Pyrocarbon Proximal Interphalangeal Joint Arthroplasty

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DECLARATION

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Part A – Protocol

RESEARCH PROPOSAL

PYROCARBON PROXIMAL INTERPHALANGEAL JOINT ARTHROPLASTY: OUTCOMES OF A COHORT STUDY

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Introduction

Arthritis of the proximal interphalangeal joint of the hand can be a debilitating disease resulting in pain and stiffness. Treatment is initially conservative but with disease progression surgical treatment often becomes necessary. Arthroplasty is one of the surgical options available. Since 1968 silicone arthroplasty has been commonly used. In 2001 a semi-constrained implant made of pyrocarbon became available for use worldwide. We have identified 7 articles reporting the results of these implants, the largest series being 53 joints with minimum 2 year follow-up.

From the records of the Martin Singer Hand Unit and the Cape Hand Clinic (based at Vincent Palotti Hospital) we have identified 46 patients who have had 57 pyrocarbon PIP joints implanted with minimum 12 month clinical and xray follow-up.

Materials and methods

We propose to review each patient along with retrospective review of their records and xrays to analyse the outcome of pyrocarbon PIP joint arthroplasty in our unit.

The information will be recorded on a proforma (attached) and we will analyse the data to record outcomes, most importantly patient satisfaction, improvements in pain and range of motion, subsidence of implants, and complications including the need for revision, further surgery, squeaking, swan neck and boutonniere deformities.

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Part B – Literature review

Objectives

The objective of this literature review is to gain an understanding of the development of proximal interphalangeal (PIP) joint replacements of the hand as well as to review the results of the various implants available. The first PIP joint replacement was performed in 1968 using a silicone prosthesis. The pyrocarbon PIP joint replacement was first introduced in 2000.

In this review I will attempt to review the silicone prosthesis with its advantages and disadvantages, and to identify the need to improve on its design. The pyrocarbon prosthesis is relatively new and studies have been done reviewing the results of this implant, with mostly encouraging results. These results need to be analysed to establish the benefit of the pyrocarbon PIP joint replacement and whether it would be an improvement on the silicone prosthesis.

The results of the studies on the pyrocarbon prosthesis need to be compared to the results of our study to establish whether our results are comparable to the literature and whether we are correct in our patient selection, indication for surgery, surgical technique and postoperative rehabilitation program.

Literature search strategy

My strategy for my literature search was to use the internet data bases Pubmed and Google Scholar. The search was for articles about silicone and pyrocarbon proximal interphalangeal joint replacements. All related articles that were found from the search were reviewed, as well as references in articles read that might have pertained to the area of interest of my topic. In particular review articles on the subject were sought.

Review

Arthritis of the hand affects millions of people worldwide and can be a very debilitating condition. Arthritis can affect all joints of the hand.[1] Arthritis of the proximal interphalangeal (PIP) joint can result in pain, loss of range of motion, deformity and restriction in activities of daily living. It may be caused by post-traumatic arthritis as well as non-traumatic arthritis which may be inflammatory (e.g. rheumatoid arthritis) or non-inflammatory (e.g. osteoarthritis).

There are numerous treatment options for PIP joint arthritis including surgical and non-surgical options. Most patients with mild disease are managed conservatively with activity modification, rest, anti-inflammatory medication, analgesics and occasional corticosteroid injections. With disease progression and when conservative methods become exhausted, most surgeons opt for surgical intervention.[2] The two broad categories for surgical intervention include arthrodesis or arthroplasty. Both provide effective pain relief but arthroplasty retains a range of motion whereas arthrodesis does not. Arthrodesis results in a lower patient satisfaction as compared to arthroplasty. Most surgeons therefore opt for arthroplasty. Arthrodesis has largely been abandoned as the first line of surgical treatment in most centres. It does however still offer a good alternative as a salvage procedure. Unfortunately arthroplasty does have many drawbacks, and in the words of world renowned hand surgeons Burton and Pellegrini: "Surgical treatment of the osteoarthritic proximal interphalangeal joint remains an unsolved problem".[3]

Arthroplasty for the PIP joint of the hand was first introduced in 1968 by Swanson where he used a silicone implant.[4] Silicone PIP joint implants are flexible, fully constrained, hinged implants.[5] They have a flexible stem and use no cement fixation. The Swanson implant has historically been recognized as a mainstay in small joint arthroplasty of the hand for both PIP joints and metacarpophalangeal (MCP) joints. However, high rates of implant fracture (as high as 82% within 5 years of insertion) and other complications have prompted investigators to search for alternatives.[6]

For many years silicone arthroplasty was advocated for the middle, ring and little fingers, and arthrodesis was recommended for the index finger PIP joint.[7] The reason for arthrodesis of the index finger PIP joint being recommended was the high incidence of coronal plane deformities that occurred in this finger with the silicone implant.[7] The other fingers did not develop these deformities as often as they are generally used less for pinch movements. Silicone implants are also associated with endosteal bone resorption which may be progressive.[3] Durability of silicone implants have been demonstrated to diminish over time.[8] Other

complications of silicone implants include implant fracture, heterotopic bone formation, implant loosening, silicone synovitis, implant deformation, implant settling and decreased range of movement.[7,8,9]

Silicone PIP joint replacements do not do as well in patients with rheumatoid arthritis as opposed to patients with osteoarthritis.[10] These implants rely on soft tissue structures for their stability. In rheumatoid patients often the capsule, collateral ligaments and supporting soft tissues are degenerate and incompetent, and as a result instability is often a problem in these patients.[11]

As a result of these problems with silicone implants there have been many designs over the years which have attempted to find a better implant for PIP joint replacement. Efforts were made to match the success of large total joint replacement, but difficulties were encountered when trying to transfer large joint technology to small joints of the hands.[12] Most notable were the small size of joints, their place within the kinetic chain, complex soft tissue investments, and relationships to adjacent rays.

