

Surface Replacement Proximal Interphalangeal joint (SR-PIPJ) arthroplasty – A CASE SERIES

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ABSTRACT

Surface replacement (SR) proximal interphalangeal joint replacement consists of a cobalt-chrome alloy component articulating with an ultra-high molecular weight polyethylene component. After experiencing a high rate of subsidence and complications with a pyrocarbon implant, our unit has changed to the cemented SR system in the hope of decreasing these complications. The main aim of this study was to determine whether this change in practice has led to a decrease in subsidence and complications. A retrospective chart review was performed including 43 joints in 28 patients. Subsidence was noted in 26% of the joints and complications in 31% of the joints. Even though subsidence remains a problem, the change in implant has led to a decrease in subsidence and other complications.

Level of evidence: Level 4

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Part A

Research Protocol

Surface Replacement Proximal Interphalangeal joint (SR-PIPJ) arthroplasty – A CASE SERIES

I. Background

a) Introduction

The proximal interphalangeal joint (PIPJ) is involved in 18% of individuals with osteoarthritis. Inflammatory arthritis may also affect the PIPJ. ¹ Pain is managed with analgesics and anti-inflammatories, but when conservative management fails, surgery is indicated. Surgical options include arthrodesis and arthroplasty. Arthrodesis reliably relieves pain but function and patient satisfaction may be affected by a lack of motion. The goal of joint replacement is to maintain range of motion while removing pain.¹

Many different types of prostheses exist, but the most commonly used are silicone, pyrocarbon and metal on polyethylene (Surface replacement PIPJ Arthroplasty).

Our institution recently published our experience with pyrocarbon PIPJ replacements. Even though the study concluded that pyrocarbon PIPJ replacements are safe and effective, the incidence of complications was fairly high.² As a result, our institution has started using Surface Replacement PIPJ Replacements in view of the high incidence of complications.

Surface replacement PIPJ arthroplasty consists of a proximal cobalt chromium alloy and a distal ultrahigh molecular weight polyethylene component, and relies on the presence of the collateral ligaments and the volar plate for stability, similar to a knee replacement.³

b) Literature review

Silicone implants have been used since 1966. Main concerns with silicone implants have been poor long term range of motion, implant fracture, silicone synovitis and poor coronal stability. Poor coronal stability is more an issue in the index finger where a strong and stable pinch grip is required.^{4, 5} Lack of coronal stability in the index finger has led some authors to prefer arthrodesis over arthroplasty in the index finger.⁴

The development of newer semi-constrained resurfacing implants eliminate the complications associated with silicone. However, implant loosening, subsidence, swan-neck and boutonnière deformities are problematic.

Silicone implants are linked, whereas the surface replacement implants are unlinked. As a result, these implants should be used with caution in patients with inflammatory arthritis where collateral ligament integrity and joint stability may be compromised.

Daecke et al compared three different implants: Silicone (SI), Titanium-polyethylene (TI) and Pyrocarbon (PY). They found no difference in subjective and objective clinical outcome. But

the potential for achieving good postoperative motion was increased in the TI and PY groups. The complication rate was also higher in these groups with especially the PY group showing a higher incidence of progressive implant loosening, as well as swan neck and boutonnière deformities.⁵

Johnstone et al compared cemented and uncemented implants and found a significantly higher incidence of implant subsidence in the uncemented group.⁶

Most published series report on their experience with uncemented implants. Amirtharajah et al. published a small series on cemented implants. Their patients showed an increase in range of motion, good function and pain relief. A Large amount of radiographic subsidence was noted, but none of these has had revisions for loosening. They postulate that these radiographic changes may represent stable settling of the implant, but that longer term follow up is needed to confirm this.⁷

II. Purpose of the study

The purpose of the study is to determine whether our change in practice from pyrocarbon to cemented metal on polyethylene implants have led to a decrease in the number of complications. This will allow us to determine the best possible management for our patients and to compare our results to the international literature.

III. Methodology

We will perform a retrospective chart review of patients who had a SR PIPJ arthroplasty performed by the senior authors at Groote Schuur and Vincent Palloti Hospitals and the Sport Science Institute from 2011 to 2014. Data regarding demographics, indications for surgery, pre and post-operative range of motion, surgical approach and complications will be collected. Patients will be contacted to determine patient satisfaction. Certain patients may be called back to assess final range of motion.

IV. Descriptions of risks and benefits

Risks:

A retrospective chart review will be performed with no risks to any patients.

Benefits:

To benefit future patients in determining which implant has better results and outcomes when performing PIPJ arthroplasty.

V. Ethical considerations

A retrospective chart review will be performed and no patient information will be disclosed.

VI. Data Safety and Reimbursement

All patients' names and folder numbers will be removed from the data stream. This study adheres to the Declaration of the Helsinki 2013. There will be no reimbursement.

VII. Researchers

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VIII. References

1. Adams J, Ryall C, Pandyan A, Metcalf, Stokes M, Bradley S, Warwick DJ. Proximal interphalangeal joint replacement in patients with arthritis of the hand, a meta-analysis. *J Bone Joint Surg Br.* 2012, 94-B: 1305-12
2. McGuire DT, White CD, Carter L, Solomons MW. Pyrocarbon proximal interphalangeal joint arthroplasty: outcomes of a cohort study. *J Hand Surg Eur.* 2012, 37: 490-496
3. Johnstone BR. Proximal interphalangeal joint surface replacement arthroplasty. *Hand Surgery.* July 2001, 6(1): 1-11
4. Sweets TM, Stern PJ. Proximal Interphalangeal Joint Prosthetic Arthroplasty. *J Hand Surg.* 2010, 35A: 1190-1193
5. Daecke W, Kaszap B, Martini AK, Hagen FW, Rieck B, Jung M. A prospective Randomized Comparison of 3 Types of proximal interphalangeal joint arthroplasty. *J Hand Surg.* 2012, 37A: 1770-1779
6. Johnstone BR, Fitzgerald M, Smith KR, Currie LJ. Cemented versus uncemented surface replacement arthroplasty of the proximal interphalangeal joint with a mean 5 year follow up. *J Hand Surg.* 2008, 33A: 726-732
7. Amirtharajah M, Fufa D, Lightdale N, Weiland A. Clinical, Radiographic and patient-reported results of surface replacing proximal interphalangeal joint arthroplasty of the hand. *Iowa Orthop J.* 2011,31:140-4

Part B

Literature Review

I. Objectives

- a. To discuss the extent of the disease
- b. To discuss the management options for proximal interphalangeal joint (PIPJ) arthritis of the hand
- c. To discuss the rationale for arthroplasty of the PIPJ of the hand
- d. To discuss the different types of arthroplasty of the PIPJ of the hand
- e. To present similar studies discussing their results of surface replacement PIPJ arthroplasty
- f. To discuss the rationale for performing this study

II. Search Methodology

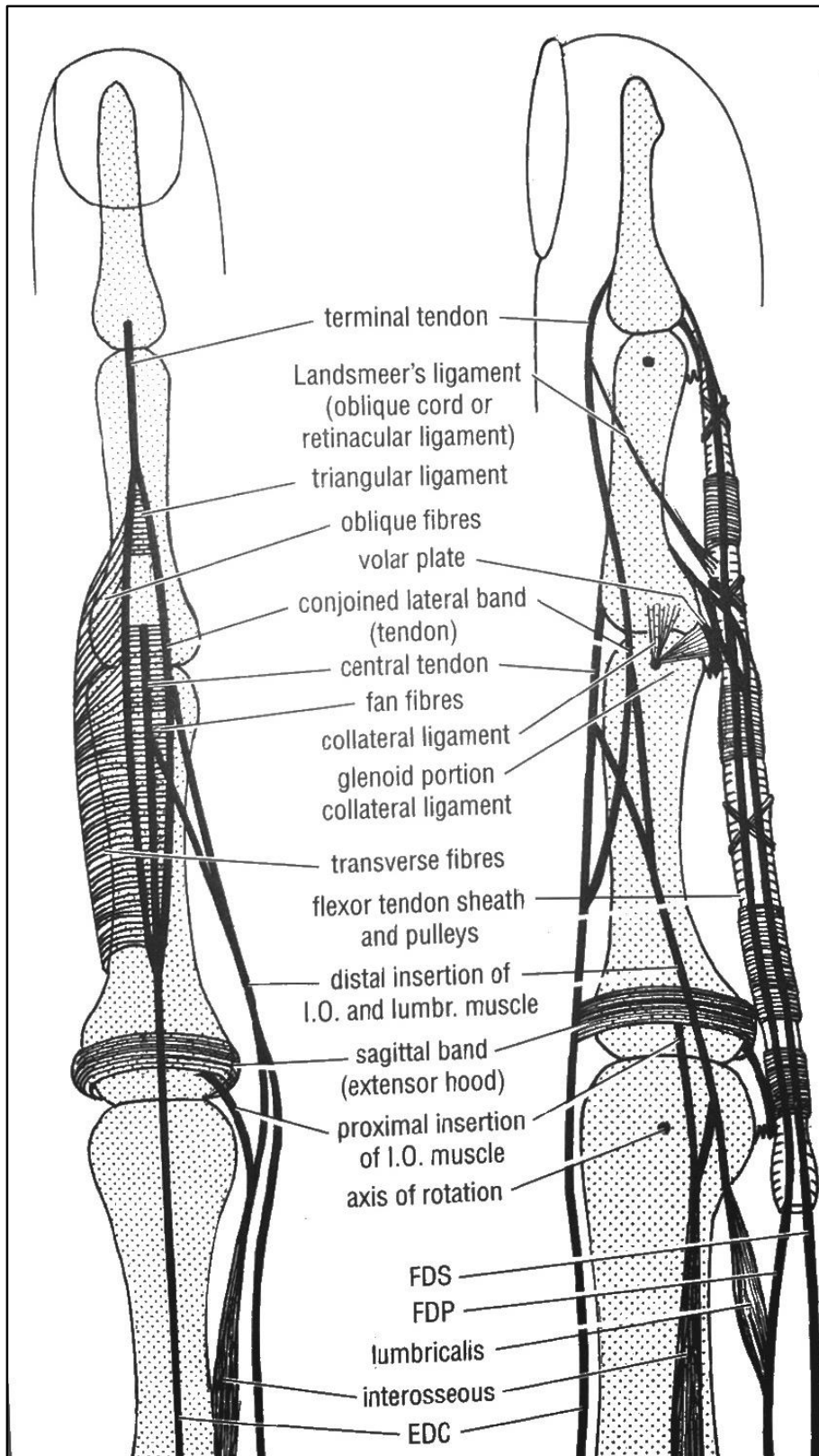
An internet based search was performed using PubMed. These and any relevant publications noted amongst the references of these articles were reviewed and used if applicable.

