Internal fixation and comparisons of different fixation methods for treating distal radial fractures in adults (Protocol)

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[Intervention Protocol]

Internal fixation and comparisons of different fixation methods for treating distal radial fractures in adults

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To evaluate the effectiveness of internal fixation for fractures of the distal radius in skeletally mature people. Additionally, to evaluate the relative effectiveness of different surgical methods of treating these fractures.

More specifically, we will compare the effectiveness of:

- internal fixation versus conservative treatment;
- different methods of internal fixation, including different techniques associated with inserting implants, different implants, and different types and durations of immobilisation after internal fixation;
- different fixation methods (percutaneous pinning, external fixation, internal fixation); and different combinations of surgical methods;
- different techniques (e.g. use of arthroscopy) and approaches (e.g. surgical repair of the triangular fibrocartilagenous complex (fibrous tissue which binds together the distal ends of the radius and ulnar)) not already covered.

We will consider these outcomes primarily in terms of patient-assessed functional outcome and satisfaction, and other measures of function and impairment, pain and discomfort, the incidence of complications, anatomical deformity and use of resources.

If data allow it, we intend to study the outcomes in different age groups and for different types of fractures, especially whether they are extra-articular or intra-articular.

BACKGROUND

Note: This is one of five reviews that will cover all surgical interventions for treating distal radial fractures in adults. Each review will provide updated evidence for one of the several surgical categories that are presented together in the currently available review (Handoll 2003a). Following publication of the five reviews, Handoll 2003a will be converted to an 'umbrella' review summarising the evidence for surgical treatment for these fractures.

Description of the condition: distal radial fracture in adults

Fractures of the distal radius, often referred to as "wrist fractures", are common in both children and adults. They are usually defined as occurring in the distal radius within three centimetres of the radiocarpal joint, where the lower end of the radius interfaces with two (the lunate and the scaphoid) of the eight bones forming the carpus (the wrist). The majority are closed injuries, the overlying skin remaining intact.

Distal radial fracture are one of the most common fractures in adults, occurring predominantly in white and older populations in the developed world (Sahlin 1990; Singer 1998; Van Staa 2001). In women, the incidence of these fractures increases with age, more rapidly from the age of 40 years (McQueen 2003). Before this age, the incidence is higher in men (Singer 1998). A recent multicentre study in the United Kingdom of patients aged 35 years and above with distal radius fracture reported an annual incidence of 9/10,000 in men and 37/10,000 in women (O'Neill 2001).

Young adults usually sustain this injury as a result of high-energy trauma, such as a traffic accident. In older adults, especially females, the fracture more often results from low-energy or moderate trauma, such as falling from standing height. This reflects the greater fragility of the bone, resulting from osteoporosis. It has been estimated that, at 50 years of age, a white woman in the USA or Northern Europe has a 15% lifetime risk of a distal radius fracture whereas a man has a lifetime risk of just over two per cent (Cummings 1985). More recent estimates (Van Staa 2001) of lifetime risk of radius or ulna fracture at 50 years of age are similar: 16.6% for women versus 2.9% for men.

Distal radial fractures are usually treated on an outpatient basis. It is estimated that around 20% of patients (mainly older people) require hospital admission (Cummings 1985; O'Neill 2001). This figure includes all people receiving surgery.

Classification

Surgeons have classified fractures by anatomical configuration and fracture pattern, to aid communication, research and guide management. Simple classifications were based on clinical appearance and often named after those who described them. In the distal radius, the term "Colles' fracture" is still used for a fracture in which there is an obvious and typical clinical deformity (commonly referred to as a 'dinner fork deformity') - reflecting dorsal displacement, dorsal angulation, dorsal comminution (fragmentation), and radial shortening. The introduction of X-rays and other imaging methods made it clear that the characteristic deformity may be associated with a range of different fracture patterns, which may be important determinants of outcome, and therefore the way in which treatment is conducted. For example, the fracture through the distal radius may be extra-articular (leaving the articular surface of the radius intact) or intra-articular (the articular surface is disrupted, sometimes in a complex manner). Numerous classifications have been devised to define and group different fracture patterns (Chitnavis 1999). Brief descriptions of six commonly cited classification systems are presented in Table 1 (Cooney 1993; Fernandez 1993; Frykman 1967; Melone 1993; Muller 1991; Older 1965).

