NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of lateral elbow resurfacing for arthritis

Arthritis can cause pain, swelling and stiffness in the elbow. The outer (lateral) part of the elbow is a joint between the upper arm bone and 1 of the bones in the lower arm. In this procedure, under general anaesthetic, a cut is made in the back of the elbow and the muscle is split to access the bones. The ends of the 2 bones are cut and drilled to remove damaged tissue. An implant is then inserted into the end of each bone, to create smooth surfaces, as seen in a healthy joint (resurfacing). The muscle is then stitched back together.

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Abbreviations

Word or phrase	Abbreviation
American Shoulder and Elbow Surgeons elbow score	ASES-e
Lateral resurfacing elbow	LRE
Mayo Elbow Performance Index	MEPI
Mayo Elbow Performance Score	MEPS
Modified American Shoulder and Elbow Surgeons score	m-ASES
Oxford Elbow Score	OES
Quick Disabilities of the Arm, Shoulder and Hand	Q-DASH
Range of motion	ROM
Standard deviation	SD

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 professional opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in December 2020.

Procedure name

• Lateral elbow resurfacing for arthritis

Professional societies

- British Elbow and Shoulder Society
- British Orthopaedic Association

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• Orthopaedic Trauma Society.

Description of the procedure

Indications and current treatment

Rheumatoid arthritis is the most common form of arthritis in the elbow. Osteoarthritis that needs surgery is less common in the elbow than in weightbearing joints, such as the knee and hip. Symptoms include pain, swelling and stiffness in the elbow.

Treatment for elbow arthritis depends on the severity of the disease. Conservative treatments include analgesics and corticosteroid injections to relieve pain and inflammation, and physiotherapy and prescribed exercise to improve function and mobility. When symptoms are severe, surgery may be indicated. Options include arthroscopic debridement, interposition arthroplasty, replacement or excision of the radial head, or total elbow replacement.

What the procedure involves

Lateral resurfacing of the elbow for arthritis is usually done under general anaesthesia. The patient is typically placed on their side with the elbow uppermost. An incision is made in the back of the elbow and the triceps muscle is split to access the elbow joint. The joint is dislocated, and the articular surfaces prepared. The capitellum of the humerus is sized, and then after inserting a guidewire the capitellum is reamed using a surface cutter, and a peg hole is then created. A trial component is inserted. A guidewire is then inserted into the radial head and the surface is shaped with a cutter to produce a concave face. A peg hole is then created in the radial head and a trial component inserted. Once the trial components have been tested for stability and range of movement and there is a satisfactory result, the definitive components are implanted and the skin is closed with sutures. A cast or splint is used for 4 to 6 weeks after which function is gradually resumed.

A potential advantage of this procedure over a total elbow replacement is that it preserves the natural inner compartment of the elbow. Movements are therefore likely to be more like a natural elbow joint.

Outcome measures

Mayo Elbow Performance Score (MEPS) or Mayo Elbow Performance Index (MEPI)

The MEPI was originally a 3-part scale, which included pain, motion and stability and then became a 4-part scale, including motion, pain, strength and stability. The MEPS is derived from the MEPI and consists of 4 parts: pain (with a maximum score of 45 points for no pain), ulnohumeral motion (20 points), stability (10 points) and the ability to do 5 functional tasks (25 points). Higher scores indicate less pain and better function.

American Shoulder and Elbow Surgeons-Elbow (ASES-E) score

The ASES-E is a standardised elbow evaluation that has a patient questionnaire and a form for the physician to record elbow impairment. The patient selfevaluation form has 3 sections: pain, function and satisfaction. The physician assessment consists of 4 parts: motion, stability, strength and physical findings.

Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire

The DASH questionnaire is a 30-item questionnaire that assesses the patient's ability to do certain upper extremity activities. It is a self-report questionnaire that rates difficulty and interference with daily life on a 5-point Likert scale. The QuickDASH (Q-DASH) is an abbreviated version of the original DASH questionnaire. It contains 11 items and measures an individual's ability to complete tasks and absorb forces, and severity of symptoms. In both the DASH and Q-DASH a higher score indicates a greater level of disability and severity. The scores of both measures range from 0 (no disability) to 100 (most severe disability).

Efficacy summary

MEPS

In a case series of 27 patients, the mean MEPS improved from 43.2 before surgery to 86.5 (p<0.00001) at 1 year and 78.3 (p<0.00001) at long-term follow up (mean 8.3 years). In patients with osteoarthritis, the score improved from 44.6 to 87.9 at 1 year (p<0.00001) and 84.6 (p<0.00001) at long-term follow up. In patients with rheumatoid arthritis, the score improved from 40.5 to 83.6 at 1 year (p<0.00001) and 66.0 (p=0.032) at long-term follow up (Watkins C, 2018).

In a case series of 31 patients that compared 2 different prostheses, the mean MEPS improved from 44 before surgery to 94 (p<0.001) after a mean follow up of 6.8 years. The mean MEPS improved from 43 before surgery to 93 (p<0.001) in patients who had a Lateral Resurfacing Elbow implant and from 46 to 95 (p=0.012) in those who had a Uni-Elbow Radio-Capitellum implant (Giannicola G, 2019).

In 2 case series of 18 patients (19 elbows) and 20 patients, the mean MEPS improved from 46 and 50 before surgery to 90 (p<0.001) and 85 (p=0.001) respectively at the final follow-up visit (mean 35 months and 23 months). At the final follow up, the MEPI was categorised as excellent in 9 patients, good in 5 and fair in 3 (2 missing; Kachooei A, 2018), and excellent in 12 patients, good in 2, fair in 3 and poor in 3 (Giannicola G, 2012).

In a case series of 15 patients (16 elbows), the mean MEPS improved from 46 to 85 (p<0.01) at mean follow up of 3.4 years (Spross C, 2019).

ASES-E

In the case series of 27 patients, the mean ASES-E improved from 54.3 before surgery to 87.3 (p<0.00001) at 1 year and 76.6 (p<0.00001) at long-term follow up (mean 8.3 years). In patients with osteoarthritis, the score improved from 60.0 to 91.3 at 1 year (p<0.00001) and 83.6 (p<0.00001) at long-term follow up. In patients with rheumatoid arthritis, the score improved from 47.0 to 83.9 at 1 year (p<0.00001) and 65.5 (p=0.037) at long-term follow up (Watkins C, 2018).

