NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedures overview of prosthetic replacement of the hallux

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in February 2005.

Procedure name

- Metatarsophalangeal (MTP) joint replacement.
- Metatarsal phalangeal joint replacement.

Specialty societies

- British Orthopaedic Foot Surgery Society.
- Society of Chiropodists and Podiatrists.

Description

Indications

Osteoarthritis is a common condition in which the surface of the joint becomes worn and the adjacent bone thickens and forms osteophytes. If severely affected, the joint becomes painful and stiff.

Rheumatoid arthritis is a chronic inflammatory disease that destroys the joint and will eventually lead to end stage osteoarthritic changes.

Both kinds of arthritis commonly affect the metatarsophalangeal (MTP) joint at the base of the big toe. The joint may become predominantly stiff (hallux rigidus) or deformed (hallux valgus).

Current treatment and alternatives

Conservative treatments include exercise, physiotherapy, analgesics, non-steroidal anti-inflammatory tablets and cream, and steroid injections into the joint. Severe cases that do not respond to conservative measures may require surgery. If the only problem is an osteophyte on the surface of the joint, this may be trimmed (cheilectomy), but the three main surgical options for treating the whole joint are

fusion, which removes the painful joint and abolishes any movement, simple excision of the arthritic joint (Keller's procedure) and joint replacement with an artificial implant.

What the procedure involves

MTP joint replacement is carried out under general or spinal anaesthesia using tourniquet control. An incision is made over the joint and the capsule is exposed by dividing tissue and retracting tendon. The joint surfaces are excised and the medullary canals of the first metatarsal and proximal phalanx are enlarged to accommodate the prosthetic joint implant. A preliminary reduction with a trial implant is done to ensure a snug fit and the implant is then placed in the canal. The joint capsule is closed and a flexible splint is used postoperatively to maintain the correct position.

Efficacy

The main outcome measures reported were pain relief and patient satisfaction.

Three studies reported that 73% (8/11), 79% (46/58) and 100% (6/6) of implants were pain-free after mean follow-ups of 17 months, 12 years and 35 months respectively. Another study including 86 implants reported a statistically significant improvement in pain scores after the procedure. Two further studies reported pain relief in 66% (59/90) of implants and 88% (28/32) of patients.

Four studies reported that between 74% (29/39) and 88% (7/8) of patients were completely satisfied with the procedure.

One Specialist Advisor stated that there are a number of different types of joint replacement on the market and there is limited knowledge on the longevity of the newer implants.

Safety

The main complication reported was the formation of bone or osteophytes around the implant. This affected between 4% (2/49) and 71% (41/58) of implants. Radiologically identified fractures were seen in 0% (0/106) to 29% (21/73) of implants. At the follow-up assessment, between 0% (0/11) and 8% (3/37) of implants had needed to be removed. Other complications included sinking of the implant, infection, inflammation, dislocation and persistent pain.

The Specialist Advisors stated that potential adverse events included persistent pain, infection, implant loosening, implant fracture, osteolysis, bone over-production, cyst formation, silastic granulomas and transfer metatarsalgia. Some of these complications will necessitate removal of the joint.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to MTP joint replacement. Searches were conducted via the following databases, covering the period from their commencement to December 2004: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and Science Citation Index. Trial registries and the Internet were also searched. No language restriction was applied to the searches.

The following selection criteria were applied to the abstracts identified by the literature search. Where these criteria could not be determined from the abstracts the full paper was retrieved.

Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Patients with degeneration of the MTP joint.
Intervention/test	Replacement of MTP joint with an artificial joint.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on seven case-series reports, which are summarised in Table 1.[1-7] Other papers that were considered to be relevant are listed in Appendix A.

Existing reviews on this procedure

A Cochrane systematic review on the treatment of hallux valgus and bunions was published in 2004.[8] One trial compared an osteotomy to an arthroplasty and there was limited evidence to suggest that the osteotomy gave the better outcomes. The report concluded that surgery can help but evidence was too limited to show which forms of surgery may be more effective.