Table 1. Commonly used classification systems

Name (reference ID)	Brief outline	Comment
AO (Arbeitsgemeinschaft fur Osteosynthesefragen)(Muller 1991)	This system is organised in order of increasing fracture severity. It divides the fractures into three major groups: group A (extra-articular), group B (simple/partial intra-articular), and group C (complex/complete intra-articular). These three groups are then subdivided, yielding 27 different fracture types.	There is no assessment of the extent of fracture displacement.
Fernandez (Fernandez 1993)	This system is based on the mechanisms of injury. There are five main groups: type I (bending fractures); type II (shearing fractures); type III (compression fractures, with	The injury mechanism is not always apparent. There is no consideration of the extent of displacement.

Table 1. Commonly used classification systems (*Continued*)

	impaction); type IV (avulsion fractures); type V (combinations of bending, shearing, compression or avulsion mechanisms; all high velocity fractures). These groups are further categorised by stability, displacement pattern, number of fragments (or comminuted)and associated lesions.	
Frykman (Frykman 1967)	This system distinguishes between extra-articular fractures and intra-articular fractures of the radiocarpal and radio-ulnar joints, and the presence or absence of an associated distal ulnar (ulnar styloid) fracture. There are 8 types labelled I to VIII (1 to 8): the higher the number, the greater complexity of the fracture.	There is no assessment of the extent or direction of fracture displacement, or of comminution.
Melone (Melone 1993)	This system identifies 5 fracture types, based on 4 major fracture components: the radial shaft, the radial styloid, and the dorsal-medial and volar-medial fragments.	This is for intra-articular fractures only.
Older (Older 1965)	This system divides fractures into 4 types, labelled I to VI (1 to 4) of increasing severity. The types are defined according to extent of displacement (angulation and radial shortening)and comminution.	There is no consideration of radio-ulnar joint involvement.
'Universal Classification' (Cooney 1993)	This system divides fractures into 4 main types, labelled I to VI (1 to 4), distinguishing between extra-articular and intra-articular fractures and displaced and non-displaced fractures. Displaced fracture types II and IV are further subdivided based on reducibility (whether the fracture can be reduced; that is whether the bone fragments can be put back in place) and stability (whether, once reduced, the fragments will remain so).	This does not distinguish between the radiocarpal and radio-ulnar joints. Additionally, there is a 'trial by treatment'.

Description of the interventions: internal fixation and other fixation methods

In the last century, most distal radius fractures in adults were treated non-operatively (conservatively), by reduction (the alignment of the bony fragments) of the fracture when displaced, and stabilisation in a plaster cast or other external brace. The results of such treatment, particularly in older people with bones weakened by osteoporosis, are not consistently satisfactory (Handoll 2003b). This has resulted in attempts to develop other strategies involving surgery aimed at more accurate reduction and more reliable stabilisation. Generally, four main strategies are described in the literature (Fernandez 1996). These are percutaneous pinning (reviewed: Handoll 2007a), external fixation (reviewed: Handoll 2007b; review protocol: Handoll 2007c), bone grafts or substitutes (review protocol: Handoll 2007d) and internal fixation. These may be used by themselves or in various combinations. Percutaneous pinning involves the percutaneous (through the skin) insertion of pins, which may be threaded, and wires. In external fixation, which

is also a closed, minimally invasive method, metal pins or screws are driven into bone, generally via small incisions of the skin and after drilling, on either side of the fracture. These pins are then fixed externally with a plaster cast or an external fixator frame. For both methods, the reduction of the fracture is generally closed (*see* Handoll 2003c); although pins - such as Kirschner wires - may be used to manipulate the fracture fragments (Trumble 1998). Internal fixation, which is usually proceeded by open reduction, involves open surgery where the fractured bone is exposed to direct view. Given the invasive and technically demanding nature of open surgery, with the increased risks of infection and soft-tissue damage, internal fixation is usually reserved for more severe injuries. It is, however, an increasingly used method of surgery and an area of intense current research activity, such as the development of new implant designs (Martineau 2007; Simic 2003).

