 and 8 and 17	402
19	**limit 18 to (danish or english or german or norwegian or swedish)**	**359**

After revision of the PICO a new search for pyrocarbon prosthesis where made for MCP joints
Database: Embase (OVID SP)
Date: 2012-11-15
No of results: 17

#	Searches	Results
1	exp arthritis/	294950
2	arthritis.ti,ab,kw.	146350
3	osteoarthritis/	48347
4	osteoarthritis.ti,ab,kw.	42107
5	1 or 2 or 3 or 4	320173
6	exp metacarpophalangeal joint/	3622
7	(metacarpophalangeal or MCP).ti,ab,kw.	20598
8	6 or 7	22028
9	exp pyrocarbon/	954
10	exp pyrolytic carbon/	281
11	(pyrocarbon or pyrolytic or pyrolite).ti,ab,kw.	1744
12	9 or 10 or 11	2770
13	5 and 8 and 12	17
14	**limit 13 to (danish or english or german or norwegian or swedish)**	**17**

Database: PubMed
Date: 2012-09-26
No of results: 345 for MCP, 121 for PIP
Search strategies for MCP is shown below. A similar search for PIP where made with the words "proximal interphalangeal"[tw] OR PIP[tw].

Search	Query	Items found
#48	**Search #44 AND #47**	**345**
#47	Search Danish[lang] OR English[lang] OR German[lang] OR Norwegian[lang] OR Swedish[lang]	18721131
#44	Search #14 AND #18 AND #43	382
#43	Search #23 OR #26 OR #28 OR #32 OR #35 OR #36 OR #38 OR #41 OR #42	229442
#42	Search prosthesis[tw]	162251
#41	Search "Joint Prosthesis"[Mesh:NoExp]	8269
#38	Search "Prostheses and Implants"[Mesh:NoExp]	34211
#36	Search resurfacing[tw] OR "surface replacement"	4057
#35	Search arthroplasties[tw] OR arthroplasty[tw]	44520
#32	Search silicone[tw]	24279
#28	Search "Arthroplasty, Replacement"[Mesh:NoExp]	3562
#26	Search "Arthroplasty"[Mesh:NoExp]	6081
#23	Search "Arthroplasty, Replacement, Finger"[Mesh]	77
#18	Search #16 OR #17	16750
#17	Search Metacarpophalangeal[tw] OR MCP[tw]	16657
#16	Search "Metacarpophalangeal Joint"[Mesh]	2482
#14	Search #7 OR #8 OR #12 OR #13	225125
#13	Search "Osteoarthritis"[tw]	48512
#12	Search "Osteoarthritis"[Mesh]	38266
#8	Search "Arthritis"[tw]	157142
#7	Search "Arthritis"[Mesh]	186931

After revision of the PICO a new search for pyrocarbon prosthesis where made for MCP joints
Database: PubMed
Date: 2012-11-15
No of results: 14

Search	Query	Items found
#15	**Search #14 AND (Danish[lang] OR English[lang] OR German[lang] OR Norwegian[lang] OR Swedish[lang])**	**14**
#14	Search #5 AND #9 AND #13	15
#13	Search #10 OR #11 OR #12	1767
#12	Search pyrolite[tw]	48
#11	Search pyrolytic[tw]	1677
#10	Search pyrocarbon[tw]	81
#9	Search #6 OR #7 OR #8	16922
#8	Search MCP[tw]	13101
#7	Search Metacarpophalangeal[tw]	4276
#6	Search "Metacarpophalangeal Joint"[Mesh]	2494
#5	Search #1 OR #2 OR #3 OR #4	226502
#4	Search "Osteoarthritis"[tw]	48993
#3	Search "Osteoarthritis"[Mesh]	38614
#2	Search "Arthritis"[tw]	158022
#1	Search "Arthritis"[Mesh]	187877

Database: The Cochrane Library
Date: 2012-09-26
No of results: 22 for MCP, 1 for PIP
Cochrane reviews
Other reviews 2
Clinical trials 19 for MCP, 1 for PIP
Technology assessments 1
Economic evaluations

