■ INSTRUCTIONAL REVIEW: UPPER LIMB

Proximal interphalangeal joint replacement in patients with arthritis of the hand

A META-ANALYSIS

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We systematically reviewed all the evidence published in the English language on proximal interphalangeal joint (PIPJ) replacement, to determine its effectiveness on the function of the hand and the associated post-operative complications.

Original studies were selected if they reported clinical outcome with a minimum of one year's follow-up. Quality was assessed using the Cowley systematic review criteria modified for finger-joint replacements. Of 319 articles identified, only five were adequately reported according to our quality criteria; there were no randomised controlled trials. PIPJ replacements had a substantial effect size on hand pain of -23.2 (95% confidence interval (CI) -27.3 to -19.1) and grip strength 1.2 (95% CI -10.7 to 13.1), and a small effect on range of movement 0.2 (95% CI -0.4 to 0.8). A dorsal approach was most successful. Post-operative loosening occurred in 10% (95% CI 3 to 30) of ceramic and 12.5% (95% CI 7 to 21) of pyrocarbon replacements. Post-operative complications occurred in 27.8% (95% CI 20 to 37).

We conclude that the effectiveness of PIPJ replacement has not been established. Small observational case studies and short-term follow-up, together with insufficient reporting of patient data, functional outcomes and complications, limit the value of current evidence.

We recommend that a defined core set of patients, surgical and outcome data for this intervention be routinely and systematically collected within the framework of a joint registry.

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Osteoarthritis (OA) of the proximal interphalangeal joint (PIPJ) is relatively common, affecting approximately 18% of older adults.[1,2] The PIPJ is also commonly affected in inflammatory or autoimmune conditions such as rheumatoid arthritis and psoriatic arthropathy. Most patients are either asymptomatic or have symptoms that can be readily controlled with modification of activity and analgesic or anti-inflammatory medication. Intra-articular steroid injections can be helpful for exacerbations of pain.

Surgery is considered for persistent symptoms of pain or instability. Neurectomy may be suitable for those with painful but stable joints with a good range of movement.[3] Fusion interferes only a little with function in the index and middle fingers, which require stable pinch against the thumb, but is more disabling in the ring and little fingers, which require flexion.[4] Joint replacement aims to maintain or improve movement while removing pain.[5]

Over the past 40 years various PIPJ replacements have been designed, from simple flexible silastic hinges[6,7] to constrained hinges, and more recently anatomical surface replacements. Because PIPJ replacement is performed infrequently, individual surgeons may have limited experience. The surgeon might therefore rely on the literature for guidance. There are few review papers describing the use and outcomes of PIPJ replacements.[8-10] None has assessed or reported on the quality of the studies included: such methodology should now be mandatory for a systematic review. Only Foliart[10] described how the literature was identified. However, the search was limited to reporting Swanson silastic replacements only, and combined the complication rates of PIPJ and metacarpophalangeal joint (MCPJ) replacements. Furthermore, there is almost no information about the longer-term survival of any implant.

Unsuitable designs and a tendency towards poor early outcomes may therefore not be apparent. One design, with nearly 50% failure at six years, was only detected by chance when several surgeons with small personal series combined their results.[11] PIPJ replacement has a relatively high complication rate,[12,13] with 20% requiring reoperation in a recent series of 300 patients.[14] The orthopaedic community would not accept this level of risk or uncertainty of outcome when considering hip or knee replacement operations.