Numerous techniques and devices are and have been used for internal fixation. Intra-operative choices include: the extent of exposure; the method of reduction and visualisation of the fractured bone and adjacent structures, including via arthroscopy; the direction of approach for plating (dorsal versus volar); the type of implant (generally screws or various plates), and underlying approach or "mindset" (Martineau 2007), such as fragment specific fixation. Although basic choices in methods of internal fixation can be defined, there is likely to be variation arising from patient and surgeon characteristics in these sorts of interventions; in part reflecting the direct visualisation of the fracture pattern at surgery. Post-operative decisions include the use and duration of immobilisation, and the techniques for removal (often only where symptomatic) of implants.

Complications

Complications from this injury are diverse and frequent (McKay 2001). Some are associated with the injury itself: as well as concomitant injuries to soft tissues, fracture displacement can further compromise blood vessels, tendons and nerves, with median nerve dysfunction being the most common complication (Belsole 1993). The etiology of complex regional pain syndrome type 1 (CRPS-1), also termed reflex sympathetic dystrophy, algodystrophy, Sudeck's atrophy and shoulder-hand syndrome (Fernandez 1996), is often unclear. CRPS-1 is a major complication (Atkins 2003) requiring many months of physiotherapy to alleviate symptoms (pain and tenderness, impairment of joint mobility, swelling, dystrophy (muscle wasting), vasomotor instability (poor control of blood vessel dilation)) in serious cases. Late complications include adaptive carpal instability (dynamic instability resulting from malalignment of distal radius and carpal bones within the wrist that is associated with pain, decreased grip strength and clicking) and post-traumatic arthritis which can occur several months or years after injury (Knirk 1986; Taleisnik 1984).

Complications can also result from treatment and include residual finger stiffness, which may be due to faulty application of plaster casts (Gartland 1951), and infection and tissue-damage from surgery. Damage to tendons, either irritation (tenosynovitis) or rupture is a well known complication of plating (Arora 2007; Margaliot 2005).

Why it is important to do this review?

Internal fixation is an increasingly used method of surgery for treating unstable distal radial fractures. Much of the current research effort and interest, including in industry, revolves round internal fixation devices, particularly the design of plates (Martineau 2007). It is important to assess the clinical evidence, particularly in terms of function and adverse effects, for the use internal fixation and related techniques and devices. Additionally it is important to compare internal fixation with other commonly used methods of surgical fixation (percutaneous pinning, external fixation); and, to complete the picture, to review comparisons of all these methods, including the use of bone grafts and bone substitutes. In their meta-analysis drawing data from 46 articles, predominantly case series, comparing plate osteosynthesis with bridging external fixation, Margaliot 2005 concluded the current literature "offers no evidence to support the use of internal fixation over external fixation". However, the approach taken by Margaliot 2005 including their study inclusion criteria is substantially different from our methods and we will also include more recent evidence. Other important questions also need assessment. These include the repair of ruptured ligaments and use of adjunctive arthroscopy. The findings of the review are likely to depend on fracture configuration, bone quality and other patient factors.

OBJECTIVES

To evaluate the effectiveness of internal fixation for fractures of the distal radius in skeletally mature people. Additionally, to evaluate the relative effectiveness of different surgical methods of treating these fractures.

More specifically, we will compare the effectiveness of:

- internal fixation versus conservative treatment;
- different methods of internal fixation, including different techniques associated with inserting implants, different implants, and different types and durations of immobilisation after internal fixation;
- different fixation methods (percutaneous pinning, external fixation, internal fixation); and different combinations of surgical methods;
- different techniques (e.g. use of arthroscopy) and approaches (e.g. surgical repair of the triangular fibrocartilagenous complex (fibrous tissue which binds together the distal ends of the radius and ulnar)) not already covered.

