Brief Report

Pyrocarbon joint resurfacing of the shoulder: is it clinically safe and effective?

Reviewer | Natalie Hardaker
---|---
Date Report Completed | January 2013

Important Note:
- This report is not intended to replace clinical judgement, or be used as a clinical protocol.
- A robust evidence review of; the highest levels of evidence available relevant to the focus of this report was carried out. This does not however claim to be exhaustive.
- The document has been prepared by the staff of the research team, ACC. The content does not necessarily represent the official view of ACC or represent ACC policy.
- This report is based upon information supplied up to January 2013

Purpose

The purpose of this report is to:
- Report on the safety and clinical effectiveness of pyrocarbon joint resurfacing of the shoulder
- Discuss the comparison to current standard treatment
- Identify patient groups where pyrocarbon joint resurfacing may be most beneficial
- Consider evidence for short and long term patient outcomes following pyrocarbon joint resurfacing versus current standard treatment
- Consider the cost benefit of pyrocarbon joint resurfacing

Key findings:
- There is currently no published literature around Pyrocarbon joint replacement of the shoulder
- Pyrocarbon has been successfully used in heart valve replacement for over 30 years
- There is limited low level evidence reporting successful outcomes for pyrocarbon joint replacements of the metacarpophalangeal (MCP) and proximal interphalangeal (PIP) joints of the hand
- The Ascension PyroTITAN MCP and PIP joint replacement devices have received FDA approval
- The Ascension PyroTITAN shoulder joint replacement device does NOT yet have FDA approval
- Pyrocarbon appears to be a clinically, safe and effective alternative to conventional joint prosthesis of the MCP and PIP joints
• When considering the MCP and PIP joints, Pyrocarbon appears to be most effective for younger patients with osteoarthritis or posttraumatic arthritis

• TheAscension PyroTITAN shoulder joint replacement device is currently the only one available in New Zealand

• Expert consensus in Australia and New Zealand supports the use of Pyrocarbon in shoulder joint replacement and reports successful short term outcomes for patients

Recommendations

• Monitor the literature for the research specific to the use of Pyrocarbon in shoulder joint replacement

• Monitor the literature for FDA approval of the PyroTITAN shoulder joint replacement device

• ACC purchase on a case by case basis; with strict criteria around patient selection

• ACC considers using patient selection criteria similar to those detailed in the Paris Conference proceedings report¹

• The procedure should only be performed by those surgeons with the appropriate training and experience

• All cases performed in New Zealand should follow a simple and standardized follow up protocol (Oxford scores preoperatively and yearly follow up, X-rays post op and at yearly intervals). This information could be independently assessed over a period of a few years until more international information is available
1. Background

The purpose of this brief report is to consider the safety and clinical effectiveness of Pyrocarbon (PyC) joint resurfacing of the shoulder particularly in younger osteoarthritic patients and consider whether it is an appropriate treatment option for ACC clients in terms of positive functional outcomes and cost effectiveness.

Current standard treatment of shoulder replacement in Arthritis and traumatic injury

For patients suffering joint pain or dysfunction due to arthritis and traumatic injury, hemiarthroplasty1 and/or total joint replacement may be indicated where medical management has failed to relieve the pain or where there is a loss of function. Use of a cobalt chrome prosthesis is the current standard treatment where shoulder joint replacement/resurfacing is required2.

What is Pyrocarbon?

Pyrocarbon (PyC) is a synthetic material it is a specific form of carbon that has been tailored for durability and compatibility and has portions of 2-D and 3-D crystalline structures, resulting in excellent strength and wear properties between those of graphite and diamond3. PyC used in joint replacement is formed as a coating that is deposited onto a high-strength graphite substrate. It is a strong, ceramic-like material4.

In 1969 PyC became standard in the manufacture of artificial heart valves3 4. Over 30 years of evidence has recorded three million PyC heart-valve components being implanted, resulting in more than fifteen million patient-years of experience. The high functional demands placed on an artificial heart valve offers practical demonstration of the high-strength, fatigue wear-resistance, reliability and durability of PyC3.