There have been different anatomic and biomechanical equivalent total joint designs manufactured from metal, metaloplastic, and viscoelastic materials.[12] Other techniques used for PIP arthroplasty have included palmar plate advancement, fibrous interposition, and fibrous ingrowth.[13,14] Improved biomechanics with surface replacement arthroplasties have been introduced that mimic the physiologic articulation of the PIP joints, restoring more normal motion based on a virtual axis rather than a fixed one.[9,15] With a more anatomic construct and subsequent improved biomechanical function, it is hoped that this will translate to improved longevity of the prostheses.[9] More recently, implants have moved toward semi-constrained or non-constrained designs, and toward minimal bone resection that aims at preserving soft tissue supports to unload component stems and improve fixation while mimicking joint biomechanics.[16] The greater the constraint of the implant, the greater the transmitted stress through the prosthesis to the stem-bone interface, which can result in implant loosening.[17] The disadvantage of a non-constrained design is the greater chance of subluxation or dislocation and of coronal plane deformities.[17]

Pyrocarbon, a synthetic material created by chemical vapour deposition, has been shown to be biocompatible and durable with excellent wear characteristics. Pyrocarbon material durability has been proven in artificial heart valves over many years.[22] Pyrocarbon implants have been developed for resurfacing arthroplasty of the finger joints.[7] In 2000 a semi-constrained pyrocarbon PIP joint implant was introduced in Europe. The Ascension PIP (Ascension Orthopaedics, Inc., Austin, TX) pyrocarbon total joint is a bicondylar, anatomically shaped, articulating implant that allows joint flexion-extension, while providing some restriction of adduction-

abduction motion.[16] It is a press-fit implant with no cement fixation. These implants are made of a graphite core, coated with pyrocarbon. The Ascension PIP Pyrocarbon implant is made by the precision machining of a graphite rod into a graphite substrate implant. The graphite contains 1% atomic weight of tungsten, which allows the graphite to be radiopaque. Next, through chemical vapour deposition, a pyrolytic carbon coating is deposited onto the graphite. The articular surface is polished in the finished product.[16] These implants are unlinked and minimally constrained. Preliminary studies in primates revealed no evidence of wear or wear debris, or inflammatory reaction.[19]

Firm seating of the pyrocarbon implant achieved with a press fit theoretically resists longitudinal subsidence. Furthermore, the implant material is designed not to require cement fixation but instead is stabilized by appositional bone growth. This avoids the negative sequelae of cement use including brittleness, heterotopic bone formation, and loosening from thermal injury and precludes the need for removal if revision is required.[21]

Pyrocarbon joint arthroplasty has been used in the metacarpophalangeal joint for around three decades already with good success. A long-term study done in 1999 of early pyrocarbon metacarpophalangeal joint implant design demonstrated a 70% 16-year implant survival rate and good patient outcomes.[20] The success of pyrocarbon implants in the metacarpophalangeal joint, has now led to the development and use of pyrocarbon in the PIP joint.

The Ascension PIP (Ascension Orthopaedics, Inc., Austin, TX) pyrocarbon total joint implant for the PIP joint received approval for use in Europe in 2000, and in The United States of America in 2001 by the Food and Drug Administration.[23] More and more studies are now being published reviewing the results of these implants, with most showing encouraging results.

The chief indications for pyrocarbon PIP joint replacement are degenerative arthritis with pain that is resistant to conservative methods of treatment. These implants have been used for osteoarthritis, rheumatoid arthritis and post-traumatic arthritis.[11,23,24] In order to assess the success of these implants the studies done have assessed improvement in pain, change in the arc of motion, grip and pinch strength, deformity, radiological assessment and complications.

Results are good with most patients experiencing excellent pain relief. Many of these studies evaluated pain using a visual analogue scale with patients scoring their pain before and after the surgery. Tuttle and Stern reviewed 18 pyrocarbon PIP joint replacements in 2006. They found 8 patients were pain free after the surgery and the remaining patients all had an improvement in pain with an average score of 3.6 out of 10 on a visual analogue scale.[25] A study of 20 pyrocarbon PIP

joints by Schulz et al. in 2005 found satisfactory pain relief in all patients.[26] A large study by Bravo et al. of 50 pyrocarbon joints in 2007 found that patient's scores on a visual analogue scale improved from an average of 6 out of 10 before surgery to 1 after surgery.[23] Another study in 2010 by Wijk et al. reviewed 53 pyrocarbon joints.[28] At a minimum of 1 year follow up they found 36 out of 43 patients who were scored with a visual analogue scale to be almost pain free at rest, and 18 of 43 to be pain free during activity. No study was found in the literature where pain was not improved with the pyrocarbon PIP joint replacement.

On reviewing the literature with regard to improvement in the arc of motion, the findings are inconsistent. Bravo et al. found improvement in the arc of motion from 40° to 47° but this was not statistically significant.[23] Wijk et al found arc of motion decreased from 56° to 52°.[28] Studies by Tuttle and Stern, Chung, and Herren all found no improvement in arc of motion.[25,29,30] Branam et al compared 19 silicone joint replacements to 22 pyrocarbon joint replacements and found no improvement in arc of motion in either group.[7] Quite a marked improvement in range of motion was reported by Stutz et al. in 2005.[31] The study reviewed 13 implanted pyrocarbon joints and found the arc of motion increased from 51° pre-operatively to 77° post-operatively. Unfortunately this study did not mention whether these results were statistically significant or not.