Table I. Adapted Cowley criteria for quality review

Criteria
Purpose of the study clearly stated?
Outcomes clearly defined in Introduction or Methods section?
Model specified (pyrocarbon, polyethylene, silastic, other)?
Is method of sample selection described (probability sample, convenience sample, not reported)?
Method of outcome measurement described?
Follow-up period, range and mean given?
Number of patients deceased or lost to follow-up reported?
Conclusions supported by results?
Standardised outcomes used?
Surgical approach specified (volar, dorsal, lateral)?
Method of fixation specified (press-fit, cemented, other)?
Specification of surgeon?
Sample size justification?
Study inclusion/exclusion criteria clearly stated?
Allocation of study subject described?
Description of study sample: age, gender, type of arthritis?
Patients matched/balanced for diagnoses, age, illness grade, or activity level?
Patient blind to prosthesis type (if prospective)?
Patients selected without knowledge of outcomes (if retrospective)?
Method of randomisation identified and appropriate?
Method of outcome measurement validated?
Assessment of clinical outcome blind to prosthesis type?
Assessment of clinical outcome blind to surgeon?
Evaluation of radiological findings independent of clinical results?
Measurement of confounders?
Follow-up data compared with pre-operative data (mean and range)?
Quantification of outcome criteria?
Results given for specific models?
Results given for specific digits?
Valid statistical analysis undertaken?
Data given for deceased patients?
Bias and limitations considered?
Independence of investigators noted?

Given the resources required for purchasing PIPJ replacements, undertaking surgery and post-operative rehabilitation, as well as managing early complications and later loosening, the outcomes of PIPJ replacement should be properly understood. In this paper we sought to evaluate systematically all published evidence for PIPJ replacement, in order to determine the benefit and harm with respect to the function of the hand and post-operative complications.

Materials and Methods

Electronic databases Ebsco Medline, CINAHL, Ovid EMBASE, The Web of Science, CENTRAL, DARE and NICE up to January 2012 were searched using the terms 'finger joint', 'arthroplasty' and 'prosthesis implantation'. The reference lists of all identified articles were screened for relevant studies. Single case reports were excluded only after a search of their reference lists. Articles published in languages other than English were excluded. Results were restricted to human populations, and only original articles that reported clinical outcomes of PIPJ replacement with a minimum mean follow-up period of one year were accepted. Papers were rejected if they documented only surgical technique, post-operative protocols, joint biomechanics, or the complications of surgery, or if outcome data were combined for PIP and metacarpophalangeal joints.

Quality assessment. Two independent reviewers (SB, CR) assessed the quality of the papers. A third independent reviewer (JA) resolved discrepancies. We used the Cowley checklist[15] modified for finger joint replacements (Table I), as it was specifically designed for assessment of the orthopaedic literature where observational studies are more prevalent. It differs from other quality assessment tools in that it includes criteria to assess randomised controlled trials, comparative studies and uncontrolled case series. No absolute score is derived using this system.

Studies were selected if they were prospective, included a description of the method of sample selection, loss to follow-up, the type of replacement, the method of assessing outcome and the mean (range) follow-up.

Data extraction and analysis. Data were extracted by one reviewer (CR) and checked by a statistical reviewer (AP). Objective and subjective outcomes were extracted, including range of movement (ROM), pain, grip strength, pinch