In addition to the evident durability PyC also has very attractive mechanical properties as an orthopaedic implant material. It has an elastic modulus similar to that of cortical bone (functional part of bone; the cortex – the outer shell), which makes it biomechanically compatible with bone3.

Current clinical use (application) of Pyrocarbon

Pyrocarbon (PyC) is most commonly used in implant arthroplasty of the arthritic finger joint, the goals of which are; pain relief, correction of deformity and improvement of function. Since 1979 PyC has been used successfully as a material for the construction of load bearing prosthesis in joint resurfacing and hemiarthroplasty of the metacarpophalangeal (MCP) joint and proximal interphalangeal (PIP) joint of the hand3. Short-term results demonstrated an improvement in ROM, relief of pain, adequate biological fixation, and few complications3. The most popular alternative prostheses are silicone implants and are effective in decreasing pain and improving cosmetic appearance but less effective in re-establishing functional joint strength and motion, further to this other problems associated with silicone implants are; implant fracture, bone reaction adjacent to fracture, implant dislocation and silicone synovitis.

Reported advantages of PyC over traditional materials are:

- Elimination of wear-related failures
- Absence of osteolytic adverse tissue reactions

1 Shoulder hemiarthroplasty - humeral prosthesis without replacement of the glenoid, total shoulder arthroplasty - humeral prosthesis with glenoid resurfacing via prosthesis

Accident Compensation Corporation
Excellent fatigue resistance
Minimisation of stress-shielding effects and bone resorption
Excellent compatibility with joint cartilage and bone tissues
Non-cemented fixation via bone apposition

Destruction of articular cartilage is another problem associated with metal or silicone implants. Survival of native cartilage articulating with PyC in hemiarthroplasty of the MCP and PIP joints has been reported to be 92% compared to 20% survival of cartilage articulating with metal alloy prostheses; further demonstrating the biocompatibility of PyC in joint prostheses.

2. Methodology
Searching was carried out on Google, Cochrane library and healthcare databases – PsycINFO, Medline and Embase using search terms; “Pyrocarbon joint replacement”, “shoulder arthroplasty”, “Pyrocarbon Joint replacement of the shoulder”. Searching for articles relating to Pyrocarbon joint replacements and shoulder joint prosthesis. Initially no date limits were applied to searching.

Commercial websites were also searched for detail of published research.

3. Results
Articles were excluded if they; were animal studies, did not include either Pyrocarbon as a joint replacement technology.

There is a lack of high quality RCTs, and systematic reviews in this area; Case series and case reports are therefore included in this report to increase the volume of literature.

Literature considered for this report includes; 1 health technology assessment evidence based analysis, 1 prospective case series, 3 retrospective case reviews and 1 book chapter. The literature reported the use of PyC implants at the MCP & PIP joints.

Collectively the literature reports the highest overall n for the use of PyC at the MCP joint (n=53, 151 joints), followed by the PIP joint (n=17, 31 joints). There was no literature specifically addressing the use of PyC in shoulder joint arthroscopy.

There is no literature directly addressing the use of PyC at the shoulder joint, as such; one conference proceeding and 1 expert statement were also included as additional information and were specifically reporting PyC in shoulder joint resurfacing. The expert statement reflects practical experience of with the PyroTITAN device in a New Zealand context and is from shoulder surgeons with experience in this area.

4. Review of the Literature
The existing body of evidence is around the use of PyC implants at the MCP, PIP and CMC joints. There currently appears to be no research around the use of PyC at the shoulder joint.
<table>
<thead>
<tr>
<th>Joint</th>
<th>Number and Type of studies</th>
<th>Conclusion</th>
</tr>
</thead>
</table>
| MCP          | 1 Evidence based analysis, 1 retrospective case review | Improves restricted ROM  
Relieves pain  
Most effective in OA, not suitable for RA |
| PIP          | 1 Evidence based analysis, 2 retrospective patient review, 1 prospective case series | Relieves pain  
Most suitable for OA |
| Shoulder     | 1 Conference proceeding, 1 expert statement | PyC safe and effective alternative to cobalt chrome joint prosthesis  
Offers favourable patient outcome for pain and function at 2 year follow up |

### 4.1 Pyrocarbon implants in the PIP joints

The Ontario Health Technology Assessment series carried out an evidence based analysis\(^4\) of the use of PyC implants at the PIP joint. The analysis was inclusive of 2 unpublished case series (all available literature meeting search criteria). Combined the 2 studies represented a total of 43 patients, 22 of which had Osteoarthritis (OA). The studies had a 12-18 month follow up period.

