



PIPR™ Proximal Interphalangeal Replacement

Clinical Data Summary

Natural Function

Forever **Active**

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1 Summary overview of clinical data

Treatments for end-stage PIP joint arthritis

Treatment options for proximal interphalangeal (PIP) joint arthritis include arthrodesis and arthroplasty. While arthrodesis can work well, many patients prefer the retention of some movement to none at all; when there is concomitant disease of neighbouring joints, PIP fusion can result in increased stiffness of the whole finger and consequently reduced function [1,2]. The alternative, PIP arthroplasty, has been in use since the 1960s. However, early and current designs, including silicone single-piece and surface replacement devices, have been prone to high rates of complications including implant fracture [3,4], loosening and migration [4,5,6,7,8,9], failure to relieve pain [4,5], and failure to maintain or improve function and range of motion (ROM) [3,4,5,7,8,9].

Principles of the PIPR™

The goal of PIP arthroplasty is to restore a pain free, stable and strong grip with an acceptable ROM. Successful outcomes can be achieved with a well-fixed arthroplasty, accurately placed within the joint and with soft tissues intact. The device itself should provide an accurate match for the shape and size of the native joint. Its articulation should be based on a thorough understanding of the natural function of the PIP joint and work with the soft tissue envelope to achieve the greatest degree of stability and mobility possible for a given patient.

The PIPR™ was developed between 2002 and 2006 and is the result of in-depth study of the anatomy, soft tissues and biomechanics of the PIP joint [1] and novel research into its bony morphology [10]. The PIPR™ features an anatomical bearing design, provided in proportions and a size range appropriate for all PIP joints of the hand and for the entire population. The patented design includes an exterior profile that minimises bone resection, uniquely preserving functioning collateral ligaments, and is provided with advanced instrumentation to ensure fit and assist ligament balancing for optimum function. The conforming bearing maintains lateral and dorsal-palmar stability throughout the unrestricted flexion. It also permits the physiological rotation associated with the torsion of the head of the proximal phalanx during flexion-extension [10]. These advantages are achieved with a bearing couple that exhibits negligible wear [11]. With proven materials and press-fit cementless fixation, the device features all elements essential for implant longevity and is supported by a well-designed, accurate and repeatable surgical technique.

Clinical experience

The PIPR™ was first used in January 2006 at the Wrightington Hospital, UK, and to date more than 700 have been implanted worldwide. The PIPR™ has been demonstrated to improve pain, function and range of movement.

Throughout an extended series followed up at the Wrightington, good outcomes have been maintained [12-15]. The series now includes data for 100 PIPR™ devices implanted in 50 patients that were available for review at mean 47 months (range 24-77) [14-15]. Seventy-five percent of patients were female. Seventy-four percent were treated for osteoarthritis, 23% for rheumatoid arthritis and 3% for psoriatic arthritis.

Functional outcomes

Of the patients who had fully completed the pain scores (48 of 50 patients), 86% were completely free of pain at rest; the remainder noted a significant reduction in pain. Of the implants with complete pre- and postoperative data on ROM (61 of 100 implants), 72% had a preoperative ROM of greater than 20° and had a statistically significant improvement in ROM postoperatively. There was a significant improvement in grip strength for all patients with data on grip strength (52 of 56 hands). There was also a significant improvement in all scores for patients with complete pre- and postoperative outcome scores (66 of 100 implants). When considering each whole hand, there was a significant improvement in both Michigan Hand Outcomes Questionnaire (MHQ) and the Patient Evaluation Measure (PEM) scores.

Survivorship

From the same series of 100 PIPR™ implants, Kaplan-Meier survivorship at 6 years 5 months is 85%, with no difference in survival between osteoarthritis and rheumatoid arthritis subgroups. Reasons for revision included stiffness (5 implants), ulnar deviation (4 implants), swan neck deformity (3 implants) and one component dissociation very early in the series. Likelihood of recurrence of component dissociation has since been resolved with the implant now supplied factory assembled. There were no cases of infection. No implant had progressive loosening and none had lost their initial position at latest follow-up. Removal of the PIPR™ when required enabled successful conversion to silastic joint, arthrodesis or another PIPR™.