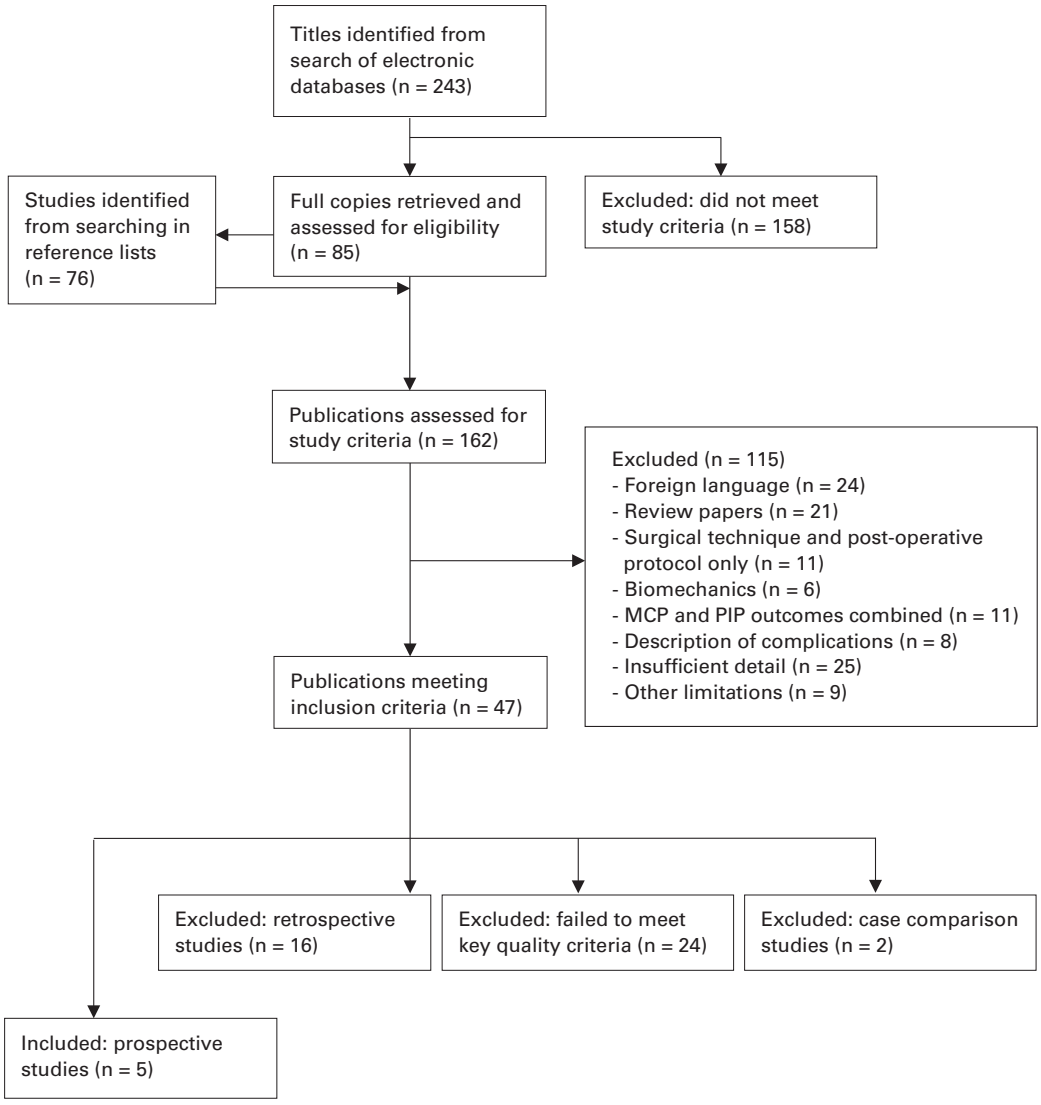

Fig. 1

Flow of papers through the study.

strength, patient satisfaction and self-reported upper limb function. Implant-related complications, including dislocation, loosening or migration, were recorded.

Individual standardised mean differences, effect sizes and odds ratios were calculated and the associated 95% confidence intervals (CI) were estimated. Calculations followed conventional data extraction and meta-analysis methods where the data were presented in the paper.

Results

The search identified 319 papers; 243 from the electronic search and 76 on searching by hand and reviewing the reference lists of relevant articles. Following a review of the electronic abstracts, 158 papers were excluded as they did not meet the study criteria, leaving 85 for further study along with the 76 above. Of this total of 162 papers, 115 were then excluded for not fulfilling the study criteria (insufficient detail on study in 25; non-English language in 24; descriptive review in 21; presenting of surgical technique and post-operative protocols only in 11; reporting of PIPJ biomechanics only in six; reporting of combined outcomes of the PIP and MCPJ in 11; reporting of complications in eight; and other wider limitations in nine).