III. Introduction

Musculoskeletal conditions are the most common cause of long term pain and physical disability. It is estimated that 9.6% of men and 18.0% of women over the age of 60 years will suffer from symptomatic osteoarthritis. A study reporting on the prevalence of osteoarthritis of the hand found that 41% of patients over the age of 40 years had radiographic evidence of osteoarthritis of at least one joint in the hand.¹ It is estimated that in 18% of patients with osteoarthritis of the hand the proximal interphalangeal joint (PIPJ) will be involved.^{2,3} Osteoarthritis is characterized by loss of cartilage of synovial joints associated with hypertrophy of bone leading to osteophytes and subchondral sclerosis. This causes inflammation, pain, tenderness, decreased range of motion and crepitus. The joints most common affected are the knees, hips, spine and hand.⁴ These patients generally present with pain, loss of motion and deformity. In patients who have multiple fingers affected, the pain and loss of motion can lead to difficulty with performing activities of daily living and substantial disability.⁵ With increasing age, the prevalence of osteoarthritis of the hand increases significantly and in patients over 80 years of age 51.1% will have radiographic evidence of osteoarthritis of their PIPJ.¹ As life expectancy increases, the scale of the problem will continue to increase, as will the burden on health services.

Management of osteoarthritis of the PIPJ is very challenging because of the intricate anatomy of the finger. Normal function of the proximal interphalangeal joint depends on a

Figure 1: Complex anatomy of the finger⁶



FDS=Flexor digitorum superficialis, FDP=Flexor digitorum profundus, EDC=Extensor digitorum communis

very delicate balance between the bones, joint, volar plate, collateral ligaments, flexor tendons and extensor apparatus. The extensor apparatus in itself is a very delicately balanced structure.⁷ It is anchored at the Metacarpophalangeal joint through the extensor hood and then continues as a flat aponeurosis which divides into the central slip, inserting onto the base on the middle phalanx, and the lateral bands, inserting onto the base of the distal phalanx. The intrinsic hand muscles (palmar and dorsal interossei and lumbricales) and the ligaments from the retinacular system also insert on the extensor apparatus and play an important role in digital balance.⁸ Any insult to this system, whether caused by trauma, inflammation or surgery, could disturb this delicate balance and lead to stiffness or disturbances of digital balance such as swan neck deformities or boutonniere deformities.⁷

The different functions of each finger also plays a role in management. The index finger and middle finger are used for fine motor activities. This requires a stable pinch against the thumb. To achieve this the PIPJ of these fingers needs to have good lateral stability. The ring finger and little finger are important for grip strength, which requires good flexion at the PIPJ of these fingers.^{9, 10}

IV. Management of arthritis of the PIPJ

The primary treatment of osteoarthritis of the PIPJ is non-surgical. Most patients respond well to oral analgesia, non-steroidal anti-inflammatory drugs, activity modification and intra-articular cortisone injections.⁷ When non-surgical management fails, the surgical options are arthrodesis or arthroplasty.² The optimal surgical management of arthritis of the PIPJ remains an unsolved problem. Post-operative pain relief has been very good, but to date no implant has been found that consistently preserves PIPJ motion and stability while demonstrating long term durability.^{11, 12}

a) Arthrodesis

Before the introduction of arthroplasty, arthrodesis was the gold standard for management of arthritis of the PIPJ and some authors feel that it still remains the gold standard.¹³ Arthroplasty has a high complication rate⁹ and the proponents of arthrodesis feel that a reliable and durable arthroplasty solution for the PIPJ is still lacking. These authors state that a standard one-stage solution for the painful arthritic PIPJ remains an arthrodesis.³ Once fusion is achieved, arthrodesis provides a stable, painless joint.^{3, 14}

Even after the introduction of arthroplasty of the PIPJ, many authors feel that the stability required for a stable pinch in the index and middle fingers can only be provided by an arthrodesis^{9, 10} and in young active patients arthrodesis may be a better option for any of the fingers.⁵ Arthrodesis provides excellent pain relief, but at the cost of losing range of motion. In the ring and little fingers this is especially a concern as this has an influence on grip strength.

The stable, painless joint provided by arthrodesis does lead to more problems than just a loss of grip strength. The American Medical Association Impairment Guide associates a fusion of the PIPJ with a 50% loss in function of the finger.⁹ The quadriga effect is a concern in the middle, ring and little finger. This happens due to the specific anatomy of the flexor digitorum profundus which has a common muscle belly. Arthrodesis of one of these fingers can lead to decreased active flexion of the adjacent fingers. This is often not a problem in the index fingers which has its own muscle belly¹⁵, but a recent publication proves that arthrodesis of the index finger impairs the kinematics of precision pinch.¹⁴

Non-union can occur in up to 15% of cases and requires revision. Other complications are superficial or deep infection, dorsal skin necrosis, prominent hardware and malunion.¹⁶

The biggest concern with arthrodesis is the loss of range of motion.

b) Arthroplasty

The purpose of arthroplasty is to give pain relief while maintaining range of motion.¹⁷ The first attempts at arthroplasty was interposition of fat by Payr in 1914. In 1954 Carroll reported on a series of resection arthroplasties. Hinged implants were attempted by Brannon and Klein in 1959 and later by Flatt. None of these attempts were very successful and have been abandoned. In the 1960's Swanson introduced the silicone PIPJ arthroplasty.¹³ To date the Swanson Finger Joint Implant (Wright Medical Technology, Arlington, TN) remains the most commonly used arthroplasty device for the PIPJ,¹⁸ but it is still not recommended for the Index finger and middle finger due to a lack of lateral stability^{9, 10, 13}. This has led to the development of new arthroplasty implants that are minimally constrained, unlinked prostheses with preserved bone stock and intact collateral ligaments allowing a more physiological joint and providing lateral stability.^{15, 18} The most widely published newer implants are a pyrocarbon prosthesis and the Surface Replacement Cobalt Chrome (Co-Cr) on ultra-high molecular weight polyethylene (UHMWPE) implant which will be discussed in more detail later.

Indications for arthroplasty include patients with osteoarthritis, inflammatory arthritis and post traumatic arthritis with pain, stiffness, deformity or instability. Absolute contraindications include persistent infection, non-reconstructable extensor apparatus or flexor tendon, Charcot arthropathy, skin loss and unstable collateral ligaments. Relative contraindications include previous infection, dorsal or volar instability, trauma changing bony anatomy, arthritis mutilans, previous arthrodesis, silicone arthropathy and static swan neck or boutonnière deformities.^{19, 20}

1. Silicone arthroplasty

Silicone implants were introduced by Swanson in the 1960's.⁵ It remains the most widely used arthroplasty for the PIPJ.¹⁸ According to a Systematic Review by Chan et al²¹ the evidence states that Silicone implants remains the most appropriate arthroplasty for the PIPJ. They provide excellent pain relief, but with no significant improvement in range of motion.^{5, 22} Most patients accept the limited range of motion because they are pain free.²³

Bales et al⁵ reported on long-term results of Swanson Silicone arthroplasty. Despite an unchanged range of motion and radiographic evidence of fracture, patients reported good pain relief and satisfaction. The 10 year survival was 90%. Lack of lateral stability remains an issue in especially the index finger which needs good lateral stability for pinch.⁵

Daecke et al²² in a prospective randomized trial compared surface replacement arthroplasty with silicone arthroplasty and even though the surface replacements groups showed a temporary superior range of motion, the silicone group showed a lower complication and revision rate.

Branam et al¹¹ compared pyrocarbon implants to silicone implants in a retrospective review. Their results showed no superiority of the newer pyrocarbon implant above the silicone implant.