Summary

The PIPR™ has been in use since 2006 with over 700 implanted worldwide.

In a published series of 100 implants followed up for a minimum of 2 years, maximum 6 years 5 months [14-15], the PIPR™ was shown to achieve:

- good pain relief
- improvement in grip strength and function
- for many, improvement in ROM
- survivorship of 85% at maximum 6 years 5 months postoperatively

2 Key PIPR™ literature

Morphological measurements of the proximal interphalangeal joint

Lawrence T, Trail IA and Noble J. J Hand Surg (Br&Euro). 2004; 29B (3): 242–247

The morphology of the proximal interphalangeal joint was determined using a photographic technique. The head of the proximal phalanx, viewed end on, has a complex trapezoid appearance characteristic for each named digit. The asymmetric condyles diverge from one another and are separated by an intercondylar groove that increases in depth from the dorsal to the palmar surface. Sagittal sections of the head of the proximal phalanx are not circular, but, sections taken in the plane of maximum dimensions of the condyle are circular with a radius of curvature of approximately one half of the height of the condyles. The articular surface of the base of the middle phalanx is not circular in outline in either the sagittal or coronal plane. In coronal sections the articular surface is biconcave convex with a prominent median ridge separating the two adjacent concave articular surfaces. The implications of this varied morphology on implant design are discussed.

MatOrtho® Proximal interphalangeal joint arthroplasty: minimum two-year follow-up

Flannery O, Harley O, Badge R, Birch A, Nuttall D and Trail IA. J Hand Surg (Eur).

The MatOrtho® proximal interphalangeal replacement is a cementless cobalt-chromium metal-on-polyethylene mobile-bearing surface replacement arthroplasty. The aim of this study is to report the outcome and complications of this implant at a minimum of 2 years follow-up from a single institution. A retrospective case review was performed on all MatOrtho® proximal interphalangeal joint replacements performed with a minimum of 2 years follow-up. Patient demographics, diagnosis, implant revision and other surgical interventions were recorded. Subjective and objective outcomes were evaluated at latest follow-up, including pain scores, range of motion, function and radiographic assessment. A total of 109 implants were inserted in 56 patients. Nine implants (six patients) were lost to follow-up. Of the remaining 100 implants, 75 had been undertaken in females. The mean age at time of surgery was 64 years and the principal diagnosis was osteoarthritis in 74%. The mean follow-up was 47 months (range 24-77). Within the group there was a statistically significant diminution in pain. There was also an improvement in functional scores post-operatively. Improvement in range of motion was seen in those joints with a pre-operative range of motion greater than 20°. Radiologically there was no evidence of loosening or of implant subsidence at final follow-up. The revision rate was 13%. Nine joints were revised to the NeuFlex (silicone rubber) prosthesis, three were converted to an arthrodesis and one had exchange of the MatOrtho® prosthesis. The survival of the MatOrtho® proximal interphalangeal joint arthroplasty was 85% at a minimum of 2-years follow-up. Patients can be advised that the procedure achieves good pain relief, improvement in functional scores and may improve range of motion. We would, however, caution against this implant's use in joints that are either stiff or have significant deformity and/or instability pre-operatively.

In vitro wear testing of a CoCr-UHMWPE finger prosthesis with hydroxyapatite coated CoCr stems

Naylor A, Talwalkar SC, Trails IA and Joyce TJ. Lubricants. 2015; 3: 244-255.

