NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES ADVISORY COMMITTEE

Interventional procedures overview of artificial trapeziometacarpal joint replacement for osteoarthritis

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) advise on the safety and efficacy of an interventional procedure previously reviewed by SERNIP. It is based on a rapid survey of published literature, review of the procedure by one or more specialist advisors and review of the content of the SERNIP file. It should not be regarded as a definitive assessment of the procedure.

Procedure name

- Artificial trapeziometacarpal (TMC) joints for osteoarthritis of the hand.

Procedure number

276 (SERNIP procedure number 003).

Specialty society

- British Society for Surgery of the Hand.

Description

Indication

Osteoarthritis of the trapeziometacarpal (TMC) joint of the thumb.

Osteoarthritis of the hand joints is a common condition that deteriorates over time, although severity of symptoms, rate of deterioration and functional effects are variable. Common sites of osteoarthritis that may be suitable for artificial implants include the TMC joint of the thumb (also called carpometacarpal joint); and metacarpophalangeal and interphalangeal joints of the fingers and thumb.

Current treatment and alternatives

Conservative treatments for osteoarthritis of the hand include anti-inflammatory and analgesic medication, and steroid injections. Other treatments include complete joint excision without replacement (also called excision arthroplasty), native graft arthroplasties, in which the patient's own tissue (typically tendons) is interposed in the space left after joint excision, and fusion of the joint (arthrodesis).

What the procedure involves

A general anaesthetic is usually used and a tourniquet is applied to the affected arm to maintain a blood-free operation site. An incision is made over the diseased joint to expose the tendons. The tendons are retracted and the joint is removed with an oscillating saw. A prosthetic joint, typically made of a silicone based material, is inserted in place of the original joint. Local anaesthetic may be injected into the surgical area or into the arm at the end of the operation. The incisions are sutured and a splint is applied to the fingers.

Proponents of artificial hand joints have suggested that they reduce pain, increase mobility and improve function compared with alternative treatments.

Efficacy

Five studies were included, describing a total of 257 patients treated with a prosthetic TMC joint replacement. In one small randomised controlled trial, comparing silicone prosthesis arthroplasty with tendon arthroplasty, the proportion of satisfied patients was similar in the two groups (80% of 15 patients versus 85% of 13 patients). The mean pain reduction was also similar in both groups of patients. A non-randomised comparative study of 89 patients reported significantly less pain at 12 months in 50 joints treated with a silicone prosthesis arthroplasty, compared with 54 joints treated with sling excision arthroplasties ($p < 0.01$). Patients in the silicone prosthesis group reported better function for most tasks and this was statistically significant for being able to carry a milk bottle and taking off the handbrake of a car. There was no statistically significant difference in patient satisfaction between the two groups. A case series study of 58 patients with a mean follow-up of 16 years reported that maximal improvement was achieved at 5 years. A small case series study reported that 88% (22/25) patients had less pain after a mean follow-up of 6.5 years.

The main concern raised by Specialist Advisors was that the long-term benefits of this procedure need to be compared with the long-term benefits of removal of the trapezium.

Safety

Four studies, including a total of 242 patients, reported some safety outcomes. In three studies, between 6% (4/62) and 20% (6/30) implants had to be removed. The reasons for removal were listed as subluxation, fracture, dislocation, infection, pain, stiffness, septic arthritis, and silicone synovitis. One study of 90 patients reported that the metacarpal component loosened in 8% (6/79) of replacement joints after a mean follow-up period of 6 years. The implant cup loosened in 9% (7/79) of replacement joints. Two studies reported that 3% (2/58) and 4% (1/25) of patients had reflex sympathetic dystrophy after the procedure.

Specialist Advisors state that the main potential adverse effects include infection, stiffness, nerve injury, silicone synovitis, and failure of the joint replacement.

Literature review

Appraisal criteria

Studies examining effects of artificial hand joints in people with hand joint osteoarthritis were included.

List of studies found

One randomised controlled trial was found(see table).[1]

Three retrospective comparisons of case series were found, two of which are described in the table.[2,3]

Thirty seven case series were found, two of which are included in the table.[4,5] References to the other studies are listed in the Appendix.