A few studies have analysed grip and pinch strength. Nunley et al. reviewed 7 joints in 2006 and found grip strength improved from an average of 47 lbs to 63 lbs after surgery.[24] Chung et al. in 2009 reviewed 21 implanted joints and found grip strength improved from 11.3kg to 15.1kg.[29] Branam et al in his 2007 study comparing pyrocarbon to silicone joint implants found grip strength improved in both groups.[7] In the pyrocarbon group it improved from 9kg to 14kg and in the silicone group it improved from 18kg to 19kg. Unfortunately in both groups the results were not statistically significant. Wijk et al. found no improvement in grip strength in his study of 53 pyrocarbon joints.[28] Bravo et al. measured both grip and pinch strength in 50 pyrocarbon joints and found an improvement in both.[23] The improvement in grip strength was not statistically significant but the improvement in pinch strength was.

Deformity post-operatively is usually found in the coronal plane. This deformity is more commonly seen in the index finger than the other fingers.[7] This is due to the increased forces exerted in this plane with pinch activities. The incidence of coronal plane deformities is only documented in a few of the studies. Branam et al found in his comparative study that 11 out of 20 joints (55%) in the silicone group developed coronal plane deformities as compared to 4 out of 19 (21%) in the pyrocarbon group.[7] The deformity in the coronal plane is usually ulnar angulation as opposed

to radial angulation.[7] Tuttle and Stern found persistent deformity in the coronal plane in 4 out of 18 joints (22%).[25]

On radiological assessment, many of the implants show a change in position on follow up as compared to their initial position on the postoperative radiograph. This change in position is due to subsidence of the implant which can be axial, angular or both. Subsidence is as a result of the way the implant interacts with bone. Unlike materials such as titanium, the pyrocarbon bone-implant interface does not develop osseous in-growth.[23] Instead sclerotic bone forms up to the implant, which is called osseous on-growth. It therefore does not develop osseo-integration. Daecke et al compared titanium implants with pyrocarbon implants in an animal model.[27] They implanted 9 titanium and 8 pyrocarbon implants into rabbits' knees. They found that in all 9 titanium implants osseointegration occurred and in all 8 pyrocarbon implants there was no evidence of osseointegration. With the elastic modulus being similar to cortical bone, the implant will change position in the early post-operative period and eventually settle into a stable position.[23] These changes occur in accordance with Wolff's law which states that when bone is placed under stress it will remodel and increase in density and strength. In Bravo's study of 53 implants, they found that subsidence occurred in 40% of the implants.[23] Parker et al. found subsidence in 15% of cases where pyrocarbon joints were implanted into metacarpophalangeal joints.[18]

On radiographic evaluation the implants often appear loose because of a radiolucent line around the implant. This line is due to the radiolucent graphite which surrounds the pyrocarbon core of the implant, and is normal. This should not be confused with loosening. Loosening should be assessed rather by serial radiographs demonstrating progressive peri-prosthetic lucency.[23] Bravo et al. found loosening in 8% of cases which then required revision.[23] Branam et al. found 2 cases of loosening (5%) in his series but neither case required revision.[7] Tuttle and Stern had loosening in 11% of their cases.[25]

Infection was found to be a very rare complication. Most studies had no episodes of infection.[7] Wijk et al found only 1 case of infection in their series (2%) which was treated with antibiotics and revision surgery.[28]

Audible squeaking of the joint is relatively common with most studies reporting fairly high rates of this complication. Tuttle and Stern found this in 8 out of 18 joints (44%) in their series.[25] Branam et al. reported this in 4 out of 19 joints (21%).[7] This seems to be a minor complication with the main problem being mild annoyance to the patient. It is not entirely clear why this occurs but Beckenbaugh who has had extensive experience with pyrocarbon implants believes that it occurs when the joints are put in under angular stress, and tension is not corrected by surgical

technique or postoperative splinting and therapy.[23] Bravo et al. in their study of 53 implants found no joints that squeaked.[23]

Dislocation is a well known complication of any joint arthroplasty. The incidence varies in the literature. Chung et al. experienced 3 dislocations out of 14 implants (21%).[29] Branam et al. found 2 cases of dislocation out of 19 (11%).[7] Meier et al. had 2 dislocations out of 24 joints (8%).[32] Bravo et al. had no dislocations in 53 joints inserted.[23] This significant difference could possibly be due to different surgical techniques or postoperative rehabilitation protocols.

Not all studies in the literature are in favour of the pyrocarbon PIP joint implant. Herren, et al. reported problematic bone fixation with these pyrocarbon implants.[30] They found migration of the prosthesis in 8 out of 17 joints and radiolucent lines in a further 3 more. Patients were evaluated at a mean follow up of 20 months. They found grip strength and range of motion outcomes to be less favourable for these patients although it was not statistically significant. Their conclusion was that the number of possibly unstable prostheses in their series raises the question as to whether pyrocarbon is suitable for uncemented press-fit fixation in combination with early functional rehabilitation. Only one patient in their study required revision though. As was discussed earlier in this review, these implants often do migrate and subside. The bone then remodels in accordance with Wolff's law and these implants become stable. The implants in this study that migrated might have been stable and might not have needed revision.