A finger prosthesis consisting of a Cobalt-chromium (CoCr) proximal component and an ultra-high-molecular-weight-polyethylene (UHMWPE) medial component (both mounted on hydroxyapatite coated stems) was evaluated to 5,000,000 cycles in an in vitro finger simulator. One "test" prosthesis was cycled through flexion-extension (90°–30°) with a dynamic load of 10N, whilst immersed in a lubricant of dilute bovine serum. Additionally, a static load of 100N was applied for 45s every 3,000 cycles to simulate a static gripping force. A second "control" prosthesis was immersed in the same lubricant to account for absorption. Gravimetric and Sa (3D roughness) measurements were taken at 1,000,000 cycle intervals. Micrographs and Sa values revealed **negligible change** to the CoCr surfaces after 5,000,000 cycles. The UHMWPE also exhibited no distinctive Sa trend, however the micrographs indicate that **polishing** occurred. Both the CoCr and UHMWPE test components progressively decreased in weight. The CoCr control component did not change in weight, whilst the UHMWPE component gained weight through absorption. To account for the disparity between surface and gravimetric results, the hydroxyapatite coatings were examined. Micrographs of the test stems revealed that the hydroxyapatite coating was partially removed, whilst the micrographs of the control stems exhibited a uniform coating.

References

1. Trail IA. Proximal Interphalangeal Joint Arthroplasty. In: Arthroplasty of the Hand and Wrist. 2010; Chapter 4: 83-110. Publ: Lawrencekirk, Amadeus Press, Cleckheaton, UK
2. Watts AC and Trail IA. Focus On: Anatomical Small Joint Replacement of the Hand. JBJS-Br. 2011; 1-6.
3. Beckenbaugh RD, Dobyns JH, Linscheid RL and Bryan RS. Review and analysis of silicone-rubber metacarpophalangeal implants. JBJS-Am. 1976; 58(4): 483-7.
4. Sweets TM and Stern PJ. Pyrolytic carbon resurfacing arthroplasty for osteoarthritis of the proximal interphalangeal joint of the finger. JBJS-Am. 2011; 93(15): 1417-25.
5. Jennings CD and Livingstone DP. Surface replacement arthroplasty of the proximal interphalangeal joint using the PIP-SRA implant: results, complications and revisions. J Hand Surg Am. 2008; 33(9): 1565.e1-11.
6. Johnstone BR, Fitzgerald M, Smith KR and Currie LJ. Cemented versus uncemented surface replacement arthroplasty of the proximal interphalangeal joint with a mean 5-year follow up. J Hand Surg Am. 2008; 33(5): 726-32.
7. Pritsch T and Rizzo M. Reoperations following proximal interphalangeal joint non constrained arthroplasties. J Hand Surg Am. 2011; 36(9): 1460-6.
8. Watts AC, Haerden AJ, Trail IA, Hayton MJ, Nuttall D and Stanley JK. Pyrocarbon proximal interphalangeal joint arthroplasty: minimum two-year follow-up.
9. Jennings CD and Livingstone DP. Surface replacement arthroplasty of the proximal interphalangeal joint using the PIP-SRA implant: long-term results. J Hand Surg Am. 2015; 40(3): 469-473.
10. Lawrence T, Trail IA and Noble J. Morphological measurements of the proximal interphalangeal joint. J Hand Surg (Br & Eur). 2004; 29B; 3: 242-247.
11. Naylor A, Talwalkar SC, Trail IA and Joyce TJ. In Vitro Wear Testing of a CoCr-UHMWPE Finger Prosthesis with Hydroxyapatite Coated CoCr Stems. Lubricants. 2015; 3: 244-255.
12. Broadbent M, Birch A, Trail I.A Short-term Review of the Finsbury Proximal Interphalangeal Joint Replacement. 2009; BSSH, Nottingham.
13. Harley O, Dalal S, Banks L, Birch A, Hayton M, Trail IA. Long-term outcomes of Finsbury PIP joint arthroplasty for osteoarthritis. 2012; BSSH, York.
14. Flannery O, Harley O, Birch A, Hayton M and Trail IA. MatOrtho Proximal Interphalangeal Joint Arthroplasty: Minimum Two-Year Follow-up. 2015; BSSH, Bahamas.
15. Flannery O, Harley O, Badge R, Birch A, Nuttall D and Trail IA. MatOrtho Proximal Interphalangeal Joint Arthroplasty: Minimum Two-Year Follow-up. J Hand Surg (EU). 2016; 41(9): 910-916



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