NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of total distal radioulnar joint replacement for symptomatic joint instability or arthritis

Instability of the distal radioulnar joint (a joint near the wrist) can be caused by injury, arthritis or failure of previous surgery. The wrist can become swollen and painful, which often limits hand movement and grip strength. This procedure is done by removing the wrist end of the ulna (one of the forearm bones) and replacing it with a metal prosthesis that also attaches to the wrist end of the radius (the other forearm bone). The aim is to increase the stability of the joint and improve pain-free movement.

Introduction

The National Institute for Health and Care Excellence (NICE) has prepared this interventional procedure (IP) 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 IP overview was prepared in April 2017.

Procedure name

- Total distal radioulnar joint replacement for symptomatic joint instability or arthritis

Specialist societies

- British Society for Surgery of the Hand
- Royal College of Surgeons of England.

Description

Indications and current treatment

Distal radioulnar joint instability can be caused by injury, arthritis or failure of previous surgery. The wrist can become swollen and painful, which often limits hand movement and grip strength.

Initial treatment includes rest, analgesia and corticosteroid injections. If symptoms do not respond to conservative measures, surgical options include excision of the ulnar head or ulnar head replacement. Another option is to fuse the ulnar head to the radius and excise a small segment of bone proximal to the joint, to allow the hand to turn over.

What the procedure involves

Total distal radioulnar replacement differs from conventional treatment because it involves replacing all 3 components of the distal radioulnar joint. The aim of the procedure is to increase the stability of the joint and improve pain-free movement.

The procedure is done with the patient under general or regional anaesthesia, and with a tourniquet applied to the upper arm. Radiological screening is used during the procedure to check the position of the joint. An incision is made along the ulnar border and the ulnar head removed, taking care to avoid damage to the ulnar nerve, tendons and artery. A plate bearing a socket is fixed to the radius and the ulna component of the prosthesis is then inserted and attached to the radial component using a ball, to allow pronation and supination. The range of motion of the joint is checked and the wound is closed. Patients are usually encouraged to start full range-of-motion exercises about 2 weeks after the procedure.

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 Patient-Rated Wrist Evaluation (PRWE) is a 15-item questionnaire designed to measure wrist pain and disability. Scores range from 0 to 100 with lower scores indicating less disability.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to total distal radioulnar joint replacement for symptomatic joint instability or arthritis. The following databases were searched, covering the period from 1 January 2002 to 28 March 2017: 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 appendix C for details of 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 symptomatic distal radioulnar joint instability or arthritis.
Intervention/test	Total distal radioulnar joint replacement.
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 approximately 300 patients from 1 systematic review and 8 case series (all of which are included in the systematic review)[1–9] .

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

Table 2 Summary of key efficacy and safety findings on total distal radioulnar joint replacement for symptomatic joint instability or arthritis

Study 1 Moulton LS (2017)

Details

Study type	**Systematic review**
Country	Not reported
Recruitment period	Search date: April 2016
Study population and number	**n=315 implants (14 studies)** Patients who had had a complete distal radioulnar joint (DRUJ) replacement.
Age and sex	Not reported
Patient selection criteria	Articles were included using the following criteria: patients had had a complete DRUJ replacement; studies had to include a minimum of 5 implants; the ranges of movement, pain, strength, complications or failure rates were reported as outcomes; minimum follow-up of at least 1 year. Exclusion criteria: case reports, cadaver studies, biomechanical studies, non-implant arthroplasty, reviews, follow-up less than 1 year, silicone arthroplasties.
Technique	All but 2 of the studies used the Aptis implant (Aptis Medical, US); the others used a prototype implant.
Follow-up	**Mean 56 months**
Conflict of interest/source of funding	None for the systematic review; not reported for individual studies within the review. Six of the studies using the Aptis implant originated from the unit of the implant designer.

Analysis

Study design issues: The systematic review was done according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement. The following outcome measures were assessed: Patient Rated Wrist Evaluation or Disabilities of the Arm, Shoulder, and Hand scores; pain score; ranges of movement; grip strength; complications, and survivorship. The quality of the evidence was determined using the design classification of levels developed by Jovell and Navarro-Rubio (levels I to IX, with level I being good [meta-analysis of RCTs] and level IX being poor [anecdotes or case reports]). The methodological quality of the studies was assessed using the Coleman method (score range 0 to 100, lower scores indicate poorer quality studies). The included studies were all low level (IV and V; case series without any controls) and there was considerable heterogeneity even within the studies. The highest Coleman score for the included studies on total DRUJ replacement was 44, demonstrating the low level of the studies.

Study population issues: There was a range of indications for total DUJ replacement in the studies. The majority of patients had had previous surgery. The indications were not stated in 2 papers. In those papers that described a single indication for surgery, this was most commonly salvage surgery after previous ulna head excision.

Other issues: There are some discrepancies between the main text of the paper and the tables. Where the numbers are different, the figures quoted in the main text have been used. There is likely to be some patient overlap between the studies.

The systematic review also included evidence on ulna head replacement, which was reported separately. This has not been included because it is not within the remit of the procedure being assessed.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **315** The highest mean pain score after treatment was 6.8 out of 10. Grip strength ranged from 46% to 90% of the contralateral side (6 studies). Mean arc of forearm rotation ranged from 115° to 167° All authors reported satisfactory or good outcomes with good patient satisfaction. In the papers using the Aptis implant (246 implants) there were 7 revisions, giving an implant survival rate of 97% at a mean follow-up of 56 months (range 24 to 75 months).	***Complications*** **Total=28% (88/313)** • Infection (deep and superficial) • Heterotopic bone formation • Tendonitis • Bone resorption • Implant fracture • Screw irritation • Loosening • Stress responses in the bones • Pain (including elbow pain and chronic pain syndrome) • Carpal tunnel syndrome • De Quervain's syndrome • Median neuropathy • Debridement of screw tip • Implant clicking • Implant malposition • Lunate implant impingement

Study 2 Rampazzo A (2015)

Details

Study type	**Case series**
Country	US
Recruitment period	2005 to 2011
Study population and number	**n=41 patients (46 implants)** Patients aged under 40 years who had total distal radioulnar joint (DRUJ) replacement for pain with or without gross instability of the joint under stress.
Age and sex	Mean 32 years (range 18 to 39); 66% (27/41) female
Patient selection criteria	Patients aged under 40 years and with a minimum of 2 years' follow-up. All patients had symptoms (persistent pain and functional limitations) that did not respond to a 6-month period of conservative treatment, which consisted of activity modification, gentle physical therapy, nonsteroidal anti-inflammatory drugs, and immobilisation. If this regimen did not work, 3 corticosteroid injections were given at 6-week intervals.
Technique	Device: Aptis-Scheker implant. In some patients, other procedures were done at the same time as the total DRUJ replacement (9 peripheral nerve decompression, 6 removal of previous fixation plates, 1 posterior interosseous nerve neurectomy, 1 debridement of distal radius dorsal lip, 1 interosseous membrane release, one 4-corner arthrodesis). In the last 37 patients, the technique of DRUJ replacement was altered to prevent extensor carpi ulnaris irritation by raising an ulnar-based adipofascial flap to cover the implant.
Follow-up	**Mean 61 months (range 24 to 99)**
Conflict of interest/source of funding	One of the authors designed the Aptis/Scheker implant and is partial owner of Aptis Medical.