Table 1 Summary of key efficacy and safety findings on metatarsophalangeal joint replacement

Study details	Key efficacy findings	Key safety findings	Comments
Hanyu T (2001)[1] Case series 1983–1990 Japan 39 patients (60 implants) Mean age: 52 years (range 29 to 79) Mean follow-up: 12 years (range 9 to 15) Indications: rheumatoid arthritis	Main outcome measures: subjective assessment of function and appearance and clinical examination No pain = 79% (46/58) Occasional pain = 14% (8/58) Moderate pain = 7% (4/58) Patient completely satisfied = 74% (29/39) Patient satisfied but with some residual pain or recurrent deformities = 18% (7/39) Patient unsatisfied due to painful calluses = 8% (3/39) Recurrence of hallux valgus at follow-up = 19% (11/58) Survival rate of implant at 10 years (Kaplan-Meier): With revision as the endpoint = 93% With radiographic implant fracture as the endpoint = 87% With suspected silicone synovitis as the endpoint = 80%	• Osteophytes around implant = 71% (41/58) • Sinking of the implant = 59% (34/58) • Implant fracture (radiographic) = 16% (9/58) • Silicone synovitis = 21% (12/58) • Late infection = 3% (2/58) • Implant removal = 7% (4/58)	The procedure was performed on 97 feet in 66 patients. At the time of follow-up, 27 patients had died. The remaining 39 patients all completed a questionnaire. 82% of patients had undergone total knee and/or hip replacements. Double-stemmed, flexible hinge silicone implant. Procedure was combined with shortening oblique osteotomy of the metatarsal neck in the lateral toes.
Shankar NS (1991)[2] Case series 1982–1986 UK 89 patients (106 implants) Mean follow-up: 28 months (range 12 to 60). Indications: hallux valgus (n = 87), hallux rigidus (n = 19).	Main outcome measures: subjective assessment of function and appearance and clinical examination. Subjective results: 'Excellent' or 'good' = 81% (86/106) 'Satisfactory' = 12% (12/106) 'Poor' = 7% (8/106) Objective results: 'Excellent' or 'good' = 58% (62/106) 'Satisfactory' = 33% (34/106) 'Poor' = 9% (10/106) Normal pressure distribution (pedobarographic analysis) = 72% (76/106)	• Postoperative infection = 1.9% (2/106) • Implant fracture = 0% (0/106)	Flexible, hinged silastic implants were used for all patients. Diagnosis was on clinical signs confirmed by roentgenograms.

Study details	Key efficacy findings	Key safety findings	Comments
Cracchiolo III A (1992)[3] Case series 1974–1987 Los Angeles, USA 66 patients (86 implants): 34 patients (37 implants) with degenerative joint disease and 32 patients (49 implants) with rheumatoid arthritis Mean age: 55.5 years for patients with degenerative joint disease, 50.1 years for patients with rheumatoid arthritis Mean follow-up: 70 months for patients with degenerative joint disease, 68.5 months for patients with rheumatoid arthritis Inclusion criteria: first metatarsal phalangeal joint that could not be salvaged, good condition of the skin and neurovascular structures, absence of any disease such as diabetes that may lead to impaired circulation or infection, adequate bone stock, no evidence of infection, willingness to permanently forego activities such as running, jogging, tennis and wearing shoes with heels higher than 5 cm.	Main outcome measures: subjective assessment of pain, function and appearance and objective measurements (range of motion, angle of hallux valgus, strength of flexion and extension) Mean pain scores for patients with degenerative joint disease (1 to 10, best value = 10): • Preoperative = 3.9 • Postoperative = 8.3, p < 0.001 Mean pain scores for patients with rheumatoid arthritis (1 to 10, best value = 10): • Preoperative = 3.4 • Postoperative = 7.6, p < 0.01 Mean walking scores for patients with degenerative joint disease (1 to 10, best value = 10): • Preoperative = 7.4 • Postoperative = 8.5, p < 0.01 Mean walking scores for patients with rheumatoid arthritis (1 to 10, best value = 10): • Preoperative = 6.4 • Postoperative = 7.1, p = not significant Mean function scores for patients with degenerative joint disease (1 to 10, best value = 10): • Preoperative = 6.8 • Postoperative = 8.4, p < 0.01 Mean function scores for patients with rheumatoid arthritis (1 to 10, best value = 10): • Preoperative = 5.1 • Postoperative = 6.0, p = not significant Patient completely satisfied: • Degenerative joint disease = 82% (28/34) • Rheumatoid arthritis = 84% (27/32) • Overall = 83% (55/66) There was no clinically important change in the average range of motion	**Patients with degenerative joint disease:** • Implant removal = 8.1% (3/37) • Moderate bone formation = 32.4% (12/37) • Severe bone formation = 8.1% (3/37) • Complete osseous bridging of implant = 2.7% (1/37) • Implant fracture (radiographic) = 8.1% (3/37) • Postoperative infection = 8.1% (3/37) **Patients with rheumatoid arthritis:** • Implant removal = 6.1% (3/49) • Moderate bone formation = 4.1% (2/49) • Complete osseous bridging of implant = 2.0% (1/49) • Implant fracture (radiographic) = 8.2% (4/49) • Symptomatic implant fracture = 2.0% (1/49) • Postoperative infection = 4.1% (2/49)	All patients were candidates for an excisional arthroplasty or joint fusion but they chose to have a silicone implant. Double-stem silicone implants were used for all patients.