Other complications specific to silicone include implant fracture (5% to 30%) and silicone synovitis²⁴ which can be seen in up to 10% of cases.¹³ Despite radiological abnormalities, most patients are satisfied with their outcomes.⁵

Silicone arthroplasty provides excellent pain relief with good patient satisfaction. The main concern remains the lack of lateral stability in especially the index finger. Despite the development of newer implants, some authors would still recommend silicone as their implant of choice for the middle and ring fingers.¹³

2. Pyrocarbon arthroplasty

The pyrocarbon implant was introduced in 2000. It consists of a graphite core coated with pyrocarbon. Pyrocarbon has a modulus of elasticity similar to cortical bone and low wear rates. It is a semi-constrained press-fit implant that requires no cement fixation. It cannot osteointegrate and as a result a high proportion of these implants migrate in the medullary canal, but usually settle in a stable position.²

In 2011 Sweets and Stern²⁵ published a retrospective series of 31 pyrocarbon arthroplasties that they had performed. The average follow up was 55 months. They observed a total of 66 complications in 28 joints and only 3 joints were complication free. At initial follow up the range of motion had improved from the pre-operative range, but at final follow up there was a significant decrease in motion when compared to the pre-operative values. Radiological signs of loosening were noted in 48% of the implants. Due to their results they are not using this implant anymore.

Branam et al¹¹ performed a retrospective review comparing Silicone implants to pyrocarbon implants. They found similar post-operative range of motion, pain relief and rate of complications in both groups. At time of publication no pyrocarbon implants had been revised versus three silicone implants.

McGuire et al² published a retrospective review of 57 pyrocarbon implants. They found excellent pain relief and a significant increase in range of motion. The complication rate was fairly high, but most were minor complications and did not require further treatment. A high subsidence rate was noted (40%), but this did not appear to affect motion or function. This study will be discussed in more detail later as it forms the basis of the current study.

Complications specific to pyrocarbon implants is subsidence due to the lack of osteointegration and squeaking.

3. Co-Cr on UHMWPE Surface Replacement arthroplasty

This implants consists of a Co-Cr proximal component and a UHMWPE distal component. It has an anatomic design with a bicondylar configuration. It relies on intact collateral ligaments, extensor apparatus, retinacular ligaments and soft tissue envelope for stability and is more physiological.^{15, 26} It can be inserted as an uncemented press fit implant or a cemented implant.

Linscheid et al¹⁵ introduced the surface replacement arthroplasty in 1997. Their number of complications were significant, but the poor results occurred primarily in cases with previous extensive injuries or static deformities. All implants were cemented and component loosening was seen in only one (out of 66) implants. Most of their problems after surgery were related to the soft tissues. They found little change in individual results after a year.

Figure 2: *The Co-Cr on UHMWPE Surface Replacement implant²⁷*



In 2012 Murray and Linscheid et al²⁰ published the long term follow up of 67 surface replacement arthroplasties in 47 patients. They performed cemented and uncemented implants and at an average follow up of 8.8 years had an 88% survival of the implant. Eight

joints had radiolucency around the implant, but only one had frank signs of loosening. Fourteen patients had a total of 22 complications. The index finger and middle finger did not show a higher failure rate and there was no difference in failure rate between the cemented and uncemented group, but the cemented group did show better functional results.

Amirtharajah et al¹⁰ reported on a series of 18 cemented implants. They noted an improvement in range of motion, function and pain relief. The most striking feature was subsidence noted in 7 out of 11 joint with a one year follow up. They have not had to revise any of these cases, which means it could represent stable settling or the follow up is too short.

Luther and German²⁸ published a series of 24 arthroplasties using a press-fit technique. They had a 58% reoperation rate, mostly due to extensor tendon adhesions. Five (20.8%) showed radiological signs of migration or loosening. They recommend using this implant in the index and middle finger.

Jennings et al²⁹ performed a retrospective review of 43 implants in 25 patients with an average follow up of 37 months using a press-fit technique in some patients and cement in others. Radiological signs of loosening was seen in 19.8% of cases. Of the eleven revisions, ten were due to loosening and all of these cases were uncemented. Results were poorer in the inflammatory arthritis and post traumatic group. They also recommend arthroplasty for the index finger.

Johnstone et al²⁷ compared cemented to uncemented implants. They noted subsidence in 4% of the cemented implants, but in 64% of the uncemented implants. Most of the problems were noted in younger patients.

4. Complications and outcomes of PIPJ Arthroplasty

Complications specific to each implant has been discussed, therefore this section will focus on general complications. In a meta-analysis on PIPJ arthroplasty⁹ it was found that the complication rate was high with a rate of 28% at one year. Except for loosening and migration, which varies vastly between the different studies, most complications are related to the surgical approach and soft tissue problems, especially the extensor apparatus^{9, 17, 28} (surgical approaches will be discussed in more detail later).

The soft tissue complications include extensor tendon adhesions with stiffness, swan neck deformities, extensor mechanism failure, volar plate contractures and flexor tendon adhesions with fixed flexion deformities.^{17, 28} Other complications include heterotopic ossification, bony spurs and infection.

Figure 3: Radiographs demonstrating loosening and subsidence in pyrocarbon implants on the left and well-fixed cemented Co-Cr on UHMWPE implants on the right with no subsidence



The best outcomes are to be expected in primary osteoarthritis^{9, 15, 29} and patients without static deformities.²⁶ The results seem to stabilise after one year and patients can expect to have little improvement or deterioration after a year.^{9, 27} Pain relief is excellent^{9, 13, 26} and grip strength demonstrated a substantial improvement.⁹ Most studies show that there will be very little improvement in range of motion and pre-operative range of motion will determine post-operative range of motion.^{9, 27, 29} Better outcomes are seen in cemented implants (when Surface Replacement Arthroplasty is performed)^{20, 29} and when surgery is performed through a dorsal approach.^{20, 29} There are very few studies with long term follow up, but in a series on surface replacement arthroplasty they had an 88% survival at an average follow up of 8.8 years and an estimated 16% failure rate at 15 years.²⁰ Long term follow up of silicone implants yielded a 90% survival at average 10 years.⁵

V. Surgical approaches to the PIPJ

The three surgical approaches used for arthroplasty of the PIPJ are the dorsal approach, the volar approach and the midlateral approach.

The dorsal approach is the most widely used and authors who have used different approaches have better results with the dorsal approach.^{20, 27} Once the dorsal skin incision has been made, the joint can be accessed through three different approaches. The first is

the Chamay approach where the extensor mechanism is elevated through a distally based triangular flap, leaving the central slip intact. The second is a central slip reflecting approach in which the central slip is detached off the middle phalanx and reattached after insertion of the prosthesis. Lastly, the extensor tendon is split longitudinally and reflected to both sides of the finger. The central slip is reattached to the base of the middle phalanx with bone sutures after insertion of the prosthesis.^{17, 19} The extensor tendon splitting approach have the best results and is the most versatile.^{17, 29} The dorsal approach causes an insult to the extensor mechanism which can lead to tendon adhesions causing stiffness and an imbalance leading to swan neck deformities.¹⁷

With the volar approach the C1, A3 and C2 pulleys of the flexor tendon sheath is reflected and the flexor tendon pulled to one side. The distal insertion of the volar plate is then reflected off the base of the middle phalanx and repaired once the prosthesis has been inserted.¹⁵ This approach can cause flexor tendon adhesions with stiffness and fixed flexion deformities. Incompetence of the volar plate can lead to swan neck deformities.

The midlateral approach uses a lateral incision and detachment of the collateral ligament, which needs to be repaired after insertion of the prosthesis.¹⁵ This approach violates the collateral ligament and the neurovascular bundles are more at risk than with the other approaches. Correct positioning of the prosthesis is more challenging.

VI. Rationale for this study

In 2012 McGuire et al² from the Martin Singer Hand Unit at Groote Schuur Hospital published an article on a cohort of 57 Pyrocarbon PIPJ replacements. Their results showed excellent pain relief, a significant improvement in range of motion and very good patient satisfaction. The major concerns were that subsidence, which was noted in 40% of the joints, and a high complications rate (42.1%). They did not notice a correlation between subsidence and range of motion and they felt most complications were minor, but the senior author felt that the subsidence rate and complication rate was too high. After similar reports from other authors, who had even worse results with pyrocarbon²⁵, he decided to change from pyrocarbon implants to cemented Co-Cr on UHMWPE implants. The aim of this study is to determine whether his change in practice did lead to less subsidence and less complications.

VII. Quality Criteria

The following steps will be taken to ensure the quality of the research:

1. All patients, with adequate follow up, who had a surface replacement arthroplasty performed by the senior researcher will be included in an attempt to avoid selection bias.
2. Patient records will be thoroughly scrutinised to ensure that all relevant information is used.

3. Where post-operative follow up is inadequate, patients will be asked to return for a final follow up for clinical assessment and final follow up radiographs.
4. All post-operative x-rays will be reviewed by two of the researchers to assess subsidence.
5. The patients will be contacted to report on their satisfaction on a standardised satisfaction scale.
6. Parameters reviewed, will be kept similar to the previous study from our unit to be able to assess whether the change in practice has led to improved patient outcomes.
7. The results of this study will be submitted to a peer reviewed journal.
8. None of the researchers will have any financial or other interests vested in the outcome of this study.