In the case series of 31 patients that compared 2 different prostheses, the mean modified ASES score improved from 35 before surgery to 90 (p<0.001) after a mean follow up of 6.8 years. The mean modified ASES score improved from 35 before surgery to 90 (p<0.001) in patients who had a Lateral Resurfacing Elbow implant and from 34 to 90 (p=0.012) in those who had a Uni-Elbow Radio-Capitellum implant (Giannicola G, 2019).

In the case series of 20 patients the mean modified ASES score improved from 49 before surgery to 83 (p=0.001) at last follow up (mean 23 months; Giannicola G, 2012).

Q-DASH

In the case series of 31 patients that compared 2 different prostheses, the mean Q-DASH score improved from 66 before surgery to 12 (p<0.001) after a mean follow up of 6.8 years. The score improved from 66 before surgery to 9 (p<0.001) in patients who had a Lateral Resurfacing Elbow implant and from 66 to 17 (p=0.012) in those who had a Uni-Elbow Radio-Capitellum implant (Giannicola G, 2019).

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In the case series of 20 patients the mean Q-DASH score improved from 52 before surgery to 23 (p=0.001) at last follow up (mean 23 months; Giannicola G, 2012).

Range of motion (ROM)

In the case series of 27 patients, the mean ROM improved from 77.1° before surgery to 103.3° (p<0.00001) at long-term follow up (mean 8.3 years). In patients with osteoarthritis, it improved from 82.4° to 111.1° (p<0.00001) at long-term follow up. In patients with rheumatoid arthritis, it improved from 77.5° to 93.0° (p<0.00001) at long-term follow up (Watkins C, 2018).

In the case series of 31 patients that compared 2 different prostheses, the mean extension/flexion arc improved from 65° before surgery to 119° (p<0.001) after a mean follow up of 6.8 years. The mean pronation/supination arc improved from 106° before surgery to 136° (p=0.010). The mean extension/flexion arc improved from 68° before surgery to 115° (p<0.001) in patients who had a Lateral Resurfacing Elbow implant and from 59° to 127° (p=0.012) in those who had a Uni-Elbow Radio-Capitellum implant. The mean pronation/supination arc improved from 131° before surgery to 147° (p=0.048) in patients who had a Lateral Resurfacing Elbow implant and from 51° to 116° (p=0.018) in those who had a

In the case series of 18 patients, the mean extension/flexion arc improved from 97° before surgery to 119° (p=0.027) after a mean follow up of 35 months. The mean pronation/supination arc improved from 121° before surgery to 139° at follow up (p=0.003) (Kachooei A, 2018). In the case series of 20 patients, the mean arc of movement improved from 65° before surgery to 95° (p=0.001) after a mean follow up of 23 months (Giannicola G, 2012). In the case series of 15 patients (16 elbows), the mean arc of motion improved from 106° to 117° (p=0.27) at follow up (mean 3.4 years; Spross C, 2019).

Patient satisfaction

In the case series of 27 patients, the mean satisfaction score measured on a visual analogue scale at final follow up was 9.3 (range 5 to 10; Watkins C, 2018). In the case series of 20 patients, patient satisfaction was 80% (16/20; Giannicola G, 2012).

Radiographic assessment

In the case series of 27 patients, there was no radiographic evidence of loosening at final follow up. Satisfactory ('anatomical') positioning of both components was achieved in all but 3 elbows. In 2 elbows, the radial component had been inserted posterior to the anatomical axis and in 1, the capitellar IP overview: lateral elbow resurfacing for arthritis

component had been placed horizontally. Apparent widening of the lateral ulnohumeral joint space was noted in 4 elbows in patients with primary osteoarthritis. Radiographic progression of ulnohumeral arthritis was evident in 21 elbows (10 with osteoarthritis, 8 with rheumatoid arthritis and 3 with post-traumatic osteoarthritis). In 7 elbows, a 'flare' of bone had formed around the base of the radial component (Watkins C, 2018).

In the case series of 31 patients, 'excellent positioning of the implant' was reported for 68% (21/31) of patients. 13% (4/31) of patients had worsening of the ulnohumeral osteoarthritis (grade 2 to 3), but this did not affect the final clinical outcome. Overall, 97% (30/31) of patients had good joint congruence; 1 had chronic dislocation associated with marked osteoarthritis and deformity (Giannicola G, 2019).

In the case series of 20 patients, 'good positioning' was reported for 85% (17/20) of patients (Giannicola G, 2012).

In the case series of 15 patients, none of the capitellar components showed any signs of loosening but 2 radial head components showed signs of loosening at final follow up (2 to 6 years after surgery). One patient had grade 3 and 1 had grade 4 loosening; both patients were asymptomatic without the need for revision. No progression of ulnohumeral degeneration was reported for 60% (9/15) of elbows. Progression increased from grade 0 to grade 1 in 3 elbows, from grade 1 to grade 2 in 1 elbow, from grade 2 to grade 3 in 1 elbow, and from grade 2 to grade 4 in 1 elbow (Spross C, 2019).

Safety summary

Infection

Deep infection necessitating removal of the implant components, was reported in 1 patient in a case series of 43 patients (Pooley J, 2007).

Reoperation

Further surgery was needed in 10% (3/31) of patients in the case series of 31 patients. Two patients developed stiffness and had arthrolysis to remove heterotopic ossification and 1 patient had 2 further procedures for chronic instability (Giannicola G, 2019).

Reoperation for recurrent elbow stiffness was reported in 15% (3/20) of patients in the case series of 20 patients. One patient had arthrolysis and removal of heterotopic ossifications 9 months after the lateral elbow resurfacing. At the last follow up, the patient had persistent pain and limitation of daily activities, both of

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which were resistant to medical treatment and physiotherapy. The second patient had reoperation for soft tissue release and heterotopic ossification removal 12 months after the lateral elbow resurfacing. He reported a good result at the last follow up. The third patient developed a flexion/extension ankylosis of the elbow associated with ulnar nerve neuropathy. The patient had open debridement and ulnar nerve neurolysis (Giannicola G, 2012).

Reoperation was reported in 31% (5/16) of elbows in the case series of 15 patients. In 3 patients, the radial head component was revised because of loosening. One of these patients still had pain after the first revision, so the radial head was removed. In another patient, only the radial head component was replaced because of ulnar impingement; the stem was well fixed and left in place. Another patient had open arthrolysis because of stiffness 1 year after the procedure (Spross C, 2019).