Search strategies for MCP is shown below. A similar search for PIP where made with the words "proximal interphalangeal" or PIP:ti,ab,kw

ID	Search	Result
#1	arthritis:ti,ab,kw (Word variations have been searched)	6841
#2	MeSH descriptor: [Arthritis] explode all trees	7643
#3	osteoarthritis:ti,ab,kw (Word variations have been searched)	4439
#4	MeSH descriptor: [Osteoarthritis] this term only	1448
#5	#1 or #2 or #3 or #4	10986
#6	metacarpophalangeal or MCP:ti,ab,kw (Word variations have been searched)	451
#7	MeSH descriptor: [Metacarpophalangeal Joint] explode all trees	63
#8	#6 or #7	455
#9	artrhoplasty or arthroplasties:ti,ab,kw (Word variations have been searched)	247
#10	MeSH descriptor: [Arthroplasty, Replacement, Finger] explode all trees	7
#11	MeSH descriptor: [Arthroplasty] this term only	152
#12	MeSH descriptor: [Arthroplasty, Replacement] explode all trees	2435
#13	silicone:ti,ab,kw (Word variations have been searched)	1887
#14	"resurfacing" or "surface replacement":ti,ab,kw (Word variations have been searched)	283
#15	MeSH descriptor: [Prostheses and Implants] explode all trees	11720
#16	MeSH descriptor: [Joint Prosthesis] explode all trees	1480
#17	"prosthesis":ti,ab,kw (Word variations have been searched)	6398
#18	#9 or #10 or #11 or #12 #13 or #14 or #15 or #16 or #17	13717
#19	**#5 and #8 and #18**	**22**

After revision of the PICO a new search for pyrocarbon prosthesis where made for MCP joints
Database: The Cochrane library
Date: 2012-11-15
No of results: 0

ID	Search	Items found
#1	arthritis:ti,ab,kw (Word variations have been searched)	6849
#2	MeSH descriptor: [Arthritis] explode all trees	7660
#3	osteoarthritis:ti,ab,kw (Word variations have been searched)	4453
#4	MeSH descriptor: [Osteoarthritis] this term only	1453
#5	#1 or #2 or #3 or #4	11006
#6	metacarpophalangeal or MCP:ti,ab,kw (Word variations have been searched)	454
#7	MeSH descriptor: [Metacarpophalangeal Joint] explode all trees	63
#8	#6 or #7	458
#9	pyrocarbon or pyrolytic or pyrolite:ti,ab,kw (Word variations have been searched)	5
#10	**#5 and #8 and #9**	**0**

Database: CRD
Date: 2012-09-26
No of results: 6 for MCP, 3 for PIP
DARE 4 for MCP, 2 for PIP
NHS EED
HTA 2 for MCP, 1 for PIP
Search strategies for MCP is shown below. A similar search for PIP where made with the words "proximal interphalangeal" OR PIP

Line	Search	Hits
1	arthritis	1076
2	osteoarthritis	624
3	#1 OR #2	1435
4	metacarpophalangeal OR MCP	17
5	**#3 AND #4**	**6**

Reference lists
28 results

The web-sites of **SBU, Kunnskapssenteret** and **Sundhedsstyrelsen** were visited
Nothing relevant to the question at issue was found

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Summary of Findings 4-1 PICO 1

Silicone prosthesis compared to prosthesis of other material in patients with arthritis in the metacarpophalangeal (MCP) joint.

Outcome variable Number of studies	Design	Study limitations	Consistency	Directness	Precision	Publication bias	Magnitude of effect	Relative effect (95%CI)	Absolute effect	Quality of evidence GRADE
Range of motion										
2	RCT	Serious limitations (-1)	No important inconsistency	Some uncertainty (?)	Serious imprecision (-1)	Unlikely	Not relevant	No differences in outcome		⊕⊕◯◯ Low
Pain										
1	RCT	Serious limitations (-1)	No important inconsistency	Some uncertainty (?)	Serious imprecision (-1)	Unlikely	Not relevant	No differences in outcome		⊕⊕◯◯ Low
Strength										
1	RCT	Serious limitations (-1)	No important inconsistency	Some uncertainty (?)	Serious imprecision (-1)	Unlikely	Not relevant	No differences in outcome		⊕⊕◯◯ Low
Patient satisfaction										
2	RCT	Serious limitations (-1)	No important inconsistency	Some uncertainty (?)	Serious imprecision (-1)	Unlikely	Not relevant	No differences in outcome		⊕⊕◯◯ Low

