

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of total wrist replacement

Arthritis causes swelling and damage to the cartilage and bone around the joints, including the wrist. If drugs are unable to relieve the pain and improve the range of movement of the affected joints, surgery may be needed. Total wrist replacement aims to create an artificial wrist joint consisting of metal implants attached to the end of the arm and to the hand, separated by a spacer to allow movement of the hand.

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in February 2008

Procedure name

- Total wrist replacement

Specialty societies

- Rheumatoid Arthritis Surgical Society (RASS)
- British Society for Surgery of the Hand
- British Orthopaedic Association
- British Society for Rheumatology

Description

Indications

Wrist joint arthritis of any aetiology (i.e. including rheumatoid, osteo-, post-traumatic and septic arthritis).

Wrist arthritis is associated with pain, stiffness and swelling as a result of inflammation within the joint between the carpus and radius where bone comes into contact with bone.

For patients with rheumatoid arthritis, the degree of joint degeneration may be measured with the Larsen's radiographic classification (grading severity from I [least severe] to V [most severe]).

Other instruments that can be used to measure function in wrist arthritis include:

- Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire, a 30-item, self-report questionnaire measuring physical function and symptoms. Low scores are better.
- Patient-rated Wrist Evaluation (PRWE), a 15-item questionnaire designed to measure wrist pain and disability. Low scores are better.

Current treatment and alternatives

Conservative management with medical therapy, particularly in mild arthritis, may include use of analgesics, non-steroidal anti-inflammatory drugs, and disease-modifying antirheumatic drugs or steroid medication (for patients with rheumatoid arthritis).

Surgical treatment options include proximal row carpectomy (if the degenerative change is limited to the radio-carpal joint and the capitate articular surface of the mid carpal joint is well preserved), limited / partial carpal fusion, or total wrist arthrodesis.

What the procedure involves

Normal wrist motion involves a complex interaction of a number of articulations which involve the radius, ulna and the carpal bones. Total wrist replacement aims to create a stable, pain-free joint with a functional range of movement¹.

Implant size is estimated preoperatively using x-ray templates. Prophylactic antibiotics are usually administered before the procedure. Under either general or regional anaesthesia, a mid-wrist longitudinal incision is made on the dorsal aspect, the skin and subcutaneous tissue are elevated, and the joint is exposed. A guide hole is made through the articular surface of the

radius and the carpus is prepared by drilling. The carpal plate of the prosthesis is inserted and fixed with bone screws (with use of bone cement if required). The radial component of the implant (often designed with a porous coating to aid osseointegration) is driven into the guide hole, followed by clipping of a polythene component onto the back of the carpal plate, and the prosthesis is reduced. An assessment by the surgeon of wrist motion, balance and stability is made before the incision is closed. Fluoroscopy is sometimes used to confirm positions of the implants.

Efficacy

A non-randomised controlled trial reported that there was no statistically significant difference between patients receiving a wrist implant (27 wrists) and patients treated by arthrodesis (24 wrists) in terms of wrist function as recorded by DASH or PRWE scores². Loss of wrist motion leading to limitation in daily activity occurred in 21% of the wrists in the implant group and 45% of the arthrodesis group; however, this difference was not statistically significant.

A case series of 19 patients (22 wrists) reported significant improvement in mean DASH score from 46.0 points at baseline to 32.1 points at 12-month follow-up ($p < 0.05$)³.

A case series of 30 patients (32 wrists) receiving artificial wrist implants reported that range of movement improved significantly from baseline to 20-month follow-up in all aspects apart from radial deviation⁴. Another case series of 27 patients (29 wrists), mostly with rheumatoid arthritis, reported an improvement in wrist extension from 7° to 24°, in flexion from 26° to 35°, and in radial deviation from 2° to 10° from baseline to 4-year follow-up ($p < 0.001$ for each). However, improvements in ulnar deviation, pronation and supination were not statistically significant⁵. A case series of 25 patients (28 wrists) reported that mean grip strength improved from 20 kgf (kilograms force) at baseline to 32 kgf at 47-month follow-up (measure of significance not stated)⁶.

A case series of 27 patients (29 wrists) reported a significant reduction in pain frequency and severity following wrist implant surgery at 4-year follow-up ($p < 0.002$, absolute figures not reported)⁵. Another case series including 25 patients receiving a wrist implant reported that pain relief was good in all patients following the procedure; however, 20% (5/25) of patients reported mild discomfort on the ulnar side¹ (follow-up period not stated). A case series of 25 patients (28 wrists) reported that 72% (18/25) of patients had no joint pain, 20% (5/25) had moderate pain and 8% (2/25) had severe pain at 47 months after the artificial wrist implant procedure⁶.

A case series of 27 patients reported that 89% (24/27) of patients stated that the insertion of a wrist implant had markedly improved their daily lives and upper extremity function⁵.

Safety

A non-randomised controlled trial reported that persistent paraesthesia occurred in 4% of patients receiving a wrist implant and 0% of patients being treated by arthrodesis (location of paraesthesia and length of follow-up not stated). Superficial wound complications occurred in 22% (6/27) and 13% (3/24) of patients, respectively. Joint instability following the wrist implant procedure occurred in 15% (4/27) of patients and was treated by casting, revision surgery or fusion².

In four case series, dislocation of the wrist implant occurred in 0%^{1,6}, 13% (4/32)⁴ and 14% (3/220)³ of wrists. Loosening of the joint (usually based on radiographic assessment) was reported at a rate of 0%¹, 0%⁶, and 16%⁴ across three of these series, and at 10%⁵ in an additional case series (29 wrists). In the non-randomised controlled trial, joint instability following the wrist implant procedure occurred in 15% (4/27) of patients and was treated by casting, revision surgery or fusion².