Other surface replacement arthroplasty implants for the PIP joint are available. One that is currently in use involves a proximal component with a cobalt chrome alloy articulating surface, and a distal component consisting of ultra high molecular weight polyethylene. Both components have a textured titanium stem allowing for press-fit fixation. Previous versions of this implant relied on cement fixation. A retrospective study comparing the long-term results of the use of the cemented and uncemented versions of this implant from a single surgeon's experience found that there was no difference in the postoperative pain scores or the postoperative arc of motion for the cemented versus the uncemented group.[33] There were significantly more cases with radiologic evidence of loosening in the uncemented group. Revision rate was higher in the uncemented group (26%) compared with that of the cemented group (8%), but this difference was not statistically significant. An earlier study by the same surgeon reviewing 20 joints in 13 patients using the cemented implant found that all patients had excellent pain relief and no patients lost motion.[34] The author did note that results improved as experience was gained and a more intensive rehabilitation protocol was used. These results are similar to the results of studies done on the pyrocarbon surface replacement implant.

Summary

Pyrocarbon PIP joint replacement is relatively new having been used for about 11 years now. Biomechanically pyrocarbon appears to be well suited for arthroplasty of the PIP joint and it has been used with success in the metacarpophalangeal joint for many years. The studies in the literature show encouraging results. All the studies show good pain relief after surgery. The results of the change in the arc of motion are conflicting though. Grip and pinch strength are generally improved. Complications reported include squeaking, dislocation, infection and migration of the implant. Squeaking seems not to be detrimental other than being an annoyance to the patient. Migration of the prosthesis seems to result in the prosthesis subsiding into a stable position with minimal effect on final outcome. The incidence of infection is very low. The dislocation rate is variable with some studies having relatively high rates and some studies finding no dislocations.

Further research is needed as to why certain outcomes are different between different studies, mainly with regard to change in the arc of motion and dislocation rates. These discrepancies are possibly due to differences in surgical technique, or differences in postoperative rehabilitation protocols. Longer follow up is also required. All joint replacements will eventually require revision. The longevity of these implants needs to be determined, and how much the lack of osseointegration will affect the rate of loosening of these implants remains to be seen.

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Part C – Manuscript

This manuscript will be submitted to The Journal of Hand Surgery – European Volume. The format and referencing style is that which is required by the journal.

Title

Pyrocarbon proximal interphalangeal joint arthroplasty: Outcomes of a cohort study

SUMMARY

Pyrocarbon arthroplasty of the proximal interphalangeal joint is a relatively new concept. Early studies have been encouraging, reporting improved pain and function, but a largely unchanged arc of motion. Subsidence of the implant is common but how it relates to outcome has not been analysed. This study was performed to review the results of 57 pyrocarbon proximal interphalangeal joints implanted. Results showed a statistically significant increase in the arc of motion with excellent pain relief and improvement of function. Subsidence was observed on radiographs in 40% of joints but no correlation was found when compared to arc of motion or function. The incidence of complications is fairly high and are usually related to the peri-articular soft tissues, but they are usually minor and do not require further treatment. From this review we can recommend the use of this implant for treatment of arthritis of the proximal interphalangeal joint.

INTRODUCTION

Arthritis of the proximal interphalangeal (PIP) joint can be a debilitating condition, resulting in pain, loss of range of motion, deformity and restriction in activities of daily living.

Arthritis is a disease affecting millions of people worldwide. With the exception of arthritis resulting from direct trauma, all other forms of arthritis are often systemic disorders and can affect many joints. Evidence of this systemic disease often first appears in the hand, therefore the hand surgeon is often the first clinician to diagnose this disease. Osteoarthritis is the most common type of arthritis encountered. It has been estimated that one quarter of post menopausal women will present with osteoarthritis of the hands. Mostly this involves the distal interphalangeal joint and the basal joint of the thumb, but in 18 % of patients the PIP joint is involved (Swanson, 1972).

Following failed conservative management of a destructive arthropathy of the PIP joint, the surgical options would include arthrodesis or arthroplasty. Arthrodesis of the PIP joint results in substantial loss of function and is associated with limited patient acceptance.

As a consequence, these patients may benefit from PIP joint replacement. This intervention is indicated when medical management has failed to relieve pain or when deformity interferes with hand function and activities of daily living. When successful, this procedure can greatly improve pain, function and quality of life.

PIPJ arthroplasty was first introduced by Swanson in 1968 using silicone implants (Swanson, 1968). Satisfactory results were obtained with these implants, although it was not without complications, which included implant fracture, subsidence, bone resorption, dislocation, silicone synovitis, heterotopic bone formation and decreased range of movement (Koboyashi and Terrono, 2003). In the last four decades there have been various modifications and designs to improve the implants including the use of different materials (Linscheid et al., 1997; Nicolle and Calnan, 1972; Uchiyama and Cooney, 2003).

In 2000 a semi-constrained pyrocarbon implant was introduced in Europe. The Ascension PIP (Ascension Orthopedics, Inc., Austin, TX) pyrocarbon total joint is a bicondylar, anatomically shaped, articulating implant that allows joint flexion and extension, while providing some restriction of adduction and abduction motion. It is a press-fit implant with no cement fixation. These implants are made of a graphite core, coated with pyrocarbon. Pyrocarbon has a very similar elastic modulus compared to cortical bone (creating a favourable environment for load transfer)

and a very low wear rate (much less than titanium or zirconia) (Cook et al., 1983; Cook et al., 1989). It is biologically inert with high strength and low friction. The pyrocarbon coating is made by heating carbon gas to 1300^{o}C. The inner graphite core is radiopaque and the outer pyrocarbon coating is radiolucent. In comparison to silicone implants, pyrocarbon finger joint implants offer biological compatibility, low wear rates, and durability, while providing pain relief and improving the arc of motion (Cook et al., 1999). Pyrocarbon implants also have the potential for long term survival because it is a biologically inert polymer and has an elastic modulus better matched to bone (Cook et al., 1999). Pyrocarbon implants have been shown to be well suited for small joint replacements and have been used with success in the metacarpophalangeal joint (Beckenbaugh, 2003; Cook et al., 1999).