The analysis highlighted that PyC had the following advantages over the existing gold standard technology (silicone finger joint implant);

- Improvement in the arc of motion
- Pain relief

Patient selection appears to be an important factor in the overall success of the PyC implant. The patient must have soft tissue and bone that can provide adequate stabilisation and fixation under high demand loading conditions after the reconstruction.

The review highlights the following factors as important considerations for patient selection;

- condition of associated soft tissues, ligaments & bone; they must provide adequate stabilisation and fixation under high demand loading conditions after the reconstruction (PyC can be considered for young patients with posttraumatic arthritis or OA where soft tissues, capsules and collateral ligaments are likely to be preserved)
- Age of the patient
- Activity level of the patient

The evidence included in the analysis does not appear to support the use of PyC implants at the PIP joint for older patients and those with severe Rheumatoid Arthritis (RA).

Further to this, the following contraindications are noted;

- Inadequate bone stock
- Sepsis or active infection of the joint
- Non-functioning and irreparable musculotendinous system problems
- Physical interference with or by other prosthesis
- Procedures requiring modification of the prosthesis
- Presence of the skin, bone, circulatory, and/or neurological deficiency at the implantation site

The Ontario Health Technology Assessment evidence based analysis also highlighted that PyC in the PIP joint has received FDA approval. At the time of market clearance the FDA made the following recommendations as indications for use:

- The presence of pain associated with arthritis
- Limited joint motion
- Joint subluxation or dislocation secondary to damage/destruction of the articular cartilage
- Where revision of existing PIP prosthesis is necessary

A retrospective cohort study (n=17, 31 joints) of PyC PIP joint implant reported a high complication rate. The study was carried out in patients with primary OA of the PIP joint for at least 2 years. Criteria for inclusion; preoperative coronal angulation <20°, adequate bone stock and intact collateral ligaments. Exclusion criteria; inflammatory arthropathy and posttraumatic arthritis.

The average range of motion (ROM) for the entire sample was 57° preoperatively. The best measurement was 67°, and occurred 11.6 months postoperatively. However at the time of final follow up average ROM had decreased to 31°. This would indicate a long term functional deficit.

Mean pain on VAS scores is reported as 3/10 at final follow up – as this was a retrospective study, preoperative scores were not available; it is therefore not possible to comment on the PyC implant impacted on pain. The reported postoperative VAS scores of 3/10 can be considered low and suggests that patients had minimal pain.

Patient satisfaction for the entire sample averaged 3.4 on a 5-point Likert scale (5, indicating very satisfied, to 1, indicating very dissatisfied). Five patients were very satisfied, five were satisfied, three were indifferent, and four (23%) were very dissatisfied. Patient ratings of the appearance (with 0 indicating poor and 10, excellent) averaged 7 and eleven of seventeen (65%) patients stated that the appearance was improved. Twelve of seventeen (71%) patients stated that they would have the operation again. This suggests that patient satisfaction with the results is reasonable.

15 patients had OA in both hands but were operated on unilaterally. Comparing scores from the Michigan hand outcomes questionnaire (MHQ) on the involved and uninvolved side reflected poorer outcomes in the operatively treated hand. Combined with the apparent decreased postoperative ROM, these results do not support PyC joint replacements as improving functional outcomes in this patient group.

There were 60 complications reported in 28 joints, including; contracture (65%), loosening (48%), squeaking (35%), dislocation (16%), subluxation (13%), wound-healing problems (6%), intraoperative fracture (6%), implant fracture (3%). Only 3 joints in total were reported to be free of complication.
This is a relatively small study with a number of limitations. It therefore is not sufficient to suggest that PyC joint prosthesis are clinically ineffective; it does however usefully highlight some potential criteria for consideration when selecting patients appropriate for receiving this technology. The inclusion and exclusion criteria used in this study are in agreement with those reported in the Ontario Evidence based analysis.