A case report described a patient who had a good range of movement in the wrist and was pain-free at 2-year follow-up after implantation of a wrist prosthesis. However, by 3 years, worsening pain had developed and radiographic assessment identified a pisiform impingement from the base of the carpal unit of the prosthesis on the ulnar aspect⁷, requiring revision surgery.

In the non-randomised controlled trial, hardware-related failure occurred in 0% of the artificial wrist group and 4% (1/24) in the arthrodesis group². In three case series, implant complications or errors in implantation occurred in 12% (3/25)¹, 19% (5/27)⁵ and 32% (8/25)⁶ of patients. Another case study reported complications or errors in 27% (6/22)³ of wrists.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to total wrist replacement. Searches were conducted via the following databases, covering the period from their commencement to 23/01/2008: 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.)

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where these 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, laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Patients with arthritic wrists.
Intervention/test	Total wrist 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 overview

This overview is based on one non-randomised controlled trial², five case series^{1,4,5,6,3}, and one case report⁷.

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.

Existing reviews on this procedure

There were no published reviews identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B details the recommendations made in each piece of guidance listed below.

Interventional procedures

- ‘Artificial metacarpophalangeal and interphalangeal joint replacement for end-stage arthritis’. NICE interventional procedures guidance 110 (2005). Available from www.nice.org.uk/IPG110
- ‘Artificial trapeziometacarpal joint replacement for end-stage osteoarthritis’. NICE interventional procedures guidance 111 (2005). Available from www.nice.org.uk/IPG111

Technology appraisals

- None

Clinical guidelines

- 'Osteoarthritis: the care and management of adults with osteoarthritis'.
NICE clinical guideline 59 (2008). Available from www.nice.org.uk/CG059