VIII. References

1. Wilder FV, Barrett JP, Farina EJ. Joint-specific prevalence of osteoarthritis of the hand. *Osteoarthritis Cartilage*. 2006;14(9):953-7.
2. McGuire DT, White CD, Carter SL, Solomons MW. Pyrocarbon proximal interphalangeal joint arthroplasty: outcomes of a cohort study. *The Journal of hand surgery, European volume*. 2012;37(6):490-6.
3. Capo JT, Melamed E, Shamian B, Hadley SR, Ng Lai W, Gerszberg K, et al. Biomechanical evaluation of 5 fixation devices for proximal interphalangeal joint arthrodesis. *The Journal of hand surgery*. 2014;39(10):1971-7.
4. Woolf A, Pfleger B. Burden of Major Musculoskeletal Conditions. *Bulletin of the World Health Organization*. 2003;81(9):646-56.
5. Bales JG, Wall LB, Stern PJ. Long-term results of Swanson silicone arthroplasty for proximal interphalangeal joint osteoarthritis. *The Journal of hand surgery*. 2014;39(3):455-61.
6. Mennen U, Van Velze C. The basic anatomy of digital balance. In: Mennen U, Van Velze C, editors. *The Hand Book*. Third ed. Pretoria: Van Schaik Publishers; 2008. p. 39.
7. Bernstein R. Arthritis of the thumb and digits: current concepts. *Instr Course Lect*. 2015;64:281-94.
8. Rongieres M. Surgical treatment of degenerative osteoarthritis of the fingers. *Chir Main*. 2013;32(4):193-8.
9. Adams J, Ryall C, Pandyan A, Metcalf C, Stokes M, Bradley S, et al. Proximal Interphalangeal Joint Replacement in patients with arthritis of the hand. A meta-analysis. *J Bone Joint Surg Br*. 2012;94(10):1305-12.
10. Amirtharajah M, Fufa D, Lightdale N, Weiland A. Clinical, Radiographic, and patient-reported results of surface replacing proximal interphalangeal joint arthroplasty of the hand. *Iowa Orthop J*. 2011;31:140-4.
11. Branam BR, Tuttle HG, Stern PJ, Levin L. Resurfacing arthroplasty versus silicone arthroplasty for proximal interphalangeal joint osteoarthritis. *The Journal of hand surgery*. 2007;32(6):775-88.
12. Amadio PC. What's new in hand surgery. *The Journal of bone and joint surgery American volume*. 2010;92(3):783-9.
13. Sweets TM, Stern PJ. Proximal interphalangeal joint prosthetic arthroplasty. *The Journal of hand surgery*. 2010;35(7):1190-3.
14. Domalain M, Evans PJ, Seitz WH, Jr., Li ZM. Influence of index finger proximal interphalangeal joint arthrodesis on precision pinch kinematics. *The Journal of hand surgery*. 2011;36(12):1944-9.

15. Linscheid RL, Murray PM, Vidal M, Beckenbaugh RD, Rochester MN. Development of Surface Replacement Arthroplasty for Proximal Interphalangeal Joints. *J Hand Surg* 1997;22A:286-98.
16. Satteson ES, Langford MA, Li Z. The Management of Complications of Small Joint Arthrodesis and Arthroplasty. *Hand clinics*. 2015;31(2):243-66.
17. Pritsch T, Rizzo M. Reoperations following proximal interphalangeal joint nonconstrained arthroplasties. *The Journal of hand surgery*. 2011;36(9):1460-6.
18. Murray PM. New-Generation Implant Arthroplasties of the Finger Joints. *J Am Acad Orthop Surg*. 2003;11:295-301.
19. Rizzo M, Beckenbaugh RD. Proximal Interphalangeal Joint Arthroplasty *J Am Acad Orthop Surg*. 2007;15(3):189-97.
20. Murray PM, Linscheid RL, Cooney WP, Baker V, Heckman MG. Long-Term Outcomes of Proximal Interphalangeal Joint Surface Replacement Arthroplasty. *The Journal of bone and joint surgery American volume*. 2012
94:1120-8.
21. Chan K, Ayeni O, McKnight L, Ignacy TA, Farrokhyar F, Thoma A. Pyrocarbon versus silicone proximal interphalangeal joint arthroplasty: a systematic review. *Plastic and reconstructive surgery*. 2013;131(1):114-24.
22. Daecke W, Kaszap B, Martini AK, Hagen FW, Rieck B, Jung M. A prospective, randomized comparison of 3 types of proximal interphalangeal joint arthroplasty. *The Journal of hand surgery*. 2012;37(9):1770-9 e1-3.
23. Herren DB, Keuchel T, Marks M, Schindele S. Revision arthroplasty for failed silicone proximal interphalangeal joint arthroplasty: indications and 8-year results. *The Journal of hand surgery*. 2014;39(3):462-6.
24. Drake ML, Segalman KA. Complications of small joint arthroplasty. *Hand clinics*. 2010;26(2):205-12.
25. Sweets TM, Stern PJ. Pyrolytic carbon resurfacing arthroplasty for osteoarthritis of the proximal interphalangeal joint of the finger. *The Journal of bone and joint surgery American volume*. 2011;93(15):1417-25.
26. Johnstone BR. Proximal interphalangeal joint surface replacement Arthroplasty. *Hand Surg*. 2001;6(1):1-11.
27. Johnstone BR, Fitzgerald M, Smith KR, Currie LJ. Cemented versus uncemented surface replacement arthroplasty of the proximal interphalangeal joint with a mean 5-year follow-up. *The Journal of hand surgery*. 2008;33(5):726-32.
28. Luther C, Germann G, Sauerbier M. Proximal Interphalangeal Joint Replacement with Surface Replacement Arthroplasty (SR-PIP): Functional Results and Complications. *Hand*. 2010;5(3):233-40.
29. Jennings CD, Livingstone DP. Surface replacement arthroplasty of the proximal interphalangeal joint using the PIP-SRA implant: results, complications, and revisions. *The Journal of hand surgery*. 2008;33(9):1565 e1-11.

Part C

Manuscript

Publication-ready format

This research will be submitted to ‘The Journal of Hand Surgery (European Volume)’.

The structure of the manuscript as well as referencing is as set out in their submission guidelines. Therefore the title page, manuscript and tables and figures are in the format required for publication in the journal.

The full guidelines can be found in ‘Part D – Appendices’.

Surface Replacement Proximal Interphalangeal joint (SR-PIPJ) arthroplasty – A CASE SERIES

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Keywords

Surface replacement, Proximal Interphalangeal Joint Arthroplasty, Pyrocarbon, Silicone, Arthritis

Conflict of Interests

None

Funding

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Ethical Approval

This research was approved by the University of Cape Town Department of Surgery Research committee (2014/032) and the University of Cape Town Faculty of Health Sciences Ethics Committee (HREC/REF: 325/2014).

Surface Replacement Proximal Interphalangeal joint (SR-PIPJ) arthroplasty – A CASE SERIES

ABSTRACT

Surface replacement (SR) proximal interphalangeal joint replacement consists of a cobalt-chrome alloy component articulating with an ultra-high molecular weight polyethylene component. After experiencing a high rate of subsidence and complications with a pyrocarbon implant, our unit has changed to the cemented SR system in the hope of decreasing these complications. The main aim of this study was to determine whether this change in practice has led to a decrease in subsidence and complications. A retrospective chart review was performed including 43 joints in 28 patients. Subsidence was noted in 26% of the joints and complications in 31% of the joints. Even though subsidence remains a problem, the change in implant has led to a decrease in subsidence and other complications.

Level of evidence: Level 4

INTRODUCTION

The Swanson Finger Joint implant (Wright Medical Technology) is the most commonly used Proximal Interphalangeal Joint (PIPJ) Arthroplasty implant (Murray, 2003) and some authors regard it as the most appropriate implant to use (Chan et al., 2013). Lateral stability remains an issue, especially in the index finger and middle finger where stability is important for pinch (Amirtharajah et al., 2011). Some authors (Sweets et al., 2010) therefore still recommend arthrodesis for the index finger. This has led to the development of the surface replacement arthroplasty for the PIPJ which relies on the intact collateral ligaments, bicondylar configuration and soft tissue envelope around the PIPJ to provide lateral stability (Linscheid et al., 1997; Johnstone et al., 2008). At least two types of surface replacement arthroplasty are currently being used: An uncemented pyrocarbon implant and a Cobalt-Chrome (Co-Cr) on Ultra High Molecular Weight Poly-ethylene (UHMWPE) implant which can be cemented or uncemented. In 2012 our institution reported on a series of 57 uncemented Pyrocarbon PIPJ implants (McGuire et al., 2012). The major concern was that subsidence was observed in 40% of the joints. Sweets and Stern noted radiological signs of loosening in 48% of their pyrocarbon implants and stopped using this implant (Sweets et al., 2011). Importantly, Johnstone compared cemented versus uncemented SR implants and noted subsidence in 68% of the uncemented group and in only 4% of the cemented group (Johnstone et al., 2008).

The 40% subsidence noted in the pyrocarbon series and the results from these other authors, led our senior author to change his practice for PIPJ arthroplasty from an uncemented pyrocarbon implant to a cemented Co-Cr on UHMWPE implant. The surgical approach and post-operative rehabilitation remained unchanged.