This left 47 papers that were then reviewed using the modified Cowley criteria (Table I). A total of 24 studies failed this quality criteria assessment, 16 were retrospective, and two further studies were found to be a comparison of the results of two sets of case series rather than a true comparative study. This left a total of five prospective studies that were then included for meta-analysis. No randomised trials were identified. The quality of the studies included was moderate by Crowley criteria. Figure 1 details

Table II. Characteristics of the hand arthritis and proximal interphalangeal joint (PIPJ) replacement studies

Authors	Study design	Study participants to complete 12-month follow-up	Presenting diagnosis*	Prosthesis	Surgical approach	Mean follow-up (mths) (range)	Outcomes reported†	Complications recorded	Post-operative splint and therapy regimen‡
Herren et al[17]	Prospective case series	14 patients, 18 implants. Gender not reported. Mean age 64 years (51 to 81)	OA (13), PTA (1), chondrocalcinosis (1)	Pyrocarbon prosthesis (18)	Dorsal Chamay approach (9), Simmen palmar approach (9)	20.5 (12 to 27)	ROM, pain	Migration, loosening, stability, radiolucency	Immediate active mobilisation for 6 weeks out of a protection splint (MCPJ flexion, PIPJ, DIPJ extension). Full functional use after 6 weeks
Nunley et al[20]	Prospective consecutive series	5 patients, 7 implants. 3 men, 2 women. Mean age 40 years (28 to 56)	PTA (5)	Pyrocarbon prosthesis (7)	Ascension dorsal approach	17 (12 to 23)	DASH, VAS, satisfaction scale, pain, ROM, grip, stability (but not reported)	Amputation, revision	Ascension rehabilitation protocol. Day 4 dressing removed, dynamic (PIPJ dynamic assisted extension 0° to 30° movement) and nocturnal static splints. By 6 weeks 0° to 75° active PIPJ ROM
Pettersson et al[18]	Prospective follow-up study	20 patients, 20 implants. 8 men, 12 women. Mean age 55 years (38 to 72)	OA (13), RA (5), PTA (1), post-infection (1)	MOJE prosthesis (20)	Dorsal approach. Central slip not detached. Press-fit technique	12	Pain, grip, ROM, ADL COPM	Loosening, heterotopic bone formation	Day 1 mobilisation programme. Dynamic splint resisted flexion, reinforced stability in extension. At 6 weeks splint removed and goal 0° to 70° ROM. Minor activity without weight loading at 8 weeks
Wijk et al[19]	Prospective case series	43 patients, 53 implants. 7 men, 36 women. Mean age 59 years (40 to 85). 50 implants available at one-year follow-up	OA (28), RA (8), PTA (7)	Pyrocarbon prosthesis (53)	Dorsal approach. Central slip divided	24 (12 to 60)	ROM, pain, grip, DASH, COPM	Post-operative arthrodesis, tenolysis, teno- arthrolysis, prosthesis change, infection, skin necrosis, loosening, deformity	Mobilisation 4 to 7 days post-operative up to 6 weeks with dynamic hand-based splint with extension block to limit last 15° to 20° extension. Splint permits active flexion in PIPJ and DIPJs. Active flexion extensions 5× per day for first wk of splinting then hourly. At 5 or 6 wks post-operative light controlled activity without splint
Chung et al[16]	Prospective follow-up study	14 patients, 21 implants. Gender not reported. 13 available for 12-month follow-up	Unclear	Pyrocarbon prosthesis (10)	Pre-operative imaging, 12 lazy S dorsal incision		Grip, key pinch, ROM, Jebsen Hand Function Test, Michigan Hand Outcomes Questionnaire	Dislocation, squeaking	At 3 wks extension splint, 1 wk post-operative at 8 wks programme of dynamic splint flexion/extension ROM. Nocturnal static resting splint for 8 wks after therapy protocol complete

* OA, osteoarthritis; PTA, post-traumatic arthritis; RA, rheumatoid arthritis
† ROM, range of movement; DASH, Disabilities of the Arm, Shoulder and Hand; VAS, visual analogue scale; ADL, activities of daily living; COPM, Canadian Occupational Performance Measure
‡ MCPJ, metacarpophalangeal joint; DIPJ, distal interphalangeal joint

the flow of papers through the review and Table II the characteristics of the studies that were included.