The pyrocarbon PIP joint replacement is well designed for treating osteoarthritis and post traumatic arthritis. Collateral ligaments, capsule and other soft tissue stabilising structures are usually intact in these cases, which add to the stability of these pyrocarbon implants. Caution should be taken when using these implants in patients with rheumatoid arthritis as these patients often have narrow medullary canals, thin cortices and soft bone. For pronounced finger deformities constrained silicone devices may be preferable as not enough stability may be achieved with the pyrocarbon implant (Beckenbaugh, 2003).

Relatively few studies have been reported on pyrocarbon PIP joint replacements (Branam et al., 2007; Bravo et al., 2007; Chung et al., 2009; Stutz et al., 2005; Tuttle and Stern, 2006; Wijk et al., 2010). Most report favourable outcomes, but there are some where the results have been less than satisfactory. Despite overall high patient satisfaction, failure to improve on preoperative range of motion and substantial complication rates continue to influence surgical indications.

This study was performed to assess our results in a cohort study using the pyrocarbon PIP joint replacement.

MATERIALS AND METHODS

We performed a retrospective review of 57 consecutive pyrocarbon PIPJ replacements performed in 46 patients between 2002 and 2011.

All surgical procedures were performed by the two senior authors. Initially the dorsal Chamay approach was used but thereafter a modified central slip splitting technique was adopted, which will now be outlined.

A dorsal curvy linear skin incision is made and a midline split of the central slip is performed. The central slip is sharply dissected off the middle phalanx. The collateral ligaments are preserved. The articular surfaces of the proximal and middle phalanx are broached. The middle phalanx is prepared with minimal bone resection and care is taken to preserve the dorsal lip. The prosthetic trials are inserted and the amount of tension is assessed. There should be no hyperextension at the joint. Before inserting the definitive implant, a suture is placed through a drill hole in the middle phalanx. The definitive implants are then inserted. The central slip is then reattached with the same suture threaded through the drill hole. Haemostasis is achieved and the skin is closed. A bulky dressing is applied with a dorsal slab. The MCP joints are held in 45^{o} flexion and the interphalangeal joints in full extension.

Postoperative rehabilitation is a team approach involving the surgeon, occupational therapists, physiotherapists, wound care sister and the patient. In earlier years, when the dorsal Chamay approach was used, the rehabilitation followed the guidelines stipulated by the manufacturers of the pyrocarbon implant. The rehabilitation regime was altered as the surgical technique was changed to a modified central slip splitting technique. The rehabilitation followed could be described as an early active protocol in view of the fact that it is slightly accelerated in comparison to the standard pyrocarbon arthroplasty protocol recommended by the manufacturers.

The active range of movement (AROM) program starts fairly early, at four to five days post surgery. AROM is started with active flexion to 45^{o} during the first week. During the second week, flexion is progressed to 60^{o}. During the third and fourth week postoperatively, AROM is gradually increased and any presence of an extensor lag is closely monitored. In cases where the extensor lag at the PIP joint is substantial, a dynamic extensor splint is then used.

The active flexion ROM is increased over the next few weeks. A pressure garment sleeve is fitted to ensure adequate control of oedema.

All patients were reviewed regularly and had a minimum of one year follow up to be included in the study.

At follow up all patients were examined by one of the authors and had an xray taken.

The following was recorded:

- Indication for surgery
- Finger operated on
- Age and sex of patient

- Surgical approach
- Arc of motion
    - Preoperatively
    - At six month follow up
    - At final follow up
    - Statistical analysis was done using the Paired Student's *t*-test.
- Satisfaction scores were recorded on a visual analogue scale and graded as:
    1. Unsatisfied. Would not want same procedure again.
    2. Less than expected. Would consider procedure again.
    3. Result as expected.
    4. Better than expected result.
    5. Fantastic result. Happy to recommend procedure.
- Complications
- Radiographs postoperatively and at final follow up looking specifically for:
    - Fracture
    - Alignment
    - Subsidence – axial and/or angular
    - Loosening
- Need for secondary surgical intervention

RESULTS

The cohort for this study includes a sequential series of 46 patients with 57 PIP joint replacements performed between 2002 and 2011. This included:

- 10 males who had 11 PIPJ replacements.
- 36 females who had 46 PIPJ replacements.

Follow up ranged from a period of 12 months to 70 months postoperatively with an average follow up of 27 months.

Average age of the patient operated on was 61 years.

Fingers operated on:

- Index: 11
- Middle: 25
- Ring: 12
- Little: 9

Indication for surgery:

- Osteoarthritis (primary or post-traumatic): 56
- Rheumatoid arthritis: 1

Average range of motion:

	Preoperatively	6 months	Final follow up
Range	$21^o – 51^o$	$10^o – 72^o$	$6^o – 72^o$
Arc	30^o	62^o	66^o

There was therefore an average increase of 36^o in the arc of movement (120% improvement).
Using statistical analysis the increase in ROM was calculated to be extremely statistically significant with a p-value less than 0.0001.

Pain relief was excellent. Patients were asked to grade their satisfaction on a visual analogue scale (see methods section above). The average score was 4.2 out of 5 which indicated a high patient satisfaction. In 88% of cases, patients gave a score of 4 or 5 on this scale.