We will consider these outcomes primarily in terms of patient-assessed functional outcome and satisfaction, and other measures of function and impairment, pain and discomfort, the incidence of complications, anatomical deformity and use of resources.

If data allow it, we intend to study the outcomes in different age groups and for different types of fractures, especially whether they are extra-articular or intra-articular.

METHODS

Criteria for considering studies for this review

Types of studies

Any randomised or quasi-randomised (method of allocating participants to a treatment which is not strictly random e.g. by date of birth, hospital record number, alternation) controlled clinical trials evaluating internal fixation or comparing different methods of surgical fixation for treating distal radial fractures in adults.

Types of participants

Skeletally mature patients of either sex with a fracture of the distal radius. Trials containing adults and children will be included provided the proportion of children was clearly small (< 5%), or separate data for adults can be obtained. Trials containing different fracture types will only be included if separate data are available for participants with distal radial fractures. Also included will be trials recruiting people whose fractures have redisplaced within two weeks of conservative management.

Types of interventions

This includes three groups of comparisons.

(A) Internal fixation

(1) Internal fixation by itself versus conservative interventions such as plaster cast immobilisation.

(2) Internal fixation as the primary method where a combination of methods is used (e.g. with supplementary percutaneous pinning, bone grafts or bone substitutes) versus conservative interventions such as plaster cast immobilisation.

(3) Different methods of internal fixation. Thus comparisons evaluating:

(a) different fixation methods (e.g. fragment-specific fixation versus fixed-angle plates; locked versus non-locking plates);

(b) different types of devices, including materials used (e.g. bioabsorbable versus metal implants);

(c) different approaches (e.g. dorsal versus volar fixation);

(d) different surgical techniques associated with internal fixation, including location and extent of skin incision and measures to assist reduction, and methods of implant removal (where indicated);

(e) type and duration of immobilisation after internal fixation;

(f) policy and timing of implant removal.

(B) Comparisons of different fixation methods (percutaneous pinning, external fixation, internal fixation)

(1) External fixation versus percutaneous pinning.

(2) Internal fixation versus percutaneous pinning.

(3) Internal fixation versus external fixation.

Within each comparison, we will consider prespecified subcategories of the methods of fixation being compared. For percutaneous pinning, these will be transfixation of the fracture fragments versus Kapandji pinning; for external fixation, these will be bridging versus non-bridging of the radiocarpal joint; for internal fixation, these will be dorsal versus volar plating; and fragment specific versus fixed-angle plating. Other subcategories will include the use of i) bone graft or substitutes and ii) supplementary pinning where these apply to either both intervention groups or to only one intervention group.

(C) 'Miscellaneous'

Randomised trials testing other comparisons of surgical fixation for these fractures that do not fall within the above categories or within the scope of the four other reviews (Handoll 2007a; Handoll 2007b; Handoll 2007c; Handoll 2007d) will be considered for inclusion on a case by case basis. Two prespecified categories follow.

(1) Surgical repair of the triangular fibrocartilagenous complex rupture or ulnar styloid fractures, or both versus no repair. Patients in both groups may otherwise receive either conservative treatment or the same type of surgical treatment.

(2) Arthroscopic versus other methods of visualisation and reduction.

Types of outcome measures

Our primary outcome of choice would be the number of people with an uncomplicated and swift restoration of a pain-free fully-functioning wrist and arm with acceptable anatomic restoration and appearance. However, compatible with the general assessment and presentation of outcome within the orthopaedic literature, we shall report outcome in the following four categories.

