

Considered Judgement Form

This form is a checklist of issues that may be considered by the Purchasing Guidance Advisory Group when making purchasing recommendations.

Meeting date: 20/03/2013

Topic: *Pyrocarbon joint resurfacing of the Shoulder*

Background and Purpose:

The purpose of this brief report is to describe the use of Pyrocarbon (PyC) for joint resurfacing and consider whether it is a safe and effective treatment option for the osteoarthritic shoulder in terms of positive client outcomes and cost effectiveness.

Pyrocarbon (PyC) is a synthetic material tailored for excellent strength and wear properties. In 1969 PyC became standard in the manufacture of artificial heart valves, demonstrating the high-strength, fatigue wear-resistance, reliability and durability of PyC.

When used in joint replacement PyC is formed as a coating that is deposited onto a high-strength graphite substrate.

In addition to the evident durability PyC also has very attractive mechanical properties as an orthopaedic joint 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 bone.

PyC has been used successfully as a material for the construction of load bearing prosthesis in joint resurfacing and hemiarthroplasty of the small joints of the hand, which has resulted in improvement in range of motion (ROM), pain relief, adequate biological fixation, and few complications. Consequently PyC implants are now preferred to the most popular alternative prostheses; silicone implants which are effective in decreasing pain and improving cosmetic appearance but less effective in re-establishing functional joint strength and motion.

PyC implant devices for the small joints of the hand have received FDA approval.

The Ascension Company (Australia) have developed the PyroTITAN device; which is a PyC resurfacing implant for the shoulder joint; the device has not yet received FDA approval, however it is being monitored very closely and results are being collected with a view to entering the American market.

PyC joint resurfacing may have a place in managing osteoarthritis and Post-traumatic arthritis of the shoulder joint, particularly in the younger patient. To date there is no published literature documenting the use of PyC at the shoulder joint.

The current standard alternative treatment to PyC resurfacing is the cobalt chrome full or hemi arthroplasty.

The purpose of this report is to summarise the evidence for the safety, effectiveness, appropriate use and any associated cost benefit of PyC resurfacing at the shoulder joint.

1. Effectiveness, Volume of Evidence, Applicability /Generalisability and Consistency / Clinical impact

Comment here on the extent to which the service/product/ procedure achieves the desired outcomes. Specific reference needs to be made to safety. Report number needed to treat and harm where possible, any issues concerning the quantity of evidence and its methodological quality and the extent to which the evidence is directly applicable or generalisable to the New Zealand Population, and the degree of consistency demonstrated by the available evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence. Comment on the clinical impact e.g. size of population, magnitude of effect, relative benefit over other management options, resource implications, balance of risk and benefit.

Effectiveness

The intended outcome when using Pyrocarbon (PyC) in joint resurfacing is; improved pain relief & long term improved functional outcomes. Upward of 80 cases with up to 2 year follow up across Australia and New Zealand demonstrate that PyC joint resurfacing at the shoulder appears to be well tolerated with minimal adverse effects (few cases requiring revision – which is a straightforward procedure) resulting in patient outcomes at least as good as current standard treatment (cobalt chrome implant), with a decreased risk of glenoid loosening or erosion.

PyC potentially offers a viable treatment option for the young osteoarthritic patient, where there is currently no suitable alternative.

The documented use of PyC in heart valve replacement^{1 2} highlights 30 years of evidence recording three million PyC heart-valve components being implanted, resulting in more than fifteen million patient-years of experience; testament to the biocompatibility and durability of the material.

PyC implants for use in the small joints of the hand have received FDA approval. There have been no clinical trials seeking FDA approval for the PyC device used at the shoulder joint; however the device is being closely monitored and results collected with the potential of entering onto the American market.

Seven pieces of evidence were included for appraisal to inform this review; 1 evidence based analysis¹, 1 prospective case series³, 3 retrospective case reviews^{4 5 6}, 1 expert statement⁷ and 1 conference proceeding⁸.

On balance there is limited evidence of low-moderate quality reporting on the use of the PyC in the orthopaedic setting. The studies included reported the use of PyC implants in the small joints of the hand. One expert statement and 1 conference proceeding document the use of PyC specifically at the shoulder in the young osteoarthritic patient. Although the expert statement and conference proceedings should only be considered as additional information rather than evidence; they are particularly useful here as there is a paucity of published literature available and they are specific to the Australian/New Zealand context. The documents also offer some practical interpretation and experience of a relatively new technology. It is noteworthy that the conference proceeding details a preliminary results from a multicentre study of reasonable quality.

Where used, PyC is consistently reported to be a safe and effective alternative to other conventional procedures for joint arthroplasties. Reported adverse events are few and are relatively minor. Where there is a need for revision the procedure is straight forward. PyC at the shoulder joint appears to be most appropriate for the young osteoarthritic patient to meet increased functional demands and decrease the likelihood of glenoid loosening or erosion associated with standard cobalt chrome full or hemi arthroplasty, respectively.