Radiologic assessment

A criticism of the pyrocarbon implant has been the reported failure of osseo-integration. This results in the migration of the implant within the medullary canal. This implant movement can be assessed by comparing immediate postoperative films to those at final follow up.
There are three ways in which the components tend to migrate. Firstly they can migrate in a longitudinal direction with no angular change. We have termed this axial subsidence. Secondly it can be in the varus/valgus or volar/dorsal direction which we have termed angular subsidence of the component. And lastly it can be a combination of both angular and axial subsidence.

The findings in our study were:

- Proximal component subsidence: 17 joints (30% of all joints)
  - Angular only: six joints (11%)
  - Axial only: eight joints (14%)
  - Angular and axial: three joints (5%)
- Distal component subsidence: six joints (11%) - Axial direction only
  No patients had angular subsidence of the distal component.
- No patient demonstrated distal component subsidence without concomitant subsidence of the proximal component.
- There was no migration of either component observed in 40 joints (70%).
- There was no correlation observed between subsidence and ROM.

See figure 1 and 2

<u>Complications</u>

Stiffness – six joints (11%)

- If patients developed substantial loss of flexion in the face of a well sited prosthesis with no obvious subsidence then a decision was made to perform a dorsal release to improve end range flexion.
- An extensor tenolysis and dorsal capsulotomy was performed.
- This relatively simple procedure improved the range of motion in all six joints by an average of 55^{o}.
- This surgery was performed between three and nine months post index procedure.

Swan neck deformity – 11 joints (19%)

- These patients developed this troublesome condition of struggling to initiate flexion from a slightly hyperextended position.
- Average arc of motion for these patients was 49^{o}.
- Two of these deformities were mild and the patients refused further surgery.
- Seven patients agreed to a FDS tenodesis which corrected the deformity and gave a pain free average arc of motion of 64^{o}.
- Two patients were considering a tenodesis at the time of print.

See figure 3

Boutonniere deformity – three joints (5.3%)

- Two patients developed this early postoperatively, but both resolved with appropriate splinting.
- One patient developed the boutonniere deformity after a fall. A release was performed. Following this the patient then developed a swan neck deformity, which later required a FDS tenodesis. On final follow up, the range of motion was 30^{o} – 90^{o} and the patient was pain free and satisfied.

Fracture at insertion – two joints (3.5%)

- One patient had a coronal split of the proximal phalanx at the time of insertion. An attempt was made to stabilise this with a circlage wire. Unfortunately this failed and the prosthesis was revised to a silicone implant at three weeks.
- One patient sustained a coronal split of the middle phalanx at the time of insertion. The fracture was deemed to be stable and was treated conservatively. The fracture had united by the six week follow up. The patient did well and had a pain free arc of motion of 45^{o} at final follow up.

Revision – five joints (8.8%)

- One joint required revision for impending cut-out of the proximal component due to angular subsidence. The proximal component was revised to a larger pyrocarbon component. The patient did well and had a pain free arc of motion of 75^{o} at final follow up. ***See figure 4***
- Three joints (in two patients) required revision to silicone joints for unexplained pain with the pyrocarbon implant in situ. No evidence of

sepsis was found pre or intraoperatively. Both of these patients were pain free with an excellent range of motion following the revision surgery.

- One joint was revised to silicone due to fracture at insertion which failed conservative treatment (discussed above).

Squeaking – two joints (3.5%)

- Both cases were swan neck deformities.
- Both cases had no component subsidence.
- Average arc of motion was 82.5^{o}
- The noise was not too bothersome to the patients.
- One patient had surgery to correct the swan neck deformity which improved the range of motion and the squeaking disappeared. The other patient elected not to have any further surgery.

DISCUSSION

Since the introduction of PIP joint replacements by Swanson in 1968, silicone has been the predominant material used in these prostheses. Overall satisfactory results have been reported in the literature with this implant. Kobayashi and Terrono in 2003 reported satisfactory long term results using silicone prostheses. They did however find varying rates of bone resorption (up to 35%) and subsidence leading to a decreased arc of motion.

Takigawa et al. in 2004 retrospectively reviewed 70 silicone implants in 48 patients at a mean follow up of six and a half years. They reported similar results to Kobayashi showing silicone arthroplasty to be effective in relieving pain but did not improve range of motion or correct deformity. Lin et al. in 1995 reported similar results. Silicone synovitis, instability and implant longevity continue to be the major concerns with the use of these implants.

Pyrocarbon PIP joint arthroplasty is a relatively new idea, first becoming available in 2000. Since then studies reviewing the use of this implant have shown encouraging results.

Chung et al. in 2009 reviewed 14 patients with 21 pyrocarbon implants at a 12 month follow up. They found good pain relief in all patients. Mean arc of motion decreased slightly from the preoperative state (mean postoperative arc = 38^{o}). Complications included three joints which developed squeaking and three joints which dislocated.

Tuttle and Stern in 2006 reviewed 18 pyrocarbon implants in eight patients with a mean follow up of 13 months. Their results were similar to Chung, et al. where they showed good pain relief but no improvement in arc of motion.

Stutz, et al. reviewed 13 joints and found good pain relief in most of the patients. Interestingly they found that the arc of motion increased from 51^{o} preoperatively to 77^{o} postoperatively which was in contrast to the studies by Chung et al. and Tuttle and Stern.

Bravo, et al. in 2007 retrospectively reviewed 50 joints in 35 patients at a mean follow up 27 months. Patient satisfaction with the procedure was 79%. Arc of motion improved from 40^{o} preoperatively to 47^{o} postoperatively, but this was not statistically significant. They noted that radiological subsidence without apparent loosening occurred in 20 joints (40%).