High quality of evidence = ⊕⊕⊕⊕
Moderate quality of evidence = ⊕⊕⊕◯
Low quality of evidence = ⊕⊕◯◯
Very low quality of evidence = ⊕◯◯◯

Summary of Findings 4-3 PICO 3

Swanson silicone prosthesis compared to other silicone prosthesis in patients with arthritis in the metacarpophalangeal (MCP) joint.

Outcome variable Number of studies	Design	Study limitations	Consistency	Directness	Precision	Publication bias	Magnitude of effect	Relative effect (95%CI)	Absolute effect	Quality of evidence GRADE
Range of motion										
5	RCT	Some limitations (-?)	No important inconsistency	Some uncertainty (?)	Serious imprecision (-1)	Unlikely	Not relevant	No differences in outcome		⊕⊕◯◯ Low
Pain										
3	RCT	Some limitations (-?)	No important inconsistency	Some uncertainty (?)	Serious imprecision (-1)	Unlikely	Not relevant	No differences in outcome		⊕⊕◯◯ Low
Strength										
5	RCT	Some limitations (-?)	No important inconsistency	Some uncertainty (?)	Serious imprecision (-1)	Unlikely	Not relevant	No differences in outcome		⊕⊕◯◯ Low
Patient satisfaction										
4	RCT	Some limitations (-?)	No important inconsistency	Some uncertainty (?)	Serious imprecision (-1)	Unlikely	Not relevant	No differences in outcome		⊕⊕◯◯ Low
Function/ ADL										
3	RCT	Some limitations (-?)	No important inconsistency	Some uncertainty (?)	Serious imprecision (-1)	Unlikely	Not relevant	No differences in outcome		⊕⊕◯◯ Low

High quality of evidence = ⊕⊕⊕⊕
Moderate quality of evidence = ⊕⊕⊕◯
Low quality of evidence = ⊕⊕◯◯
Very low quality of evidence = ⊕◯◯◯

Summary of Findings 4-4 PICO 4

Pharmacological treatment compared to silicone prosthesis cnon-surgery in patients with arthritis in the metacarpophalangeal (MCP) joint.

Outcome variable	Design	Study limitations	Consistency	Directness	Precision	Publication bias	Magnitude of effect	Relative effect (95%CI)	Absolute effect	Quality of evidence GRADE
Number of studies										
Range of motion										
1	Non-randomised controlled study	Serious limitations (-1)	No important inconsistency	Some uncertainty (?)	No imprecision	Unlikely	Not relevant	Significantly better in prosthesis group		⊕◯◯◯ Very low
Pain										
1	Non-randomised controlled study	Serious limitations (-1)	No important inconsistency	Some uncertainty (?)	No imprecision	Unlikely	Not relevant	No difference in oucome		⊕◯◯◯ Very low
Strength										
1	Non-randomised controlled study	Serious limitations (-1)	No important inconsistency	Some uncertainty (?)	No imprecision	Unlikely	Not relevant	No differences in outcome		⊕◯◯◯ Very low
Patient satisfaction										
1	Non-randomised controlled study	Serious limitations (-1)	No important inconsistency	Some uncertainty (?)	No imprecision	Unlikely	Not relevant	Significantly better in prosthesis group		⊕◯◯◯ Very low

High quality of evidence = ⊕⊕⊕⊕
Moderate quality of evidence = ⊕⊕⊕◯
Low quality of evidence = ⊕⊕◯◯
Very low quality of evidence = ⊕◯◯◯

Summary of Findings 4-5 PICO 5

Silicone prosthesis compared to prosthesis of other material in patients with osteoarthritis in the proximal interphalangeal (PIP) joint.

