NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of midcarpal hemiarthroplasty for wrist arthritis

In wrist arthritis the cartilage in the joint wears away, allowing the bones to rub against each other. This can cause pain, stiffness and difficulty gripping objects. In this procedure, an artificial wrist joint is created by replacing parts of the affected bones in the hand with a metal implant. The aim is to relieve pain and maintain movement.

Contents

Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure overview to help members of the interventional procedures advisory committee (IPAC) make 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 2019.

Procedure name

- Midcarpal hemiarthroplasty for wrist arthritis

Specialist societies

- British Society for Surgery of the Hand
- British Orthopaedic Association
- British Association of Plastic, Reconstructive and Aesthetic Surgeons
- Royal College of Surgeons of England
- Royal College of Surgeons of Edinburgh
- Royal College of Physicians and Surgeons of Glasgow.

Description of the procedure

Indications and current treatment

Wrist arthritis can be caused by rheumatoid arthritis, osteoarthritis, trauma or sepsis. It can cause pain, stiffness and swelling.

Treatments include analgesics, non-steroidal anti-inflammatory drugs, disease-modifying antirheumatic drugs and corticosteroid injections. If these do not work well enough, surgical treatments can be used. These include proximal row carpectomy, limited or partial carpal fusion, total wrist arthrodesis or total wrist arthroplasty.

What the procedure involves

The procedure is done using general or regional anaesthesia with a tourniquet applied to the upper arm. A radiographic template is created preoperatively to determine the implant size. An incision is made over the wrist, in line with the third metacarpal. The joint is exposed, and the first row of carpal bones and the radial articular cartilage are removed. A trial implant is put into position, the

carpus is reduced onto the bearing surface and the implant size, range of motion and stability are assessed. The final implant is then put in place and fully seated on the contoured subchondral plate.

Strengthening exercises are started 4 to 6 weeks after surgery and full activity can start several weeks after that. The aim is to relieve pain while keeping the midcarpal articulation and the anatomic centre of wrist rotation.

Outcome measures

The Disabilities of the Arm, Shoulder and Hand (**DASH**) questionnaire is a 30-item, self-report questionnaire measuring upper limb disability and symptoms. Scaling is ranked from 0 indicating least disability to 100 indicating most disability.

The **Mayo wrist score** is a clinician-completed scoring system to evaluate the level of disability in the wrist. It assesses 4 domains: pain, grip strength, range of motion, and return to employment. Each domain is scored out of 25 points to give a total score out of 100 points, with higher scores indicating a better result.

Efficacy summary

Disability and symptom scores

Mayo wrist score

In a case series of 9 patients, the mean Mayo wrist score (range) statistically significantly improved from 31.9 (10 to 60) before the procedure to 58.8 (30 to 80) at a mean follow-up of 31 weeks ($p=0.006$).[1]

In a case series of 20 patients, the mean Mayo wrist score statistically significantly improved from 34.1 before the procedure to 62.3 at a mean follow-up of 49 months ($p<0.05$).[2]

DASH score

In the case series of 9 patients, the mean DASH score (range) statistically significantly improved from 47.8 (22.7 to 70.5) before the procedure to 28.7 (0 to 68.2) at a mean follow-up of 31 weeks ($p=0.028$).[1]

In the case series of 20 patients, the mean DASH score statistically significantly improved from 50.3 before the procedure to 24.6 at a mean follow-up of 49 months ($p<0.05$).[2]

Range of motion

Flexion-extension arc

In the case series of 9 patients, there was no statistically significant improvement in the mean flexion-extension arc (range) after the procedure (64.6 degrees [40 to 125 degrees] before the procedure compared with 79.3 degrees [30 to 130 degrees] at a mean follow-up of 31 weeks).[1]

In the case series of 20 patients, the mean flexion-extension arc statistically significantly improved from 63 degrees before the procedure to 96 degrees at a mean follow-up of 49 months ($p<0.05$).[2]

Radio-ulnar deviation

In the case series of 9 patients, there was no statistically significant improvement in the mean radio-ulnar deviation (range) after the procedure (16.9 degrees [5 to 50 degrees] before the procedure compared with 22.9 degrees [5 to 37 degrees] at a mean follow-up of 31 weeks).[1]

In the case series of 20 patients, the mean radio-ulnar deviation statistically significantly improved from 22.7 degrees before the procedure to 32.4 degrees at a mean follow-up of 49 months ($p<0.05$).[2]

Grip strength

In the case series of 9 patients, there was no statistically significant increase in the mean grip strength (range) after the procedure (16.1 kg [6 to 35 kg] before the procedure compared with 18.9 kg [6 to 38 kg] at a mean follow-up of 31 weeks).[1]

In the case series of 20 patients, the mean grip strength statistically significantly increased from 14.1 kg before the procedure to 20.8 kg at a mean follow-up of 49 months ($p<0.05$).[2]

Return to work

In the case series of 9 patients, 71% (5/7) of patients who were working at the time of surgery had returned to their regular occupation at a mean follow-up of 31 weeks,[1] but time to return to work was not reported.