Wijk et al. reviewed their results of 53 pyrocarbon PIP joint replacements performed in 43 patients. All patients reported decreased pain. They found no improvement in range of motion and grip strength. One third of patients reported a clinically significant improvement in occupational performance and satisfaction. A total of 13% of the joints required a secondary surgical procedure.

Branam, et al. in 2007 compared the outcomes of silicone PIPJ arthroplasties to pyrolytic carbon implants in patients with osteoarthritis in a retrospective review of 41 arthroplasties in 22 patients with severe PIP joint osteoarthritis performed by a single surgeon. There were 22 silicone joints and 19 pyrocarbon joints. Their results showed that silicone had a statistically higher number of coronal plane deformities, and as a result satisfaction with appearance was better with the pyrocarbon group. Both groups had good pain relief. Arc of motion was not improved in either group.

Other studies have published poor results including problematic bone fixation with pyrocarbon implants (Herren et al., 2006). This study observed migration of the pyrocarbon prosthesis in eight out of seventeen joints and radiolucent lines in a further three more. Patients were evaluated at a mean of 20 months. Grip strength and range of motion outcomes were found to be less favourable for these patients, although it was not found to be statistically significant.

One needs to be aware of the normal radiological appearance of these implants when evaluating follow up radiographs. The carbon graphite substrate contains 1% atomic weight of tungsten, making it radiopaque, whereas the pyrocarbon outer layer is radiolucent (Bravo et al., 2007; Cook et al., 1983). This could be confusing in that the radiolucent seam around the implant may be confused with loosening, but is actually the normal appearance of the implant. Loosening should be assessed rather by serial radiographs demonstrating progressive periprosthetic lucency (Bravo et al., 2007).

Comparing our results to those in the reported literature, we find that some of our outcomes are comparable and some are conflicting.

Our overall patient satisfaction was good as judged by a visual analogue scale (average score 4.2 out of 5 indicating that patients generally thought the result was better than expected or fantastic). Other studies in the literature which also used a scoring system had similar results to ours.

Pain relief was excellent in our study. All other published reviews in the literature also reported good pain relief.

Subsidence, either angular, axial or both, occurred in 30% of joints in our series. Similar results for subsidence were found in the literature. As discussed previously these pyrocarbon implants lack the ability to osseo-integrate. As a result of this a high proportion of these implants tend to migrate in the medullary canal but they usually settle into a stable position and do not progress. In our series only one patient developed severe subsidence and impending cut out which required revision to a larger proximal component. All the other cases stabilised and we found no correlation between subsidence and range of motion. The outcome of those joints that developed subsidence was similar to those joints that did not.

Range of motion in our study improved from an average arc of 30^{o} preoperatively to 66^{o} postoperatively. This is an improvement of 120% and was calculated to be extremely statistically significant. This is in contrast with the results of the most of the studies in the literature where the arc of motion was largely unchanged or not statistically significant. We postulate that our improvement in range of motion may be due to the accelerated active flexion protocol which is facilitated by bony attachment of the extensor tendon to prevent extensor lag.

Other surface replacement arthroplasty implants for the PIP joint are available. One that is currently in use involves a proximal component with a cobalt chrome alloy articulating surface, and a distal component consisting of ultra high molecular weight polyethylene. Both components have a textured titanium stem allowing for an uncemented press-fit fixation. Previous versions of this implant relied on cement fixation. A retrospective study comparing the long-term results of the use of the cemented and uncemented versions of this implant from a single surgeon's experience found that there was no difference in the postoperative pain scores or the postoperative arc of motion for the cemented versus the uncemented group (Johnstone et al., 2008). There were significantly more cases with radiologic evidence of loosening in the uncemented group. Revision rate was higher in the uncemented group (26%) compared with that of the cemented group (8%), but this difference was not statistically significant. An earlier study by the same surgeon reviewing 20 joints in 13 patients using the cemented implant found that all patients had excellent pain relief and no patients lost motion (Johnstone, 2001). The author did note that results improved as experience was gained and a more intensive rehabilitation protocol was used. These results are similar to the results of studies done on the pyrocarbon surface replacement implant, in that excellent pain relief is achieved but range of motion is largely unchanged.

The results of our study suggest that the pyrocarbon PIP joint replacement is a safe and effective treatment for arthritis of the PIP joint. Pain relief is excellent and arc of motion is increased by more than double that of the preoperative ROM. The incidence of complications is fairly high, but most are minor and often do not need further treatment. The complications that require treatment often are relatively easy to manage and are usually associated with a successful outcome. Further research into the ideal surgical technique and improved implant materials will no doubt lead to improved outcomes. From the results we obtained using the pyrocarbon implant we can recommend its use for the treatment of osteoarthritis of the PIP joint.

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Figure legend

Figure 1: AP and lateral radiographs of a patient after multiple pyrocarbon PIP joint replacements

Figure 2: Radiograph of a pyrocarbon joint showing no subsidence

Figure 3: Lateral radiograph of a well sited pyrocarbon implant which developed a swan neck deformity

Figure 4: Radiograph of a pyrocarbon PIP joint replacement showing proximal component subsidence and angular migration, as well as distal component subsidence. Due to the impending cut-out, the proximal component was revised to a larger implant.