Patient demographics and cohort statistics. If there were discrepancies between the number of patients recruited and the data presented in the results, the individual data from the tables were used and are presented here. Data from 89 patients (18 men, 50 women, and 21 of unspecified gender) ranging in age from 28 to 85 years undergoing 101 PIPJ replacements were included. The mean follow-up was 17 months (12 to 27). The diagnosis at the time of surgery included primary OA in 53; post-traumatic arthritis (PTA) in 14; rheumatoid arthritis in 14; intractable PIPJ pain in six; post-infective arthritis in one; and chondrocalcinosis in one. Exact proportions of diagnoses could not be collated, as some papers reported the numbers of patients with disease and others the numbers of joints.

The side of surgery (dominant or non-dominant hand) was reported for only five patients, and in 27 patients the digit was recorded (two index, 12 middle, ten ring and three little fingers). All papers detailed the post-operative rehabilitation regime. Periods of post-operative immobilisation, splintage, and active and resisted exercise regimes varied considerably between studies and between types of replacement.

All studies reported the outcome at 12 months, including pain, range of PIPJ movement, grip strength, and self-reported hand and upper limb function. There was minimal loss to 12-month follow-up, with the exception of one study[16] reporting early results for a larger patient cohort.

Surgical approaches and material used. The surgical approach was detailed in all studies. The dorsal approach was used in 92 joints and the palmar approach in nine. Pyrocarbon replacements (Ascension Orthopaedics, Austin, Texas) were used in 81 joints, and unconstrained two-component ceramic MOJE replacements (Moje Keramik-Implantate, Petersberg, Germany) were used in 20 joints.

Patient functional outcomes and complications. Chung et al[16] justified reporting early results for a larger patient cohort and reported an incomplete follow-up of their patients; all other studies had minimal losses to the 12-month follow-up. All studies presented pre-operative data for comparison. The studies included self-reported pain measures,[16-19] range of PIPJ movement,[16-18,20] grip strength[16,18,19] and self-reported hand and upper limb function.[16,19]

The assessment of pain involved visual analogue scores and the pain subsection of the Michigan Hand Outcomes Questionnaire (MHQ).[21] The assessment of function including self-reported hand function (MHQ), global upper limb function (Disability of the Hand Arm and Shoulder (DASH)[22]) and global occupational functional measurement (Canadian Occupational Performance Measure),[23] was included in four of the five studies. Chung et al[16] also included the clinician-rated standardised Jebsen test of

Table III. Impairment outcomes: summary data for the five studies included in the impairment meta-analysis