Stiffness

Increasing stiffness 3 years after surgery was reported in 1 patient in the case series of 27 patients. Two attempts at manipulation under anaesthetic failed to restore a functional range of movement and the symptoms were managed conservatively (Watkins C, 2018). Minor stiffness that did not need further surgery was reported in 10% (3/31) of patients in the case series of 31 patients (Giannicola G, 2019).

Neuropathy

Persistent ulnar neuropathy was reported in 6% (2/31) of patients in the case series of 31 patients. One patient had a sensory deficit and 1 had a slight motor and sensory deficit (Giannicola G, 2019). Postoperative worsening of ulnar neuropathy was reported in 1 patient in the case series of 20 patients. The patient refused any further surgical treatment (Giannicola G, 2012).

Component displacement

Capitellar component displacement was reported in 1 patient in the case series of 18 patients (Kachooei A, 2018).

Radial head or neck resorption

Radial head or neck resorption was reported in 16% (3/19) of elbows in the case series of 18 patients (Kachooei A, 2018).

Heterotopic ossification

Heterotopic ossification was reported in 1 patient in the case series of 18 patients (Kachooei A, 2018).

Other

Dehiscence of triceps after a fall in the early postoperative period was reported in 1 patient in the case series of 27 patients. This was successfully repaired surgically.

Anecdotal and theoretical adverse events

In addition to safety outcomes reported in the literature, professional experts are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never happened). For this procedure, we received no questionnaires.

The evidence assessed

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to lateral elbow resurfacing for arthritis. The following databases were searched, covering the period from their start to 2 November 2020: 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 <u>literature search strategy</u>). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The <u>inclusion criteria shown in the following table</u> 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.

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	People with elbow arthritis.
Intervention/test	Lateral elbow resurfacing.
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.

Inclusion criteria for identification of relevant studies

List of studies included in the IP overview

This IP overview is based on about 150 patients from 6 case series (Watkins C, 2018; Giannicola G, 2019; Kachooei A, 2018; Giannicola G, 2012; Spross C, 2019 and Pooley J, 2007). There is likely to be some patient overlap between the studies.

Other studies that were considered to be relevant to the procedure but were not included in the main <u>summary of the key evidence</u> are listed in the <u>appendix</u>.

Summary of key evidence on lateral elbow resurfacing for arthritis

Study 1 Watkins C (2018)

Study details

Study type	Case series
Country	UK
Recruitment period	2005 to 2008
Study population	n=27 patients (30 elbows)
and number	Patients with elbow arthritis
Age and sex	Mean 61 years (range 25 to 82); 56% (15/27) female
Patient selection criteria	Patients with significant pain in the elbow despite conservative management, and degenerative changes that were confined to the lateral compartment of the elbow, irrespective of the cause, primary hypotrophic osteoarthritis, post-traumatic osteoarthritis, or rheumatoid arthritis.
Technique	The lateral resurfacing elbow (LRE) arthroplasty system (Biomet UK Ltd, UK) was used, including resurfacing of the capitellum and radial head. In 3 elbows, a 'hemi-LRE arthroplasty' using only a capitellar component was converted to a 'Total-LRE arthroplasty' by insertion of a radial head resurfacing component.
	Unrestricted activities were allowed after 3 months, with a progressive phased return to work at that stage in the younger patients.
Follow up	Mean 8.3 years (range 7.3 to 9.4)
Conflict of interest/source of funding	1 or more of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article.

Analysis

Follow-up issues: A total of 26 patients (96%) were available for review. One patient who developed severe dementia was excluded from the analysis of outcome. It was confirmed that she had not had further surgery and this arthroplasty was therefore included in the analysis of survival.

Study design issues: Single centre case series of consecutive patients. The main outcome measures were the Mayo Elbow Performance Score (MEPS), the American Shoulder and Elbow Surgeons elbow score (ASES-e), the mean range of movement and the radiological outcome. Outcomes were recorded preoperatively and at 3, 6, and 12 months after surgery by a specialised physiotherapist, and at final follow-up by a specialist registrar. Both were independent of the operating surgical team. All radiographs were analysed by a consultant orthopaedic surgeon, who was not the operating surgeon. Satisfaction was measured on a visual analogue scale.

Study population issues: Of the 27 patients, 12 (14 elbows) had osteoarthritis, 5 had post-traumatic osteoarthritis and 10 (11 elbows) had rheumatoid arthritis. There is some patient overlap with Pooley J, 2007.

Other issues: all operations were done by a single surgeon, who also designed the implant.

Key efficacy findings

Number of patients analysed: 26

Mean scores for all patients and by type of arthritis, p<0.00001 for each time interval unless otherwise stated

Patient group	Parameter	Before surgery	3 months	6 months	1 year	Long term follow-up
All patients	MEPS	43.2	80.3	82.2	86.5	78.3
All patients	ASES-e	54.3	81.6	85.9	87.3	76.6
All patients	ROM	77.1	-	-	-	103.3
Osteoarthritis	MEPS	44.6	77.1	82.5	87.9	84.6
Osteoarthritis	ASES-e	60.0	84.7	87.7	91.3	83.6
Osteoarthritis	ROM	82.4	-	-	-	111.1
Post-traumatic osteoarthritis	MEPS	51.0	84.0	88.8	89.0	85.0
Post-traumatic osteoarthritis	ASES-e	54.5	78.9	83.1	83.7	79.2
Post-traumatic osteoarthritis	ROM	71.6	-	-	-	102.0
Rheumatoid arthritis	MEPS	40.5	82.7	79.1	83.6	66.0 p=0.032
Rheumatoid arthritis	ASES-e	47.0	79.1	84.7	83.9	65.5 p=0.037
Rheumatoid arthritis	ROM	77.5	-	-	-	93.0

• Mean satisfaction score at final follow-up=9.3 (5 to 10).