Public health

- None

Table 2 Summary of key efficacy and safety findings on total wrist replacement

Abbreviations used: DASH – Disabilities of the Arm Shoulder and Hand questionnaire, PRWE – Patient-rated Wrist Evaluation, ROM – Range of movement																																													
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<p>Murphy D M (2003)²</p> <p>Non-randomised controlled trial</p> <p>USA</p> <p>n = 51 wrists (27 arthroplasties)</p> <p>Study Period: 1997 to 2001</p> <p>Population: Mean age = 51 years, male = 29%</p> <p>Indications: Rheumatoid arthritis (not further defined)</p> <p>Technique: Total wrist arthroplasty with the Universal Total Wrist implant versus arthrodesis with a variety of techniques (most commonly a dorsal plate).</p> <p>Mean follow-up: 26 months for arthroplasty, 48 months for fusion.</p> <p>Disclosure of interest: One or more authors received benefits from manufacturer</p>	<p>Joint function</p> <p>There were no significant differences between the groups in either the overall DASH or PRWE scores, nor in any individual components of these scales.</p> <p>There was a positive correlation between age at baseline and the DASH (r=0.48) and PRWE (r=0.38) at follow-up with older patients having worse functional scores.</p> <p>Patients who had their dominant hand operated on had worse PRWE scores (p<0.04); it is not clear if this relates to either study group or both.</p> <p>Loss of wrist movement leading to limitation in daily activities occurred in 21% of the arthroplasty group and 45% of the arthrodesis group (absolute numbers not stated); however, this difference was not statistically significant (p<0.12).</p>	<p>Complications</p> <table border="0"> <tr> <td>Outcome</td> <td>Arthroplasty</td> <td>Arthrodesis</td> </tr> <tr> <td>Major complication</td> <td>11% (3/27)</td> <td>22% (5/24)</td> </tr> <tr> <td>Minor complication</td> <td>41% (11/27)</td> <td>35% (8/24)</td> </tr> </table> <p>No significant differences between groups (rates per wrist treated). No definition given for major or minor complication.</p> <table border="0"> <tr> <td>Outcome</td> <td>Arthroplasty</td> <td>Arthrodesis</td> </tr> <tr> <td>Persistent nerve paraesthesia</td> <td>4% (1/27)</td> <td>0%</td> </tr> <tr> <td>Superficial wound complication</td> <td>22% (6/27)</td> <td>13% (3/24)</td> </tr> <tr> <td>Complex regional pain syndrome</td> <td>0%</td> <td>4% (1/24)</td> </tr> <tr> <td>Haematoma</td> <td>0%</td> <td>4% (1/24)</td> </tr> <tr> <td>Tenolysis required</td> <td>0%</td> <td>8% (2/24)</td> </tr> <tr> <td>Tendon rupture</td> <td>0%</td> <td>4% (1/24)</td> </tr> <tr> <td>Carpal tunnel syndrome with surgical release</td> <td>0%</td> <td>17% (4/24)</td> </tr> <tr> <td>Adhesions over the plate</td> <td>0%</td> <td>25% (6/24)</td> </tr> <tr> <td>Hardware related fracture</td> <td>0%</td> <td>4% (1/24)</td> </tr> <tr> <td>Prosthetic instability</td> <td>15% (4/27)</td> <td>0%</td> </tr> </table> <p>Of 4 patients with instability, 2 responded to casting, 1 was treated by capsular reconstruction and 1 converted to fusion.</p>	Outcome	Arthroplasty	Arthrodesis	Major complication	11% (3/27)	22% (5/24)	Minor complication	41% (11/27)	35% (8/24)	Outcome	Arthroplasty	Arthrodesis	Persistent nerve paraesthesia	4% (1/27)	0%	Superficial wound complication	22% (6/27)	13% (3/24)	Complex regional pain syndrome	0%	4% (1/24)	Haematoma	0%	4% (1/24)	Tenolysis required	0%	8% (2/24)	Tendon rupture	0%	4% (1/24)	Carpal tunnel syndrome with surgical release	0%	17% (4/24)	Adhesions over the plate	0%	25% (6/24)	Hardware related fracture	0%	4% (1/24)	Prosthetic instability	15% (4/27)	0%	<p>All arthroplasties undertaken by the same clinician.</p> <p>Two matched cohorts from other institutions with patients treated over the same period were used as a control; 90% of eligible patients agreed to participate as controls. There were no significant differences between the groups in demographic or clinical characteristics.</p> <p>Patients in the arthrodesis group had a significantly longer mean follow-up period than those receiving prostheses (48 vs. 26 months, p<0.002), making comparison difficult.</p> <p>Validated patient outcome surveys were used..</p> <p>A rheumatologist categorised a medication score from 1 to 6 (least to most) based on frequency and of use of a range of immunosuppressants.</p>
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<p>Rahimtoola Z O (2004)⁴</p> <p>Case series</p> <p>Holland</p> <p>n = 30 (32 wrists)</p> <p>Study Period: Jul 1999 – Aug 2002</p> <p>Population: Mean age = 60 years, male = 13%</p> <p>Indications: Rheumatoid arthritis n = 29, osteoarthritis n = 1. Previous wrist implants n = 5. Larson's radiographic classification grade V = 17, grade IV = 9, grade III = 1, grade I = 1.</p> <p>Technique: Total wrist arthroplasty with the Micromed implant; 10 implants were of constrained design and 22 unconstrained versions. The wrist was immobilised with a splint for 5 days and used at night only for a further 6 weeks.</p> <p>Mean follow-up: 20 months</p> <p>Disclosure of interest: Not stated</p>	<p>Joint pain</p> <p>At rest</p> <table border="1"> <thead> <tr> <th></th> <th>Baseline</th> <th>Follow up</th> </tr> </thead> <tbody> <tr> <td>None</td> <td>13% (4/32)</td> <td>81% (26/32)</td> </tr> <tr> <td>Mild</td> <td>44% (14/32)</td> <td>19% (6/32)</td> </tr> <tr> <td>Moderate</td> <td>31% (10/32)</td> <td>0%</td> </tr> <tr> <td>Severe</td> <td>13% (4/32)</td> <td>0%</td> </tr> </tbody> </table> <p>Significance level not presented.</p> <p>On movement</p> <table border="1"> <thead> <tr> <th></th> <th>Baseline</th> <th>Follow up</th> </tr> </thead> <tbody> <tr> <td>None</td> <td>0%</td> <td>69% (22/32)</td> </tr> <tr> <td>Mild</td> <td>13% (4/32)</td> <td>25% (8/32)</td> </tr> <tr> <td>Moderate</td> <td>31% (10/32)</td> <td>6% (2/32)</td> </tr> <tr> <td>Severe</td> <td>56% (18/32)</td> <td>0%</td> </tr> </tbody> </table> <p>Significance level not presented.</p> <p>Joint function</p> <table border="1"> <thead> <tr> <th></th> <th>Baseline</th> <th>Follow- up</th> <th>P</th> </tr> </thead> <tbody> <tr> <td>Extension</td> <td>23° (-10 to 60)</td> <td>31° (-30 to 60)</td> <td>0.02</td> </tr> <tr> <td>Flexion</td> <td>23° (0 to 60)</td> <td>32° (0 to 50)</td> <td>0.02</td> </tr> <tr> <td>Pronation</td> <td>73° (70 to 90)</td> <td>88° (75 to 90)</td> <td>0.01</td> </tr> <tr> <td>Supination</td> <td>66° (10 to 90)</td> <td>82° (10 to 90)</td> <td>0.01</td> </tr> <tr> <td>Ulna deviation</td> <td>11° (0 to 25)</td> <td>16° (0 to 40)</td> <td>0.01</td> </tr> <tr> <td>Radial deviation</td> <td>6° (-15 to 20)</td> <td>8° (0 to 20)</td> <td>0.31</td> </tr> </tbody> </table> <p>Grip strength increased in 27 wrists and remained the same in 5 wrists.