The aim of this study was to determine whether the change to a cemented Co-Cr on UHMWPE would lead to an improvement in subsidence rates as well as other complications.

METHODS

We performed a retrospective chart review of all patients who had a cemented Co-Cr on UHMWPE surface replacement arthroplasty of the PIPJ performed from 2011 to 2013 with at least 12 month follow up.

The surgical approach and post-operative rehabilitation remained the same as in the pyrocarbon series, but we will outline the important aspects. All surgeries were performed by the senior author.

A dorsal approach with an extensor tendon splitting technique was performed. The central slip is split and sharply dissected off the middle phalanx. A small power saw is used to perform the bony resection of the articular surface of the proximal phalanx and middle phalanx. Care is taken to preserve the dorsal lip of the middle phalanx for later anatomic reattachment of the extensor. The collateral ligaments are preserved. The intramedullary canal of the proximal and middle phalanx is opened with an awl. A trial prosthesis is inserted to confirm the correct size. Before insertion of the definitive prosthesis a drill hole is made in the dorsum of the base of the middle phalanx and sutures passed through it for attachment of the central slip. The prosthesis is cemented into position. The central slip is reattached to the middle phalanx with a suture passed through a drill hole. After skin closure a bulky dressing is applied with a dorsal slab. The metacarpophalangeal joints (MCPJ) are held in 70° flexion and the interphalangeal joints (IPJ) in extension.

At four to five days post-operatively the plaster slab is removed and exchanged for a hand based dorsal thermoplastic splint. The splint keeps the MCPJ in 70° of flexion and the PIPJ in 15° of flexion. The patient is encouraged to flex to 45° in the first week and 60° in the second week. After the second week unrestricted active flexion is allowed. No passive flexion is allowed for the first 4 weeks. After 2 weeks the splint is only used at night.

The following data were recorded: Age, gender, finger involved, indication for surgery, pre-operative range of motion, range of motion at final follow up, time to final follow up, patient satisfaction,

complications, presence or absence of subsidence on final follow up x-ray and any secondary surgery. Patient satisfaction was recorded according to a Likert scale (See table 1). Subsidence was regarded as any change in position of the implant in relation to the bone when comparing the first post operative x-ray to the x-ray at final follow up.

Table 1: Likert scale used to assess patient satisfaction

The primary aim of the study was to determine whether the change from an uncemented Pyrocarbon to a Cemented Co-CR on UHMWPE implant would lead to an improvement in subsidence rates. The secondary aim was to determine the complication rate.

Statistical analysis

Statistical analysis was performed using the Student t-test. Statistical significance was defined as $p < 0.01$.

RESULTS

Fifty two replacements were performed in this time, of which 43 replacements, in 28 patients, had a 12 month follow up. Final follow up x-rays were obtained in 34 joints. There were three male patients and 24 female patients. The mean age was 59.5 (range 51 – 80) years. The mean follow up was 26.5 (range 14 – 41) months. The ring finger was the most commonly operated finger, with 14 replacements, followed by the middle finger with 12 replacements, the index finger with 11 replacements and the little finger with five replacements. The indication for replacement was primary osteoarthritis in 38 fingers, post traumatic arthritis in three fingers and inflammatory arthritis in one finger.

Range of motion

Post operative range of motion was obtained for all 43 fingers, but pre-operative range of motion was only available for 37 fingers. Average range of motion was calculated for these 37 fingers.

The average pre-operative range of motion was 13.7° (range 0° - 60°) to 58.6° (range 25° - 80°) with an arc of motion of 44.9°. The average post operative range of motion was 5.7° (range 10° - 80°) to 67° (range 0° - 100°) with an arc of motion of 61.3°. The improvement in arc of motion was not statistically significant (p=0.02).

Figure 1: Range of motion

Patient Satisfaction

Patient satisfaction was measured according to a five point Likert scale. The average satisfaction was 3.3 out of 5. Figure 2 has the complete patient satisfaction results. Seven of the ten patients with a satisfaction score of one, were living far away.

Figure 2: Patient Satisfaction

Complications

The total number of fingers with complications were 13 (31%), which included stiffness, swan neck deformities, fixed flexion deformities and a cement loose body.

Stiffness was encountered in eight fingers. Any patient with an arc of motion of less than 30 degrees was regarded as being stiff. The indication in one of the patients was post traumatic arthritis and the patient had a poor range of motion pre-operatively already. An extensor tenolysis and capsulotomy were performed in two patients of which one had a very good result and the other patient progressed to a stiff swan neck deformity. One patient had loosening noted and had a revision performed with no improvement in range of motion with loosening noted again on final follow up x-

ray. One patient was a revision from a pyrocarbon implant. The other patients with stiffness were satisfied with their result and has had no further surgery.

Three fingers developed a swan neck deformity after the initial arthroplasty. Two were successfully managed with splinting and one is awaiting surgery for a flexor digitorum superficialis tenodesis.

A fixed flexion deformity occurred in one patient. This was managed with a surgical release, but the deformity recurred.

One patient had a cement loose body which was successfully removed.

Subsidence

We classified subsidence as any change of the position of the implant in relation to the bone when comparing the initial post operative x-ray to the final follow up x-ray. Subsidence was noted in nine (26%) joints. Of the nine joints, four were in the index finger, three in the middle finger and two in the ring finger. This group's average range of motion was 1° to 29° (arc 28°) compared to the 4.2° to 69.1° (arc 64.9°) of the group without subsidence (n=25) This difference in ROM was statistically significant (p=0.003). Their average satisfaction was 1.6 compared to 4 of the group without subsidence (p=0.001).

DISCUSSION

In 2010 Amadio said that PIPJ arthritis remains an unsolved problem. Results in terms of restoration of motion and durability has been disappointing, but post operative pain relief has been good (Amadio, 2010). The SR PIPJ replacment was developed to provide a more stable implant by retaining the collateral ligaments (Linscheid et al., 1997). This provides an alternative to arthrodesis in especially the index finger where the silicone implants have failed to provide enough stability (Amirtharajah et al., 2011). A number of authors have published on their experiences with SR PIPJ implants, but the main purpose of this study was to determine whether the change from pyrocarbon

to cemented Co-Cr on UHMWPE at our institution would improve our results in terms of specifically subsidence and complications (McGuire et al., 2012).

There were 43 replacements with a mean age of 59.5 years and mean follow up of 26.5 months. The most common indication by an overwhelming majority was primary osteoarthritis. This compares well with McGuire et al who had 57 implants with a mean age of 61 years and mean follow up of 27 months and with their most common indication being osteoarthritis (McGuire et al., 2012).

There was an improvement in range of motion, but this was not statistically significant. This differs from McGuire et al who found an extremely significant improvement in range of motion. Our results are similar to other authors who found only a small or no increase in range of motion (Sweets et al., 2010; Adams et al., 2012). Johnstone et al (Johnstone et al., 2008) and Johnstone (Johnstone, 2001) found that post operative range of motion will be determined by pre-operative range of motion and therefore a large improvement in motion should not be expected.

Figure 3

The average patient satisfaction was 3.3, which is not as good as McGuire et al. who had an average score of 4.2 (we used the same satisfaction score). A score of 3.3 does however equate to a satisfied patient with a result as expected. When looking only at patients with no radiological signs of subsidence, the average satisfaction score does improve to 4. Interestingly, seven of the ten patients with a satisfaction score of one were living far away. We can only speculate, but this may be due to a decreased number of post operative follow up visits or lack of sufficient post operative rehabilitation. This should be discussed with patients pre-operatively and plans should be made to address this.

In a meta-analysis on PIPJ replacements it was noted that 28% of all replacements were associated with at least one complication in the first 12 Months (Adams et al., 2012). Linscheid also noted a significant number of complications (Linscheid et al., 1997). The number (31%) and type of

complications we found are similar to what the literature suggest. There was however an improvement in complications when compared to the pyrocarbon series (McGuire et al., 2012) who found complications in 42% of their cases. We did not expect to see an improvement in complications as the surgical approach remained the same. Complications are mostly related to surgical approach rather than implant as it is related to soft tissue (especially the extensor mechanism) problems (Linscheid et al., 1997;Luther et al., 2010;Pritsch et al., 2011). This explains why stiffness and swan neck deformities were the most common complications. Herren et al stated, most patients accept their limited range of motion, because they are satisfied with being pain free (Herren et al., 2014).

Subsidence in our series was seen in 26% of joints, which is an improvement when compared to McGuire et al who noticed subsidence in 40% of joints. They did not see a correlation between subsidence and range of motion and regarded the subsidence as settling into a stable position (McGuire et al., 2012). This is in contrast to what we found. The group with subsidence had a statistically significant decrease in arc of motion ($p=0.003$) as well as satisfaction score ($p=0.001$).

Figure 4

Our subsidence rates does not compare well to other authors who have used cemented prostheses.

In a retrospective review by Amirtharajah at one year follow up of 18 SR PIP joints, which were all cemented, seven of the eleven patients (64%) with serial radiographs showed signs of subsidence (Amirtharajah et al., 2011).

Jennings and Livingstone performed a retrospective review of 43 surface replacement arthroplasties (PIP-SRA implant)in 25 patients with an average follow up of 37 months. Two of the 45 (4%) cemented components loosened and 16 of the 41 (39%) of the uncemented components loosened. Eleven (26%) of their joints were revised, of which most were due to loosening. All of these were uncemented and nine of them were high demand patients (Jennings et al., 2008).