Mean scores by age and gender

Parameter	Male	Female	р	Age <70 years	Age ≥70 years	р
MEPS, baseline	43.4	42.8	Not significant	44.6	33.8	Not significant
MEPS, 3 months	82.5	77.9	Not significant	80.0	82.5	Not significant

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MEPS, 6 months	85.0	78.9	Not significant	80.0	96.3	0.011
MEPS, 1 year	89.7	82.9	Not significant	85.0	96.3	0.046
MEPS, long-term	85.0	70.0	0.034	78.1	80.0	Not significant
follow-up						
Increase in MEPS	41.6	26.2	Not significant	33.5	45.0	Not significant
ASES-e, baseline	57.2	51.1	Not significant	55.8	44.0	Not significant
ASES-e, 3 months	84.8	77.7	Not significant	81.2	84.0	Not significant
ASES-e, 6 months	87.6	83.9	Not significant	85.5	88.5	Not significant
ASES-e, 1 year	89.7	84.0	Not significant	86.9	89.5	Not significant
ASES-e, long-term	83.7	67.8	0.018	75.8	83.3	Not significant
follow-up						
Increase in ASES-e	26.5	16.1	Not significant	20.0	38.2	Not significant
ROM, baseline	74.1	80.9	Not significant	80.4	49.3	0.003
ROM, long-term	107.8	87.7	Not significant	104.0	96.7	Not significant
follow-up						
Increase in ROM	33.7	15.6	0.011	23.7	35.5	Not significant
Satisfaction score at	9.4	9.3	Not significant	9.3	10.0	Not significant
long-term follow-up						

Implant survival=100% (Kaplan–Meier survival analysis)

There was no radiographic evidence of loosening such as a change in alignment of a component or progression of radiolucent lines at final follow-up. Satisfactory ('anatomical') positioning of both components was achieved in all but 3 elbows. In 2 elbows, the radial component had been inserted posterior to the anatomical axis and in 1, the capitellar component had been placed horizontally.

Apparent widening of the lateral ulnohumeral joint space was noted in 4 elbows in patients with primary osteoarthritis. Radiographic progression of ulnohumeral arthritis was evident in 21 elbows (10 with osteoarthritis, 8 with rheumatoid arthritis and 3 with post-traumatic osteoarthritis). In 7 elbows, a 'flare' of bone had formed around the base of the radial component.

Key safety findings

Complications

- Dehiscence of triceps after a fall in the early postoperative period, n=1; successfully repaired surgically)
- Increasing stiffness, n=1; patient with rheumatoid arthritis developed increasing stiffness 3 years after surgery. Her preoperative arc of movement had been limited (flexion/extension 70° to 90°). Two attempts at manipulation under anaesthetic failed to restore a functional range of movement. Her symptoms were managed conservatively.

Study 2 Giannicola G (2019)

Study details

Study type	Case series (comparing 2 radiocapitellar prostheses)
Country	Italy
Recruitment period	2007 to 2014
Study population and number	n=31 (17 Lateral Resurfacing Elbow [LRE] implant and 14 Uni-Elbow Radio-Capitellum Implant [UNI-E] arthroplasties)
	Patients with degenerative or traumatic conditions of the elbow
Age and sex	Mean 54 years (range 27 to 73); 32% (10/31) female
Patient selection criteria	Not reported.
Technique	Devices: Lateral Resurfacing Elbow implant (LRE; Biomet, UK) and the Uni-Elbow Radio-Capitellum Implant (UNI-E; Small Bone Innovations Inc., US) were used. The UNI-E implant entails replacing the entire radial head.
	The LRE implant was used when the radiocapitellar joint had foveal degenerative changes, while the UNI-E implant was used when there was marked radiocapitellar osteoarthritis. In particular, the UNI-E implant was used in post-traumatic conditions when the radial head needed to be resected because of severe osteoarthritis or deformity.
Follow up	Mean 6.8 years (range 3.8 to 11.5)
Conflict of interest/source of funding	None

Analysis

Follow-up issues: An additional 6 patients were treated during the study period but were lost to follow-up; 2 patients died, 3 moved residence and 1 patient, who had gastric cancer, was lost to follow-up after 6 years. All 6 patients reported satisfactory results at the last follow-up.

Study design issues: Prospective multicentre case series. The clinical and radiological evaluation at the last follow-up was done by 2 surgeons who had not been involved in the surgery. All patients had preoperative imaging with radiographs and CT scans. MRI was done in patients with osteonecrosis. The pre- and postoperative clinical evaluations included the Mayo Elbow Performance score and Index (MEPS and MEPI), the Quick Disabilities of the Arm, Shoulder and Hand (Q-DASH) score, and the modified American Shoulder and Elbow Surgeons (m-ASES) score. The 2 patients with a fracture did not have a preoperative clinical evaluation.

Study population issues: A LRE implant was used in 9 patients with primary osteoarthritis, 7 with posttraumatic osteoarthritis, and 1 with osteonecrosis. The UNI-E implant was used in 9 patients with posttraumatic osteoarthritis, 2 with osteonecrosis, 2 with acute fractures, and 1 who needed revision of a radial head arthroplasty.

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Key efficacy findings

• Number of patients analysed: 31

MEPI

At baseline, the MEPI was poor in 5 patients and fair in 24. At the final follow-up, the MEPI was excellent in 24 patients, good in 6, and fair in 1.

Preoperative and postoperative clinical and functional outcomes

Parameter	Preoperative	Postoperative	р
Mean extension, degrees (range)	37 (10 to 90)	15 (0 to 45)	<0.001
Mean flexion, degrees (range)	101 (55 to 140)	134 (100 to 150)	<0.001
Mean extension/flexion arc, degrees (range)	65 (0 to 130)	119 (55 to 150)	<0.001
Mean pronation, degrees (range)	52 (0 to 85)	70 (20 to 85)	<0.001
Mean supination, degrees (range)	54 (0 to 85)	66 (10 to 85)	0.021
Mean pronation/supination arc, degrees (range)	106 (0 to 170)	136 (30 to 170)	0.010
Mean MEPS (range)	44 (25 to 65)	94 (15 to 100)	<0.001
Mean Q-DASH (range)	66 (16 to 89)	12 (0 to 89)	<0.001
Mean m-ASES (range)	35 (5 to 86)	90 (10 to 100)	<0.001

Clinical parameters and functional scores in the 2 types of implant

Parameter	LRE			UNI-E		
	Preoperative	Postoperative	р	Preoperative	Postoperative	р
Mean extension,	35	17	0.002	41	10	0.011
degrees						
Mean flexion, degrees	102	132	<0.001	99	137	0.011
Mean extension/flexion arc, degrees	68	115	<0.001	59	127	0.012
Mean pronation, degrees	66	77	0.005	22	58	0.018
Mean supination, degrees	65	71	0.305	29	58	0.018
Mean pronation/supination arc, degrees	131	147	0.048	51	116	0.018
Mean MEPS	43	93	<0.001	46	95	0.012
Mean Q-DASH	66	9	<0.001	66	17	0.012
Mean m-ASES	35	90	<0.001	34	90	0.012

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Comparison between 2 types of implant

Parameter	Preoper	ative		Postoperative			
	LRE	UNI-E	р	LRE	UNI-E	р	
Mean extension, degrees	35	41	0.798	17	10	0.204	
Mean flexion, degrees	102	99	0.932	132	137	0.187	
Mean extension/flexion arc, degrees	68	59	0.754	115	127	0.187	
Mean pronation, degrees	66	22	0.005	77	58	0.015	
Mean supination, degrees	65	29	0.013	71	58	0.334	
Mean pronation/supination arc, degrees	131	51	0.006	147	116	0.170	
Mean MEPS	43	46	0.511	93	95	0.675	
Mean Q-DASH	66	66	0.440	9	17	0.103	
Mean m-ASES	35	34	1.000	90	90	0.243	

Implant survival=100%, no revisions were needed.