Study details	Key efficacy findings	Key safety findings	Comments
Granberry WM (1991)[4] Case series 1982–1986 Texas, USA 63 patients (90 implants) Mean age: 55 years (range 23 to 78) Mean follow-up: 3 years (range 24 to 61 months) Diagnoses: failed resection arthroplasty (25 joints), hallux rigidus (14 feet), rheumatoid arthritis (21 feet), failed bunionectomy (12 feet), failed hemiarthroplasty of the toe (16 feet), shotgun wound (1 foot), chronic infection (1 foot) Inclusion criteria: pain and stiffness of the first metatarsal phalangeal joint unresponsive to non-steroidal medications and restriction of activity	Main outcome measures: subjective assessment of pain, function and appearance and objective measurements (radiographic appearance, pedobarographic examination) 'Good' or 'excellent' result (according to patient) = 74% (67/90) 'Poor' result (according to patient) = 7% (6/90) Diminished pain = 66% (59/90) After 4 years, 26% (5/19) implants had grade 1 deformation and 32% (6/19) had grade 2 Survivorship analysis showed that half of the implants would be expected to fail by 4.0 years Biomechanical and physical examination showed that the implants did not restore normal function The range of motion was decreased from normal Pedobarographic analysis revealed that none of the patients exerted weight-bearing pressures on the affected toe	• Postoperative infection = 1.1% (1/90) • Implant removal = 4.4% (4/90) • Painful plantar keratosis = 69% (50/73) • Osteophytes around implant = 53% (39/73) • Implant fracture (identified radiographically or at reoperation) = 29% (21/73)	Patients were sent a questionnaire approximately 3 years after the procedure. 73 patients were operated on during the study period; three patients had died and the remaining seven were either lost to follow-up or refused to participate. Flexible, hinged silicone implants were used for all patients. Clinical analysis was only available for 73 joints. The frequency of fracture increased with the duration of implantation of t he prosthesis. A pedobarograph consists of a transparent weight-bearing platform covered by a plastic mat, which reflects light in proportion to the pressure applied to its surface.

Study details	Key efficacy findings	Key safety findings	Comments
Bommireddy R (2003)[5] Case series 1981–1996 UK 32 patients (42 implants) Mean age at follow-up = 64 years Mean follow-up = 8 years (range 4 to 19) Indications: hallux rigidus and hallux valgus with degenerative osteoarthritis that failed to respond to conservative treatments including advice on footwear and steroid injections Exclusion criteria: rheumatoid arthritis, patients with a high functional demand or local infection	Main outcome measures: patient satisfaction with surgery and pain relief, clinical grading and radiographic appearance Patient completely satisfied = 75% (24/32) Patient somewhat satisfied (would have the same operation on the other side) = 12.5% (4/32) Patient dissatisfied = 12.5% (4/32) Excellent pain relief = 44% (14/32) Good pain relief = 44% (14/32) Fair pain relief = 6% (2/32) Poor pain relief = 6% (2/32) Excellent clinical grading (complete axial alignment) = 53% (17/32) Good clinical grading (valgus < 15°) = 59% (19/32) Fair clinical grading (valgus 15–30°) = 12.5% (4/32) Poor clinical grading (valgus deformity > 30°) = 6% (2/32)	• Moderate bone formation = 21% (9/42) • Severe bone formation (> 50% encroachment) = 9.5% (4/42) • Complete osseous bridging = 0% (0/42) • Postoperative inflammation or poor wound healing = 28% (12/42) • Implant fracture = 2% (1/42) • Stress fracture = 2% (1/42)	An additional 12 patients had the procedure: 4 had rheumatoid arthritis and were excluded from analysis; 3 patients had died and 5 were lost to follow-up. Double-stem silicone implant.