Primary outcomes

(1) Functional outcome and impairment

- Patient functional assessment instruments such as Short Form-36 (SF-36), the Disability of the Arm, Shoulder, and Hand questionnaire (DASH) and the Patient-Rated Wrist Evaluation (PRWE) (MacDermid 2000)
- Return to previous occupation, including work, and activities of daily living
- Grip strength
- Pain
- Range of movement (wrist and forearm mobility): range of movement for the wrist is described in terms of six parameters: flexion (ability to bend the wrist downwards) and extension (or

upwards); radial deviation (ability to bend the wrist sideways on the thumb side) and ulnar deviation (on the little finger side); and pronation (ability to turn the forearm so that the palm faces downwards) and supination (palm faces upwards)

(2) Clinical outcome

- Residual soft tissue swelling
- Early and late complications associated with distal radial fractures or their treatment, including complex regional pain syndrome type 1 (CRPS-1), late tendon rupture and post traumatic osteoarthritis
- Cosmetic appearance
- Patient satisfaction with treatment

Secondary outcomes
(3) Anatomical outcome (anatomical restoration and residual deformity)

- Radiological parameters include radial length or shortening and shift, dorsal angulation, radial inclination or angle, ulnar variance, and for intra-articular fractures: step off and gap deformity of the articular surface (Fernandez 1996; Kreder 1996). Composite measures include malunion and total radiological deformity. Definitions of four of the most commonly reported radiological parameters are presented in Table 2.

Table 2. Definitions of key radiological parameters

Parameter	Definition	Normal value
Dorsal angulation (dorsal or volar or palmar tilt)	Angle between a) the line which connects the most distal points of the dorsal and volar cortical rims of the radius and b) the line drawn perpendicular to the longitudinal axis of the radius. Side view of wrist.	Palmar or volar tilt: approximately 11-12 degrees.
Radial length	Distance between a) a line drawn at the tip of the radial styloid process, perpendicular to the longitudinal axis of the radius and b) a second perpendicular line at the level of the distal articular surface of the ulnar head. Frontal view.	Approximately 11-12 mm.
Radial angle or radial inclination	Angle between a) the line drawn from the tip of the radial styloid process to the ulnar corner of the articular surface of the distal end of the radius and b) the line drawn perpendicular to the longitudinal axis of the radius. Frontal view.	Approximately 22-23 degrees.
Ulnar variance	Vertical distance between a) a line drawn parallel to the proximal surface of the lunate facet of the distal radius and b) a line	Usually negative variance (e.g. -1 mm) or neutral variance.

Table 2. Definitions of key radiological parameters (*Continued*)

	parallel to the articular surface of the ulnar head.	

(4) Resource use

- Hospital stay, number of outpatient attendances, physiotherapy and other costs.

Intervention-specific outcomes

Complications associated with hardware failure and subsequent extraction of internal fixation devices will be collected, and presented in the analyses. For autografts, outcomes including pain and complications associated with the surgical removal of bone from the donor site will be collected, where reported, and presented in the analyses.

Search methods for identification of studies

Electronic searches

We will search the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register, the Cochrane Central Register of Controlled Trials (in *The Cochrane Library*) (*see* Appendix 1), MEDLINE, EMBASE, CINAHL and reference lists of articles. We will also search Current Controlled Trials at www.controlled-trials.com and the UK National Research Register at www.update-software.com/national/ for ongoing and recently completed trials. No language restrictions will be applied.

In MEDLINE (OVID-WEB) the search strategy will be combined with all three sections of the optimal MEDLINE search strategy for randomised trials (Higgins 2005) (*see* Appendix 2).

Similar search strategies will be used for EMBASE (OVID-WEB) and CINAHL (OVID-WEB) (*see* Appendix 3).

Searching other resources

We will include the findings from handsearches of the British Volume of the Journal of Bone and Joint Surgery supplements (1996 onwards) and abstracts of the American Society for Surgery of the Hand annual meetings (2000 onwards: www.assh.org/), the American Orthopaedic Trauma Association annual meetings (1996 onwards: www.ota.org/education/archives.html) and American Academy of Orthopaedic Surgeons annual meeting (2004 onwards: www.aaos.org/). We will also include handsearch results from the final programmes of SICOT (1996 & 1999) and SICOT/SIROT (2003), and the British Orthopaedic Association Congress (2000, 2001, 2002 and 2003), and various issues of Orthopaedic Transactions and of Acta Orthopaedica Scandinavica Supplementum.