Collectively the research suggests that PyC implants at the PIP joint are most effective in relieving pain. It is unclear how effective PyC is at improving functional outcomes in this patient group. Care should be taken interpreting the results of such small studies. Further research inclusive of a larger study group and longer term follow up is required.

4.2 Pyrocarbon implants in the MCP joints

The Ontario Health Technology Assessment series carried out an evidence based analysis of the use of PyC implants at the MCP joint. The analysis was inclusive of 1 multisite case series (all available literature meeting search criteria), which is the same case series returned from searching carried out for this brief report.

The retrospective review of long term (11.2 years post operative) outcome of PyC implants at the MCP joint represented a total of 53 patients (151 joints), 44 of which had RA, 3 had OA, 5 had post traumatic arthritis (PTA) and 1 had Systemic Lupus Erythematosus (SLE). The average age at time of operation was 58 years. The study reported 12% of implants needed revision, due to; subluxation, dislocation, soft tissue imbalance and in one case fracture due to heavy lifting. Seventy seven percent of joints were replaced with an alternative implant, the remainder had another PyC implant inserted with the addition of bone cement or bone graft. At long term follow up no patients reported pain specific to the implant and all demonstrated increased ROM and were subjectively satisfied with functional outcome (determined by the ability to return to sport/ADL and work).

This review was also used by the FDA for summary of safety and effectiveness data. Patients were evaluated in groups for success criteria. Patients with RA and SLE (group 1) were grouped together and patients with OA and PTA (group 2) were grouped together. Success was determined by the long term effectiveness of the implant. Group 1 (RA/SLE) demonstrated a 59% success rate 5 years postoperatively. Group 2 had a success rate of 78% 2 years postoperatively. The elevated success rate seen in the OA group suggests that the PyC implant is more effective for OA than RA. However it is important to note that it could also be due to the following factors;

- shorter follow up time 2 years vs 5 years in RA
- fewer cases with OA allowing for less complications

Rationale from the FDA around the different follow up periods for determining success is not defined.

The analysis highlighted that PyC offers the following benefits at the MCP joint;

- low rate of fracture
- low rate of revision
- high rate of patient satisfaction
- improved finger function
- pain relief
- no evidence of particulate synovitis or intracellular wear particles
The evidence included in the analysis supports the use of PyC implants at the MCP joint, offering favourable outcomes, particularly in younger patients with OA and PTA.

4.3 Pyrocarbon in shoulder joint replacement

Refer to additional information - Section 7

4.4 Adverse effects

Adverse effects reported when using PyC implants:
- at the PIP joint were: contracture, loosening, squeaking, dislocation, subluxation, wound-healing problems, intraoperative fracture, implant fracture
- at the MCP joint were: subluxation, dislocation, soft tissue imbalance and in one case fracture due to heavy lifting

All of the above complications have also been associated with standard metal and silicone implants.

To date no complications have been noted when using PyC at the shoulder.

4.5 Cost of procedures

There is no research directly investigating the cost benefit PyC.

The cost of the implant is $3755. It is reported to be a relatively quick procedure and could therefore be considered cost effective.

5. Conclusion

There is a paucity of high level (RCT, systematic reviews) research investigating the use of PyC in joint prosthesis. Available evidence is low level (case series, expert statement). The literature that does exist to date reports positive results for the use of PyC at the PIP and MCP joints.

Collectively the research suggests that:

- PyC appears to address some of the problems associated with current ‘gold standard’ treatment for joint replacement in the PIP and MCP joints of the hand
- PyC may be effective in reducing pain and improving functional ROM in problematic joints associated with OA and PTA
- PyC appears to be a safe and effective alternative to metal and silicone joint prosthesis
- PyC appears to be more suitable in younger patients
- The complications reported with PyC are similar to those reported with current standard joint prosthesis
- PyC appears to be less effective in older patients and those suffering RA
- PyC has the potential to address the problems associated with cobalt chrome joint prosthesis at the shoulder (including; damage to native tissues in contact with implant)
• The use of PyC in shoulder joint replacement is not yet fully understood; though it is now being closely monitored

• Based on expert opinion PyC appears to be a viable alternative to cobalt chrome for joint replacement of the shoulder in the young osteoarthritic patient

• To date no complications or adverse effects have been reported in Australia and New Zealand, though this procedure remains in its infancy

As such ACC should remain conservative and have strict criteria around those clients that are selected for PyC joint replacement at the shoulder and should restrict the procedure to those surgeons with appropriate training and experience.