Summary of key efficacy and safety findings

Study details	Key efficacy findings	Key safety findings	Key reliability and validity issues
Tagil M[1] Randomised controlled trial Lund, Sweden. 1991 - 1995 n = 28 adults with thumb osteoarthritis randomised to: • Swanson silicone interposition endoprostheses (SSE) (n = 15) • abductor pollicis longus tendon arthroplasty (APL) (n = 13) Exclusion criteria: not provided Follow-up: 6 months	At 6 months: Patient satisfaction: • SSE 80% (12/15) • APL 85% (11/13) Pain free for light work = 71% (20/28) Pain free for heavier work = 18% (5/28) Mean pain reduction on visual analogue score (no further details of scale provided): • similar in both groups: 6.6 preoperatively to about 2.3 postoperatively CI and significance not reported	Complications not reported	Trial reported as conference abstract only. The following not reported: • power calculation • randomisation method • blinding • baseline characteristics • a priori definition of endpoints. Apparently no drop out, although not explicitly reported. Pain scale not described and validity/ reliability not provided.

Study details	Key efficacy findings	Key safety findings	Key reliability and validity issues
Alnot JY[2] Retrospective comparison of case series Paris, France Date not stated (published 1998) n = 115 adults with osteoarthritis (median age 61 years) • GUEPAR prosthesis (n = 90) • Excision, ligament reconstruction and tendon interposition (n = 25) Mean follow-up: • prosthesis 6 years • tendon 4 years	Clinical results 'good' (not defined): • prosthesis 92% (73/79) • tendon 95% (18/19) Range of movement and grip strength reported *(not translated)* No functional effects reported	Loosening of implant cup in prosthesis group: 9% (7/79) (3 patients required Swanson implant) Loosening of metacarpal component in prosthesis group: 8% (6/79)	Written in French; data obtained mainly from English abstract. Large losses to follow up: 12% in prosthesis group, 24% in tendon group. No comparisons between groups and no significance tests reported. Baseline characteristics not presented. Choice of treatment based on clinical and radiological criteria. Functional effects not reported.

Study details	Key efficacy findings	Key safety findings	Key reliability and validity issues
Lovell ME[3] Retrospective comparison of case series Appley Bridge, UK 1991-1996 n=99 adults with osteoarthritis; 114 joints: • Swanson silastic arthroplasty (implant group) (n = 58) • Sling excision arthroplasties (sling group) (n = 56) Included in analysis: n = 89 adults with osteoarthritis; 104 joints: • Swanson silastic arthroplasty (implant group) (n = 50) • Sling excision arthroplasties (sling group) (n = 54) Mean follow-up: 62 months (range 18-90 months)	Based on questionnaires returned for 84% (87/104) of joints. Pain at 6 months (visual analogue score 0 to 100; worst to best): • implant v sling (84 v 80, p = not significant) Pain at 12 months (visual analogue score 0-100; worst-best): • implant v sling (90 v 83, p < 0.01) Function (visual analogue score 0-100; worst-best) (mean score for implant v sling, non significant unless stated): • thumb 'working' (77 v 72) • thumb strength (68 v 65) • ability to pick up pen (92 v 86) • jar opening (50 v 43) • key turn (74 v 65) • fastening zip (73 v 61) • carrying milk bottle (83 v 63, p < 0.01) • using car handbrake (78 v 60, p < 0.01) Patient satisfaction (visual analogue score 0 -100; worst-best): • Similar (87 v 80, not significant)	Removal of implants: 14% (8/58) Reasons (number of patients): • subluxed at 3-4 months (4) • fracture (1) • gross pain (1) • gross stiffness (1) • septic arthritis (1) In sling group, one arthroplasty failed after disruption due to a fall (1) Revision operations: similar in both groups (numbers not provided) Re-exploration for pain: • 'less likely' in implant group than sling group sling (numbers not presented)	Response rate to questionnaires 84%. Baseline data not presented. Times to outcomes not stated except for pain. Patients with complications or requiring further surgery excluded from analysis (n = 10). Multiple post-hoc comparisons were performed.