In the case series of 20 patients, 77% (10/13) of patients who were employed at the time of surgery had returned to work at a mean follow-up of 49 months.[2] Time to return to (original) work was not reported.

Safety summary

Wrist stiffness

Wrist stiffness was reported in 22% (2/9) of patients after the procedure in a case series of 9 patients. This was treated by wrist manipulation under anaesthesia.[1]

Wrist stiffness was reported in 15% (3/20) of patients in a case series of 20 patients. The patients had closed manipulation under anaesthesia at an average of 3.2 months after surgery. After this, 1 patient gained 50 degrees in flexion/extension, 1 patient gained 29 degrees, and 1 patient did not benefit from manipulation.[2]

Conversion to total wrist arthroplasty or fusion

In the case series of 20 patients, the conversion rate was 15% (3/20). One patient had a successful conversion to total wrist arthroplasty for aseptic loosening 1 year after surgery. There was 1 patient diagnosed with complex regional pain syndrome before the procedure who had a conversion to a total wrist arthroplasty but his pain persisted. Another patient had a wrist fusion to treat ulnar-sided pain.[2]

Anecdotal and theoretical adverse events

In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might happen, even if they have never happened). For this procedure, specialist advisers listed the following anecdotal adverse events: stiffness and pain. They considered that the following were theoretical adverse events: metallosis and implant breakage.

The evidence assessed

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to midcarpal hemiarthroplasty for wrist arthritis. The following databases were searched, covering the period from their start to 13 February 2019: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see the literature search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were 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, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with wrist arthritis.
Intervention/test	Midcarpal hemiarthroplasty.
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 IP overview

This IP overview is based on 29 patients from 2 case series.[1,2]

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) are listed in the appendix.

Table 2 Summary of key efficacy and safety findings on midcarpal hemiarthroplasty for wrist arthritis

Study 1 Vance M (2012)

Details

Study type	**Case series**
Country	Not reported
Recruitment period	Not reported
Study population and number	n=**9** patients with wrist arthritis
Age and sex	Mean 44 years; 67% (6/9) female
Patient selection criteria	All patients had chronic, painful degenerative wrist arthritis that limited use of the hand for daily and recreational activities. Posteroanterior and lateral wrist radiographs confirmed the diagnosis in all patients.
Technique	Midcarpal hemiarthroplasty with the KinematX implant (Extremity Medical).
Follow-up	**Mean 31 weeks**
Conflict of interest/source of funding	One or more of the authors receive royalties and consulting fees from Extremity Medical, LLC.

Analysis

Study population issues:
The dominant hand was involved in 6 patients.

The indications for surgery were as follows: scapholunate advanced collapse (SLAC) stage 2 (1 patient), SLAC stage 3 (1 patient), scaphoid non-union advanced collapse (SNAC) stage 3 (1 patient), post-traumatic osteoarthritis (3 patients), inflammatory arthritis (2 patients; rheumatoid arthritis and psoriatic arthritis), and Keinböck's stage 4(1 patient).

There were 2 patients who had preoperative radiographic evidence of early joint space narrowing of the capitolunate articulation. Previous surgery for wrist pain had been done in 2 patients (radial styloidectomy for SLAC I, distal radioulnar joint arthroplasty for posttraumatic osteoarthritis).

Key efficacy and safety findings

<table>
<tr><td>Efficacy</td><td>Safety</td></tr>
<tr><td>Number of patients analysed: 9