Suggested patient criteria should follow that reported in the Paris report;

• Primary diagnosis of Osteoarthritis or post-traumatic arthritis (ordinarily following proximal humeral fracture or recurrent dislocation)

• Patient age is at least 18 years (and is skeletally mature) and not more than 75 years at time of surgery

• Consider integrity of rotator cuff (prior rotator cuff surgery – may not be suitable) best assessed by ultrasound or MRI

• Patient willing and able to comply with necessary rehabilitation program

• Patient does not require glenoid replacement
6. References

7. Additional information

7.1 Conference proceeding presented at Paris International Shoulder course; Shoulder arthroplasty current concepts, Paris, France 2013

In May 2012 a prospective multi centre study was launched to assess clinical results and outcomes of Pyrocarbon (PyC) humeral resurfacing arthroplasty in shoulder osteoarthritis for 147 device implants around the world. The data included in this conference presentation are from 84 patients followed within Australia.

The study does not include a comparison or control group.

Inclusion and exclusion criteria were defined with regards to age, previous surgery, pathological diagnoses and rotator cuff status.

Patients (n=84) included in this presentation were; a mean age 60.5 years, 69% male and the dominant side was affected in 57% of the cases. The preoperative diagnosis was mainly primary osteoarthritis. Results reflect 1 year (n=44) and 2 year (n=40) follow up.

Patients were clinically and radiographically evaluated preoperatively and re-evaluated postoperatively with comparable clinical and radiographic tools at 3 & 6 months and 1 & 2 years to date. It is anticipated that these patients will continue to be closely monitored at 5 and 10 years post operatively.

Overall results are excellent in regards to pain relief and functional outcomes. Pain decreased significantly in the first three months and continued to decrease at 1 year. Patients with more than 1 year follow up (n=40) scores for function and pain relief still showed continued improvement.

None of the implants followed showed any loosening or erosion of the native glenoid. There were no infections or dislocations reported.

There were 2 revisions - due to device fractures occurring in the early post operative period (One patient 65 years old, fell from a high bed on to his shoulder and fractured the cap. One patient 65 years old presented with a fracture after clinical results deteriorated). Both patients scheduled for surgical revision one with another PyroTITAN device, and one with a straight forward conversion to a standard total shoulder arthroplasty. Clinical progress subsequent to revision is satisfactory in both cases at this stage.

It is reported and of note that the procedure is technically demanding. It remains unclear; how stable the implant is, how the cartilage reacts and how the bone evolves under the cap. It is anticipated that this study will go some way to define the precise indication of PyC joint resurfacing at the shoulder.

This is the first study to report the evaluation of PyC resurfacing in the shoulder joint. It is important to monitor this ongoing study to fully understand the longer term outcome of PyC in shoulder joint arthroplasty.

Early results suggest that PyroTITAN is a clinically safe and effective device and appears to be comparable to total shoulder joint arthroplasty with cobalt chrome. PyroTITAN demonstrates superior pain relief and improved function one year post operatively.

Although this study is at present unpublished it should be considered of relevance and is of reasonable quality. It is recommended that the results of this study continue to be monitored. The patient selection criteria used in this study may also be useful to guide ACC in identifying those patients that may benefit from PyC joint resurfacing at the shoulder.
7.2 New Zealand Expert opinion - Pyrocarbon joint resurfacing of the shoulder

A suitable alternative for younger patients to avoid loosening of the glenoid

Introduction

Following a recent surgical request for Pyrocarbon (PyC) joint resurfacing at the shoulder, the ACC is seeking evidence informed purchasing guidance around the safety and effectiveness of this procedure. In the absence of published literature focused on the use of PyC specifically at the shoulder joint; this expert statement aims to outline the clinical rationale and experience of this procedure and is based on clinical experience in New Zealand. It is considered that the product may have a role in reducing or delaying the need for total shoulder joint replacement and is less costly in the immediate term.