Analysis

Follow-up issues: Patients were only included if they had at least 2 years clinical or radiological follow up.

Study design issues: Patients were identified using a prospectively maintained database. Pain level was assessed with a visual analogue scale from 0 to 10. Preoperative and postoperative Disabilities of the Arm, Shoulder and Hand (DASH) and Patient-Rated Wrist Evaluation (PRWE) scores were calculated. Grip strength was measured using a Jamar Hydraulic Hand Dynamometer. Range of motion of the wrist and forearm was measured according to American Medical Association guidelines. Three authors who were not involved in the original surgery independently reviewed the X-rays.

Study population issues: All patients had pain as an indication for the procedure and 5 patients also had gross instability of the joint under stress. Twelve patients had comorbidities (4 Madelung deformity, 2 Ehlers-Danlos syndrome, 2 connective tissue disease, 2 post-burn scarring, 1 stroke, 1 cervical radiculopathy). In 37 wrists, there were an average of 1.7±1.2 procedures (range 1 to 7) done before the total DRUJ replacement.

Other issues: This study is included in the systematic review by Moulton L and Giddins G (2017), but it was excluded from the survival analysis because of patient crossover with other studies that were included.

Key efficacy and safety findings

Efficacy

Number of patients analysed: 41 patients (46 wrists)

Outcome measurements

Test	Preoperative (mean ± sd)	Postoperative (mean ± sd)	p value
Grip (kg)	31±16	49±25	<0.001
Lifting (kg)	10±7	17±6	0.018
DASH score (lower scores better)	56±22	27±27	0.008
PRWE score (lower scores better)	64±22	30±30	0.002
VAS score (0 to 10)	8±2	2±2	<0.001
Pronation (degrees)	69±20	77±13	0.48
Supination (degrees)	62±24	73±20	0.021
Extension (degrees)	55±16	56±24	0.28
Flexion (degrees)	53±17	56±21	0.065
Radial deviation (degrees)	17±7	21±10	0.93
Ulnar deviation (degrees)	30±6	28±12	0.23

On preoperative X-rays, 10 wrists revealed dorsal instability. After the procedure, no implants showed volar or dorsal instability (mean radiological follow-up=48 months).

Further surgery that was not related to complications was needed in 32.6% (15/46) of wrists, including peripheral nerve decompression.

Patients who did not have salvage procedures before DRUJ replacement had a greater reduction in pain compared with patients who had salvage procedures (p<0.01).

Kaplan–Meier 5-year survival=96% (95% confidence interval 0.899 to 1.0)

4.9% (2/41) of patients were not satisfied with the procedure and would not advise patients with the same pathology to have the procedure.

Median time to return to work=2 months

Safety

Further surgery for complications after DRUJ replacement=32.6% (15/46) of wrists

Postoperative complications

- extensor carpi ulnaris tendonitis=19.6% (9/46)
- infection=2.2% (1/46) (implant was removed and replaced when the infection had resolved)
- ectopic bone formation around the ulnar stem=6.5% (3/46)
- clicking with active motion=4.3% (2/46)
- radial plate malposition=2.2% (1/46)
- implant failure=2.2% (1/46)
- lunate-implant impingement=2.2% (1/46)
- osteophytes=8.7% (4/46) (developed within 2 years and were removed from the distal ulnar stem)

In 1 patient, the implant was replaced after the patient fell and fractured the radius and bent the collar of the ulnar stem.

2 polyethylene balls were replaced because of clicking of the joint during active motion.

Other secondary operations included replacement of the ulnar stem (n=2) and 1 instance each of posterior interosseous nerve neuroma excision, radial plate repositioning, and partial lunate excision.

Abbreviations used: DASH, Disabilities of the Arm, Shoulder and Hand; DRUJ, distal radioulnar joint; PRWE, Patient-Rated Wrist Evaluation; sd, standard deviation; VAS, visual analogue scale

Study 3 Schuurman AH (2010)

Details

Study type	**Case series**
Country	The Netherlands
Recruitment period	2002 to 2007
Study population and number	**n=19** Patients with decreased grip, decreased forearm movement, and pain due to ulnar impingement syndrome and instability of the distal ulna.
Age and sex	Mean 45 years (range 22 to 62); 90% (17/19) female
Patient selection criteria	The main indications for the procedure were decreased grip, decreased forearm movement, and pain due to ulnar impingement syndrome and instability of the distal ulna.
Technique	The DRUJ prosthesis consisted of an ulnar and a radial component, which come together at the location of the former ulnar head. Prostheses used in the study were custom made. During the study, the design evolved from prototype A (n=4) to B (n=5) to C (n=10).
Follow-up	**Mean 4 years and 1 month (range 1 to 7 years)**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: There were no losses to follow-up.

Study design issues: Range of motion, grip strength and pinch strength were measured and patients completed the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire. Wrist pain was assessed using a visual analogue scale from 0 to 10. Follow-up measurements were done at 3, 6 and 12 months after surgery and at yearly intervals thereafter.

Study population issues: Ten patients had a previous Darrach procedure (ulnar head excision) and 7 had a Suavé-Kapandji procedure (resection of a portion of distal ulna shaft and fusion of the ulnar head to the radius), with unsatisfactory results. All 17 patients had an unstable distal ulna. Of the other 2 patients, 1 joint was destroyed by trauma and the other by progressive synovitis.

Other issues: This study is included in the systematic review by Moulton L and Giddins G (2017).

Key efficacy and safety findings

<table>
<tr><th>Efficacy</th><th>Safety</th></tr>
<tr><td>
Number of patients analysed: 19

Prosthesis A (n=4) had no failures. Prosthesis B was removed in all 5 patients because of loosening. Prosthesis C was removed in 2 of the 10 patients, 1 because of continuing pain and 1 at the request of the patient.

For those prostheses that failed, the mean time between placement and removal was 1 year (range 4 to 21 months)

Range of motion (n=12; prosthesis A and C)
<table>
<tr><th>Test</th><th>Preoperative (sd)</th><th>Postoperative (sd)</th><th>Mean difference</th><th>p value</th></tr>
<tr><td>Extension (degrees)</td><td>48 (18.3)</td><td>59 (19.5)</td><td>23%</td><td>0.01</td></tr>
<tr><td>Flexion (degrees)</td><td>39 (16.1)</td><td>46 (20.3)</td><td>18%</td><td>0.29</td></tr>
<tr><td>Radial deviation (degrees)</td><td>12 (7.5)</td><td>14 (10.4)</td><td>11%</td><td>0.66</td></tr>
<tr><td>Ulnar deviation (degrees)</td><td>19 (10.9)</td><td>24 (12.5)</td><td>26%</td><td>0.26</td></tr>
<tr><td>Pronation (degrees)</td><td>79 (8.8)</td><td>88 (4.0)</td><td>11%</td><td>0.01</td></tr>
<tr><td>Supination (degrees)</td><td>70 (15.1)</td><td>72 (18.6)</td><td>3</td><td>0.7</td></tr>
</table>
Grip and pinch strength (n=12; prosthesis A and C)
<table>
<tr><th>Test</th><th>Preoperative (sd)</th><th>Postoperative (sd)</th><th>Mean difference</th><th>p value</th></tr>
<tr><td>Grip (kg)</td><td>10 (3.7)</td><td>16 (7.7)</td><td>56%</td><td>0.01</td></tr>
<tr><td>Tip (kg)</td><td>1.9 (1.2)</td><td>2.3 (1.3)</td><td>21%</td><td>0.26</td></tr>
<tr><td>Lateral (kg)</td><td>3.0 (1.5)</td><td>3.4 (1.6)</td><td>13%</td><td>0.37</td></tr>
</table>
DASH and VAS score (n=12; prosthesis A and C)
<table>
<tr><th>Test</th><th>Preoperative (sd)</th><th>Postoperative (sd)</th><th>Mean difference</th><th>p value</th></tr>
<tr><td>DASH (lower scores better)</td><td>39 (10.5)</td><td>31 (18.3)</td><td>-21%</td><td>0.07</td></tr>
<tr><td>Pain VAS (range 0 to 10)</td><td>5.3 (2.8)</td><td>3.5 (3.1)</td><td>-33%</td><td>0.02</td></tr>
</table>
</td><td>The paper stated that there were no postoperative infections and no complex regional pain syndrome.</td></tr>
<tr><td colspan="2">Abbreviations used: DASH, Disabilities of the Arm, Shoulder and Hand; sd, standard deviation; VAS, visual analogue scale</td></tr>
</table>