Radiological evaluation

Radiological evaluation at final follow-up showed excellent positioning of the implant in 67.7% (21/31) of patients. The LRE humeral component was positioned too proximally in 1 patient (no clinical consequences). There was 'slight overstuffing' in 29.4% (5/17) of patients who had an LRE implant, all of whom reported excellent clinical outcomes. Overstuffing of the UNI-E was seen in 28.6% (4/14) of patients who had a UNI-E implant, because of an excessive length of the radial component. Asymptomatic periprosthetic radiolucent lines around the stem of the UNI-E prosthetic radial head component were seen in 35.7% (5/14) patients who had a UNI-E implant, 2 of whom had gross loosening.

12.9% (4/31) of patients had worsening of the ulnohumeral osteoarthritis (grade 2 to 3), but this did not affect the final clinical outcome.

Overall, 96.8% (30/31) of patients had good joint congruence; 1 had chronic dislocation associated with marked osteoarthritis and deformity.

Key safety findings

There were no implant-related complications.

Postoperative heterotopic ossification=19.4% (6/31); 3 class 1, 2 class 2B, 1 class 2A

Reoperation

9.7% (3/31) of patients needed further surgery: 2 patients developed stiffness and had arthrolysis to remove heterotopic ossification and 1 patient had 2 further procedures for chronic instability.

Complications that did not need reoperation

- Minor stiffness=9.7% (3/31)
- Persistent ulnar neuropathy=6.4% (2/31) (1 patient had a sensory deficit and 1 had a slight motor and sensory deficit).

Study 3 Kachooei A (2018)

Study details

Study type	Case series
Country	The Netherlands
Recruitment period	2007 to 2016
Study population	n=18 (19 elbows)
and number	Patients with isolated symptomatic radiocapitellar degenerative arthritis refractory to nonoperative treatment
Age and sex	Mean 53 years; 58% (11/19) female
Patient selection criteria	Isolated radiocapitellar degenerative arthritis was defined as pain over the radiocapitellar joint with palpation, inability to perform activities of daily living because of the pain, and radiographic signs of degenerative arthritis of the joint. Limited motion and some extent of valgus instability were also present in most of the patients.
Technique	The LRE system (Biomet, US) was used in 15 patients and the Uni-Elbow Radio Capitellum system (Small Bone Innovations, US), in which the fixation is different, and excision of the native radial head is needed, was used in 3 patients. A custom radiocapitellar prosthesis (Techmedica, US) was used in 1 of the 3 patients who had a revision operation.
	Radiocapitellar prosthetic arthroplasty was the primary treatment in 16 elbows, and 3 were revision radial head arthroplasty with concomitant capitellar resurfacing.
Follow up	Mean 35 months (range 12 to 88); average radiographic follow-up was 53 months (range 19 to 93)
Conflict of interest/source of funding	None

Analysis

Follow-up issues: Patients with less than 12 months of follow-up were excluded.

Study design issues: Retrospective, single-centre case series. The primary aim of the study was to assess the short to mid-term functional and radiographic results after the procedure. Clinical assessment included preoperative and final postoperative range of motion, pain, instability, and ability to perform the activities of daily living. Function was assessed using MEPI and the Oxford Elbow Score (OES). MEPI scores of 95 to 100 were graded as excellent, 80 to 94 as good, 60 to 79 as fair, and 60 or less as poor. Conversion to total elbow arthroplasty was considered a failure in survival.

Study population issues: Of the 19 elbows, 15 (79%) had arthritis, 1 (5%) had osteonecrosis of the capitellum and 3 (16%) had a radial head prosthesis with capitellum erosion.

Key efficacy findings

• Number of patients analysed: 18 (19 elbows)

MEPI

At the final follow-up, the MEPI was excellent in 9 patients, good in 5, and fair in 3 (2 missing).

Variable	All elbows (n=19)			LRE prosthesis (n=15)		Non-LRE prosthesis (n=4)	
	Before	After	р	Before	After	Before	After
Range of motion, mean (SD), degrees							
Flexion	121 (10)	131 (9.8)	0.051	120 (11)	130 (9.3)	123 (5)	136 (11)
Flexion contracture	24 (14)	13 (13)	0.065	25 (13)	12 (13)	20 (18)	16 (14)
Arc	97 (21)	119 (29)	0.027	95 (21)	118 (20)	103 (22)	121 (20)
Pronation	63 (8)	70 (16)	0.002	63 (9.0)	69 (19)	60 (5.0)	73 (5.0)
Supination	59 (14)	69 (20)	0.041	58 (16)	66 (22)	60 (5.0)	80 (5.0)
Arc	121 (19)	139 (34)	0.003	122 (21)	136 (38)	120 (5.0)	153 (5.0)
Valgus instability, no. (%)							
None	6 (32)	9 (47)	0.41	6 (40)	7 (47)	0	2 (50)
Grade 1	12 (63)	10 (53)		9 (60)	8 (53)	3 (75)	2 (50)
Grade 2	1 (5)	0		0	0	1 (25)	0
MEPS, mean (SD)	46 (14)	90 (12)	<0.001	39 (9.0)	90 (11)	62 (10)	88 (17)
OES, mean (SD)	21 (9)	84 (69)	0.024	24 (13)	86 (77)	20 (7.5)	76 (31)

Function and stability before and after surgery (final follow up visit)

There was a statistically significant improvement in pain at the final follow-up visit, with no pain in 11 patients, mild pain in 5, and moderate pain in 3 (p=0.004). All patients reported the ability to perform activities of daily living independently at the final follow-up visit, whereas 7 reported inability in doing hair, 4 in doing shoes, 1 in hygiene, 3 in feeding, and 3 in putting on a shirt before surgery.