We will also scrutinise weekly downloads of "Fracture" articles in new issues of 15 journals (Acta Orthop Scand; Am J Orthop; Arch Orthop Trauma Surg; Clin J Sport Med; Clin Orthop; Foot Ankle Int; Injury; J Am Acad Orthop Surg; J Arthroplasty; J Bone Joint Surg Am; J Bone Joint Surg Br; J Foot Ankle Surg; J Orthop Trauma; J Trauma; Orthopedics) from AMEDEO (www.amedeo.com).

Data collection and analysis

Selection of studies

Both review authors will independently assess potentially eligible trials identified via the search for inclusion using a pre-piloted form. Any disagreement will be resolved by discussion.

Data extraction and management

Using a data extraction form, both review authors will independently extract trial details and data for new trials, and one author (HH) will repeat data extraction of trials already included in Handoll 2003a and check for consistency with her previous data extraction. HH will enter the data into RevMan. Any disagreement for new trials will be resolved by discussion. Extraction of results from graphs in trial reports will be considered where data are not provided in the text or tables. We will contact trialists of trials not reported in full journal publications for additional information or data. Contact with other trial authors will be dictated by the vintage of the publication, a general impression of the expected gain, and anticipated or known difficulty in locating trial authors.

Results will be collected for the final follow-up time for which these are available. We will, however, note instances where a marked and important difference between groups in the pattern of functional recovery has been found at an intermediate assessment.

Assessment of methodological quality of included studies

In this review, risk of bias will be assessed indirectly in terms of different aspects of methodological quality.

Both review authors will independently assess methodological quality of the newly included trials using a pre-piloted form. One author (HH) will reassess the trials already included in Handoll 2003a. Any disagreement will be resolved by discussion. Titles of journals, names of authors or supporting institutions will not be masked at any stage. A modification of the quality assessment tool used in the current 'umbrella' review will be used. Instead of scores, each item will be graded either 'Y', '?' or 'N', respectively indicating that the quality criteria were met for the item ("Yes"), or possibly or only partially met for the item ("Possible, partial"), or not met ("No"). The rating scheme covering 11 aspects of trial validity plus brief notes of coding guidelines for selected items are given in Table 3.

Table 3. Methodological quality assessment scheme

Items	Scores	Notes
(1) Was the assigned treatment adequately concealed prior to allocation?	Y = method did not allow disclosure of assignment. ? = small but possible chance of disclosure of assignment or unclear. N = quasi-randomised, or open list or tables.	Cochrane code (see Handbook): Clearly yes = A; Not sure = B; Clearly no = C.
(2) Were the outcomes of participants who withdrew described and included in the analysis (intention-to-treat)?	Y = withdrawals well described and accounted for in analysis. ? = withdrawals described and analysis not possible, or probably no withdrawals. N = no mention, inadequate mention, or obvious differences and no adjustment.	
(3) Were the outcome assessors blinded to treatment status?	Y = effective action taken to blind assessors. ? = small or moderate chance of unblinding of assessors, or some blinding of outcomes attempted. N = not mentioned or not possible.	
(4) Were important baseline characteristics reported and comparable?	Y = good comparability of groups, or confounding adjusted for in analysis. ? = confounding small, mentioned but not adjusted for, or comparability reported in text without confirmatory data. N = large potential for confounding, or not discussed.	Although many characteristics including hand dominance are important, the principal confounders are considered to be age, gender, type of fracture.
(5) Were the trial participants blind to assignment status after allocation?	Y = effective action taken to blind participants. ? = small or moderate chance of unblinding of participants.	