			Mean (SD) value			Joint outcome (n, %)			
Authors	**Outcome**	**Number assessed (12-month)**	**Pre**	**Post**	**Effect size (95% CI)**	**No change**	**Worse**	**Improved**	**Complication rate (%, 95% CI)**
Herren et al[17]	PIPJ ROM* (°)	18 (18)	33.6 (16.3)	41.1 (20.8)	0.4 (-1.5 to 2.3)	1 (*6*)	9 (*50*)	8 (*44*)	72 (49 to 88)
	Pain†	18 (18)	7.6 (1.1)	1.3 (0.6)	-7.1 (-8.7 to -5.5)	0	0	18 (*100*)	
Nunley et al[20]	PIPJ ROM (°)	7 (7)	31.9 (13.2)	25.3 (22.7)	-0.4 (-3.0 to 2.3)	0	5 (*71*)	2 (29)	71 (36 to 92)
	Grip (psi)	5 (5)	42.2 (25.6)	56.4 (26.5)	0.5 (-5.8 to 6.9)	0	2 (*40*)	3 (*60*)	
	Self-report DASH	5 (5)	32.4 (15.1)	35.4 (24.0)	0.2 (-1.7 to 2.0)	0	3 (*60*)	2 (*40*)	
Pettersson et al[18]	PIPJ ROM (°)	20 (20)	43.3 (24.7)	59.8 (22.3)	0.7 (-3.0 to 4.4)	3 (*15*)	2 (*10*)	15 (*75*)	10 (2 to 30)
	Grip (N)	20 (20)	169.4 (136.5)	365.0 (137.0)	1.4 (-40.1 to 44.3)	0	5 (*25*)	15 (*75*)	
	Pain†	20 (20)	3.0 (2.5)	0.9 (1.5)	-1.0 (-1.8 to -0.2)	4 (*20*)	2 (*10*)	14 (*70*)	
Wijk et al[19]	Pain at rest†	50 (50)	3.1 (2.8)	0.4 (1.0)	-1.3 (-1.8 to -0.7)	No individual data, but seven revisions			14 (7 to 26)
	Pain on activity†	50 (50)	6.2 (2.6)	2.0 (2.1)	-1.8 (-2.5 to -1.1)	-	-	-	
Chung et al[16]	Power grip (kg)	13 (6)	11.3 (9.9)	15.1 (12.9)	0.3 (-1.2 to 1.9)	No individual data, but three dislocations			23 (8 to 50)
	Key grip (kg)	13 (6)	6.6 (2.8)	9.2 (2.9)	0.9 (-0.4 to 2.2)	-	-	-	
	Jebsen§	13 (6)	33.7 (6.6)	27.8 (2.7)	-1.0 (-3.1 to 1.1)	-	-	-	
	PIPJ ROM (°)	13 (6)	40 (17)	38 (18)	-0.1 (-1.3 to 1.0)	-	-	-	
	MHQ¶ (overall)	13 (6)	45 (11)	72 (15)	2.2 (-6.4 to 10.8)	-	-	-	
	MHQ (pain)	13 (6)	66 (13)	22 (19)	-2.9 (-17.0 to 11.1)	-	-	-	

* PIPJ ROM, proximal interphalangeal joint range of movement
† pain as assessed on a visual analogue scale (0 = no pain to 10 = extreme pain)
‡ DASH, Disabilities of the Arm Shoulder and Hand questionnaire (0 = normal, 100 = total disability)
§ Jebsen score (time to manipulate seven objects (in seconds))
¶ MHQ, Michigan Hand Outcome Questionnaire (0 = total disability, 100 = normal function)

hand function.[24] Table II indicates which outcome measures were used in the various studies.

Hand pain. The meta-analysis of outcome data on hand pain for these five studies demonstrates a substantial improvement in self-reported hand pain (-23.2 (95% CI -27.3 to -19.1)). Table III shows that in each study PIPJ replacement was associated with a substantial effect on the reduction of pain in the hand. Where individual data were available, 100% success in improving levels of PIPJ pain was reported by one study[18] and a 70% improvement in another.[19] Unsurprisingly, the degree of improvement was greater when recorded during hand activity than during rest (-1.8 (95% CI -2.5 to -1.1) *versus* -1.3 (95% CI -1.8 to -0.7)). The largest improvement in hand pain was reported using a simple 100 mm visual analogue score (VAS) for pain (-7.1 (95% CI -8.7 to -5.5)) in a patient population suffering predominantly from OA.[18] The other studies using composite assessments or parts of larger functional questionnaires recorded more modest improvements.

Grip strength. Improvement in grip strength also demonstrated a substantial improvement when all the studies were considered (1.2 (95% CI -10.7 to 13.1)). Within individual studies, improvement in grip strength was evident in 60% of the joints replaced.[19,21] Key grip strength improved to a greater degree than power grip force when compared within studies (0.9 (95% CI -0.4 to 2.2) *vs* 0.3 (95% CI -1.2 to 1.9)).[17] The largest effect size for improvement of grip was reported for the MOJE implants, where the central slip was not detached at surgery (1.4 (95% CI -40.4 to 43.3)).