Study 4 Scheker L (2013)

Details

Study type	**Case series**
Country	US
Recruitment period	1997 to 2001 (first-generation prosthesis) 2005 onwards (second-generation prosthesis)
Study population and number	**n=31 patients (first-generation prosthesis)** **n=35 patients (second-generation prosthesis)** Patients with deranged distal radioulnar joints (DRUJs).
Age and sex	Not reported
Patient selection criteria	Contraindications included severe osteoporosis, unresolved osteomyelitis, and systemic disease that debilitated the patient both physically and mentally. The use of the implant is also contraindicated when bone, musculature, tendons or adjacent soft tissues are compromised by disease or infection and would not provide adequate support or fixation for the prosthesis. The implant should not be used in patients who have not reached skeletal maturity.
Technique	The first-generation Scheker prosthesis was made of medical-grade stainless steel and with a 3-point fixation of the ulnar stem. This was changed for the second-generation prosthesis to cobalt chromium with a titanium plasma spray. When the procedure was initially done, patients were routinely given a long arm splint in neutral position for 3 weeks but this was stopped as the authors gained more experience. In the current technique, patients are given a bulky soft dressing and immediate limited motion can begin according to patient tolerance. The dressing remains in place for 2 weeks, when the stitches are removed and full range-of-motion exercises are encouraged. Patients can move through a full range of motion and bear weight immediately after surgery.
Follow-up	**Mean 5.9 years (range 4 to 8 years) (first generation prosthesis)** **5 years (second generation prosthesis)**
Conflict of interest/source of funding	One of the authors is part owner of Aptis Medical, manufacturer of the Scheker total DRUJ replacement prosthesis.

Analysis

Follow-up issues: No losses to follow-up were described.

Study design issues: Pain level was assessed with a visual analogue scale from 0 to 5. Postoperative Disabilities of the Arm, Shoulder and Hand (DASH) and Patient-Rated Wrist Evaluation (PRWE) scores were calculated. Preoperative values for these measures were not available.

Study population issues: Of the 31 wrists treated by a first-generation prosthesis, 22 had not been previously treated by partial or total wrist fusion. Most of the patients who had a second-generation prosthesis had between 2 and 14 prior procedures on the DRUJ (from partial excision of the DRUJ to wide excision of the ulna).

Other issues: This study is included in the systematic review by Moulton L and Giddins G (2017).

Key efficacy and safety findings

Efficacy

Number of patients analysed: **31 (first generation); 35 (second generation)**

Outcomes for first-generation prosthesis (n=31) at long-term follow-up (mean 5.9 years, range 4 to 8 years)

Outcome	Preoperative	Follow-up
Mean patient-rated wrist evaluation (PRWE) score	Not reported	29 (range 1 to 68)
Mean disabilities of the arm, shoulder and hand (DASH) score	Not reported	23 (range 0 to 76)
Mean pain score (VAS, 0 to 5)	4.2 (range 1 to 5)	1.0 (range 0 to 4)
Mean pronation	Not reported	79° (range 15 to 90°)
Mean supination	Not reported	72° (range 30 to 90°)
Mean extension*	Not reported	56° (range 14 to 90°)
Mean flexion*	Not reported	52° (range 5 to 85°)
Mean ulnar deviation	Not reported	21.5° (range 5 to 30°)
Mean radial deviation	Not reported	10.5° (range (5 to 15°)
Grip strength	25 lb (range 0 to 80 lb)	49 lb (range 0 to 100 lb)

* in the 22 wrists without previous partial or total wrist fusion

94% (29/31) of patients were able to bear weight on the operative side.

77% (24/31) of patients returned to their regular activities, 4 returned to their previous activities with a permanent weight-bearing restriction, 1 patient filed for disability and 2 patients retired.

At final follow-up radiograph, there was no radiolucency around any of the 31 implants. None of the implants were reported to have failed under normal conditions.

Outcomes for second-generation prosthesis (n=35) at 5-year follow-up

Outcome	Preoperative	Follow-up
Mean patient-rated wrist evaluation (PRWE) score	Not reported	14 (n=19)
Mean disabilities of the arm, shoulder and hand (DASH) score	Not reported	22 (n=18)
Mean pronation	62°	83°
Mean supination	51°	75°
Grip strength	31 lb (44% of contralateral side)	51 lb (94% of contralateral side)

Pain ‘decreased significantly’, both at rest and with activity (scores not reported).

Mean forearm weight bearing in the neutral position was 16.3 pounds in the DRUJ prosthesis arm versus 16.8 pounds in the contralateral arm.

Survival rate of prosthesis at 5-year follow-up=100% (27/27)

Mean satisfaction score=9.6 out of 10

Safety

Complications

Second-generation prosthesis

- Minor soft tissue infection=5.7% (2/35)
- Extensor carpi ulnaris (ECU) tendonitis=17.1% (6/35)
- Ectopic bone formation=14.3% (5/35)
- Screw/cap loosening=2.9% (1/35)

1 patient had ECU hypersensitivity 4 years after the procedure, which was attributed to a failed tendon repair before having the prosthesis. The symptoms were resolved with a corticosteroid injection.

In 1 patient, the ulnar stem was replaced 4 years after the procedure, when a larger ulnar stem implant became available. At the time of the original implant, the prosthesis was too small for his medullary cavity but the patient elected to have the procedure anyway.

Abbreviations used: DASH, Disabilities of the Arm, Shoulder and Hand; DRUJ, distal radioulnar joint; ECU, extensor carpi ulnaris; PRWE, Patient-Rated Wrist Evaluation; VAS, visual analogue scale

Study 5 Galvis EJ (2014)

Details

Study type	**Case series**
Country	US
Recruitment period	2005 to 2011
Study population and number	**n=17 patients (19 joints)** Patients with rheumatoid arthritis.
Age and sex	Mean 57 years (range 38 to 85 years); 71% (12/17) female
Patient selection criteria	Not reported. All patients complained of wrist pain as the presenting symptom.
Technique	Device: self-stabilising total DRUJ prosthesis (APTIS Medical LLC, US). One patient had a first-generation implant made of stainless steel. The remaining patients had a second-generation cobalt chromium porous-coated prosthesis. All procedures were done with regional anaesthesia. Ancillary procedures were done in 9 of the 17 patients (extensor digitorum communis reconstruction [n=6], extensor tenosynovectomy [n=3], cubital tunnel release, hardware removal, extensor digitorum communis centralisation, and metacarpophalangeal joint silicone arthroplasty [1 each]).
Follow-up	**Mean 39 months (range 12 to 79 months)**
Conflict of interest/source of funding	One of the authors holds a patent and is co-owner of APTIS Medical.