</p>			Baseline	Follow up	None	13% (4/32)	81% (26/32)	Mild	44% (14/32)	19% (6/32)	Moderate	31% (10/32)	0%	Severe	13% (4/32)	0%		Baseline	Follow up	None	0%	69% (22/32)	Mild	13% (4/32)	25% (8/32)	Moderate	31% (10/32)	6% (2/32)	Severe	56% (18/32)	0%		Baseline	Follow- up	P	Extension	23° (-10 to 60)	31° (-30 to 60)	0.02	Flexion	23° (0 to 60)	32° (0 to 50)	0.02	Pronation	73° (70 to 90)	88° (75 to 90)	0.01	Supination	66° (10 to 90)	82° (10 to 90)	0.01	Ulna deviation	11° (0 to 25)	16° (0 to 40)	0.01	Radial deviation	6° (-15 to 20)	8° (0 to 20)	0.31	<p>Complications</p> <table border="1"> <thead> <tr> <th>Complication</th> <th>Rate</th> </tr> </thead> <tbody> <tr> <td>Soft tissue infection requiring IV antibiotics</td> <td>3% (1/32)</td> </tr> <tr> <td>Traumatic luxation of the joint requiring repeat procedure</td> <td>3% (1/32)</td> </tr> <tr> <td>Progressive subluxation of the wrist requiring or awaiting reintervention</td> <td>16% (5/32)</td> </tr> </tbody> </table> <p>Follow-up period at which events occurred was not stated.</p> <p>No general systemic complications occurred postoperatively.</p> <p>5 of the 32 wrists showed signs of loosening on radiographic assessment as indicated by more than 2 mm of radiolucency, or progressive subsidence. None of these wrists were revised.</p>	Complication	Rate	Soft tissue infection requiring IV antibiotics	3% (1/32)	Traumatic luxation of the joint requiring repeat procedure	3% (1/32)	Progressive subluxation of the wrist requiring or awaiting reintervention	16% (5/32)	<p>Range of movement and grip strength outcomes were recorded using an objective measurement device.</p> <p>Not clear that all outcomes are measures at the 'final' follow-up point.</p> <p>No details provided of independent outcome assessment.</p> <p>No details given of any potential patient selection.</p> <p>It is possible that these patients were the first to be treated with a new implant type at this institution.</p>
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<p>Rahimtoola Z O (2003)⁵</p> <p>Case series</p> <p>Holland</p> <p>n = 27 (29 wrists)</p> <p>Study Period: Mar 1992 – Nov 1999</p> <p>Population: Mean age = 59 years, male = 41%</p> <p>Indications: Rheumatoid arthritis n = 24, osteoarthritis n = 2, psoriatic arthritis n = 1. Dominant side operated on in 16 patients. Larson's radiographic classification grade V = 21, grade IV = 6</p> <p>Technique: Total wrist arthroplasty with the RWS implant. The wrist was immobilised with a splint for 5 days.</p> <p>Mean follow-up: 4 years</p> <p>Disclosure of interest: Not stated</p>	<p>Joint pain</p> <p>There was a significant reduction in pain frequency and severity following the implant surgery ($p \leq 0.002$).</p> <p>Joint function</p> <p>Ability to perform daily activities (measure of significance not reported for any of these outcomes).</p> <table border="1"> <thead> <tr> <th>Perineal care</th> <th>Baseline</th> <th>Follow up</th> </tr> </thead> <tbody> <tr> <td>No difficulty</td> <td>33% (9/27)</td> <td>48% (13/27)</td> </tr> <tr> <td>Occasional</td> <td>4% (1/27)</td> <td>26% (7/27)</td> </tr> <tr> <td>Mod. / severe</td> <td>59% (16/27)</td> <td>22% (6/27)</td> </tr> <tr> <td>Impossible</td> <td>4% (1/27)</td> <td>4% (1/27)</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th>Dental care</th> <th>Baseline</th> <th>Follow up</th> </tr> </thead> <tbody> <tr> <td>No difficulty</td> <td>26% (7/27)</td> <td>52% (14/27)</td> </tr> <tr> <td>Occasional</td> <td>15% (4/27)</td> <td>15% (4/27)</td> </tr> <tr> <td>Mod. / severe</td> <td>52% (14/27)</td> <td>26% (7/27)</td> </tr> <tr> <td>Impossible</td> <td>7% (2/27)</td> <td>7% (2/27)</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th>Drinking from a glass</th> <th>Baseline</th> <th>Follow up</th> </tr> </thead> <tbody> <tr> <td>No difficulty</td> <td>22% (6/27)</td> <td>59% (16/27)</td> </tr> <tr> <td>Occasional</td> <td>15% (4/27)</td> <td>15% (4/27)</td> </tr> <tr> <td>Mod. / severe</td> <td>52% (14/27)</td> <td>26% (7/27)</td> </tr> <tr> <td>Impossible</td> <td>11% (3/27)</td> <td>0%</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th>Opening a jar</th> <th>Baseline</th> <th>Follow up</th> </tr> </thead> <tbody> <tr> <td>No difficulty</td> <td>4% (1/27)</td> <td>26% (7/27)</td> </tr> <tr> <td>Occasional</td> <td>11% (3/27)</td> <td>19% (5/27)</td> </tr> <tr> <td>Mod. / severe</td> <td>81% (22/27)</td> <td>52% (14/27)</td> </tr> <tr> <td>Impossible</td> <td>4% (1/27)</td> <td>4% (1/27)</td> </tr> </tbody> </table>		Perineal care	Baseline	Follow up	No difficulty	33% (9/27)	48% (13/27)	Occasional	4% (1/27)	26% (7/27)	Mod. / severe	59% (16/27)	22% (6/27)	Impossible	4% (1/27)	4% (1/27)	Dental care	Baseline	Follow up	No difficulty	26% (7/27)	52% (14/27)	Occasional	15% (4/27)	15% (4/27)	Mod. / severe	52% (14/27)	26% (7/27)	Impossible	7% (2/27)	7% (2/27)	Drinking from a glass	Baseline	Follow up	No difficulty	22% (6/27)	59% (16/27)	Occasional	15% (4/27)	15% (4/27)	Mod. / severe	52% (14/27)	26% (7/27)	Impossible	11% (3/27)	0%	Opening a jar	Baseline	Follow up	No difficulty	4% (1/27)	26% (7/27)	Occasional	11% (3/27)	19% (5/27)	Mod. / severe	81% (22/27)	52% (14/27)	Impossible	4% (1/27)	4% (1/27)	<p>Complications</p> <p>Loosening was observed in 10% (3/29) of prostheses with radiolucency of more than 2mm seen. One wrist was fused, one patient died, and one was not revised at 4 years follow up.</p> <table border="1"> <thead> <tr> <th>Radiographic findings</th> <th>Rate</th> </tr> </thead> <tbody> <tr> <td>Misaligned prong of carpal element of implant</td> <td>11% (3/27)</td> </tr> <tr> <td>Fracture of distal tip of the carpal element at 1-year follow-up</td> <td>4% (1/27)</td> </tr> <tr> <td>Stem of radial element not lying on radial axis</td> <td>4% (1/27)</td> </tr> </tbody> </table> <p>None of these caused clinical problems at final follow-up.</p> <p>There were no systemic complications relating to surgery or anaesthesia.</p> <table border="1"> <thead> <tr> <th>Complication</th> <th>Rate</th> </tr> </thead> <tbody> <tr> <td>Carpal tunnel syndrome (decompressed uneventfully)</td> <td>11% (3/27)</td> </tr> <tr> <td>Reflex sympathetic dystrophy</td> <td>4% (1/27)</td> </tr> </tbody> </table>	Radiographic findings	Rate	Misaligned prong of carpal element of implant	11% (3/27)	Fracture of distal tip of the carpal element at 1-year follow-up	4% (1/27)	Stem of radial element not lying on radial axis	4% (1/27)	Complication	Rate	Carpal tunnel syndrome (decompressed uneventfully)	11% (3/27)	Reflex sympathetic dystrophy	4% (1/27)	<p>Potential overlap / duplication of patients with the Rahimtoola (2004) paper, although a different type of implant is described here.</p> <p>Loss to follow-up was 7% (2/29) of wrists. One patient died and one refused to participate in follow-up. However, some clinical and complication details are described for these two patients</p> <p>Range of movement and grip strength outcomes were recorded using an objective measurement device.</p> <p>No patient data is provided for pain outcomes, either at baseline or at follow-up. In addition, the categories used for frequency of pain and severity of pain are not clearly defined and the significance of this outcome is hard to substantiate.</p> <p>Not clear why Larson's radiographic classification is provided for non-rheumatoid arthritis.</p>