Johnstone et al performed a retrospective review comparing cemented to uncemented surface replacement implants. They noted subsidence in only 4% of the cemented group (n=24) and in 68% of the uncemented group (n=19) (Johnstone et al., 2008).

In a long term follow up (average 8.8 years) by Murray et al of 67 joints (SR PIP implant), a radiolucency was noted in 12% of joints and frank loosening in only one joint. They found no difference between cemented and uncemented implants in terms of failure, but found better functional outcomes in the cemented group. The rate of failure was not higher in the index finger or middle finger (Murray et al., 2012)

Luther et al in a series of uncemented implants recommends PIPJ replacements for the index and middle finger (Luther et al., 2010).

Our numbers are too small to be significant, but of the nine joints with subsidence, seven were in either the index finger or middle finger.

In 2014 Amadio (Amadio, 2014) said that he PIPJ constantly challenges the hand surgeon, but: “Progress is clearly being made. But it seems that we can expect future episodes in the ongoing saga of the PIP joint in future editions of this report.”

Even once the perfect prosthesis has been found, soft tissue balance around the PIP joint will still remain a major challenge.

CONCLUSION

The change from pyrocarbon to cemented Co-Cr on UHMWPE has resulted in satisfied patients without a significant improvement in range of motion. It has resulted in less complications and a decrease in the number of joints with subsidence. The rate of subsidence, however, is still high and work will continue in an attempt to improve this.

REFERENCES

- Adams J, Ryall C, Pandyan A, Metcalf C, Stokes M, Bradley S, Warwick DJ. Proximal Interphalangeal Joint Replacement in patients with arthritis of the hand. A meta-analysis. *J Bone Joint Surg Br* 2012, **94**: 1305-1312.
- Amadio PC. What's new in hand surgery. *J Bone Joint Surg Am* 2010, **92**: 783-789.
- Amadio PC. What's new in hand surgery. *J Bone Joint Surg Am* 2014, **96**: 522-526.
- Amirtharajah M, Fufa D, Lightdale N, Weiland A. Clinical, Radiographic, and patient-reported results of surface replacing proximal interphalangeal joint arthroplasty of the hand. *Iowa Orthop J*, 2011, **31**: 140-144.
- Chan K, Ayeni O, McKnight L, Ignacy TA, Farrokhyar F, Thoma A. Pyrocarbon versus silicone proximal interphalangeal joint arthroplasty: a systematic review. *Plast Reconstr Surg* 2013, **131**: 114-124.
- Herren DB, Keuchel T, Marks M, Schindele S. Revision arthroplasty for failed silicone proximal interphalangeal joint arthroplasty: indications and 8-year results. *J Hand Surg Am* 2014, **39**: 462-466.
- Jennings CD, Livingstone DP. Surface replacement arthroplasty of the proximal interphalangeal joint using the PIP-SRA implant: results, complications, and revisions. *J Hand Surg Am* 2008, **33**: 1561-1511.
- Johnstone BR. Proximal interphalangeal joint surface replacement Arthroplasty. *Hand Surg* 2001, **6**: 1-11.

Johnston BR, Fitzgerald M, Smith KR, Currie LJ. Cemented versus uncemented surface replacement arthroplasty of the proximal interphalangeal joint with a mean 5-year follow-up. *J Hand Surg Am* 2008, **33**: 726-732.

Linscheid ML, Murray PM, Vidal M, Beckenbaugh RD, Rochester MN. Development of Surface Replacement Arthroplasty for Proximal Interphalangeal Joints. *J Hand Surg* 1997. **22A**: 286-298.

Luther C, Germann G, Sauerbier M. Proximal Interphalangeal Joint Replacement with Surface Replacement Arthroplasty (SR-PIP): Functional Results and Complications. *Hand (N Y)* 2010, **5**: 233-240.

McGuire DT, White CD, Carter SL, Solomons MW. Pyrocarbon proximal interphalangeal joint arthroplasty: outcomes of a cohort study. *J Hand Surg Eur* 2012, **37**: 490-496.

Murray PM. New-Generation Implant Arthroplasties of the Finger Joints. *J Am Acad Orthop Surg* 2003, **11**: 295-301.

Murray PM, Linscheid RL, Cooney WP, Baker V, Heckman MG. Long-Term Outcomes of Proximal Interphalangeal Joint Surface Replacement Arthroplasty. *J Bone Joint Surg Am* 2012, **94**: 1120-1128.

Pritsch T Rizzo M. Reoperations following proximal interphalangeal joint nonconstrained arthroplasties. *J Hand Surg Am* 2011, **36**: 1460-1466.

Sweets TM, Stern PJ. Proximal interphalangeal joint prosthetic arthroplasty. *J Hand Surg Am* 2010, **35**: 1190-1193.

Sweets TM, Stern PJ. Pyrolytic carbon resurfacing arthroplasty for osteoarthritis of the proximal interphalangeal joint of the finger. *J Bone Joint Surg Am* 2011, **93**: 1417-1425.

Tables and figures

Table 1: Likert scale used to assess patient satisfaction

Score	Description
1	Unsatisfied/Would not want same procedure again
2	Less than expected/Would consider having same procedure again
3	Result as expected
4	Result better than expected
5	Fantastic result/Would recommend procedure