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Radiographic assessment at the final follow up visit

Variable	All elbows (n=19)			LRE prosthesis (n=15)		Non-LRE prosthesis (n=4)	
	Before	After	р	Before	After	Before	After
Carrying angle, mean (SD), degrees	158 (3.1)	162 (4.5)	0.002	157 (3.3)	162 (4.8)	160 (2.0)	162 (3.7)
Ulnohumeral arthritis, no. (%)			0.102				
None	7 (37)	5 (26)		3 (20)	2 (13)	4 (100)	3 (75)
Grade 1	8 (42)	8 (42)		8 (53)	8 (53)	0	0
Grade 2	4 (21)	6 (32)		4 (27)	5 (34)	0	1

The mean difference in carrying angle was not large enough to be clinically significant.

Implant survival=100%

Key safety findings

There were no major complications, including infection, revision, disassembly of the components, or conversion to total elbow arthroplasty.

Radiographic assessment at the final follow up visit

Variable	All elbows (n=19)			LRE prosthesis (n=15)		Non-LRE prosthesis (n=4)	
	Before	After	р	Before	After	Before	After
Capitellum osteopenia, no. (%)			0.014				
No	12 (63)	6 (32)		10 (66)	5 (34)	2 (50)	1 (25)
Yes	7 (37)	13 (68)		5 (34)	10 (66)	2 (50)	3 (75)
Other complications, no. (%)							
Heterotopic ossification		1 (5.3)			0		1 (5.3)
Capitellar component displacement		1 (5.3)			1 (5.3)		0
Radial head or neck resorption		3 (16)			1 (5.3)		2 (11)

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Study 4 Giannicola G (2012)

Study details

Study type	Case series
Country	Italy
Recruitment period	2006 to 2010
Study population	n=20
and number	Patients with primary or post-traumatic osteoarthritis
Age and sex	Mean 55 years (range 31 to 73); 40% (8/20) female
Patient selection criteria	All study patients had mild to severe pain and stiffness and degenerative changes in the lateral compartment associated with ulnohumeral osteophytosis.
	In 14 patients, conservative treatment with physiotherapy and nonsteroidal anti- inflammatory drugs for more than 6 months had not been beneficial. In 6 patients, intra-articular cortisone injections had been administered because of severe pain, with only temporary and partial benefit.
	Exclusion criteria: recent or active infection; severe neuromuscular deficit, which could jeopardise elbow function, particularly of biceps and triceps brachii muscles; severe reduction of wrist and hand function; severe bone loss of the posterior aspect of the lateral column, which could compromise the stability of the humeral component; severe deformity of the radiohumeral and proximal radioulnar joint, which could affect the implant stability of both LRE components; and marked wear of the medial compartment (ulnohumeral joint) in patients older than 60 years.
Technique	Open debridement and insertion of LRE prosthesis (17 total LRE and 3 hemi-LRE).
	All patients had rehabilitation therapy: 12 were assisted by a physiotherapist, and 8 had self-managed physiotherapy in accordance with the surgeons' indications. Activities of daily life could begin after 8 weeks. Strenuous activities were permitted after 4 to 6 months.
Follow up	Mean 22.6 months (range 6 to 47)
Conflict of interest/ source of funding	None

Analysis

Follow-up issues: An additional 4 patients were treated during the study period but were lost to follow-up.

Study design issues: Prospective, multicentre case series. Clinical evaluation was done using MEPS, the m-ASES, and the Q-DASH. Implant positioning was evaluated using preoperative and postoperative radiographs and those taken at the last follow-up.

Study population issues: Of the 20 patients, 11 had primary osteoarthritis and 9 had post-traumatic osteoarthritis. One patient had had arthroscopic debridement and 1 had had multiple open debridements.

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Key efficacy findings

• Number of patients analysed: 20

MEPI

Before surgery, the MEPI was good in 2 patients, fair in 3 and poor in 15. At the last follow-up, the MEPI was excellent in 12 patients, good in 2, fair in 3 and poor in 3.

Clinical outcomes at last follow-up, mean (range; SD)

Variable	Before surgery	After surgery	р
MEPS	50 (30 to 85; 15.9)	85 (50 to 100; 17.1)	0.001
m-ASES score	49 (5 to 86; 23.5)	83 (55 to 100; 16.7)	0.001
Q-DASH score	52 (9 to 89; 21.7)	23 (0 to 73; 25)	0.001
Extension, degrees	37 (10 to 70; 16.4)	25 (0 to 65; 19.5)	0.014
Flexion, degrees	100 (30 to 140; 25.2)	125 (25 to 150; 27.8)	0.001
Arc of movement, degrees	65 (0 to 130; 25.9)	95 (0 to 150; 34)	0.001
Pronation, degrees	53 (0 to 85; 31)	70 (15 to 85; 17.9)	Not reported
Supination, degrees	52 (0 to 85; 31.5)	75 (35 to 85; 14.9)	Not reported

Good elbow stability was found in all but 3 patients. In a 75-year-old patient with Parkinson disease, operated on for primary osteoarthritis and chronic elbow instability, a recurrent instability occurred leading to dislocation of the prosthetic component. The patient refused further surgical treatment. In the remaining 2 patients, mild varus and valgus instability was found, respectively; however, both patients reported good results at the last follow-up.

Implant survival=100%

Radiographic evaluation

Good positioning=85% (17/20)

In 2 patients, who both had an unsatisfactory clinical outcome because of stiffness, the humeral component was positioned too horizontally. In 1 patient, who had good range of motion and mild positive valgus stress, the humeral component was too proximal.

Slight overstuffing=25% (5/20) (4 of these patients reported satisfactory clinical outcomes and 1 patient had a poor outcome).

Patient satisfaction=80% (16/20)

Key safety findings

- Recurrent elbow stiffness=15% (3/20).
 - 1 patient had reoperation for arthrolysis and removal of heterotopic ossifications 9 months after the lateral elbow resurfacing. At the last follow-up, the patient had persistent pain and limitation of daily activities, both of which were resistant to medical treatment and physiotherapy.
 - 1 patient had reoperation for soft tissue release and heterotopic ossification removal 12 months after the lateral elbow resurfacing. He reported a good result at the last follow-up.
 - The third patient developed a flexion/extension ankylosis of the elbow associated with ulnar nerve neuropathy. The patient had open debridement and ulnar nerve neurolysis.
- Postoperative worsening of ulnar neuropathy=5% (1/20); the patient refused any further surgical treatment.