Range of movement. The increase in ROM was small when the results of all the studies were considered. The effect size was small and unlikely to be clinically significant at 0.2 (95% CI -0.4 to 0.8). The data within studies also indicate that ROM may be lost following surgery. Nunley et al[20] reported that 71% of joints lost movement at 12 months after surgery; both Nunley[20] and Chung[16] reported negative effect sizes, -0.4 (95% CI -3.1 to 2.4) and -0.1 (95% CI -1.3 to 1.00), respectively. The largest individual increase in ROM was recorded by Petterson et al,[18] with 14% of the joints unchanged, 10% having deteriorated and 76% improved. It was not evident from these studies whether the available arc of post-operative PIPJ movement was within a functional range for the digit. No study documented the measurement protocols or reliability estimates for ROM, both of which could affect interpretation.

Upper limb function. Because function was not reported by more than one study, the results could not be pooled for the purposes of this study. Table III details the individual study data, which show that self-reported global upper limb function, as measured by the DASH questionnaire, recorded a small effect size of 0.1 (95% CI -1.7 to 2.0), whereas a large effect size of 2.2 (95% CI -6.4 to 10.8) was recorded when the hand-specific Michigan Hand Outcomes Questionnaire was used.

Complications. Post-operative complications were reported in all studies. These included amputation of a finger, revision, migration and loosening; the 95% CIs for population estimates were high (Table III). Loosening occurred in 12.5% (95% CI 7 to 21) of pyrocarbon replacements and 10% (95% CI 3 to 30) of ceramic replacements. Of these loosened joints, eight (9%) occurred following a dorsal approach and three (33%) following a palmar approach. Migration occurred in 12% (n = 10) of pyrocarbon replacements, constituting 11% of all replacements introduced through a dorsal approach. There was no report of migration with ceramic replacements.

Discussion

The replacement of arthritic PIPJs has been used for over five decades to avoid the functional impairment associated with fusion. Immobilisation of a single PIPJ causes decreased excursion of the profundus tendon, thereby restricting movement in all fingers of the same hand and reducing overall hand function.[25] The American Medical Association Impairment Guide[26] associates PIP fusion with a 50% impairment of function of the finger. If a joint replacement can reliably restore joint anatomy and thereby kinematics,[27,28] this functional impairment is avoided. However, if the replacement fails, the salvage is likely to be the fusion it tried to avoid[29] after a more complex and unpredictable procedure.

Varying designs of PIPJ replacement have been introduced. Few have stood the test of time. The large variety of devices reflects the ongoing search for an ideal replacement, which should be pain free, mobile, stable, durable and salvageable.[30] Many designs have been brought to market and then withdrawn as their shortcomings became apparent in clinical practice, for example the Niebauer, Flatt, LPM, IPP2, Biomeric and MOJE replacements.

This strict systematic review of the literature provides some reliable conclusions on the outcome of PIPJ replacement. There is good evidence of reduced pain in the hand at least 12 months after surgery. This improvement is greatest during functional activity rather than at rest. Patients with osteoarthritic hands gained the greatest pain relief. This is consistent with other reports that patients with OA and post-traumatic arthritis have better outcomes than patients with inflammatory joint disease.[31,32] This review also demonstrates that the effect size for the improvement of grip strength can be large following replacement, which is to be expected as pain in the hand and grip strength are strongly correlated in patients with arthritis. However, when individual patient data are reported, up to 40% of joints in a small PTA cohort had worse grip strength following PIPJ replacement, even if the mean showed improvement. We found that improvement in ROM after PIPJ replacement was only modest. An arc of PIPJ movement from 35° to 85° may still provide normal function,[28] and so small changes in ROM are consistent with larger effect sizes for grip and levels of pain. The relevance of these ROM changes is difficult to assess specifically, as few papers report which digit was involved, which is important to know as the relevant arc of movement is different for each finger, with the ring and little fingers requiring an arc towards flexion (for power grip) whereas the index and middle fingers require an arc more towards extension (for pinch grip).