Analysis

Follow-up issues: Two patients with unilateral implants were lost to follow-up.

Study design issues: Retrospective chart review. Pain level was measured using a 10-point visual analogue scale, where 0 was no pain and 10 was the worst possible pain. All patients completed a postoperative Disabilities of the Arm, Shoulder, and Hand (DASH) and Patient-Rated Wrist Evaluation (PRWE) questionnaire. Preoperative values for these measures were not reported.

Study population issues: Ten patients had 14 previous wrist procedures (wrist prosthesis [n=3], ulna shortening, wrist fusion and synovectomy [2 each], and triangular fibrocartilage complex repair, Darrach resection, cubital tunnel release, carpal tunnel and pronator teres release, and extensor tendon primary repair [1 each]).

Other issues: This study is included in the systematic review by Moulton L and Giddins G (2017).

Key efficacy and safety findings

<table>
<tr><th>Efficacy</th><th>Safety</th></tr>
<tr><td>
Number of patients analysed: 17 patients (19 joints)

Preoperative and postoperative pain and range of motion
<table>
<tr><th></th><th>Preoperative</th><th>Postoperative</th><th>Improvement</th><th>p value</th></tr>
<tr><td>Mean Pain VAS</td><td>7.4 (range 2 to 10)</td><td>2.2 (range 0 to 9)</td><td>70%</td><td>0.001</td></tr>
<tr><td>Pronation (°)</td><td>56 (range 30 to 90)</td><td>78 (range 30 to 90)</td><td>39%</td><td>0.30</td></tr>
<tr><td>Supination (°)</td><td>56 (range 10 to 80)</td><td>72 (range 54 to 90)</td><td>27%</td><td>0.04</td></tr>
</table>
Mean DASH score after surgery=24 (range 0 to 91, CI ±16; n=15).
Final PRWE score=24 (range 0 to 93, CI ±19; n=15).

Self-assessment of pain using the survey questionnaire was obtained in 15 of the 17 patients. 14 out of 15 patients reported improvement in the wrist general motion. All 15 patients reported decreased need for pain medication compared to before surgery.

All 15 patients stated that they would recommend the prosthesis to another patient and that they would have this prosthetic replacement on the contralateral wrist if indicated.

12 patients were capable of lifting 3.9 kg; 3 patients were unable to lift any weight because of non-functioning structures unrelated to the DRUJ.
</td><td>
Remodelling or bone resorption detected by radiographs was noted in the distal 5 mm of 6 ulnas. This occurred early on but did not progress.

A 2 mm radiolucent zone was noted around the peg in the distal portion of the radius plate 4 years after the procedure in 1 patient.

Additional surgery=11.8% (2/17) of patients
(1 patient was the only patient in the series to have a first-generation implant; pain and loosening of the implant occurred and revision with a second-generation implant was done. The second patient developed pain along the ECU tendon and tenolysis was done; a dermoadipose graft harvested from the groin area was placed between the prosthesis and the tendon to create a smooth gliding surface.)

At final review, 6 patients had had radiocarpal arthrodesis, 1 related to prior total radiocarpal prosthesis loosening. In addition, 1 patient had previously had arthrodesis and the wrist spontaneously fused in 1 patient. Therefore, a total of 42% (8/19) of wrists with a DRUJ prosthesis had radiocarpal fusions.
</td></tr>
<tr><td colspan="2">Abbreviations used: CI, confidence interval; DASH, Disabilities of the Arm, Shoulder and Hand; DRUJ, distal radioulnar joint; ECU, extensor carpi ulnaris; PRWE, Patient-Rated Wrist Evaluation; VAS, visual analogue scale</td></tr>
</table>

Study 6 Axelsson P (2013)

Details

Study type	**Case series**
Country	Sweden
Recruitment period	2006 to 2010
Study population and number	**n=9** **Patients with pain and gross instability with DRUJ derangement (n=8) or post-traumatic DRUJ synostosis (n=1)**
Age and sex	Median 44 years (range 33 to 71 years); 67% (6/9) female
Patient selection criteria	Pain and gross instability with DRUJ derangement or post-traumatic DRUJ synostosis. All patients had at least 1 previous operation of the DRUJ area.
Technique	Device: Scheker DRUJ prosthesis (Aptis, US; titanium plasma-sprayed stem with cobalt chromium alloy radial component). With the exception of the patient with post-traumatic DRUJ synostosis, patients were immobilised in a dorsal wrist splint for 10 to 14 days. After 2 weeks, the patients gradually increased loading and active motion exercises. Six weeks after surgery, normal functional activity was permitted. There were no restrictions regarding use or loading of the prosthesis beginning 3 months after surgery.
Follow-up	**Mean 45 months (range 24 to 62 months)**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: No patients were lost to follow-up.

Study design issues: Prospectively collected data. The Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire was administered to all patients before and after the procedure. Pain was evaluated on a 10-cm visual analogue scale. The surgeon who treated the patients also did the follow-up visits and measurements.

Study population issues: Patients had a mean 3.6 previous surgical treatments of the DRUJ area (range 1 to 7).

Other issues: This study is included in the systematic review by Moulton L and Giddins G (2017).

Key efficacy and safety findings

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

Clinical data and health scores before the procedure and at latest follow-up (mean 45 months); median values
<table>
<tr><td></td><td>Preoperative</td><td>Postoperative</td><td>Contralateral side</td><td>p value</td></tr>
<tr><td>Supination (°)</td><td>80</td><td>80</td><td>90</td><td>0.17</td></tr>
<tr><td>Pronation (°)</td><td>60</td><td>70</td><td>75</td><td>0.14</td></tr>
<tr><td>Grip strength (kg)</td><td>17</td><td>21</td><td>29</td><td>0.09</td></tr>
<tr><td>Pain VAS (cm)</td><td>6.0</td><td>0.3</td><td>-</td><td>0.01</td></tr>
<tr><td>DASH (points)</td><td>43</td><td>26</td><td>-</td><td>0.03</td></tr>
</table>
2 patients had inferior results. 1 patient had worse pain at the 1-year follow-up despite an initial improvement. The radiographs showed midcarpal arthritis, which was treated by a 4-corner arthrodesis. At 2-year follow-up, her pain score was 0.3 compared with 4.5 at baseline. Her function was impaired according to the DASH score, probably because of decreased grip strength and severe radiocarpal stiffness. The second patient had a chronic pain syndrome and experienced minor or no improvement for all parameters.</td><td>There were 4 minor postoperative adverse events:
• Transient carpal tunnel syndrome, n=1
• De Quervain’s disease, n=1 (patient needed surgery 1 year after DRUJ replacement)
• Lateral elbow pain, n=2 (responded to conservative treatment)

Radiographic evaluation showed bone resorption of the distal ulna from around the implant stem of more than 2 mm in 6 patients (median 2.5 mm, range 0 to 8 mm). One patient developed bone resorption around a screw tip of the radial component.