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<p>Levadoux M (2003)^o</p> <p>Case series</p> <p>France and Belgium</p> <p>n = 25 (28 wrists)</p> <p>Study Period: Mar 2002 – Nov 2000</p> <p>Population: Mean age = 63 years, male = 80%</p> <p>Indications: Post-traumatic arthritis; 1 patient undergoing revision surgery. Mean ROM 20° extension, 26° flexion, 7° radial deviation, 25° ulnar deviation, 60° pronation, 45° supination.</p> <p>Technique: Total wrist arthroplasty with the Destot implant. The wrist was supported with a plastic splint for 3 days.</p> <p>Mean follow-up: 47 months</p> <p>Disclosure of interest: Not stated</p>	<p>Joint function</p> <table border="1"> <thead> <tr> <th>ROM (means)</th> <th>Baseline</th> <th>Follow up</th> </tr> </thead> <tbody> <tr> <td>Extension</td> <td>20° (5 to 40)</td> <td>41° (30 to 50)</td> </tr> <tr> <td>Flexion</td> <td>26° (5 to 42)</td> <td>48° (10 to 70)</td> </tr> <tr> <td>Radial deviation</td> <td>7° (0 to 10)</td> <td>12° (5 to 20)</td> </tr> <tr> <td>Ulnar deviation</td> <td>25° (20 to 31)</td> <td>22° (10 to 30)</td> </tr> <tr> <td>Pronation</td> <td>60° (30 to 90)</td> <td>90°</td> </tr> <tr> <td>Supination</td> <td>45° (20 to 70)</td> <td>77° (50 to 90)</td> </tr> </tbody> </table> <p>Measurement of significance not stated.</p> <p>Mean grip strength improved from 20 kgf (range 5–35) at baseline to 32 kgf (range 10–70) at 47-month follow-up.</p> <p>Following the procedure the Meuli wrist score was rated as excellent (11–12 points) in 68% (17/25) of patients, good (9–10 points) in 24% (6/25), fair (7–8 points) in 4% (1/25), and poor (6 points or less) in 16% (4/25).</p> <p>4- year survival with functioning wrist was 85%.</p> <p>Joint pain</p> <p>Following the procedure 72% (18/25) patients rated joint pain as 'none', 20% (5/25) as 'moderate' and 8% (2/25) as 'severe'.</p>		ROM (means)	Baseline	Follow up	Extension	20° (5 to 40)	41° (30 to 50)	Flexion	26° (5 to 42)	48° (10 to 70)	Radial deviation	7° (0 to 10)	12° (5 to 20)	Ulnar deviation	25° (20 to 31)	22° (10 to 30)	Pronation	60° (30 to 90)	90°	Supination	45° (20 to 70)	77° (50 to 90)	<p>Complications</p> <table border="1"> <thead> <tr> <th>Radiographic findings</th> <th>Rate</th> </tr> </thead> <tbody> <tr> <td>Migration of the carpal element of implant</td> <td>24% (6/25)</td> </tr> <tr> <td>Metacarpal stem fracture</td> <td>8% (2/25)</td> </tr> <tr> <td>Loosening of the radial stem of the implant</td> <td>0%</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th>Postoperative</th> <th>Rate</th> </tr> </thead> <tbody> <tr> <td>Infection (1 immediately post-op, 1 at 6 months)</td> <td>24% (6/25)</td> </tr> <tr> <td>Fusion</td> <td>16% (4/25)</td> </tr> <tr> <td>Dislocation of prosthesis</td> <td>0%</td> </tr> <tr> <td>Surgical repair of metacarpal stem fracture</td> <td>4% (1/25)</td> </tr> </tbody> </table>	Radiographic findings	Rate	Migration of the carpal element of implant	24% (6/25)	Metacarpal stem fracture	8% (2/25)	Loosening of the radial stem of the implant	0%	Postoperative	Rate	Infection (1 immediately post-op, 1 at 6 months)	24% (6/25)	Fusion	16% (4/25)	Dislocation of prosthesis	0%	Surgical repair of metacarpal stem fracture	4% (1/25)	<p>Outcomes evaluated by an independent clinician.</p> <p>Wrist function was evaluated using the Meuli total wrist arthroplasty score which uses 6 factors (both subjective and objective) and provides a score from 0 (worst) to 12 (best).</p> <p>Many reported outcomes were not compared with baseline scores.</p> <p>Two patients who required fusion had previous proximal row carpectomy.</p> <p>Authors state that loosening may occur at a greater rate in post-traumatic arthritis than in rheumatoid arthritis due to a greater level of activity in these patients.</p>
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Divelbliss BJ (2002) ³ Case series USA and Sweden n = 19 (22 wrists) Study Period: 1997 to 1999 Population: Mean age = 48 years, male = 0% Indications: Rheumatoid arthritis n = 19. Technique: Under general or regional anaesthesia, total wrist arthroplasty with the Universal implant. The wrist was immobilised with a plaster splint for 2–4 weeks depending on the stability achieved during surgery. Mean follow-up: at 2 years for 8 wrists, and 1 year for 14 wrists. Disclosure of interest: Supported by grant from academic institution.	Joint function Mean scores (standard deviation or range not given). <table border="1"> <thead> <tr> <th></th> <th>Baseline (n=22)</th> <th>6 months (n not stated)</th> <th>12 months (n=14)</th> <th>24 months (n=8)</th> </tr> </thead> <tbody> <tr> <td>Extension</td> <td>17°</td> <td>28°*</td> <td>27°*</td> <td>35°*</td> </tr> <tr> <td>Flexion</td> <td>31°</td> <td>35°</td> <td>38°</td> <td>41°</td> </tr> <tr> <td>Radial deviation</td> <td>1°</td> <td>7°*</td> <td>6°*</td> <td>9°*</td> </tr> <tr> <td>Ulna deviation</td> <td>16°</td> <td>17°</td> <td>19°</td> <td>19°</td> </tr> <tr> <td>Pronation</td> <td>72°</td> <td>80°</td> <td>79°</td> <td>88°*</td> </tr> <tr> <td>Supination</td> <td>66°</td> <td>76°*</td> <td>74°*</td> <td>80°*</td> </tr> <tr> <td>DASH score</td> <td>46.0</td> <td>37.0*</td> <td>32.1*</td> <td>22.4</td> </tr> </tbody> </table> *p<0.05 vs baseline.					Baseline (n=22)	6 months (n not stated)	12 months (n=14)	24 months (n=8)	Extension	17°	28°*	27°*	35°*	Flexion	31°	35°	38°	41°	Radial deviation	1°	7°*	6°*	9°*	Ulna deviation	16°	17°	19°	19°	Pronation	72°	80°	79°	88°*	Supination	66°	76°*	74°*	80°*	DASH score	46.0	37.0*	32.1*	22.4	Complications <table border="1"> <thead> <tr> <th>Radiographic findings</th> <th>Rate</th> </tr> </thead> <tbody> <tr> <td>Misplaced or misaligned screws (no adverse clinical effects)</td> <td>18% (4/22)</td> </tr> <tr> <td>Void in cement mantle around radial component of prosthesis (no adverse clinical event)</td> <td>5% (1/22)</td> </tr> <tr> <td>Failure of intercarpal fusion (no evidence of screw loosening or component migration)</td> <td>5% (1/22)</td> </tr> <tr> <td>Subsidence of the radial component at 1 year</td> <td>5% (1/22)</td> </tr> <tr> <td>Haematoma</td> <td>5% (1/22)</td> </tr> <tr> <td>Prosthesis dislocation (requiring revision surgery)</td> <td>14% (3/22)</td> </tr> </tbody> </table> No intraoperative complications occurred.	Radiographic findings	Rate	Misplaced or misaligned screws (no adverse clinical effects)	18% (4/22)	Void in cement mantle around radial component of prosthesis (no adverse clinical event)	5% (1/22)	Failure of intercarpal fusion (no evidence of screw loosening or component migration)	5% (1/22)	Subsidence of the radial component at 1 year	5% (1/22)	Haematoma	5% (1/22)	Prosthesis dislocation (requiring revision surgery)	14% (3/22)	All procedures undertaken by 2 surgeons. Study sample is the initial number of consecutive patients treated. Authors state that sample size was probably too small to demonstrate a significant improvement in DASH scores. Dislocations occurred in the earliest patients treated. Authors describe discontinuity between different subjective wrist function scoring systems. Authors state that patient selection and precise handling of the bone and soft tissues are important.
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Subsidence of the radial component at 1 year	5% (1/22)																																																											
Haematoma	5% (1/22)																																																											
Prosthesis dislocation (requiring revision surgery)	14% (3/22)																																																											