Pre- and post-operative data (all patients, n=9, mean [range])
<table>
<tr><td></td><td>Before the procedure</td><td>Latest follow-up (mean 31 weeks)</td><td>p value</td></tr>
<tr><td>Mayo wrist score</td><td>31.9 (10–60)</td><td>58.8 (30–80)</td><td>0.006</td></tr>
<tr><td>DASH score</td><td>47.8 (22.7–70.5)</td><td>28.7 (0–68.2)</td><td>0.028</td></tr>
<tr><td>FE arc, degrees</td><td>64.6 (40–125)</td><td>79.3 (30–130)</td><td>0.362</td></tr>
<tr><td>RD-UD arc, degrees</td><td>16.9 (5–50)</td><td>22.9 (5–37)</td><td>0.262</td></tr>
<tr><td>Grip, kg</td><td>16.1 (6–35)</td><td>18.9 (6–38)</td><td>0.496</td></tr>
<tr><td>Grip, % of opposite side</td><td>56.3 (30–77.8)</td><td>61.7 (31–91)</td><td>0.501</td></tr>
</table>
Pre- and post-operative data (post-traumatic patients only [inflammatory arthritis excluded], n=7, mean)
<table>
<tr><td></td><td>Before the procedure</td><td>Latest follow-up (mean 31 weeks)</td><td>p value</td></tr>
<tr><td>Mayo wrist score</td><td>35</td><td>67.5</td><td>0.006</td></tr>
<tr><td>DASH score</td><td>43.2</td><td>15.9</td><td>0.006</td></tr>
<tr><td>FE arc, degrees</td><td>58.7</td><td>90.8</td><td>0.039</td></tr>
<tr><td>RD-UD arc, degrees</td><td>13.3</td><td>24.7</td><td>0.035</td></tr>
<tr><td>Grip, kg</td><td>17.8</td><td>22.5</td><td>0.217</td></tr>
</table>
Return to work: 71% (5/7) of patients who were working at the time of surgery had returned to their regular occupation at a mean follow-up of 31 weeks.</td><td>Postoperative wrist stiffness: 22% (2/9)
The patients had to be manipulated under anaesthesia.</td></tr>
<tr><td colspan="2">Abbreviations used: DASH, disabilities of the arm; FE, flexion extension; RD-UD, radioulnar deviation; SLAC, scapholunate advanced collapse.</td></tr>
</table>

Study 2 Anneberg M (2017)

Details

Study type	**Retrospective case series**
Country	Not reported
Recruitment period	2011-2013
Study population and number	n= **20** patients with wrist arthritis
Age and sex	Mean 51 years; 45% (9/20) female
Patient selection criteria	All patients had failed nonsurgical treatment including orthosis wear, hand therapy, and steroid injection before surgery. All had pain, limited range of motion, and substantial impairment of functional activities. All patients had a wrist arthroscopy before surgery and were excluded if there was exposed bone on the articular surface of the capitate. Absolute contraindications to the procedure included recent or remote infection, previous surgical fusion, or lack of active wrist extension.
Technique	Midcarpal hemiarthroplasty with the KinematX implant (Extremity Medical). Active digital, elbow, and shoulder motion was started immediately, and active wrist motion was started in a supervised therapy program after suture removal on day 10. Weight-bearing began 4 to 6 weeks after surgery and full activity was permitted at 8 weeks with no activity restrictions.
Follow-up	**Mean 4 years**
Conflict of interest/source of funding	G.P. is a consultant with Extremity Medical, LLC; J.J.C. receives royalties from Extremity Medical, LLC; S.W. receives speaking honoraria from Trimed, Inc., consulting fees and an industry research grant from Conventus Orthopaedics, Inc., publishing royalties as an editor for Elsevier, and consulting fees and royalties from Extremity Medical, LLC. The rest of the authors declare that they have no relevant conflicts of interest.

Analysis

Study design issues:
There was only 1 surgeon doing the procedures.

All patients were evaluated before and after surgery by a hand therapist who measured wrist range of motion and grip strength and was independent of the study. The DASH and Mayo wrist scores were completed at each visit. Radiographs were evaluated for loosening, osteolysis of the capitate, or component migration at each follow-up visit.

Study population issues:
Of the 20 patients, 13 had the surgery on their dominant wrist.

The diagnoses were SLAC wrist (9 patients), noninflammatory osteoarthritis (OA; 5 patients), SNAC wrist (2 patients), psoriatic arthritis (2 patients), rheumatoid arthritis (1 patient), and Kienböck disease (1 patient).

Key efficacy and safety findings

Efficacy

Number of patients analysed: **20**

Pre- and post-operative data (all patients, n=20, mean)

	Before the procedure	Latest follow-up (mean 49 months)	p value
Mayo wrist score	34.1	62.3	**<0.05**
DASH score	50.3	24.6	**<0.05**
F/E arc (degrees)	63	96	**<0.05**
R/U arc (degrees)	22.7	32.4	**<0.05**
Grip (kg)	14.1	20.8	**<0.05**

Pre- and post-operative data (inflammatory patients, n=3, mean)

	Before the procedure	Latest follow-up (mean 52 months)	p value
Mayo wrist score	23.3	31.7	NS
DASH score	68.2	56.6	NS
F/E arc (degrees)	52.0	69.7	NS
R/U arc (degrees)	16.3	22.7	NS
Grip (kg)	3.3	9.5	NS

Pre- and post-operative data (non-inflammatory patients, n=17, mean)

	Before the procedure	Latest follow-up (mean 48 months)	p value
Mayo wrist score	36	67.7	**<0.05**
DASH score	47.1	18.9	**<0.05**
F/E arc (degrees)	64.9	100.6	**<0.05**
R/U arc (degrees)	23.8	34.1	**<0.05**
Grip (kg)	16	24.8	**<0.05**

Return to work at latest follow-up: 77% (10/13) of patients who were employed at the time of surgery had returned to work at a mean follow-up of 49 months. The occupations of the 10 patients were broker (n=1), secretary (n=1), director (n=1), student (n=1), retailer (n=1), bricklayer (n=1), retailer (n=1), banker (n=1), and office workers (n=2).