Pyrocarbon joint resurfacing

Documented evidence for the use of Pyrocarbon (PyC) joint replacement devices is limited, of low quality and focussed on the small joints of the hand. Despite the state of the evidence, PyC implants for the small joints of the hand are becoming standard practice and have received FDA approval.

Current thinking around shoulder arthroplasty is now changing; there is ongoing concern around the progressive wear of the glenoid with proximal and medial migration of the head associated with the standard cobalt chrome hemiarthroplasty. This is a particular concern in younger osteoarthritic patients who typically have higher functional demands and require significant and lasting pain relief. Hemiarthroplasty is normally indicated for the young osteoarthritic patient with a perfectly centred glenoid and a preserved rotator cuff. Although hemiarthroplasty may be easier to perform, it tends to lead to unsatisfactory pain relief for the patient and progressive glenoid erosion. PyC demonstrates incredibly low wear rates against native articular cartilage and bone and may provide an excellent option in this patient group where there is currently no suitable alternative; which in turn will reduce the need for surgical revision.

Using PyC for humeral resurfacing appears to offer a clinically acceptable solution.

Fundamental principles around joint anatomy, physiology and biomechanics that underpin the use of PyC at the small joints of the hand may also be applied to the shoulder together with considered clinical rationale for the use of PyC in shoulder joint resurfacing.

The PyC surface replacement in the shoulder has been developed by the Ascension Company (Australia) and much of the early trial work has been undertaken by Australian shoulder surgeons; Mark Ross and Philip Dukes in Brisbane.

Further detail around Australian experience with this device is included in the attached case series presentation; excellent results are reported and PyC is now being used in preference to a total shoulder replacement. It is noteworthy that if the prosthesis is damaged due to trauma, the results are currently unknown. The material is brittle and if it does crack, then removal should be relatively straightforward and a revision option to a hemi or total arthroplasty can occur.

New Zealand Experience

Michael Caughey and Ian Penny visited Philip Duke and Mark Ross in Brisbane to observe and upskill in the PyC surface replacement procedure. PyC has since been used in 8 patients (Michael Caughey 5 patients, Ian Penny 3 patients) in New Zealand, resulting in positive outcomes for the patients. One of the five patients who has the device also had a rotator cuff repair and was slow to improve but is now very happy with the shoulder. The
device is being released responsibly by Ascension to surgeons who have visited Mark Ross and are utilising the prosthesis.

Conclusions

In summary, although experience is limited with PyC resurfacing at the shoulder it provides an exciting option where currently there is no suitable alternative for the young osteoarthritic patient.

Collaboratively, clinical experience in Australia and New Zealand offers favourable results and appears to support PyC as clinically safe and effective for use at the shoulder joint in the young osteoarthritic patient. Short term patient outcomes are positive for pain relief and improved function.

PyC is indicated for the young arthritic patient with a preserved rotator cuff, which is best assessed by ultrasound or MRI.
### 8. Appendix

<table>
<thead>
<tr>
<th>Study/Type</th>
<th>Detail</th>
<th>Outcome/comment</th>
</tr>
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<tbody>
<tr>
<td><strong>Cook et al (1999) Long term follow up of Pyrolytic Carbon Metacarpophalangeal Implants</strong>&lt;sup&gt;7&lt;/sup&gt;</td>
<td>8 year retrospective study reporting long term (11.2 years) outcome of pyrocarbon implants at the mcp joint &lt;br&gt;n=53; total of 151 implants &lt;br&gt;Patients had rheumatoid, posttraumatic, osteo arthritis and 1 case of systemic lupus erythmatosus</td>
<td>Pyrocarbon implants decreased pain &amp; increased ROM. &lt;br&gt;High prevalence of joint stability &lt;br&gt;No adverse remodelling or resorption of bone &lt;br&gt;94% evidence of osseointegration, with sclerosis around the end and shaft of the prosthetic stems. There was minimal to moderate subsidence (&lt;4mm) in 34 implants; most of the subsidence occurred immediately postoperatively &lt;br&gt;Annual failure rate of 2.1% &amp; 16 year survival rate of 70.3% &lt;br&gt;5 &amp; 10 year survival rates were 82.3% &amp; 81.4% &lt;br&gt;Adverse reactions; 4 instances of chronic inflammatory tissue &amp; 3 instances of proliferative synovitis were noted histologically</td>
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</table>