Abbreviations used: DASH – Disabilities of the Arm Shoulder and Hand questionnaire, PRWE – Patient-rated Wrist Evaluation, ROM – Range of movement			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Johnson S T (2007)⁷</p> <p>Case report</p> <p>USA</p> <p>n = 1</p> <p>Study Period: Aug 2003</p> <p>Population: Age = 64 years, male = 0%</p> <p>Indications: Rheumatoid arthritis.</p> <p>Technique: Total wrist arthroplasty with the Universal 2 implant, in addition to transfer of half the flexor carpi ulnaris followed by allograft dermis wrapping for symptomatic distal ulna instability.</p> <p>Follow-up: at 3 years</p> <p>Disclosure of interest: None</p>	<p>Joint function</p> <p>At 2-year follow-up, ROM was 55° of extension, 15° of flexion, 15° of ulna deviation, 10° of radial deviation, 90° of pronation and 85° of supination.</p> <p>Grip strength reached 60% of the non-operated wrist.</p> <p>At 2-week follow-up after revision surgery the patient maintained preoperative range of movement</p> <p>Joint pain</p> <p>At 2-year follow-up there was no pain and the patient was very satisfied.</p> <p>At approximately 3-year follow-up the patient presented with worsening pain focused in the volar, ulnar aspect of the wrist.</p> <p>At 2-week follow-up after revision surgery the patient reported complete resolution of pain.</p> <p>Radiographic evaluation</p> <p>The implant appeared to be well positioned and aligned; however, there was some shape change to the pisiform on the volar edge of the carpal base plate.</p> <p>Fluoroscopic evaluation confirmed pisiform impingement on the edge of the carpal component of the implant.</p>	<p>Complications</p> <p>Revision surgery included excision of the pisiform via a curvilinear, longitudinal volar incision.</p> <p>No histological examination was performed despite presence of metallic debris from wear.</p>	<p>Single case with impingement described; no details provided of denominator number of procedures undertaken at the institution.</p> <p>Short follow-up after revision surgery of 2 weeks.</p> <p>Operator experience not described.</p>