Complications following PIPJ replacement were high, with 28% of all replacements associated with at least one complication within 12 months. These complications are prevalent in both silicone arthroplasty, which has been in use for decades,[33,34] as well as for the newer-generation anatomical replacements (e.g. pyrocarbon and metal–polyethylene) considered in this paper. The thresholds for recording post-operative complications were inconsistent between studies: Herren et al[17] reported four possible separate categories, Nunley et al[20] three, Pettersson et al[18] and Wijk et al[20] one and Chung[16] two. The definition of complications varied and the sensitivity of detecting them was therefore also inconsistent. The replacement with the greater number of complications may not have been more hazardous, but merely assessed using more sensitive assessment thresholds.

A strength of this review is the explicit search strategy and the use of a recognised quality checklist to identify papers for inclusion, and the acceptance of only prospective studies. Although there is a large body of evidence that presents retrospective, small case series and short-term follow-up, we excluded these. Even large, frequently cited case series[35] were excluded, as there was inadequate description of patient recruitment and loss to follow-up. Articles describing 16 different implants were identified in the electronic search, but most were excluded as they failed to meet even basic quality criteria for the review. Papers describing the outcomes of the Digitos and Condamine implants were not available in English and so were excluded. Only studies reporting data on the MOJE ceramic and Ascension pyrocarbon replacements fulfilled the quality criteria for this review. This cannot imply that the other replacements are less effective, merely that they have been assessed in studies that were designed and reported less robustly.

Using meta-analysis on case series data is not without challenges and limitations. We recognise that case series are at greater risk from potential biases than randomised controlled methods, and that there is debate about the inclusion of quasi-controlled data in a meta-analysis.[36] Combining data involving different surgical techniques, different digits and different post-operative protocols may have obscured possible trends.

The shortcomings of the existing evidence and literature, whether review articles or original papers, remain a cause for concern. Most papers report inadequate inclusion/exclusion criteria, patient demographic data and specific detail regarding hand data, for example dominance and operated digit. Few studies include clearly defined standardised measurements of outcomes, and there is no

reference to measurement reliability and validity. Details of and follow-up data on post-operative therapy regimes are also lacking. Even the prospective studies that we have included are flawed by reporting discrepancies and small sample sizes, with consequent underpowered clinical and statistical significance analyses. Comparing the outcome of patients with a replacement against a control group without implants is not possible in surgical studies. Randomised studies to compare one replacement with another do not yet exist. Such studies are complex, expensive, and a long follow-up is required to obtain survival data. Large sample sizes are needed to show a difference in outcome. Quasi-control groups could be recruited in future from patients declining surgery but who continue to be assessed and measured. Reliable evidence upon which the widespread use of these replacements can be justified will require large-scale prospective series with defined descriptions of study population characteristics, surgical techniques, validated outcome measures and adequate follow-up periods. Systematic reviews and meaningful comparison of different devices and techniques could then be compiled from these studies.

It is proposed that all PIPJ replacements should be followed routinely with a core data set and for long enough to establish survival. The surgeon's choice should be one that has compelling design features, with independent regulatory approval.

To overcome the problem of small numbers the individual surgeon could help by contributing to a larger database or registry, which could be supported by industry, by the surgeon's professional bodies or by the state. A joint registry can provide invaluable preliminary data and detect devices prone to early failure. Labek et al[37] argue a compelling case for a joint registry, concluding that registry data surpass clinical studies because they monitor considerably larger samples under better-described, standardised and comparable conditions. They also demonstrated that registers can yield valid results more quickly than sample-based clinical studies and surveys. In the UK, there are no specific ICD-9 codes relating to PIPJ replacement, without which it is impossible to report how many procedures are performed. Although a voluntary national hand register exists in Norway, it appears ineffective:[38] in 2009 just three PIPJ procedures were recorded. The experience of the British National Joint Registry suggests that mandatory data collection imposed by the state, funded by industry and encouraged by the professional bodies, is the most feasible approach. This registry could be expanded to include hand implants.

The evidence to justify PIPJ replacement is weak; the devices used usually improve pain with some benefit on function. There are inadequate data on most replacements and there are no compelling longer-term survival data.

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