Study 5 Spross C (2019)

Study details

Study type	Case series
Country	Switzerland
Recruitment period	2010 to 2015
Study population	n=15 patients (16 elbows)
and number	Patients with post-traumatic or primary radiohumeral osteoarthritis
Age and sex	Mean 51.9 years (range 32 to 65); 73% (11/15) female
Patient selection criteria	Patients with post-traumatic or primary radiohumeral osteoarthritis.
Technique	The UNI-Elbow System (Stryker, US) was used in 15 elbows and a custom capitellar replacement was used in 1 patient who had previously had a floating radial head prosthesis (Wright Medical, US). In 3 elbows, a radial head prosthesis was already implanted and was converted to radiocapitellar arthroplasty by exchanging the metal head with a component with a polyethylene articulation.
	No additional surgical procedures were done at the same time. Patients were allowed to mobilise their elbow without restriction on the first postoperative day. Usually, no physiotherapy was prescribed unless a range of motion deficit was present after 6 weeks. After 3 months, unrestricted activity was allowed.
Follow up	Mean 3.4 years (range 2 to 6 years).
Conflict of interest/ source of funding	One author is a consultant with Acumed and Wright Medical.

Analysis

Follow-up issues: Only patients with at least 2 years follow-up were included in the study.

Study design issues: Prospective, single centre case series. The main outcome measures were the MEPS and radiographical assessment (using the Kellgren-Lawrence classification, grades 0 to 4).

Study population issues: Of the 16 elbows, 10 had post-traumatic osteoarthritis and 6 had primary osteoarthritis. Ten patients had previous surgical procedures.

Key efficacy findings

• Number of patients analysed: 15 (16 elbows)

MEPS

The mean MEPS improved from 46 points to 85 points (p<0.01). This was mainly because of an improvement in pain scores at final follow-up compared with preoperative pain levels. The arc of motion improved from 106° before surgery to 117° at final follow-up (p=0.27). Flexion improved from 133° to 134° (p=0.67), and the extension deficit improved from 26° to 17° (p=0.22).

Radiographic evaluation

At 6 weeks, 7 elbows had no signs of ulnohumeral joint degeneration, 3 showed joint space narrowing (grade 1), and 5 showed osteophytic changes (grade 2).

At final follow-up (2 to 6 years postoperatively), 9 elbows (60%) showed no progression of ulnohumeral degeneration. Progression increased from grade 0 to grade 1 in 3 elbows, from grade 1 to grade 2 in 1 elbow, from grade 2 to grade 3 in 1 elbow, and from grade 2 to grade 4 in 1 elbow.

At final follow-up, none of the capitellar components showed any signs of loosening but 2 radial head components showed signs of loosening. One patient had grade 3 and 1 had grade 4 loosening; both patients were asymptomatic without the need for revision.

Key safety findings

Reoperation=31.3% (5/16)

One patient had an open arthrolysis because of stiffness 1 year after the procedure.

In 3 patients, the radial head component was revised because of loosening (1 bipolar and 2 unipolar). One of these patients still had pain after the first revision, so the radial head was removed. In another patient, only the radial head component was replaced because of ulnar impingement; the stem was well fixed and left in place.

In these 5 patients, the mean MEPS improved from 46 points before surgery to 71 points at final follow-up (p=0.05). There was a statistically significant improvement in pain (p<0.01). The clinical outcome (MEPS) of patients who needed revision surgery was statistically significantly worse than that of patients who did not need subsequent surgery (p=0.01).

Study 6 Pooley J (2007)

Study details

Study type	Case series
Country	UK
Recruitment period	2005 onwards
Study population and number	n=43 patients (44 elbows); baseline characteristics and efficacy outcome data were only reported for the first 10 patients
	Patients with primary or post-traumatic osteoarthritis or rheumatoid arthritis
Age and sex	Mean 52.5 years; 40% (4/10) female
Patient selection criteria	Not reported
Technique	LRE implant was used.
	A hemi-lateral compartment arthroplasty (capitellar resurfacing) was done in 22 elbows which had residual articular cartilage on the radial head. In the other 22 elbows, in which there was complete loss of articular cartilage from the lateral compartment, a total lateral resurfacing arthroplasty was carried out.
	Patients were discharged under physiotherapy supervision. Active assisted pronation/supination in flexion was done on days 2 to 14. An elbow splint was worn at night until 6 weeks after surgery when progressively increasing normal activity was permitted.
Follow-up	9 to 18 months
Conflict of interest/ source of funding	Not reported

Analysis

Follow-up issues: Efficacy outcome data were only reported for the first 10 patients with at least 9 months' follow-up.

Study design issues: Prospective, single-centre case series. Patients were independently assessed by physiotherapists preoperatively and postoperatively using the MEPS and the ASES-e scoring systems.

Study population issues: There is some patient overlap with Watkins C et al., 2018. Of the 10 patients, 8 had osteoarthritis and 2 had rheumatoid arthritis.

Key efficacy findings

• Number of patients analysed: 10

MEPI

According to the MEPI, the outcomes were categorised as excellent in 6 patients, good in 3 patients, and fair in 1 patient.

Patient	Diagnosis	Implant	Flexion/Extension	Flexion/Extension	MEPS	MEPS
no.			Preop	Postop	Preop	Postop
1	Rheumatoid arthritis	Hemi	45–110	33–140	60	100
2	Osteoarthritis	Hemi	40–130	25–135	40	95
3	Osteoarthritis	Total	80–120	30–140	65	100
4	Osteoarthritis	Total	25–130	10–140	40	90
5	Osteoarthritis	Hemi	25–95	25–130	35	100
6	Osteoarthritis	Total	20–135	5–145	55	100
7	Osteoarthritis	Hemi	50–110	40–130	50	80
8	Osteoarthritis	Total	25–120	15–140	50	85
9	Osteoarthritis	Hemi	35–120	25–135	55	85
10	Rheumatoid arthritis	Total	35–120	30–135	30	65

Summary of results in first 10 patients followed up for a minimum of 9 months

All patients who were followed up for more than 3 months were satisfied with their pain relief and had regained a functional range of movement comparable to patients who had a conventional total elbow joint replacement. Four patients returned to relatively heavy work within 3 months of surgery.