There were no signs of loosening.</td></tr>
<tr><td colspan="2">Abbreviations used: DASH, Disabilities of the Arm, Shoulder and Hand; DRUJ, distal radioulnar joint; VAS, visual analogue scale</td></tr>
</table>

Study 7 Kachooei AR (2014)

Details

Study type	**Case series**
Country	US
Recruitment period	2005 to 2014
Study population and number	**n=13 patients (14 wrists)** Patients having DRUJ replacement for persistent instability, chronic pain, and stiffness.
Age and sex	Mean 44 years; 71% (10/13) female
Patient selection criteria	All patients had at least 1 previous operation around the wrist relevant to the existing problem.
Technique	Device: Aptis prosthesis (Aptis Medical, US). One patient with Ehlers-Danlos syndrome had non-simultaneous bilateral DRUJ implant arthroplasty within a 3-year interval. After the procedure, the arm was kept in a splint for the first 2 weeks and physical therapy was started thereafter.
Follow-up	**Median 60 months**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: 2 patients were lost to follow-up for the prospective data collection part of the study.

Study design issues: Records and follow-up visits were retrospectively reviewed to find final postoperative symptoms, pain, range of motion and grip strength with a mean follow-up of 12 months (range 2 to 25 months). Patients were also contacted prospectively by phone to administer the disabilities of the arm, shoulder and hand (DASH), patient rated wrist evaluation (PRWE) and visual analogue scale (VAS) and to interview regarding satisfaction and progress in daily activities (median follow-up of 60 months, range 2 to 102 months).

Study population issues: Preoperative diagnoses were chronic instability (n=8), post-traumatic arthrosis (n=2), stiff DRUJ (n=1), DRUJ deformity (n=1), Ehlers-Danlos syndrome (n=1). Previous operations included wrist arthroscopy (n=9), Darach or hemiresection (n=7), distal ulnar tenodesis after failed Darach (n=3), wrist arthrodesis (n=3), DRUJ release (n=2) and triangular fibrocartilage complex repair (n=2).

Other issues: This study is included in the systematic review by Moulton L and Giddins G (2017).

Key efficacy and safety findings

<table>
<tr><th>Efficacy</th><th>Safety</th></tr>
<tr><td>
Number of patients analysed: 13

In clinic follow-up examination results after DRUJ replacement (mean follow-up=12 months, range 2 to 25 months)
<table>
<tr><th></th><th>Mean (sd)</th><th>Range</th></tr>
<tr><td>Flexion</td><td>62 (16)</td><td>50 to 90</td></tr>
<tr><td>Extension</td><td>54 (8.9)</td><td>40 to 60</td></tr>
<tr><td>Supination</td><td>51 (30)</td><td>5 to 80</td></tr>
<tr><td>Pronation</td><td>64 (26)</td><td>20 to 90</td></tr>
<tr><td>Radial deviation</td><td>13 (6.5)</td><td>5 to 20</td></tr>
<tr><td>Ulnar deviation</td><td>28 (13)</td><td>10 to 40</td></tr>
<tr><td>Grip strength – involved</td><td>47 (15)</td><td>32 to 70</td></tr>
<tr><td>Grip strength – non-involved</td><td>68 (23)</td><td>40 to 90</td></tr>
</table>
Patients' follow-up after DRUJ replacement (median follow-up=60 months, range 2 to 102 months)
<table>
<tr><th></th><th>Median</th><th>Range</th></tr>
<tr><td>VAS (0 to 10)</td><td>0</td><td>0 to 6</td></tr>
<tr><td>Satisfaction (0 to 10)</td><td>10</td><td>7 to 10</td></tr>
<tr><td>DASH score (0 to 100)</td><td>1.3</td><td>0 to 72</td></tr>
<tr><td>PRWE score (0 to 100)</td><td>2.5</td><td>0 to 61</td></tr>
<tr><td>PRWE Pain score (0 to 50)</td><td>2.0</td><td>0 to 30</td></tr>
<tr><td>PRWE Function score (0 to 50)</td><td>0.0</td><td>0 to 31</td></tr>
<tr><td>Lifting capacity, 0 to 20 lbs – involved</td><td>20</td><td>5 to 20</td></tr>
<tr><td>Lifting capacity, 0 to 20 lbs – non-involved</td><td>20</td><td>10 to 20</td></tr>
</table>
No patient needed removal of the prosthesis.
All patients reported that they would recommend the procedure to other patients, and if the same injury happens, they would get the same prosthesis in their other wrist.
All patients responded 'yes' to whether they feel better than before getting the prosthesis. All patients were satisfied with their wrist motion and ability to perform activities of daily living.
</td><td>
All of the wounds healed well without any patients experiencing infection. One patient presented 4 days postoperatively with a tight splint and an area of redness about the elbow. This was controlled with oral and intravenous antibiotics.

Secondary unplanned surgery=14% (2/14; debridement of prominent screw tip on radial styloid)
</td></tr>
<tr><td colspan="2">Abbreviations used: DASH, Disabilities of the Arm, Shoulder and Hand; DRUJ, distal radioulnar joint; PRWE, Patient-Rated Wrist Evaluation; sd, standard deviation; VAS, visual analogue scale</td></tr>
</table>

Study 8 Kakar S (2014)

Details

Study type	**Case series**
Country	US
Recruitment period	2008 to 2010
Study population and number	**n=10** Patients with DRUJ arthritis or instability.
Age and sex	Mean 47 years; 80% (8/10) female
Patient selection criteria	Patients with radioulnar convergence instability, multiple failed DRUJ procedures and therapies or DRUJ deformity with advanced arthrosis.
Technique	Device: Aptis prosthesis (Aptis Medical, US).
Follow-up	**Mean 4 years (range 2.4 to 5.6 years)**
Conflict of interest/source of funding	One author gets royalties from Small Bone Innovation, Inc. Ulnar head endoprosthesis. One author has a consultancy with Arthrex and Skeletal Dynamics.

Analysis

Follow-up issues: An additional patient was treated during the study period but was lost to follow-up. The questionnaire was returned by 70% (7/10) of patients.

Study design issues: Retrospective chart review. The senior authors independently reviewed the pre- and postoperative radiographs. Patients were also contacted by telephone and asked to complete disabilities of the arm, shoulder and hand (DASH) and patient-rated wrist evaluation (PRWE) questionnaires. There were no preoperative DASH and PRWE scores.

Study population issues: Patients had a mean 4.1 wrist operations before the DRUJ replacement (range 0 to 7). Only 1 patient had not had any previous wrist surgery.

Other issues: This study is included in the systematic review by Moulton L and Giddins G (2017).