Validity and generalisability of the studies

- Various outcome measures for wrist joint function were used across the studies making comparison between them difficult.
- Few objective outcomes reported, and most scoring systems rely on subjective patient self-reporting
- Only one comparative study comparing artificial wrists with arthrodesis was available.
- Few long-term data currently available on newer prosthesis designs.
- Study reports are generally of poor methodological quality, often with no absolute patient results stated, occasionally with outcomes following surgery not compared to those at baseline.

Specialist advisers' opinions

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

Mr N Gillham, Mr Greg Packer (British Orthopaedic Association)

Mr R Bhatia, Mr N Trial (British Society for Rheumatology)

- The Specialist Advisers thought that total wrist replacement was established, while one thought it as a novel procedure with uncertain safety and efficacy
- Advisers listed the key efficacy outcomes by which to consider the procedure as long-term pain relief, range of motion, functional movement and prosthesis survival.
- Key safety outcomes should include rates of infection, dislocation, loosening, stiffness and neurovascular complications.
- One Adviser stated that long-term studies are not currently available.

- Advisers stated that they are awaiting good implants, which, when available, will see a rapid increase in procedures.
- There is a particular concern about the fixation of the carpal component of the prosthesis.
- Patients with bilateral wrist arthritis often cope badly with two fused wrists.
- Most suitable patients are those with low demand and rheumatoid arthritis.
- Known or reported adverse events following the procedure include dislocation, stiffness, loosening, infection and neurovascular problems.
- Additional, theoretical adverse events may include tendon rupture, periprosthetic fracture, complex regional pain syndrome, poor fixation of the carpal component, and implant failure.
- Rheumatologists are involved in the care of patients, particularly in early-stage disease, and will refer patients for surgical management.
- The procedure should be undertaken by experienced surgeons able to perform fusion if conversion is necessary. They require experience in joint replacement.
- Cadaveric or dry bone training is provided by implant manufacturers.
- Wrist replacement is not included in the national joint register. Ongoing registry is being collected at the Wrightington Hospital.
- If found to be safe and efficacious, three Specialist Advisers thought that the procedure would be offered at a minority of UK hospitals, but at least 10. One Adviser thought that uptake would be limited to less than 10 specialist centres.

Issues for consideration by IPAC

- Studies reporting on prostheses that are currently used in the UK were prioritised in the overview table 2 (based on information received by clinical experts recommended by IPAC lead).
- Non-English-language studies were excluded, as English-language articles were available.
- Some implants are designed with an optional ulnar component.
- A number of implants are available with CE marking (at present) including the Biaxial total wrist replacement (DePuy), RWS Prosthesis (Howmedica), APH prosthesis (Implant-Service Vertriebs – GmbH), Meuli Prosthesis – ball and cup, Destot Prosthesis, Silicone wrist implant (Wright Medical), ‘Semiconstrained’ wrist (Branemark), and uHead endoprosthesis (Small bone Innovations).
- The Universal / Universal 2 total wrist (KMI – now Integra Life Sciences) prosthesis does not currently have a CE mark but has been widely used in the studies included in this overview.

References

- 1 Anderson MC, Adams BD (2005) Total wrist arthroplasty. *Hand Clinics* 21: 621–30.
- 2 Murphy DM, Khoury JG, Imbriglia JE et al. (2003) Comparison of arthroplasty and arthrodesis for the rheumatoid wrist. *The Journal of Hand Surgery* 28: 570–6.
- 3 Divelbiss BJ, Sollerman C, Adams BD (2002) Early results of the Universal total wrist arthroplasty in rheumatoid arthritis. *The Journal of Hand Surgery* 27: 195–204.
- 4 Rahimtoola ZO, Hubach P (2004) Total modular wrist prosthesis: a new design. *Scandinavian Journal of Plastic and Reconstructive Surgery and Hand Surgery* 38: 160–5.
- 5 Rahimtoola ZO, Rozing PM (2003) Preliminary results of total wrist arthroplasty using the RWS Prosthesis. *Journal of Hand Surgery (Edinburgh, Scotland)* 28: 54–60.
- 6 Levadoux M, Legre R (2003) Total wrist arthroplasty with Destot prostheses in patients with posttraumatic arthritis. *The Journal of Hand Surgery* 28: 405–13.
- 7 Johnson ST, Patel A, Calfee RP et al. (2007) Pisiform impingement after total wrist arthroplasty. *The Journal of Hand Surgery* 32: 334–6.

Appendix A: Additional papers on total wrist replacement not included in summary table 2