| **Stanley et al (2008) Replacing joints with Pyrolytic Carbon**<sup>3</sup> | Detail of established use of PyC for MCP, PIP and CMC joints in RA, OA and post trauma <br>Detail of physical and mechanical properties and advantages over metal implants/joint prosthesis | Informative sound chapter but really highlights the limited use of PyC to date. Discussing the potential for further use. |

<p>| <strong>Sweets &amp; Stern (2011)</strong>&lt;sup&gt;9&lt;/sup&gt; | OA of the PIP &lt;br&gt;N=17, total 31 arthroplasties by one surgeon &lt;br&gt;Age 52-79yrs average 64yrs &lt;br&gt;ROM/Patient satisfaction/pain | 12/17 patient would have repeat surgery &lt;br&gt;3.4/5 satisfaction score &lt;br&gt;Complications included; &lt;br&gt;Implant fracture – 1 joint &lt;br&gt;Dislocation – 5 joints |</p>
<table>
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<tr>
<th>Study&gt;Type</th>
<th>Detail</th>
<th>Outcome/comment</th>
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<tr>
<td></td>
<td>Average follow up time 55 months (min 2 years)</td>
<td>Squeaking – 11 joints</td>
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<tr>
<td></td>
<td>No patients lost to follow up</td>
<td>Loosening – 15 joints</td>
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<tr>
<td></td>
<td>Outcome measure – Michigan Hand Outcomes Questionnaire</td>
<td>IP joint contracture – 20 joint</td>
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<td></td>
<td>Inclusion criteria;</td>
<td>Revision – 6 joints</td>
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<tr>
<td></td>
<td>- Primary OA of PIP</td>
<td>Consider surgeons competency/experience with technique</td>
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<tr>
<td></td>
<td>- OA &gt; 2 years</td>
<td>Authors conclude; high complication rate at PIP joint, poor patient outcomes and variable patient satisfaction – therefore no longer use PyC implant</td>
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<tr>
<td></td>
<td>- preoperative coronal angulation &lt;20 degrees</td>
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<td></td>
<td>- adequate bone stock</td>
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<td></td>
<td>- intact collateral ligaments</td>
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<tr>
<td>Moriatos (2011) Commentary and perspective of Sweets and Stern study (detailed above)</td>
<td>Longest term follow up of PyC to date</td>
<td>PyC is not without it's disadvantages – squeaking, loosening, movement, need for revision.</td>
</tr>
<tr>
<td></td>
<td>Collectively literature covers RA, OA &amp; posttraumatic arthritis</td>
<td>Favourable wear properties and inert biochemical profile of PyC only really been proven long term in cardiac valve replacement.</td>
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<td></td>
<td>In short term – most studies show high patient satisfaction</td>
<td>Reports of radiographic change at implant-bone interface are concerning</td>
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<tr>
<td></td>
<td>Nearly all studies report some clinical or radiographic loosening</td>
<td>The 2 longest term studies suggest bone does not form stable interface with implants.</td>
</tr>
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<td></td>
<td>1 other long term study (37 months) 1/3 joints needed revision</td>
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<tr>
<td>Ontario Health technology assessment (2004), volume 4 number 6</td>
<td>Includes detail of conditions; RA, OA, PTA, SLE</td>
<td>MCP – Low rate of fracture, low rate of revision, high rate of patient satisfaction, improved finger function (short &amp; long term), pain relief (level 4b – case series)</td>
</tr>
<tr>
<td>Pyrocarbon Finger Joint Implant. An Evidence-based Analysis</td>
<td>Types of joints PyC has been used in</td>
<td>PIP - Improved arc of motion, pain relief</td>
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<tr>
<td></td>
<td>MCP joints – studies published to date</td>
<td>(Level 4g – case series unpublished)</td>
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<tr>
<td></td>
<td>PIP joints – studies published to date</td>
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