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **10** **At a mean follow-up of 4 years, 9 out of 10 prostheses survived free from revision or removal.** 5 patients had secondary surgical procedures not involving component revision. All 10 patients reported moderate or severe pain preoperatively. Al the last follow-up, 3 patients reported moderate pain (p<0.01). Mean change in wrist flexion=18° (p=0.62) Mean change in forearm rotation=10° (p=0.16) Mean change in grip=23.8 N (p=0.30) When compared with the contralateral side, grip strength improved from 38% strength before the procedure to 52% at follow-up (p=0.23). Mean DASH score after the procedure=27 (range14 to 54; n=7) Mean PRWE score after the procedure=33 (range 15 to 75; n=7) All 7 of the patients who responded were either satisfied or very satisfied with the outcome of their surgery and would choose to have the procedure again.	1 patient needed revision surgery for aseptic ulnar component loosening at 7 months. 1 patient had a screw exchange for symptomatic hardware. 3 patients needed a small surgical procedure to burr down the prominent ends of the screw tips. 1 patient developed a median neuropathy after the procedure, which had resolved by the 1-year follow-up.
Abbreviations used: DASH, Disabilities of the Arm, Shoulder and Hand; PRWE, Patient-Rated Wrist Evaluation	

Study 9 Bizimungu RS (2013)

Details

Study type	**Case series**
Country	US
Recruitment period	2005 to 2010
Study population and number	**n=10** Patients with a dysfunctional distal radioulnar joint (DRUJ).
Age and sex	Mean 56 years; 50% (5/10) female
Patient selection criteria	One patient was excluded because the prosthesis was removed shortly after implantation because of infection. One patient was excluded because of concurrent implantation of the Scheker prosthesis and a UNI 2 total wrist implant. Eight patients were excluded because they had less than 2 years of follow-up or incomplete datasets.
Technique	Device: Aptis prosthesis (Aptis Medical, US). A well-padded splint was applied for 2 weeks after the procedure. Afterward, the patient could start active range of motion and hand therapy.
Follow-up	**Mean 5 years (range 2.8 to 6 years)**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: An additional 8 patients were treated during the study period but were excluded because they had less than 2 years of follow-up or incomplete datasets.

Study design issues: Retrospective chart review. All 10 patients were brought into the clinic for final follow-up. Pain was measured on a visual analogue scale from 0 to 10.

Study population issues: Seven patients had post-traumatic DRUJ disease, 1 patient had DRUJ osteoarthritis, 1 patient had Madelung deformity and 1 patient had cancerous destruction of the distal ulna. Four patients had an unsuccessful ulnar resection or ulnar head implant before the total DRUJ replacement.

Other issues: This study is included in the systematic review by Moulton L and Giddins G (2017).

Key efficacy and safety findings

<table>
<tr><td>Efficacy</td><td>Safety</td></tr>
<tr><td>Number of patients analysed: 10

Preoperative to postoperative comparison of mean outcome measures (5±1.1 years follow-up)
<table>
<tr><td>Outcome measure</td><td>Preoperative</td><td>Postoperative (n=10)</td><td>p value</td></tr>
<tr><td>Wrist flexion (°)</td><td>45±21.4, n=7</td><td>32.1±22.8</td><td>0.29</td></tr>
<tr><td>Wrist extension (°)</td><td>35±14.6, n=7</td><td>44.8±13.9</td><td>0.22</td></tr>
<tr><td>Supination (°)</td><td>63.6±16.6, n=7</td><td>72.5±14.4</td><td>0.30</td></tr>
<tr><td>Pronation (°)</td><td>64.3±21.3, n=7</td><td>69.5±14.6</td><td>0.61</td></tr>
<tr><td>Ulnar deviation (°)</td><td>21.7±11.4, n=6</td><td>25.3±5.4</td><td>0.53</td></tr>
<tr><td>Radial deviation (°)</td><td>10.8±5.3, n=6</td><td>13±8.8</td><td>0.58</td></tr>
<tr><td>Grip strength (lb)</td><td>55.5±25.6, n=3</td><td>54.9±23.7</td><td>0.98</td></tr>
<tr><td>Pain (VAS, 0 to 10)</td><td>4.75±2, n=6</td><td>3.6±3.1</td><td>0.40</td></tr>
</table>
The average wrist flexion was skewed by 1 patient who developed an extension contracture of the wrist postoperatively secondary to concomitant extensor tendon repairs.</td><td>The authors noted that only 1 out of 20 patients who had had the Scheker prosthesis at their clinic needed the prosthesis removed (for infection).</td></tr>
<tr><td colspan="2">Abbreviations used: DASH, Disabilities of the Arm, Shoulder and Hand; PRWE, Patient-Rated Wrist Evaluation</td></tr>
</table>

Efficacy

Pain

In a case series of 41 patients, there was a statistically significant decrease in the mean pain score (measured on a visual analogue scale [VAS] from 0 to 10) from 8 before the procedure to 2 at follow-up (mean 61 months, range 24 to 99; p<0.001)[2]. In a case series of 19 patients, there was a statistically significant decrease in the mean pain score (measured on a VAS from 0 to 10) from 5.3 before the procedure to 3.5 at follow-up (mean 4 years, range 1 to 7; p=0.02)[3]. In a case series of 17 patients, there was a statistically significant decrease in the mean pain score (measured on a VAS from 0 to 10) from 7.4 before the procedure to 2.2 at follow-up (mean 39 months, range 12 to 79; p=0.001)[5].

Disability and symptom scores

In the case series of 41 patients, there was a statistically significant decrease in the disabilities of the arm, shoulder and hand (DASH) score (range 0 to 100; lower scores better) from 56 before the procedure to 27 at follow-up (mean 61 months, range 24 to 99; p=0.008)[2]. There was also a statistically significant decrease in the patient-rated wrist evaluation (PRWE) score (range 0 to 100; lower scores better) from 64 before the procedure to 30 at follow-up (mean 61 months, range 24 to 99; p=0.002)[2]. In the case series of 19 patients, there was a decrease in the DASH score from 39 before the procedure to 31 at follow-up (mean 4 years, range 1 to 7; p=0.07)[3]. In a case series of 35 patients who had a second-generation prosthesis, the mean PRWE score at 5-year follow-up was 14 (n=19) and the mean DASH score was 22 (n=18)[4]. In the case series of 17 patients, the mean PRWE score at follow-up (mean 39 months) was 24 (range 0 to 93; n=15) and the mean DASH score was 24 (range 0 to 91; n=15)[5].

Range of motion

In the case series of 41 patients, mean pronation increased from 69° to 77° (p=0.48), supination increased from 62° to 73° (p=0.021), extension increased from 55° to 56° (p=0.28) and flexion increased from 53° to 56° (p=0.065)[2]. In the case series of 19 patients, mean pronation increased from 79° to 88° (p=0.01), supination increased from 70° to 72° (p=0.7), extension increased from 48° to 59° (p=0.01) and flexion increased from 39° to 46° (p=0.29)[3]. In the case series of 35 patients who had a second-generation prosthesis, the mean pronation increased from 62° to 83° and the mean supination increased from 51° to 75° at 5-year follow-up (p values not reported)[4]. In the case series of 17 patients, mean pronation increased from 56° to 78° (p=0.30) and mean supination increased from 56° to 72° (p=0.04) at follow-up (mean 39 months, range 12 to 79)[5].

Grip strength

In the case series of 41 patients, there was a statistically significant increase in mean grip strength after the procedure from 31 kg to 49 kg (p<0.001)[2]. In the case series of 19 patients, there was a statistically significant increase in mean grip strength after the

procedure from 10 kg to 16 kg (p=0.01)[3]. In the case series of 35 patients who had a second-generation prosthesis, the mean grip strength increased from 44% of the contralateral side to 94% of the contralateral side at 5-year follow-up (p value not reported)[4].

Implant survival

In a systematic review of 315 patients, for those papers using 1 particular type of implant, there were 7 revisions of 246 implants, giving an implant survival rate of 97% at a mean follow-up of 56 months (range 24 to 75 months)[1].