Study details	Key efficacy findings	Key safety findings	Comments
Ibrahim T (2004)[6] Case series 1999 onwards UK 8 patients (11 joints) Mean age: 58 years (range 51 to 80.5) Mean follow-up: 17 months (range 10 to 22) Indications: hallux rigidus, Freiberg's disease	Main outcome measures: subjective assessment of function and appearance. Patient satisfied = 87.5% (7/8) No pain at rest = 73% (8/11) No pain at exercise = 27% (3/11) Mild pain at exercise = 54% (6/11) No limitations on activity = 36% (4/11) Improved mobility 73% (8/11) Deteriorated mobility = 9% (1/11)	• Postoperative dislocation of implant = 18% (2/11) • Persistent pain = 9% (1/11) • Implant removal = 0% (0/11)	Two additional patients received implants during the study period but did not agree to participate in the study. Press-fit ceramic implant. Subjective questionnaire based on the American Orthopaedic Foot and Ankle Society (AOFAS) scale.
Malviya A (2004)[7] Case series 2000–2002 UK 6 patients (7 implants) Mean age: 60.2 years (range 55 to 68) Mean follow-up: 35 months (range 24 to 43) Indications: grade III hallux rigidus	Main outcome measures: subjective assessment of function, clinical examination and radiological appearance. Pain and discomfort score (visual analogue scale): • Preoperative = 7 to 8 • Postoperative = 1 to 2, $p < 0.001$ No pain at rest or during weight bearing = 100% (6/6) Mean Foot Function Index: • Preoperative = 75.6 • Postoperative = 8.6, $p < 0.001$	No complications were noted in any patient.	Patient selection not described. Press-fit ceramic implant. The Foot Function Index is a validated scoring system with subscales for pain, disability and activity limitation.

Validity and generalisability of the studies

- The studies use a variety of implants that may have different safety and efficacy profiles.
- One study only included patients with rheumatoid arthritis[1] and one study specifically excluded patients with rheumatoid arthritis.[5] The remaining studies included patients with a mixture of indications.
- Most of the outcome measures were subjective.
- Two studies specified that they excluded patients with a high functional demand. [3,5]

Specialist Advisors' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

- Arthritis of the first MTP joint is a common condition.
- There are many different types of MTP joint implant available and there is limited evidence on the longevity of the newer designs.
- MTP joint arthrodesis or joint excision arthroplasty would be the appropriate comparators.
- The procedure is likely to benefit carefully selected patients.
- Training is important.

Issues for consideration by IPAC

None other than those described above.

References

1 Hanyu T, Yamazaki H, Ishikawa H, et al. Flexible hinge toe implant arthroplasty for rheumatoid arthritis of the first metatarsophalangeal joint: long-term results. *Journal of Orthopaedic Science* 2001; 6: 141–7.

2 Shankar NS, Asaad SS, Craxford AD. Hinged silastic implants of the great toe. *Clinical Orthopaedics and Related Research* 1991; 272: 227–34.

3 Cracchiolo A III, Weltmer JB, Lian G, et al. Arthroplasty of the first metatarsophalangeal joint with a double-stem silicone implant. *The Journal of Bone and Joint Surgery* 1992; 74-A: 552–63.

4 Granberry WM, Noble PC, Bishop JO, et al. Use of a hinged silicone prosthesis for replacement arthroplasty of the first metatarsophalangeal joint. *The Journal of Bone and Joint Surgery* 1991; 73-A: 1453–9.

5 Bommireddy R, Singh SK, Sharma P, et al. Long-term follow-up of silastic joint replacement of the first metatarsophalangeal joint. *Foot* 2003; 13: 151–5.

6 Ibrahim T, Taylor GJSC. The new press-fit ceramic Moje metatarsophalangeal joint replacement: short-term outcomes. *Foot* 2004; 14: 124–8.

7 Malviya A, Udwadia A, Doyle J. Pressfit ceramic arthroplasty of the first metatarsophalangeal joint. A short-term review. *Acta Orthopaedica Belgica* 2004; 70: 455–60.

8 Ferrari J, Higgins JPT, Prior TD. Interventions for treating hallux valgus (abductovalgus) and bunions. *The Cochrane Database of Systematic Reviews* 2004, Issue 1. Art. No.: CD000964. DOI: 10.1002/14651858.CD000964.pub2.

Appendix A: Additional papers on metatarsal phalangeal joint replacement not included in the summary tables