Study details	Key efficacy findings	Key safety findings	Key reliability and validity issues
Bezwada HP[4] Case series Philadelphia, USA 1975 to 1990 n = 58 patients (49 osteoarthritis, 7 rheumatoid arthritis, 2 systemic lupus erythematosus); 62 joints. 52 implants derived from high-performance silicone, 10 implants made from common silicone elastomer. Age range: 44 to 78 years Mean follow-up: 16 years (range 10 to 25 years)	Pain relief: • Little or no pain = 84% (52/62) • Mild to moderate pain = 13% (8/62) (all 8 patients had osteoarthritis) • Moderate to severe pain = 3% (2/62) Maximal improvement was noted at the 5-year follow-up. Average grip strength improved from 13.2 to 19.1 kg at its peak (5 years) and declined to 14.4 kg at 20-year evaluation. Average tip pinch increased from 2.1 to 2.5 kg at 5 years, and decreased to 2.1 kg at 20 years. Ability to touch the base of the small finger with the thumb tip: • Before surgery = 34% (21/62) • After surgery = 84% (52/62) • At 15 year follow-up = 54% (23/42) • At 20 year follow-up = 40% (4/10)	Transient reflex sympathetic dystrophy = 3% (2/58) Revision for implant failure = 6% (4/62) (3 osteoarthritis) Dislocation caused by implant fracture = 2% (1/62) Subluxation = 19% (12/62) (10 osteoarthritis, 1 rheumatoid arthritis, 1 systemic lupus erythematosus) No patient manifested clinical findings of synovitis.	A total of 85 patients (90 joints) were treated during this time period. Follow-up evaluation was available for 68% (58/85) of patients (15 patients had died, 4 patients had inadequate follow-up data, and 8 patients were lost to follow-up). Includes some patients with indications other than osteoarthritis.

Study details	Key efficacy findings	Key safety findings	Key reliability and validity issues
Roth JH[5] Case series Canada 1983 to 1992 n = 36 patients with osteoarthritis Mean age = 64 years (range 41 to 82 years) Mean follow-up = 6.5 years (range 3 - 10 years)	Subjective results (Visual analogue score -10 to +10 worst to best): Satisfaction = 5.6 Pain 5.7 Range of motion = 4.6 Strength = 2.2 Activities of daily living = 4.2 88% (22/25) of patients reported some pain improvement Significantly more time was required for the operative hand to manipulate large objects compared with the non-operated side ($p < 0.02$) Average tip pinch was significantly weaker on the operated side compared with the non-operated side ($p < 0.05$) Longer follow-up was associated with a poorer outcome	Removal of implants = 20% (6/30) Reasons (number of joints): • fracture (3) • infection (1) • dislocation (1) • silicone synovitis (1) reflex sympathetic dystrophy = 4% (1/25) clinical instability of implant = 48% (12/25) subluxation = 36% (9/25) dislocation = 20% (5/25) Tenderness or swelling at the base of the thumb = 30% (9/30) Prosthetic wear averaged 15%, with a range of 0% to 70%	Patients with a minimum follow-up of 12 months were eligible for study. 70% (25/36) patients were reviewed. The reasons for no review: 3 patients died, 3 patients were unwell, 1 had emigrated, 2 refused and 2 were lost to follow-up. Subjective evaluation included a 5-item questionnaire with a visual analogue scale. Questionnaire relied on the patient's recall of preoperative status. Better subjective results were reported in patients older than 60 years. There was no statistically significant correlation between the subjective results and the functional test results.

Validity and generalisability of the studies

The settings of all described studies appear applicable to the UK.

The randomised controlled trial is very small and has not been reported in full.[1]

The results of comparisons between the types of arthroplasty may be confounded by baseline differences in the two non-randomised comparative studies. [2,3,]

One study includes a small proportion of patients with indications other than osteoarthritis. [4]

Specialist advisor's opinion

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

The procedures are currently uncommon and largely confined to specialist hand surgeons. Spread of the technique is likely to reflect the growth of hand surgery as a specialty. Uptake will probably remain limited for many years, because most patients are managed adequately with conservative treatments.

The Specialist Advisors drew attention to the range of joints and joint implants that are available and noted that newer implants are unproven. They expressed concern over long term effects compared with older techniques, such as arthrodesis or excision arthroplasty, and concurred that evidence is limited.

The British Society for Surgery of the Hand has recently set up a voluntary register for artificial hand joint procedures. There are no suitable codes for these procedures.

Issues for consideration by IPAC

None other those discussed above.

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Overview prepared by:
Bazian Ltd
138 Upper Street
London
N1 1 QP

t: 0207 288 0544
f: 0207 226 3341
e: info@bazian.com

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Appendix: references for relevant studies excluded from summary table

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