Figure 1: Range of motion

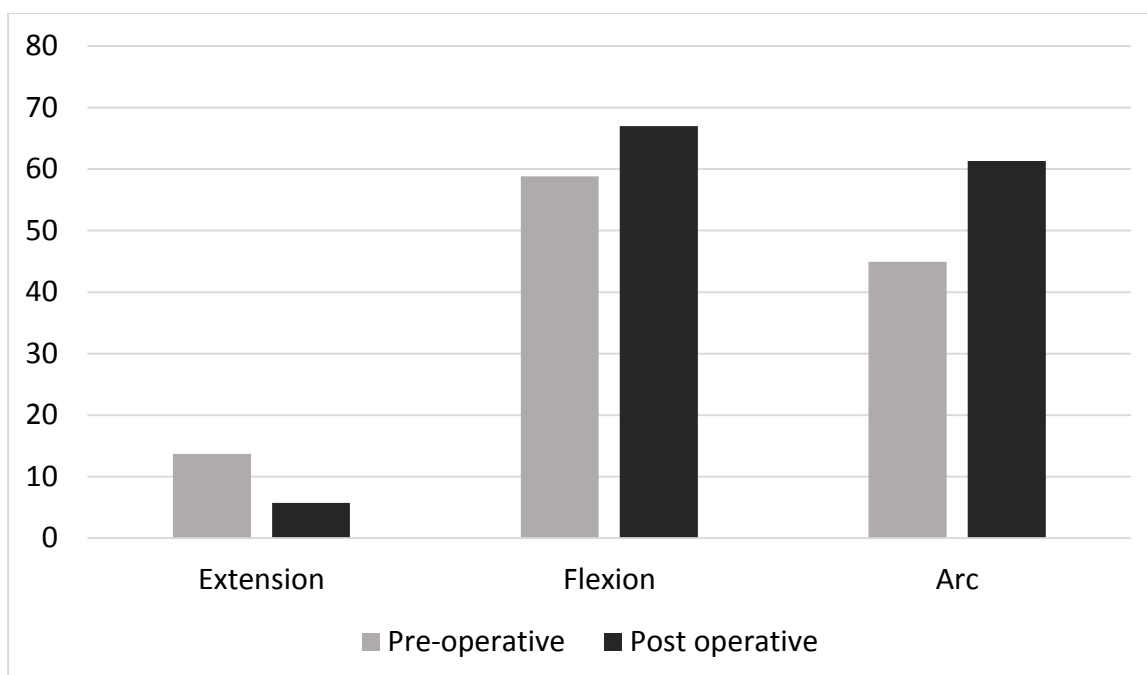


Figure 2: Patient Satisfaction

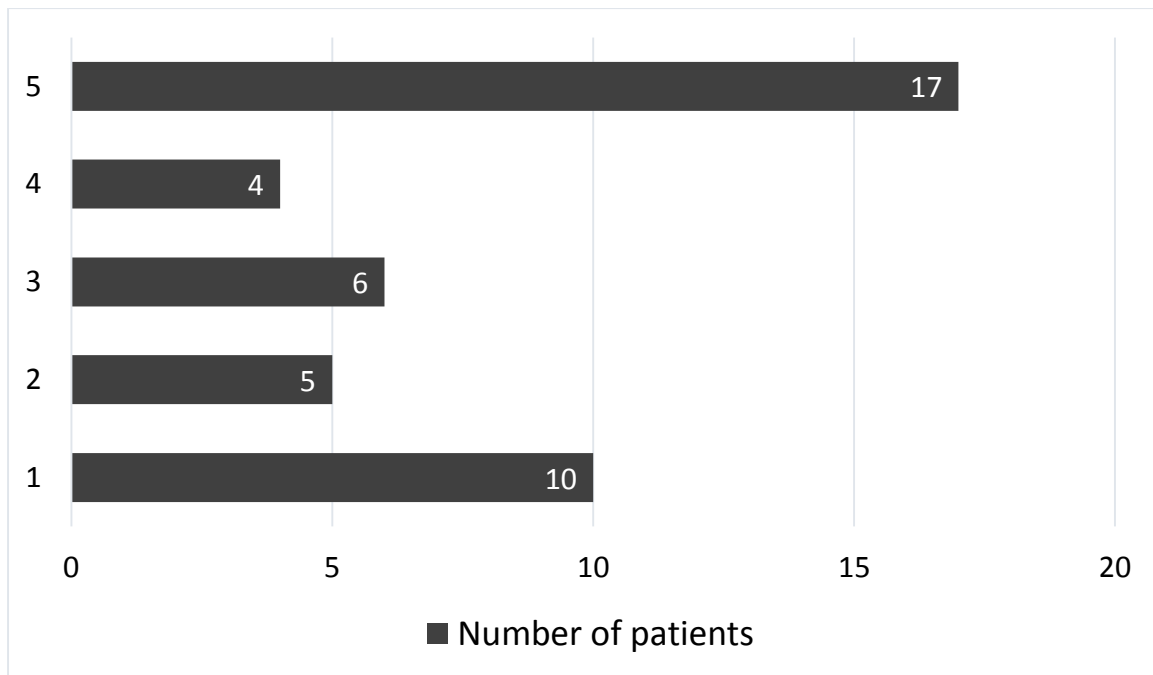


Figure 3: A patient who had all four of her PIP joints replaced. Her satisfaction score for each finger was 5 and ROM in each finger was 0° to 90°



Figure 4: X-ray of patient showing lucency around the distal component and migration of the proximal component of the index finger



Part D

Appendices

I. Acknowledgements

Description of roles played by each editor

Dr P W Jordaan: Principle investigator and primary author

Dr M Solomons: Supervisor and editor of final script

Dr D McGuire: Co-supervisor

II. Journal of Hand Surgery (European) Guidelines

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The Journal of Hand Surgery (European Volume)

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 - 2.2 Ethical standards
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 - 9.3.1 Style for scientific papers (excluding case reports)
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7. Acknowledgements

All contributors who do not meet the criteria for authorship should be listed under 'Acknowledgements' (see http://www.icmje.org/ethical_1author.html# for definition of authorship). Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a departmental chair who provided only general support. Place acknowledgments on the Title page only.

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Please include all funding information under a separate heading entitled “Funding” on the Title page only. For more information on the guidance for Research Funders, Authors and Publishers, please visit: <http://www.rin.ac.uk/funders-acknowledgement>

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9. Presentation

9.1 File types

Only electronic files conforming to the journal's guidelines will be accepted. The preferred format for the text and tables of your manuscript is Word and .jpg or .tif for figures. Please also refer to additional guidelines on submitting artwork [and supplemental files] below.

9.2 Manuscript Preparation

Word-process the text in double spacing with a margin of at least 3 cm all round. Left justify the text **and include line-numbers and page-numbers.**

Submit papers in Journal style. Failure to do so will result in return of the manuscript for correction and resubmission by the authors before it is sent out for review. Please refer to "Terminology for Hand Surgery" published by the International Federation of Societies for Surgery of the Hand (IFSSH) to ensure correct terminology is used: www.ifssh.info/TerminologyOfHandSurgery.html.

9.2.1 Keywords and Abstracts

The title, keywords and abstract are vital in ensuring that readers find your article online through search engines such as Google. Please refer to the information and guidance on how best to title your article, write your abstract and select your keywords by visiting SAGE's Journal Author Gateway Guidelines on [How to Help Readers Find Your Article Online](#).

9.2.2 Guidelines for submitting artwork, figures and other graphics

Submit electronic files of illustrations and figures. Preferred formats are .jpg or .tif. Pdf and PowerPoint files are not acceptable.

Line illustrations: All line illustrations should present a crisp black image on an even white background, and should be at a minimum of 600 dpi. Illustrations will be reduced in size during production and you must allow for this when choosing the size of any lettering.

Photographic illustrations and radiographs: Photographs and radiographs should be submitted as clear images at a resolution of at least 300 dpi for an image width of 10 cm. Submit radiographs as photographic images, carefully made to bring out the detail to be illustrated, with an overlay indicating the area of significance if necessary. Any lettering should be in capitals and of an appropriate size taking into account any necessary reduction in size of the illustration during production.

State the original magnification of microscopy images in the figure legend, or include a length guide on the image. Label all illustration files with a figure number.

Type figure legends, double spaced, in a separate section of the manuscript after the reference list. Number figures consecutively as they appear in the manuscript and ensure that all figures are referred to in the text. Keep legends brief, with no more than 40 words if possible.

For further guidance on the preparation of illustrations, pictures and graphs in electronic format, please visit SAGE's [Manuscript Submission Guidelines](#).

9.2.3 Guidelines for submitting supplemental files

The Journal is able to host approved supplemental materials online, alongside the full-text of articles. Supplemental files may be uploaded to Editorial Manager and will be subjected to peer-review alongside the article. For more information on copyright, acceptable formats and size, please refer to SAGE's [Guidelines for Authors on Supplemental Files](#).

9.2.4 English Language Editing

Non-English speaking authors who would like to refine their use of language in their manuscripts should have their manuscript reviewed by colleagues with experience of preparing manuscripts in English.

Alternatively it might be useful to consider using a professional editing service. Visit <http://www.sagepub.co.uk/authors/journal/submission.sp> for further information.

9.3 Journal Style

9.3.1 Style for scientific papers (excluding case reports)

Set out manuscripts as follows, starting each section on a separate page: title, abstract, main text, reference list, figure legends. You must also provide a separate Title page.

Title page: Give the following information: 1) title of article; 2) initials and surname of each author*; 3) name and address of the department(s) or institution(s) to which the work should be attributed, indicating which author is from where; 4) name, address, telephone numbers and email address of the corresponding author; 5) four to six keywords; 6) acknowledgements; 7) declaration of conflicting interests; 8) funding statement; 9) Ethical approval details (if required); 10) Details of informed consent (if required).

* There should be no more than six authors for a full paper and no more than three for a case/short report. All authors must have made a significant contribution to the work and must have read the manuscript before submission. The work of other contributors can be recorded

in the Acknowledgements, which should be included on the title page. See http://www.icmje.org/ethical_1author.html# for guidance on authors and contributors.

Abstract: Summarize the contents of the article in a single paragraph with no side-headings, not exceeding 150 words. State the purpose of the study, the basic procedures used, the main findings and principal conclusions. State the level of evidence at the end of the Summary (see chart at the end of this document). Do not include statistical significance values, abbreviations, footnotes or references.

Main text: The manuscript is usually split into sections under the headings Introduction, Methods, Results and Discussion. The use of other headings may be appropriate depending on the nature of the paper. Avoid excessive use of subheadings. Normally only two categories of headings should be used: type major headings (such as Methods, Results and Discussion) in capital letters in the centre of the page in **BOLD**; type minor headings in lower case (with an initial capital letter) at the left margin and **Bold**. Do not number headings.

In the manuscript please note:

Do not use "he", "his" etc where the sex of a person is unknown; use a non-gendered term such as "the patient". Do not refer to patients/participants as "subjects". Avoid claiming priority.

Proprietary (trade) names: Use non-proprietary names of drugs, suture materials, instruments etc. whenever possible. Give the proprietary name in brackets after the approved name and spell it with a capital letter followed by company name, city, state, country. For example, Axon BX-15 screw extruder (Axon, Åstorp, Sweden).

Abbreviations: Avoid abbreviations. If used, explain unusual abbreviations when they first occur in the text. Record the size of sutures as 2-0, 3-0 etc., not 2/0 etc.

Hyphens: The use of hyphens is subjective. However, do not use a hyphen for nonunion, malunion, interphalangeal, metacarpophalangeal, scapholunate, radiolunate or radioscapoid. It is acceptable to insert a hyphen to separate two vowels, for example intra-articular and extra-articular.

Units: Use SI units throughout. Always insert a space between a number and a unit, e.g. 5 mm.

Numbers: Spell out one to ten except when used for units of measurement (mass, time, length); for numbers over ten, use numerals except when starting a sentence. Do not give percentages if the total number in the sample is less than 50. Round percentages greater than

10 to the nearest whole number.

Statistical methods: There is no need to document the computer program used for statistical analysis, e.g. "Data was analysed using SPSS (Chicago, Illinois)". It is, however, essential that the statistical tests used are documented. Analyse numerical data by appropriate statistical methods which must be stated clearly in the Methods section of the paper. State in text or tables whether data are given as means and standard error of mean (SEM) or means and standard deviation (SD), then, when appropriate, give individual data as mean (SEM) or mean (SD). Do not use the "±" sign, e.g. 12.3 (SD 0.5) **not** 12.3 ± 0.5. Provide confidence intervals for data when appropriate. *It is strongly recommended that statistical advice is obtained and acknowledged when preparing an article as submissions may be reviewed by a statistician.* See Sauerland S, Lefering R, Bayer-Sandow T et al. Fingers, hands or patients? The concept of independent observations. J Hand Surg Br. 2003, 29: 102-5.