Safety

Wrist stiffness: 15% (3/20)

The patients had closed manipulation under anaesthesia at an average of 3.2 months after surgery. After this, 1 patient gained 50 degrees in flexion/extension, 1 patient gained 29 degrees, and 1 patient did not benefit from manipulation.

One patient died of unrelated causes, but her results at 31 months were good and there were no known issues with her implant.

Procedure failure and conversion to total wrist arthroplasty or fusion

1 patient had radiographic evidence of component loosening and had a successful conversion to total wrist arthroplasty for aseptic loosening at 1 year after surgery.

1 patient was diagnosed with complex regional pain syndrome before hemiarthroplasty surgery. This persisted following surgery, and despite conversion to a total wrist arthroplasty, his pain persisted. There was no sign of prosthetic loosening or capitate osteolysis on radiographs and the capitate cartilage was intact at reoperation.

1 patient had a wrist fusion by another surgeon to treat ulnar-sided pain.

Abbreviations used: DASH, disabilities of the arm; F/E, flexion/extension; NS, no statistically significant difference; R/U, radio-ulnar deviation; SLAC, scapholunate advanced collapse.

Validity and generalisability of the studies

- There are only 2 small case series and no comparative studies were found.
- There is probably an overlap of patients between the 2 studies included.
- There is only 1 surgeon doing this procedure worldwide.
- The maximum length of follow-up has a mean of 4 years.
- Patient populations within and between studies are heterogeneous, including patients with and without inflammatory arthritis.
- There was only 1 device used in the studies included.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure.

Interventional procedures

- Total distal radioulnar joint replacement for symptomatic joint instability or arthritis. NICE interventional procedures guidance 595 (2017). Available from http://www.nice.org.uk/guidance/ipg595
- Total wrist replacement. NICE interventional procedures guidance 271 (2008). Available from http://www.nice.org.uk/guidance/ipg271

Additional information considered by IPAC

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by specialist advisers, in the form of the completed questionnaires, is normally published in full on the NICE website during public

consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. There was 1 Specialist Advisor Questionnaire for midcarpal hemiarthroplasty for wrist arthritis submitted and this can be found on the NICE website.

Patient commentators' opinions

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

Company engagement

A structured information request was sent to 1 company who manufacture a potentially relevant device for use in this procedure. NICE received 1 completed submission. This was considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

Issues for consideration by IPAC

There are no ongoing studies.

References

1. Vance M C, Packer G, Tan D et al. (2012) Midcarpal hemiarthroplasty for wrist arthritis: Rationale and early results. Journal of Wrist Surgery 1(1), 61-68

2. Anneberg M, Packer G, Crisco J J et al. (2017) Four-Year Outcomes of Midcarpal Hemiarthroplasty for Wrist Arthritis. Journal of Hand Surgery - American Volume 42(11), 894-903

Literature search strategy

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane)	13/02/2019	Issue 2 of 12, February 2019
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane)	13/02/2019	Issue 2 of 12, February 2019
HTA database (CRD website)	13/02/2019	n/a
MEDLINE (Ovid)	13/02/2019	1946 to February 12, 2019
MEDLINE In-Process (Ovid) & MEDLINE Epubs ahead of print (Ovid)	13/02/2019	February 12, 2019
EMBASE (Ovid)	13/02/2019	1974 to 2019 Week 06
BLIC (British Library)	13/02/2019	n/a

Trial sources searched

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

Websites searched

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- EuroScan
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1 Arthritis/

2 ((wrist* or radiocarpal* or midcarpal* or pancarpal*) adj4 (arthrit* or inflam* or osteoarthrit*)).tw.

3 ('Scapholunate Advanced Collapse' or SLAC or Kienbock*).tw.

4 or/1-3

5 Joint Prosthesis/

6 Hemiarthroplasty/ or Arthroplasty, Replacement/

7	((wrist* or radiocarpal* or midcarpal* or pancarpal*) adj4 (hemiarthroplast* or hemi-arthroplast* or artificial or implant* or prosthes* or replac* or reconstruct* or arthroplast*)).tw.
8	or/5-7
9	KinematX*.tw.
10	8 or 9
11	4 and 10
12	Animals/ not Humans/
13	11 not 12

Appendix

There were no additional papers identified.