The following table outlines the studies that are considered potentially relevant to the 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
Groot, D. (2006) Wear-Induced Osteolysis and Synovial Swelling in a Patient With a Metal-Polyethylene Wrist Prosthesis. <i>Journal of Hand Surgery</i> 31 (10) 1615-1618	Case report n=1 FU= 11 years	Recurrent synovial swelling on the ulnar side. Surgical exploration showed synovitis, worn and broken polythene insert with wear particles, and titanium debris from corrosion.	This prosthesis has been withdrawn from the UK market.
Kistler, U., Weiss, A. P., Simmen, B. R., et al (2005) Long-term results of silicone wrist arthroplasty in patients with rheumatoid arthritis. <i>Journal of Hand Surgery - American Volume</i> 30 (6) 1282-1287	Case series n=25 (27 wrists) FU= 15 years	Good or very good outcome on subjective assessment in 12 patients. 3 conversions to fusion.	Different prosthesis design to those included in table 2
Lundborg, G., Besjakov, J., and Branemark, P. I. (2007) Osseointegrated wrist-joint prostheses: a 15-year follow-up with focus on bony fixation. <i>Scandinavian Journal of Plastic & Reconstructive Surgery & Hand Surgery</i> 41 (3) 130-137	Case series n=5 FU=15 years	Patients had little or no mild activity related pain. Active extension varies from 15° to 35°, and flexion from 0° to 15°. In 3 patients elements of the implant had to be replaced.	Different prosthesis design to those included in table 2
Minami, M. (2004) A total wrist arthroplasty in rheumatoid arthritis: A case followed for 24 years. <i>Modern Rheumatology</i> 14 (6) 488-493	Case report n=1 FU= 24 years	No recurrence of synovitis, and no destructive changes on roentgenograms	Different prosthesis design to those included in table 2
Radmer, S., Andresen, R., and Sparmann, M. (2003) Total wrist arthroplasty in patients with rheumatoid arthritis. <i>Journal of Hand Surgery - American Volume</i> 28 (5) 789-794.	Case series n=40 FU=52 months	Because of deterioration of results and high revision rate authors do not consider wrist prosthesis as a suitable implant of rheumatoid arthritis.	Different prosthesis design to those included in table 2
Stegeman, M., Rijnberg, W. J., and van Loon, C. J. (2005) Biaxial total wrist arthroplasty in rheumatoid arthritis. Satisfactory functional results. <i>Rheumatology International</i> 25 (3) 191-194	Case series n=14 (16 wrists) FU=25 months	Good to excellent results on the Hospital for special surgery scoring system in 69% of patients. 4 implants dislocated of which 1 was revised.	This prosthesis has been withdrawn from the UK market.
Takwale, V. J., Nuttall, D., Trail, I. A., et al. (2002) Biaxial total wrist replacement in patients with rheumatoid arthritis. <i>Clinical review,</i>	Case series n=66	Pain was relieved in 67% of patients. 83% survival at 8 years before revision surgery.	This prosthesis has been withdrawn from the UK market.

survivorship and radiological analysis. Journal of Bone & Joint Surgery - British Volume 84 (5) 692-699	FU=52 months		
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Appendix B: Related NICE guidance for total wrist replacement

Guidance	Recommendation
Interventional procedures	<p data-bbox="824 428 1377 548">IPG 110 Artificial metacarpophalangeal and interphalangeal joint replacement for end-stage arthritis</p> <p data-bbox="824 611 1382 852">1.1 Current evidence on the safety and efficacy of artificial metacarpophalangeal (MCP) and interphalangeal (IP) joint replacement of the hand for end-stage arthritis appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance.</p> <p data-bbox="824 898 1382 1108">1.2 Most of the evidence was based on a single type of joint prosthesis. The range of prostheses used is continually changing and clinicians are encouraged to submit their results to the appropriate joint-replacement registry for evaluation of long-term outcomes of different types of prosthesis.</p> <p data-bbox="824 1205 1349 1276">IPG 111 Artificial trapeziometacarpal joint replacement for end-stage osteoarthritis</p> <p data-bbox="824 1297 1382 1507">1.1 Current evidence on the safety and efficacy of artificial trapeziometacarpal (TMC) joint replacement for end-stage osteoarthritis appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance.</p> <p data-bbox="824 1549 1382 1759">1.2 Most of the evidence was based on a single type of joint prosthesis. The range of prostheses used is continually changing and clinicians are encouraged to submit their results to the appropriate joint replacement registry for evaluation of long-term outcomes of different types of prosthesis.</p>
Technology appraisals	None applicable

Clinical guidelines	<p>CG XX: Osteoarthritis: the care and management of adults with osteoarthritis (due Feb 2008).</p> <p>Consultation recommendations.</p> <p>1.5.1.1 Clinicians with responsibility for referring people with OA for consideration of joint surgery should ensure that patients are offered at least the core (non-surgical) treatment options.</p> <p>1.5.1.2 Referral for joint replacement surgery should be considered for patients who experience joint symptoms (pain, stiffness, reduced function) that impact substantially on their quality of life and are refractory to non-surgical treatment. Referral should be made before there is prolonged and established functional limitation and severe pain.</p> <p>1.5.1.3 Patient-specific factors (including age, gender, smoking, obesity and co-morbidities) should not be a barrier to referral.</p> <p>1.5.1.4 Decisions on referral thresholds should be based on discussions between patient representatives, referring clinicians and surgeons, rather than using current scoring tools for prioritisation.</p>
Public health	None applicable

Appendix C: Literature search for total wrist replacement

IP 494: Total Wrist Replacement		
Database	Date searched	Version searched
Cochrane Library	23/01/2008	Issue 4, 2007
CRD databases (DARE & HTA)	23/01/2008	December 2007
Embase	23/01/2008	<u>1980 to 2008 Week 03</u>
Medline	23/01/2008	1950 to January Week 2 2008
Premedline	23/01/2008	<u>January 22, 2008</u>
CINAHL	23/01/2008	<u>1982 to December Week 1 2007</u>
British Library Inside Conferences	23/01/2008	-
NRR	23/01/2008	-
Controlled Trials Registry	23/01/2008	-

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

1. exp Arthritis/
2. arthriti\$.tw.
3. (joint\$ adj3 (inflam\$ or swelling or swollen or stiff\$)).tw.
4. or/1-3
5. Wrist/
6. Wrist Joint/
7. Carpal Joints/
8. Carpal Bones/
9. Radius/
10. or/5-9
11. Arthroplasty/
12. Arthroplasty Replacement/
13. "Prostheses and Implants"/

14. Joint Prosthesis/
15. or/11-14
16. 4 and 10 and 15
17. (wrist\$ adj3 (replace\$ or arthroplast\$ or implant\$ or prosth\$)).tw.
18. (radius adj3 (replace\$ or arthroplast\$ or implant\$ or prosth\$)).tw.
19. ((carpus or carpal) adj3 (replace\$ or arthroplast\$ or implant\$ or prosth\$)).tw.
20. or/17-19
21. 4 and 20
22. 16 or 21
23 .Animal/
24. Human/
25. 23 not (23 and 24)
26. 22 not 25