Outcome variable Number of studies	Design	Study limitations	Consistency	Directness	Precision	Publication bias	Magnitude of effect	Relative effect (95%CI)	Absolute effect	Quality of evidence GRADE
Range of motion										
2	1 RCT 1 Non-randomised controlled study	Serious limitations (-1)	No important inconsistency	Some uncertainty (?)	Very serious imprecision (-2)	Unlikely	Not relevant	No differences in outcome		⊕◯◯◯ Very low
Pain										
1	RCT	Serious limitations (-1)	No important inconsistency	Some uncertainty (?)	Very serious imprecision (-2)	Unlikely	Not relevant	No differences in outcome		⊕◯◯◯ Very low
Strength										
2	1 RCT 1 Non-randomised controlled study	Serious limitations (-1)	No important inconsistency	Some uncertainty (?)	Very serious imprecision (-2)	Unlikely	Not relevant	No differences in outcome		⊕◯◯◯ Very low
Function/ ADL										
1	RCT	Serious limitations (-1)	No important inconsistency	Some uncertainty (?)	Very serious imprecision (-2)	Unlikely	Not relevant	No differences in outcome		⊕◯◯◯ Very low

High quality of evidence = ⊕⊕⊕⊕
Moderate quality of evidence = ⊕⊕⊕◯
Low quality of evidence = ⊕⊕◯◯
Very low quality of evidence = ⊕◯◯◯

Appendix 5.

ETHICAL ANALYSIS OF IMPLANTATION OF FINGER JOINT PROSTHESIS VERSUS CONSERVATIVE THERAPY

Question	Answer/ comment
1. From the patient's perspective, how does prosthetic arthroplasty affect the patient's quality of life and life expectancy?	There is a positive effect on quality of life reflected in a significantly improved patient satisfaction after implantation of a joint prosthesis. There is no anticipated effect on life expectancy.
2. How severe is the patient's need that the prosthetic arthroplasty must meet?	The severity of the patient's need is great. The beneficial effect of arthroplasty can enable the patient to continue his/her paid employment, to perform the activities of daily living, and to be independent, or at least, less dependent on supportive care at work as well as at home.
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)?	Yes, probably. The patient's perception of himself/herself may increase in many individuals when the deformities of the hands are corrected, and the symptoms and disabilities are positively affected. This may also positively influence how other people perceive the patient.
4. Can prosthetic arthroplasty affect the patient's ability and possibility to be independent?	Yes. See item 2 above.
5. If implemented, does prosthetic arthroplasty require any special steps to not compromise the patient's autonomy?	No.
6. How does prosthetic arthroplasty affect the patient's physical, moral and personal integrity?	It has a positive effect on both physical (see item 2) and personal integrity (see item 3). With regard to the moral integrity it probably does not have any major effects.
7. Is prosthetic arthroplasty cost-effective?	Most probably. However, there are no published health economy analyses that confirm this view.
8. How does prosthetic arthroplasty affect resources?	Presently, it does not affect the available resources. If the need of finger joint arthroplasty will increase it will require more 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?	Yes, in a positive way. The need for supportive care at home or at work will decrease (se item 2).
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?	No.
15. Can an introduction of prosthetic arthroplasty influence the trust of the health care system?	Not applicable. (Arthoplasties of deformed joints (hip, knee, shoulder ,fingers) have been in use for many years.
CONCLUSIONS	Prosthetic arthroplasty of finger joints have positive effects on the patient's activities of daily living and most probably on his/her physical and personal integrity, as well as on the perception of himself/herself.