Article title	Number of patients/ follow-up	Comments	Direction of conclusions
Bonet J, Taylor DT, Lam AT et al. Restrospective analysis of Silastic implant arthroplasty of the first metatarsophalangeal joint. *The Journal of Foot & Ankle Surgery* 1998; 37: 128–34.	27 patients (40 feet) Mean follow-up = 8.25 years.	Case series. Silicone implant.	96% of patients would undergo procedure again.
Ess P, Hamalainen M, Leppilahti J. Non-constrained titanium-polyethylene total endoprosthesis in the treatment of hallux rigidus. *Scandinavian Journal of Surgery* 2002; 91: 202–7.	10 patients. 2-year follow-up.	Case series. Titanium-polyethylene implant.	Good or excellent outcome = 60% Poor outcome = 20% Patient satisfaction = 80%. Painfree or mild, occasional pain = 90%.
Harrison WJ, Loughead JM. Silastic metatarsophalangeal arthroplasty very long-term results of single-stem implants in degenerative joint disease. *Foot* 2003; 13: 146–50.	18 patients (21 implants) Mean follow-up = 18 years 9 months.	Case series. Silastic implant. 22% (18/82) of patients originally treated were reviewed.	Patients treated for hallux rigidus had significantly better clinical outcome than those treated for hallux valgus. No late revision surgery was necessary.
Kampner SL. Long-term experience with total joint prosthetic replacement for the arthritic great toe. *Bulletin of the Hospital for Joint Diseases Orthopaedic Institute* 1987; 47: 153–77.	98 patients (130 joints) Mean follow-up = 9.4 years.	Case series.	Excellent or good pain relief = 81% Poor pain relief = 11% Excellent or good rating for cosmesis = 73% Poor rating for cosmesis = 11% Implant removal = 11% Implant fracture = 8% A greater proportion of poor results were seen in rheumatoid arthritis patients.
Lemon B, Pupp GR. Long-term efficacy of total SILASTIC™ implants: a subjective analysis. *The Journal of Foot & Ankle Surgery* 1997; 36: 341–6.	50 patients. Mean follow-up = 13.4 years.	Case series. Silicone implant.	Pain relief = 97% Overall success rate = 91%.
Olms K, Dietze A. Replacement arthroplasty for hallux rigidus. 21 patients with a 2-year follow-up. *International Orthopaedics* 1999; 23: 240–3.	21 patients. 24 month follow-up.	Case series.	Less pain or no pain = 81% Lack of toe purchase = 24% Metatarsalgia = 19%
Omonbude OD, Faraj AA. Early results of ceramic/ceramic first metatarsophalangeal joint replacement. *Foot* 2004; 14: 206.	13 patients (14 implants). Mean follow-up 24.5 months.	Case series. Ceramic press-fit implant.	At 6 months, 92% of patients were pain free. Mean American Orthopaedic Foot Association score increased significantly.

Article title	Number of patients/ follow-up	Comments	Direction of conclusions
Papagelopoulos PJ, Kitaoka HB, Ilstrup DM. Survivorship analysis of implant arthroplasty for the first metatarsophalangeal joint. *Clinical Orthopaedics and Related Research* 1994; 302: 164–72.	79 patients (93 implants). Mean follow-up = 12 years.	Case series. 4 types of implant used.	Young age was a significant risk factor for poor survival of implant. Overall survival = 86% at 10 years.
Redfern DJ, Coleridge SD, Bendall SP. Early failure of the Moje screw-fit ceramic metatarsophalangeal joint replacement. *Foot* 2003; 13: 204–8.	119 patients. Follow-up = 1 year.	Case series. Screw-fit ceramic implant (withdrawn from use in August 2000).	Success = 78% Failure requiring revision = 14%. A further 5% were symptomatically loose at 1 year.
Sebold EJ, Cracchiolo A III. Use of titanium grommets in silicone implant arthroplasty of the hallux metatarsophalangeal joint. *Foot & Ankle International* 1996; 17: 145 – 151.	32 patients (47 feet). Mean follow-up = 51 months.	Case series. Double-stem silicone implants protected by titanium grommets.	62.5% completely satisfied. 25% of patients (all with rheumatoid arthritis) had some minor postoperative complaints.
Swanson AB, de Groot, Swanson G. Use of grommets for flexible hinge implant arthroplasty of the great toe. *Clinical Orthopaedics & Related Research* 1997; 340: 87–94.	90 joints.	Case series.	Absence of complications related to particulate reactivity, implant or grommet fracture.

Appendix B: Literature search for metatarsophalangeal joint replacement

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in EMBASE, Current Contents, PreMedline and all EMB databases.

For all other databases a simple search strategy using the key words in the title was employed.

1	Metatarsophalangeal Joint/su [Surgery] (201)
2	metatarsal bones/su (317)
3	metatarso?phalangeal.tw. (509)
4	(metatars$ adj3 phalangeal).tw. (59)
5	or/1-4 (843)
6	arthroplasty, replacement/ (1055)
7	arthroplast$.tw. (7478)
8	replacement$.tw. (47624)
9	or/6-8 (53857)
10	5 and 9 (92)
11	(moje adj10 prosthe$).tw. (0)
12	(swanson$ adj10 arthroplast$).tw. (28)
13	(mtpj adj10 replacement$).tw. (0)
14	(mtp adj10 joint$ adj10 replacement$).tw. (1)
15	(metatars$ adj5 phalangeal adj5 joint$ adj5 replacement$).tw. (0)
16	5 and 12 (1)
17	or/11,13-16 (2)
18	10 or 17 (92)