NICE guidance

Total distal radioulnar joint replacement for symptomatic joint instability or arthritis

Interventional procedures guidance
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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful

discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Recommendations

1.1 Current evidence on the safety and efficacy of total distal radioulnar joint replacement for symptomatic joint instability or arthritis is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to do total distal radioulnar joint replacement for symptomatic joint instability or arthritis should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having total distal radioulnar joint replacement for symptomatic joint instability or arthritis (see section 7.1).

1.3 Patient selection and the procedure should only be done by clinicians with special expertise in hand and wrist surgery.

1.4 Further research should provide information on patient selection, and continue to collect long-term outcomes. NICE may update the guidance on publication of further evidence.

2 Indications and current treatments

2.1 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.

2.2 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.

3 The procedure

3.1 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 stability of the joint and improve pain-free movement.

3.2 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 is 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.

4 Efficacy

This section describes efficacy outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

4.1 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 months to 99 months; p<0.001). 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 and 1 month, range 1 year to 7 years; p=0.02). 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 months to 79 months; p=0.001).

4.2 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 (p=0.008). 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 (p=0.002). 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 (p=0.07). 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).

4.3 In the case series of 41 patients, mean pronation increased from 69° to 77° (p=0.48), supination from 62° to 73° (p=0.021), extension from 55° to 56° (p=0.28) and flexion from 53° to 56° (p=0.065) at follow-up. In the case series of 19 patients, mean pronation increased from 79° to 88° (p=0.01), supination from 70° to 72° (p=0.7), extension from 48° to 59° (p=0.01) and flexion from 39° to 46° (p=0.29) at follow-up. 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). 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.

4.4 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) at follow-up. 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) at follow-up. 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).

4.5 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 months to 75 months).

4.6 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. 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 10.0. 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. 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.

4.7 The specialist advisers listed the following key efficacy outcomes: pain reduction, reduction in feeling of instability, improved function, grip and lifting strength, restoration of forearm range of motion, and return to work and pre-existing activity.

4.8 Four commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

5 Safety

This section describes safety outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

5.1 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. Additional surgery was needed by 1 patient who developed pain along the ECU tendon in a

case series of 17 patients.

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

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

5.4 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.

5.5 Screw or cap loosening was reported in 1 patient in the case series of 35 patients. 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. Aseptic ulnar component loosening, which needed revision surgery, was reported in 1 patient in a case series of 10 patients.

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

5.7 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 distal radioulnar joint replacement. 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. Radial plate malposition, implant failure, and lunate-implant impingement were each reported in 1 patient in the case series of 41 patients.

5.8 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers described the following anecdotal adverse event: the ulna stem breaking after

high energy trauma. They considered that the following was a theoretical adverse event: the polyethylene ball component wearing out over time.

5.9 Four commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

6 Committee comments

6.1 There is more than 1 device available for this procedure but most of the evidence is from just 1 device.

6.2 The procedure is often done in relatively young patients and there is a need for long-term follow-up data.

6.3 Revision surgery, if needed, can be technically challenging.

7 Further information

7.1 This guidance requires that clinicians doing the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion).

Information for patients

NICE has produced information on this procedure for patients and carers (information for the public). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.