Region Västra Götaland, HTA-centrum

Health Technology Assessment
Regional activity-based HTA

HTA

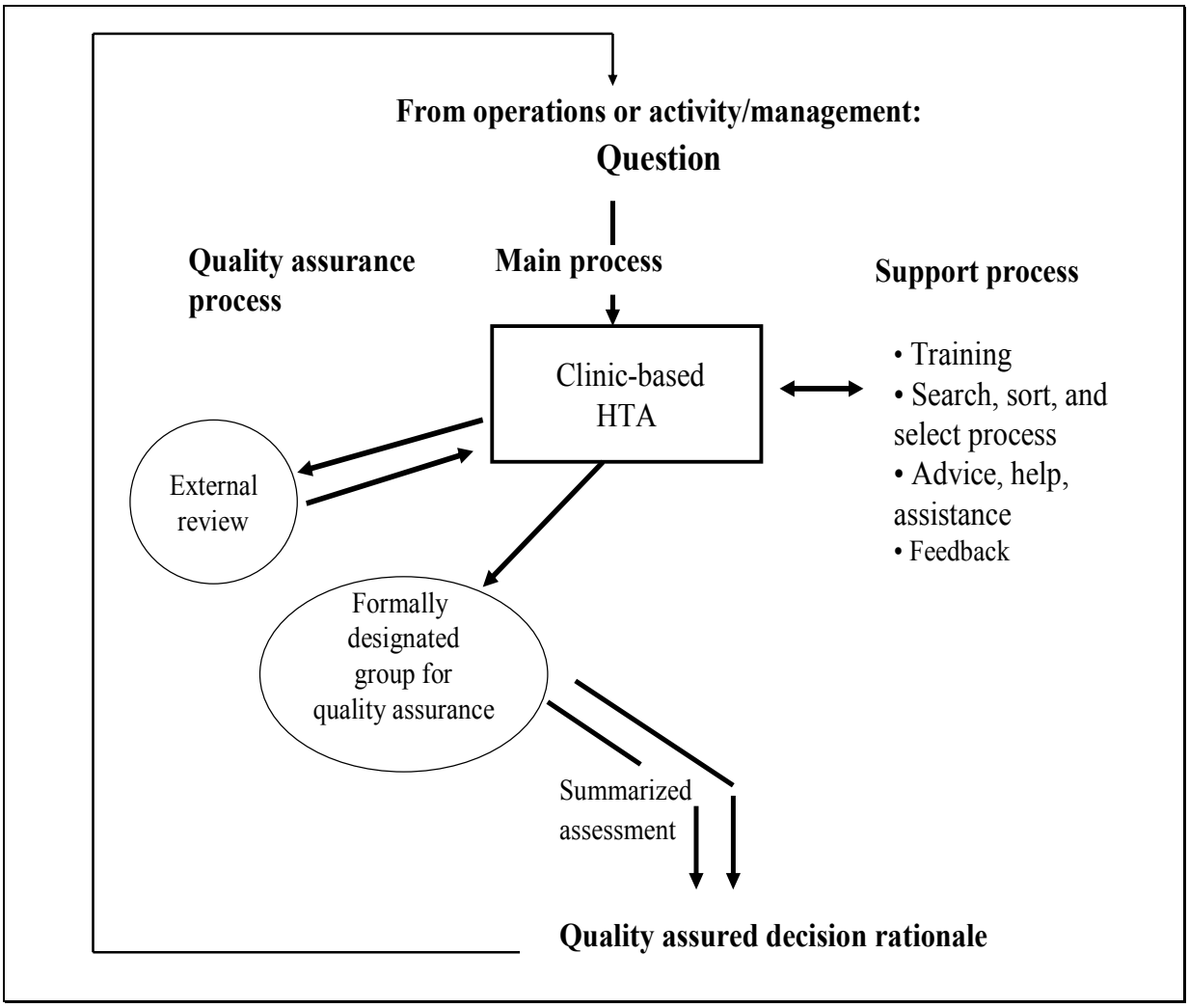
Health technology assessment (HTA) is the systematic evaluation of properties, effects, and/or impacts of health care technologies, i.e. interventions that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care. It may address the direct, intended 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 ⊕⊕⊕O)
Low quality of evidence	= (GRADE ⊕⊕OO)
Very low quality of evidence	= (GRADE ⊕OOO)

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


From operations or activity/management:
Question
Quality assurance process
Main process
Support process
Clinic-based HTA
• Training
• Search, sort, and select process
• Advice, help, assistance
• Feedback
External review
Formally designated group for quality assurance
Summarized assessment
Quality assured decision rationale

VÄSTRA GÖTALANDSREGIONEN
SAHLGRENSKA UNIVERSITETSSJUKHUSET

Sahlgrenska Universitetssjukhuset, HTA-centrum
Röda Stråket 8, 413 45 Göteborg
www.sahlgrenska.se/hta-centrum