Tables: Avoid big tables containing large amounts of data; if this information is essential split it into smaller tables. Type each table on a separate sheet using double spacing and only horizontal rules. In Microsoft Word, the correct table style is "Table Simple 1", which can be found in Word 2003 by selecting the table and going to Table Autoformat, selecting "Table Simple 1" and unchecking the boxes "Color" and "Apply special format to the last column". In Word 2007, select the table and click on the Design tab in Table Tools. Scroll down the Table Styles to find "Table Simple 1" (hover the mouse over the style to display its name); then set Shading to "No Color" and uncheck the Last Column box under Table Style Options. In Word 10, select the table and click on the Design tab in Table Tools. Hover over the Table Styles and choose the black and white Light Shading style. Then choose "No Color" from the Shading options.

Give an identification number and title above each table and any other explanatory information in footnotes below. Include all units and explain uncommon ones in the footnote. Refer to all tables in the text. Do not duplicate material in tables in the text or figures.

9.3.2 Style for short report letters

A case report or technical tip should be submitted to the Journal as a one page letter containing no more than 1000 words, though its length should be reduced by 200 words for each figure or table. Thus if a case report contains two figures or tables it should be no more than 600 words long. The format should be:

Title

Dear Sir

The text of the letter without section headings

The reference list (no more than four references)

Figure legends

Upload onto the system as 'manuscript (without authors' names, affiliations)'. You must also upload a separate Title Page which includes the same information as set out above for scientific papers under **9.3.1**

Provide a brief abstract in the relevant section of the submission process. This would not be published but is used for review purposes.

9.4 Reference style for all submissions

The accuracy of references is the responsibility of the authors, who are encouraged to download reference details from MedLine or another accurate database, in order to avoid inaccuracies and typographical errors. References are checked during the review process and if inaccuracies are found, the submission will be returned to the authors for correction before the review process can be continued. Limit citations to those that are pertinent and essential to your study; for example, it is not necessary to cite Dupuytren's original publication in every paper about Dupuytren's disease.

Submit references in the correct style for this journal. Our reference style is available on Endnote. Please check the Output page at www.endnote.com or go to:

<http://www.endnote.com/support/enstyles.asp> and carry out a search using the words exactly as follows: Journal of Hand Surgery (European Volume)

In the text, citations should give the author's name and date of publication in brackets. Do not use superscript numerals. If there are two authors, link their names with "and", not "&" - for example (Sauerland and Davis, 2004). If there are three or more authors give the name of the first and follow it with "et al." - for example (Kalbermatten et al., 2008). When several references are given together in brackets in the text, list them in alphabetical order, with each reference separated by a semicolon.

Type the reference list double spaced and separately from the main text. List references in alphabetical order of their first author. If there are more than six authors, give the first three followed by "et al.". When referencing a journal article, list the authors, the title of the article, the journal title abbreviation used by PubMed (<http://www.ncbi.nlm.nih.gov/pubmed/>), the year, the volume number and the first and last page - this style is similar to that used in PubMed. Authors are advised to "copy and paste" from PubMed and then adjust the reference, or use reference management software.

Note the following examples of references:

Articles in journals

Kalbermatten DF, Erba P, Mahay D et al. Schwann cell strip for peripheral nerve repair. *J Hand Surg Eur.* 2008, 33: 587-94.

Sauerland S, Davis TRC. The consolidated standards of reporting trials (CONSORT); better presentation of surgical trials in the *Journal of Hand Surgery*. *J Hand Surg Br.* 2004, 29: 621-4.

Sauerland S, Lefering R, Bayer-Sandow T, Brüser P and Neugebauer E A M. Fingers, hands or patients? The concept of independent observations. *J Hand Surg Br.* 2003, 28: 102-5.

Book

Dawson DM, Hallett M, Millender LH. *Entrapment neuropathies*, 2nd Edn. Boston, Little, Brown, 1990: 81.

Chapter in a book

Kaplan EB, Spinner M. Normal and anomalous innervation patterns in the upper extremity. In: Omer GE, Spinner M (Eds.) *Management of peripheral nerve problems*. Philadelphia, WB Saunders, 1980: 75-115.

Chapter in a book with volumes

O'Brien BMC. Experimental research in hand surgery. In: Tubiana R (Ed.) *The hand*. Philadelphia, WB Saunders, 1981, Vol. 1: 501-10.

Internet publication

AAOS (American Academy of Orthopaedic Surgeons) Clinical practice guideline on treatment of carpal tunnel syndrome. Rosemont (IL): American Academy of Orthopaedic Surgeons, 2008.

<http://www.aaos.org/research/guidelines/CTStreatmentguide.asp> (date accessed).

Do not refer to abstracts, personal communications and unpublished material such as lectures, posters, correspondence club letters and submitted but not published manuscripts.

CHECKLIST

Carefully check the following before submission:

Submission letter (containing information described above)

Title page (which includes a 'Declaration of Conflicting Interests' and a 'Funding' statement and, if required, details of Ethical Approval and/or Informed Consent)

Abstract (a single paragraph, maximum 150 words, no side-headings)

Manuscript uploaded as 'Manuscript without authors' names or affiliations' (which should not show authors' identities but should show the title of the paper and include summary/abstract, main text, figure legends and references.)

Tables

Figures

Patient consent for identification

Permission to use previously published material

Submit via the journal's online submission system at <http://jhse.edmgr.com>

If you would like to discuss your paper prior to submission or seek advice please contact the Editor: editor@journalofhandsurgery.com

10. After acceptance

10.1 Proofs

We will email a PDF of the proofs to the corresponding author. Corrections should be limited to typographical amendments. Authors' approval will be assumed if corrections are not returned by the date indicated.

10.2 E-Prints and Complimentary Copies

SAGE provides authors with access to a PDF of their final article. For further information please visit <http://www.sagepub.co.uk/authors/journal/reprint.sp>.

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We value your feedback to ensure that we continue to improve our author service levels. On publication all corresponding Authors will receive a brief survey questionnaire on your experience of publishing in the *Journal of Hand Surgery (European Volume)* with SAGE.

10.4 OnlineFirst Publication

Accepted articles and short report letters are published OnlineFirst; a feature offered through SAGE's electronic journal platform, SAGE Journals Online. This allows completed articles in queue for assignment to an upcoming issue to be hosted online prior to their inclusion in a final print and online journal issue. This significantly reduces the lead time between submission and publication. For more information please visit our [OnlineFirst Fact Sheet](#).

11. Further information

Any queries should be directed to: editor@journalofhandsurgery.com

Submit via the journal's online submission system at <http://jhse.edmgr.com>

12. Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence

Level of evidence should be included at the end of the Abstract for all clinical studies but need not be given for laboratory/pure science studies

Question	Step 1 (Level 1*)	Step 2 (Level 2*)	Step 3 (Level 3*)	Step 4 (Level 4*)	Step 5 (Level 5*)
How common is the problem?	Local and current random sample surveys (or censuses)	Systematic review of surveys that allow matching to local circumstances**	Local non-random sample**	Case-series**	n/a
Is this diagnostic or monitoring test accurate? (Diagnosis)	Systematic review of cross sectional studies with consistently applied reference standard and blinding	Individual cross sectional studies with consistently applied reference standard and blinding	Non-consecutive studies, or studies without consistently applied reference standards**	Case-control studies, or "poor or non-independent reference standard**	Mechanism-based reasoning
What will happen if we do not add a therapy? (Prognosis)	Systematic review of inception cohort studies	Inception cohort studies	Cohort study or control arm of randomized trial*	Case-series or case control studies, or poor quality prognostic cohort study**	n/a
Does this intervention help? (Treatment Benefits)	Systematic review of randomized trials or <i>n</i> -of-1 trials	Randomized trial or observational study with dramatic effect	Non-randomized controlled cohort/follow-up study**	Case-series, case-control studies, or historically controlled studies**	Mechanism-based reasoning
What are the COMMON harms? (Treatment Harms)	Systematic review of randomized trials, systematic review of nested case-control studies, <i>no</i> -1 trial with the patient you are raising the question about, or observational study with dramatic effect	Individual randomized trial or (exceptionally) observational study with dramatic effect	Non-randomized controlled cohort / follow-up study (post-marketing surveillance) provided there are sufficient numbers to rule out a common harm. (For long-term harms the duration of follow-up must be sufficient.)**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning
What are the RARE harms? (Treatment Harms)	Systematic review of randomized trials or <i>n</i> -of-1 trial	Randomized trial or (exceptionally) observational study with			

		dramatic effect			
Is this (early detection) test worthwhile? (Screening)	Systematic review of randomized trials	Randomized trial	Non -randomized controlled cohort / follow-up study**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning

*** Level may be graded down on the basis of study quality, imprecision, indirectness (study PICO does not match questions PICO), because of inconsistency between studies, or because the absolute effect size is very small; Level may be graded up if there is a large or very large effect size.**

**** As always, a systematic review is generally better than an individual study.**

How to cite the Levels of Evidence Table

OCEBM Levels of Evidence Working Group*. "The Oxford 2011 Levels of Evidence".

Oxford Centre for Evidence-Based Medicine. <http://www.cebm.net/index.aspx?o=5653>

** OCEBM Table of Evidence Working Group = Jeremy Howick, Iain Chalmers (James Lind Library), Paul Glasziou, Trish Greenhalgh, Carl Heneghan, Alessandro Liberati, Ivan Moschetti, Bob Phillips, Hazel Thornton, Olive Goddard and Mary Hodgkinson*