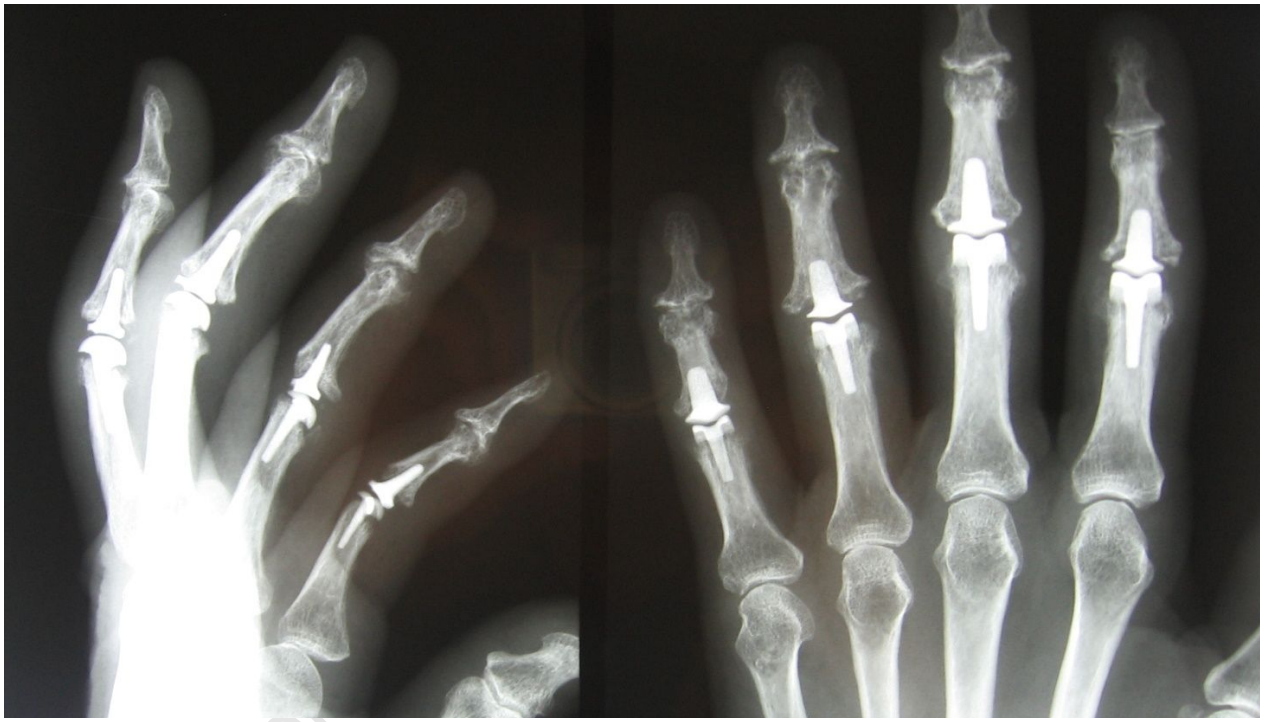

Figure 1

Figure 2

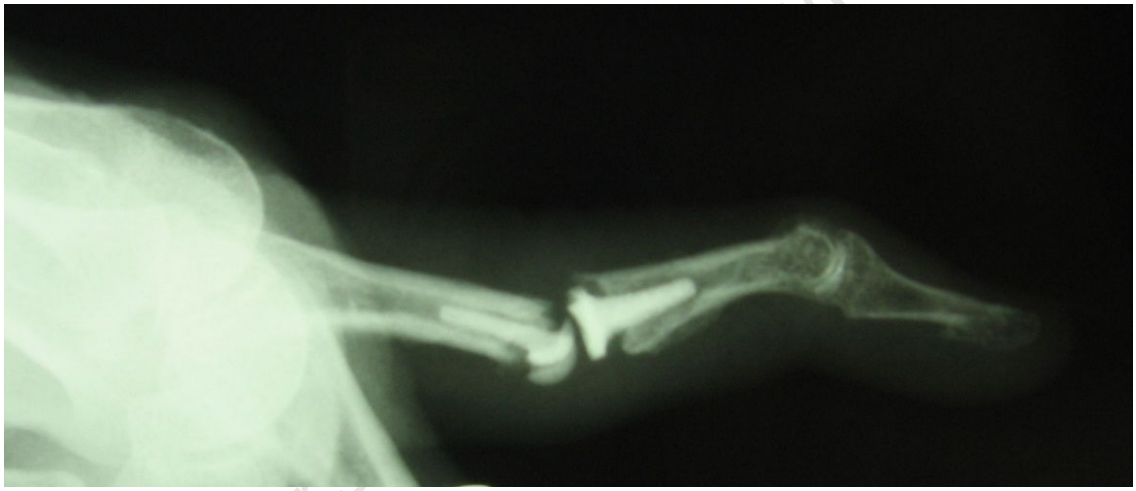

Figure 3

Figure 4

Part D – Supporting documents

PROFORMA: PYROCARBON PIP JOINT REPLACEMENT

PT. INFO

Pt Initials:
DOB:
Age at surgery:
Approach used:

ARC OF MOVEMENT

Pre op ROM:
6 m ROM:
Final ROM:

OUTCOME

Satisfaction score (1-5):
Final XR:
Evidence of subsidence:

COMPLICATIONS

Swan Neck
Boutonniere
Stiffness
Revision
Infection
Pain
Squeaking
Migration
Dislocation

FURTHER SURGERY

OTHER

Satisfaction score sheet : Visual analogue scale

SATISFACTION WITH RESULT

5  FANTASTIC RESULT, HAPPY TO RECOMMEND PROCEDURE

4  BETTER THAN EXPECTED RESULT

3  RESULT EXPECTED

2  LESS THAN EXPECTED - WOULD CONSIDER PROCEDURE AGAIN

1  UNSATISFIED, WOULD NOT WANT SAME PROCEDURE AGAIN