Patient satisfaction

In the case series of 41 patients, 5% (2/41) of patients were not satisfied with the procedure and would not advise patients with the same pathology to have the procedure[2]. In the case series of 35 patients who had a second-generation prosthesis, the mean satisfaction score after the procedure was 9.6 out of 10[4]. In a case series of 13 patients with a median follow-up of 60 months, all patients were satisfied with their wrist motion and ability to perform activities of daily living[7]. In a case series of 10 patients, all 7 patients who responded to a follow-up questionnaire were either satisfied or very satisfied with the outcome of their surgery[8].

Safety

Tendonitis

Extensor carpi ulnaris (ECU) tendonitis was reported in 17% (6/35) and 20% (9/46) of wrists in 2 case series of 35 and 41 patients respectively[2,4]. Additional surgery was needed by 1 patient who developed pain along the ECU tendon, in a case series of 17 patients[5].

Infection

Infection was reported in 1 patient in the case series of 41 patients; the implant was removed and replaced after the infection had resolved[2]. Minor soft tissue infection was reported in 6% (2/35) of patients in the case series of 35 patients[4].

Ectopic bone formation

Ectopic bone formation around the ulnar stem was reported in 7% (3/46) of patients in the case series of 41 patients[2]. Ectopic bone formation was reported in 14% (5/35) of patients in the case series of 35 patients[4].

Osteophytes

Osteophytes were reported in 9% (4/46) of joints in the case series of 41 patients; they developed within 2 years of the procedure and were removed from the distal ulnar stem[2].

Loosening of prosthesis

Screw or cap loosening was reported in 1 patient in the case series of 35 patients[4]. Loosening of the implant and pain was reported in 1 patient who had a first-generation implant in the case series of 17 patients; a revision was done with a second-generation implant[5]. Aseptic ulnar component loosening, which needed revision surgery, was reported in 1 patient in a case series of 10 patients[8].

Prominent screw tips

Debridement of prominent screw tips on the radial styloid was reported in 14% (2/14) of joints in a case series of 13 patients[7]. A small surgical procedure to burr down the prominent ends of the screw tips was reported in 30% (3/10) of patients in a case series of 10 patients[8].

Other

De Quervain's disease was reported in 1 patient in a case series of 9 patients; the patient needed further surgery 1 year after the DRUJ replacement[6]. Transient carpal tunnel syndrome was reported in 1 patient in the same study. Median neuropathy was reported in 1 patient in the case series of 10 patients[8]. Radial plate malposition, implant failure, and lunate-implant impingement were each reported in 1 patient in the case series of 41 patients[2].

Validity and generalisability of the studies

- Most of the studies are from the US and a number of them originate from the designer of an implant used for the procedure.
- All of the primary studies are small case series.
- Patient populations within and between studies are heterogeneous.
- For most patients, the procedure was salvage surgery but there were some patients for whom it was primary surgery.
- Some patients had other procedures done at the same time as the DRUJ replacement.
- Some of the studies collected postoperative data only for certain outcomes, making it difficult to assess efficacy of the procedure.

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. Appendix B gives details of the recommendations made in each piece of guidance listed.

Interventional procedures

- Total wrist replacement. NICE interventional procedure guidance 271 (2008). Available from http://www.nice.org.uk/guidance/IPG271

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. Three Specialist Adviser Questionnaires for total distal radioulnar joint replacement for symptomatic joint instability or arthritis were submitted and can be found on the NICE website.

Patient commentators' opinions

NICE's Public Involvement Programme will send questionnaires to NHS trusts for distribution to patients who had the procedure (or their carers). When NICE has received the completed questionnaires, these will be discussed by the committee.

Company engagement

A structured information request was sent to 1 company that manufactures a potentially relevant device for use in this procedure. NICE did not receive a completed submission.

Issues for consideration by IPAC

None other than those described above.

References

1. Moulton LS and Giddins GE (2017) Distal radio-ulnar implant arthroplasty: a systematic review Journal of Hand Surgery European Volume: 1753193417692506
2. Rampazzo A, Gharb BB, Brock G, et al. (2015) Functional Outcomes of the Aptis-Scheker Distal Radioulnar Joint Replacement in Patients Under 40 Years Old Journal of Hand Surgery - American Volume 40: 1397-1403.e3
3. Schuurman AH and Teunis T (2010) A new total distal radioulnar joint prosthesis: Functional outcome Journal of Hand Surgery 35: 1614–19
4. Scheker LR and Martineau DW (2013) Distal radioulnar joint constrained arthroplasty Hand Clinics 29: 113–21
5. Galvis EJ, Pessa J and Scheker LR (2014) Total joint arthroplasty of the distal radioulnar joint for rheumatoid arthritis Journal of Hand Surgery 39: 1699–1704
6. Axelsson P and Sollerman C (2013) Constrained implant arthroplasty as a secondary procedure at the distal radioulnar joint: Early outcomes Journal of Hand Surgery 38: 1111–18
7. Kachooei AR, Chase SM and Jupiter JB (2014) Outcome Assessment after Aptis Distal Radioulnar Joint (DRUJ) Implant Arthroplasty Archives of Bone & Joint Surgery 2: 180–4
8. Kakar S, Fox T, Wagner E, et al. (2014) Linked distal radioulnar joint arthroplasty: an analysis of the APTIS prosthesis Journal of Hand Surgery: European Volume 39: 739–44
9. Bizimungu RS, Dodds SD (2013) Objective outcomes following semi-constrained total distal radioulnar joint arthroplasty. Journal of Wrist Surgery 2: 319–23

Appendix A: Additional papers on total distal radioulnar joint replacement for symptomatic joint instability or arthritis

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Atwal NS, Clark DA, Amirfeyz R, et al. (2010) Salvage of a failed Sauve-Kapandji procedure using a total distal radio-ulnar joint replacement Hand Surgery 15 (2): 119-22	Case report n=1	This is the first report in the literature of a patient treated with a DRUJ replacement after Sauve-Kapandji procedure failed due to pain and instability.	Case report.
Coffey MJ, Scheker LR, Thirkannad SM (2009) Total Distal Radioulnar Joint Arthroplasty in Adults with Symptomatic Madelung's Deformity. HAND 4: 427–31	Case series n=3 FU= 2 years	Total DRUJ arthroplasty should be considered a viable treatment option, with the goal of improving quality of life in patients with Madelung's deformity who have had previous procedures and continue to have pain and limited range of motion.	Small case series.
Degreef I and De Smet L (2013) The Scheker distal radioulnar joint arthroplasty to unravel a virtually unsolvable problem Acta Orthopaedica Belgica 79 (2): 141-5	Case series n=4	In selected cases with unsolvable distal radioulnar instability and loss of the DRUJ joint, the Scheker arthroplasty may offer a valuable solution.	Small case series
Ewald TJ, Skeete K and Moran SL (2012) Preliminary experience with a new total distal radioulnar joint replacement Journal of Wrist Surgery 1 (1): 23-30.	Case series n=4 FU=mean 46 months	Final range of motion showed mean pronation of 80° and mean supination of 64°. Final grip strength on the operated extremity was 25.5 kg and averaged 73% of contralateral side. This was an improvement from preoperative grip strength of 14.5 kg visual analogue pain scale decreased from 8 to 2.5 after surgery (scale: 1 to 10). Patient satisfaction was 100%.	Small case series.
Laurentin-Perez LA, Goodwin AN, Babb BA, et al. (2008) A study of functional outcomes following implantation of a total distal radioulnar joint prosthesis Journal of Hand Surgery: European Volume 33 (1): 18-28	Case series n=31 FU=mean 5.9 years	Pronation increased from a mean of 65.5° to 74° and supination from 53° to 70° while greatly diminishing or eliminating pain. Grip increased from a mean of 10 kg to 24 kg. Weight bearing was restored or increased in 29 of 31 patients.	There appears to be considerable patient overlap with Scheker L et al, 2013, which is included in table 2. This study is included in the systematic review by Moulton L and Giddins G (2017).