2. Cost

Where possible and reported in the published research literature any economic analysis of the new treatment is considered. Where possible the following will be considered; total costs of the new intervention and number of claimants likely to be affected are considered, along with comparison with the cost of current treatments or interventions, actuarial assessment of the impact of the intervention on scheme liability (including direct and indirect impact e.g. other services and access), expected "accrued benefit" in terms of quality of life, longer life or speedier return to the workforce, implications of cost to the wider health sector.

The cost of the PyroTITAN (Ascension company) shoulder implant is NZD\$3755; additional to this will be the cost of the procedure

There is no documented research for the cost benefit of PyC implant at the shoulder joint. It is a relatively quick surgical procedure; suggesting it could be cost effective.

3. Equity

The extent to which the intervention reduces disparities in health status; in particular equity of access and health outcome. The extent to which the intervention supports the objectives of the Maori access strategy and will encourage access to assessment, treatment and rehabilitation services for those groups where there is evidence of that access is problematic.

There are no equity issues directly associated with the use of this product.

4. Consistency with the intent of the IPRC Act

Purchasing decisions made by ACC must be consistent with and reflect consideration of factors described in the IPRC Act, Schedule 1, clause 2(1 and 2) and these decisions must be defensible against this statutory requirement in respect of individual claimants.

5. Possible Purchasing Options

List the possible purchasing options.

The options are –

1. purchase,
2. don't purchase and,
3. purchase on a case by case basis on the decision of the Corporate Medical Advisor

6. Evidence Statement

Summarise the advisory group's synthesis of evidence relating to this service, product or procedure, taking the above factors into account, and indicate the evidence level that applies.

There is currently no documented evidence for the use of PyC joint resurfacing at the shoulder.

There is limited, low to moderate quality evidence for the use and effectiveness of PyC as a successful alternative to silicone implants for the small joints of the hand. The Ascension company (Australia) worked with shoulder surgeons in Australia to develop PyroTITAN, a PyC implant for use at the shoulder.

Best evidence specifically for the shoulder is a conference proceeding⁸ reporting a case series (n=80) of patients in Australia receiving PyC joint resurfacing (81% with a primary diagnosis of Osteoarthritis) shows significant and lasting improvement for both pain relief and function up to 2 years postoperatively. The patients will continue to be monitored up to 10 years post operatively.

Anecdotally, 5 shoulder surgeries using PyC joint resurfacing in New Zealand have been reported. The

surgeries were carried out by 2 surgeons who have spent time in Australia up skilling on the procedure.

Collectively the evidence suggests that the use of PyC in joint arthroplasty is safe and effective for the small joints of the hand. There is reasonable clinical rationale and early unpublished evidence to support the use of PyC for joint resurfacing at the shoulder; particularly in the young osteoarthritic patient to accommodate the increased functional demands.

7. Purchasing Recommendations

What recommendation(s) does the advisory group draw from this evidence?

Suggested purchasing recommendations:

It is recommended to monitor the literature and update this report with results from any FDA trials and also those results from the ongoing patient follow-up reported in the Paris conference proceedings.

Purchasing approval through corporate medical advisor only. Consider;

- procedure should only be performed by those surgeons with the appropriate training and experience
- for patients with a primary diagnoses of osteoarthritis or post traumatic arthritis
- patient is between 18-75 years of age at the time of surgery
- patient is willing & able to take part in necessary rehabilitation
- the integrity of the rotator cuff (prior rotator cuff surgery may not be suitable)
- patient does not require glenoid replacement

PGAG Discussions:

Include criteria from the Paris report in the recommendations

NH will follow up with Michael Caughey to get further clarification around consideration of the integrity of the rotator cuff

NH continue to monitor state of the evidence and follow up on further outcomes of the Paris conference report

2/04/2013

Received feedback from external peer review of the Pyrocarbon report from Khalid Mohammed – Shoulder surgeon. Largely in agreement with the report as it is, with one additional recommendation:

All cases performed in New Zealand should follow a simple and standardized follow up protocol. An independent reviewer could assess this information at some stage. This could be used over a period of a few years until more international information is available. A suggested protocol would be

- Oxford scores preoperatively, and at yearly intervals post op
- X-rays post operatively and at yearly intervals

References

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4. Bravo CsJ, Rizzo M, Hormel KB, Beckenbaugh RD. Pyrolytic Carbon Proximal Interphalangeal Joint Arthroplasty: Results With Minimum Two-Year Follow-Up Evaluation. The Journal of Hand Surgery 2007;32(1):1-11.
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7. Caughey M. Expert statement; The clinical safety and effectiveness of Pyrocarbon joint resurfacing at the shoulder. In: Hardaker N, editor, 2013.
8. Pyrocarbon humeral resurfacing - An option in hemiarthroplasty. Paris International Shoulder course: Shoulder arthroplasty current concepts; 2013; Paris, France.