Key safety findings

Complications

- Deep infection making it necessary for the components to be removed, n=1
- Repair of a triceps muscle dehiscence resulting from a fall in the early postoperative period, n=1

Validity and generalisability of the studies

- All the studies identified were small case series. No randomised controlled studies were identified and no evidence comparing lateral elbow resurfacing with conventional treatment was identified.
- Most patients had osteoarthritis and there is little evidence on patients with rheumatoid arthritis.
- There are some data from the UK.
- There are some longer term outcomes.
- There is more than 1 device used in the studies.

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.

NICE guidelines

- Rheumatoid arthritis in adults: management. NICE guideline 100 (2018).
 Available from http://www.nice.org.uk/guiance/NG100
- Osteoarthritis: care and management. NICE Clinical guideline 177 (2014). Available from <u>http://www.nice.org.uk/guidance/CG177</u>

Additional information considered by IPAC

Professional experts' opinions

Expert advice was sought from consultants who have been nominated or ratified by their professional Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The

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advice provided by professional experts, 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. No Professional expert questionnaires for lateral elbow resurfacing for arthritis were submitted.

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 who manufactures 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

None other than those described above.

References

- Watkins CEL, Elson DW, Harrison JWK et al. (2018) Long-term results of the lateral resurfacing elbow arthroplasty. The Bone & Joint Journal 100b: 338–45
- 2. Giannicola G, Calella P, Bigazzi P et al. (2019) Midterm results of radiocapitellar arthroplasty of the elbow: a multicentre prospective study on two different implants. The Bone & Joint Journal 101b: 1362–69
- 3. Kachooei AR, Heesakkers NAM, Heijink A et al. (2018) Radiocapitellar prosthetic arthroplasty: short-term to midterm results of 19 elbows. Journal of Shoulder and Elbow Surgery 27: 726–32
- 4. Giannicola G, Angeloni R, Mantovani A et al. (2012) Open debridement and radiocapitellar replacement in primary and post-traumatic arthritis of the elbow: a multicenter study. Journal of Shoulder and Elbow Surgery 21: 456–63
- 5. Spross C, Jak W, van Riet RP (2019) Radiocapitellar arthroplasty: a consecutive case series with 2 to 6 years' follow-up. Journal of Shoulder and Elbow Surgery 28: 131–36
- Pooley J (2007) Unicompartmental elbow replacement: development of a lateral replacement elbow (LRE) arthroplasty. Techniques in Shoulder and Elbow Surgery 8: 204–12

Literature search strategy

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane)	02/11/2020	Issue 11 of 12, November 2020
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane)	02/11/2020	Issue 11 of 12, November 2020
International HTA database (INAHTA)	02/11/2020	n/a
MEDLINE (Ovid)	02/11/2020	1946 to October 30, 2020
MEDLINE In-Process (Ovid)	02/11/2020	1946 to October 30, 2020
MEDLINE Epubs ahead of print (Ovid)	02/11/2020	October 30, 2020

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)
- 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.

Literature search strategy

1	Elbow/ or Elbow Joint/
2	Arthritis, Rheumatoid/ or Arthritis/
3	Osteoarthritis/ or Osteocronosis/
4	2 or 3
5	1 and 4

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6	((elbow* or radiocapitellar or capitellum or 'radial head') adj4 (arthrit* or arthros* or OA or osteoarthr* or osteonecros* or cartilag* or degenerat* or diseas* or deteriorat* or injur* or defect*)).tw.
7	5 or 6
8	Arthroplasty, Replacement, Elbow/
9	elbow prosthesis/
10	((radiocapitellar or capitell* or 'radial head' or unicompartmental) adj4 (resurfac* or prosthes* or implant* or arthroplast* or replac* or repair* or artificial or implant* or reconstruct*)).tw.
11	(lateral adj4 resurfac*).tw.
12	LRE.tw.
13	or/8-12
14	7 and 13
15	animals/ not humans/
16	14 not 15

Appendix

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the <u>summary of the key evidence</u>. It is by no means an exhaustive list of potentially relevant studies.

Additional papers identified

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in summary of key evidence
Aroca-Peinado M, Cecilia- Lopez D, Jimenez-Diaz V (2017) Resurfacing arthroplasty as an alternative to the posttraumatic sequelae of fractures of the external column of the humerus in the young adult. Revista espanola de cirugia ortopedica y traumatologia 62: 80-85	Case report n=1	After the procedure, the patient had evident improvement of pain and of elbow range of motion, keeping the possibility of performing other rescue techniques open if they were to be necessary in the future.	Case report
Bigazzi P, Biondi M, Ceruso M (2016) Radiocapitellar prosthetic arthroplasty in traumatic and post-traumatic complex lesions of the elbow. European Journal of Orthopaedic Surgery & Traumatology: Orthopedie Traumatologie 26: 851- 858	Case series n=7 FU=mean 40 months	All patients presented with a marked improvement in elbow function, no signs of overstuffing or ulnohumeral degeneration were observed. Two patients developed a clinically asymptomatic aseptic loosening of the radial press-fit stem.	Small case series and patient overlap with Giannicola G, 2019.
Heijink A, Morrey BF Eygendaal D (2014) Radiocapitellar prosthetic arthroplasty: a report of 6 cases and review of the literature. Journal of Shoulder and Elbow Surgery 23: 843–9	Case series n=6 FU=mean 50 months	Implant survival rate=100%. Pain improved in all patients and all patients were satisfied. The mean flexion-extension arc increased from 98° (range 75 to 115°) to 110° (range 105° to120°) (p=0.17) and the mean	The same patients are included in a later publication (Kachooei A, 2018).

		pronation-supination arc increased from 133° (range 75° to 115°) to 143° (range 120° to 170°) (p=0.34). The mean Disabilities of the Arm, Shoulder and Hand score was 24.3 (range 6.7 to 52.5). According to the MEPS, there were 3 excellent and 3 good results.	
Schmidt I (2017) A complicated course of a coronal shear fracture type IV of the distal part of humerus resulting in resurfacing radiocapitellar joint replacement. The Open Orthopaedics Journal 11: 248-254	Case report n=1 FU=2 years	At the 2-year follow-up after that procedure, there was an excellent subjective and functional outcome. Radiographically, no loosening or subsidence of implant without any signs of overstuffing could be found. The patient reported that she would have the same procedure again.	Case report