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Martinez Villen G, Garcia Martinez B and Aso Vizan A (2014) Total distal radioulnar joint prosthesis as salvage surgery in multioperated patients Chirurgie de la Main 33 (6): 390-5	Case series n=5 FU=mean 4.3 years	Average postoperative increase in range of motion was 28.8° for flexion-extension; 2.2° for radial and ulnar deviation, and 18° for pronation-supination, reaching 86%, 85% and 81% of the contralateral hand function, respectively. Grip strength increased by 6.8 kg, with recovery of 78% of the strength of the unaffected hand. VAS score decreased to a mean of 6.2 postoperatively. There were 2 complications. All 5 patients showed no signs of implant loosening or movement. The quick DASH score decreased from a mean of 85 preoperatively to 38.6 postoperatively. The modified Mayo wrist score increased from a mean of 24 preoperatively to 73 at final follow-up.	Small case series.
Savvidou C, Murphy E, Mailhot E, et al. (2013) Semiconstrained distal radioulnar joint prosthesis Journal of Wrist Surgery 2 (1): 41-8.	Case series n=35 FU=5 years	The majority of patients regained adequate range of motion and improved their strength and lifting capacity to the operated side. Pain and activities of daily living were improved. Twelve patients experienced complications, most commonly being extensor carpi ulnaris (ECU) tendinitis, ectopic bone formation, bone resorption with stem loosening, low-grade infection, and need for ball replacement. The Aptis total DRUJ replacement prosthesis is an alternative to salvage procedures that enables a full range of motion as well as the ability to grip and lift weights encountered in daily living activities.	There appears to be considerable patient overlap with Scheker L et al, 2013, which is included in table 2. This study is included in the systematic review by Moulton L and Giddins G (2017).
Scheker LR (2008) Implant arthroplasty for the distal radioulnar joint. Journal of Hand Surgery 33A: 1639–44	Case series n=49 FU=2 years	Mean postoperative grip strength increased from 38.3 lb to 44.5 lb on the operated side (63% of contralateral side). Lifting capacity increased from 1.2 kg to 5.3 kg. Pain scores decreased from 3.8 to 1.3 (scale 0 to 5). Mean pronation was 79° and mean supination was 72°.	A more recent publication by the same author, with longer follow-up, is included. The paper focuses on surgical technique rather than patient outcomes. This study is included in the systematic review by Moulton L and Giddins G (2017).

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Schuurman AH (2013) A new distal radioulnar joint prosthesis Journal of Wrist Surgery 2 (4): 359-62	Case series n=19 FU=mean 4 years and 1 month	All 5 prostheses in group B had to be removed because of loosening, while only 2 prostheses in group C had to be removed, for non-prosthetic reasons. For the 12 patients who retained their prosthesis, forearm function increased while grip strength increased significantly. Pain scores decreased and the Disabilities of the Arm, Shoulder, and Hand (DASH) score improved but remained high. The prosthesis offers a new treatment option for ulnar instability following distal ulnar resection.	Appears to be the same patient population as Schuurman A et al., 2010.
Zimmerman RM, Jupiter JB (2011) Outcomes of a self-constrained distal radioulnar joint arthroplasty: a case series of six patients. HAND 6: 460–5	Case series n=6 FU=mean 2.4 years	Final postoperative range-of-motion was excellent, with 80.0° supination and 86.7° pronation. Grip strength was 48.6 lb and 82.2 lb on the operative and non-operative sides, respectively, at final follow-up, representing 59% of contralateral grip strength in the operative wrist. 2 patients continued to have wrist pain. Four out of 5 patients would again elect to have total DRUJ implant arthroplasty.	Small case series. This study is included in the systematic review by Moulton L and Giddins G (2017).

Appendix B: Related NICE guidance for total distal radioulnar joint replacement for symptomatic joint instability or arthritis

Guidance	Recommendations
Interventional procedures	**Total wrist replacement. NICE interventional procedure guidance 271 (2008).** 1.1 There is evidence that total wrist replacement relieves pain, but this is based on small numbers of patients and there is insufficient evidence of its efficacy in the long term. The procedure is associated with a risk of the recognised complications of prosthetic joint replacement. Therefore total wrist replacement should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake total wrist replacement should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the possible alternatives to total wrist replacement and the uncertainty about its efficacy in the long term, such that further surgery may be required, including fusion of the wrist joint. They should provide them with clear written information. In addition, the use of the Institute's information for patients ('Understanding NICE guidance') is recommended. • Audit and review clinical outcomes of all patients having total wrist replacement (see section 3.1). 1.3 This procedure should be undertaken only on carefully selected patients, by surgeons with special expertise in interventions for the hand and wrist. 1.4 Further publication of safety and efficacy outcomes will be useful. The Institute may review the procedure upon publication of further evidence.

Appendix C: Literature search for total distal radioulnar joint replacement for symptomatic joint instability or arthritis

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane)	28/03/2017	Issue 3 of 12, March 2017
HTA database (Cochrane)	28/03/2017	Issue 3 of 12, March 2017
Cochrane Central Register of Controlled Trials (Cochrane)		Issue 3 of 12, March 2017
MEDLINE (Ovid)	28/03/2017	1946 to March Week 3 2017
MEDLINE In-Process (Ovid)	28/03/2017	March 24, 2017
EMBASE (Ovid)	28/03/2017	1974 to 2017 Week 13
PubMed	28/03/2017	-
BLIC (British Library)	28	n/a

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

1 joint prosthesis/
2 (Joint* adj3 (prosthes* or Implant*)).tw.
3 ((wrist* or ulnar or radioulnar or radio-ulnar or radio ulnar or forearm* or joint*) adj4 (replace* or arthroplasty or reconstruct* or prosthes* or implant*)).tw.
4 DRUJ.tw.
5 scheker.tw.
6 APTIS.tw.
7 TWA.tw.
8 or/1-7
9 Arthritis/
10 arthrit*.tw.
11 joint instability/
12 ((wrist or ulnar or radioulnar or radio-ulnar or forearm* or sigmoid*) adj4 (instabil* or unstab* or injur* or fractur* or dislocat* or arthrit* or fail* or destroy*)).tw.
13 Hand Strength/
14 (hand adj4 streng*).tw.
15 or/9-14
16 (wrist or ulnar or radioulnar or radio-ulnar or radio ulnar or forearm* or sigmoid).tw.
17 8 and 15 and 16
18 (2017* or 2016* or 2015* or 2014* or 2013* or 2012* or 2011* or 2010* or 2009* or 2008* or 2007* or 2006* or 2005* or 2004* or 2003* or 2002*).ed.
19 17 and 18
20 Animals/ not humans/
21 19 not 20