Table 3. Methodological quality assessment scheme (*Continued*)

	N = not possible, or not mentioned (unless double-blind), or possible but not done.	
(6) Were the treatment providers blind to assignment status?	Y = effective action taken to blind treatment providers. ? = small or moderate chance of unblinding of treatment providers. N = not possible, or not mentioned (unless double-blind), or possible but not done.	
(7) Were care programmes, other than the trial options, identical?	Y = care programmes clearly identical. ? = clear but trivial differences, or some evidence of comparability. N = not mentioned or clear and important differences in care programmes.	Examples of clinically important differences in other interventions are: time of intervention, duration of intervention, anaesthetic used within broad categories, operator experience, difference in rehabilitation.
(8) Were the inclusion and exclusion criteria for entry clearly defined?	Y = clearly defined (including type of fracture). ? = inadequately defined. N = not defined.	
(9) Were the outcome measures used clearly defined?	Y = clearly defined. ? = inadequately defined. N = not defined.	
(10) Were the accuracy and precision, with consideration of observer variation, of the outcome measures adequate; and were these clinically useful and did they include active follow up?	Y = optimal. ? = adequate. N = not defined, not adequate.	
(11) Was the timing (e.g. duration of surveillance)clinically appropriate?	Y = optimal. (> 1 year) ? = adequate. (6 months - 1 year) N = not defined, not adequate. (< 6 months)	

Measures of treatment effect

Quantitative data reported in individual trial reports for outcomes listed in the inclusion criteria will be presented in the text and in the analyses, using relative risks with 95% confidence intervals for dichotomous outcomes, and mean differences with 95% confidence intervals for continuous outcomes.

Unit of analysis issues

The unit of randomisation in these trials is usually the individual patient. Exceptionally, as in the case of trials including people with bilateral fractures, data for trials may be presented for fractures or limbs rather than individual patients. Where such unit of analysis issues arise and appropriate corrections have not been made, we will consider presenting the data for such trials only where the disparity between the units of analysis and randomisation is small. Where data are pooled, we will perform a sensitivity analysis to examine the effects of pooling these incorrectly analysed trials with the other correctly analysed trials.

Dealing with missing data

Where appropriate, we will perform intention-to-treat analyses to include all people randomised to the intervention groups. We will investigate the effect of drop outs and exclusions by conducting worse and best scenario analyses. We will be alert to the potential mislabelling or non identification of standard errors and standard deviations. Unless missing standard deviations can be derived from confidence interval data, we will not assume values in order to present these in the analyses.

Assessment of heterogeneity

Heterogeneity will be assessed by visual inspection of the forest plot (analysis) along with consideration of the test for heterogeneity and the I^2 statistic (Higgins 2003).

Assessment of reporting biases

In the unlikely event that sufficient data are available, we would attempt to assess publication bias by preparing a funnel plot. Our search of 'grey literature' and pursuit of trials listed in clinical trial registers should help to avoid publication bias.

Data synthesis (meta-analysis)

If considered appropriate, results of comparable groups of trials will be pooled. Initially we will use the fixed-effect model and 95% confidence intervals. We will also consider using the random-effects model, especially where there is unexplained heterogeneity.

Subgroup analysis and investigation of heterogeneity

We plan subgroup analyses by age (under 50; 50 or above) and gender and type of fracture (primarily extra-articular versus intra-articular fractures). Presentation in separate subgroups will be considered where there is a fundamental difference in bone scaffolding (such as bone graft versus bone substitute). To test whether the subgroups are statistically significantly different from one another, we will test the interaction using the technique outlined in Altman 2003.

Sensitivity analysis

Where possible, we plan sensitivity analyses examining various aspects of trial and review methodology, including the effects of missing data, study quality (specifically allocation concealment, outcome assessor blinding and reportage of surgical experience), and inclusion of trials only reported in abstracts. We will use the test of interaction to establish whether the subgroups are statistically significantly different from one another (Altman 2003).

Interpretation of the evidence

To assist our interpretation of the evidence, we will grade the findings of the treatment comparisons according to the six categories of effectiveness used by contributors to Clinical Evidence (BMJ 2006) (*see* Table 4).

Table 4. Categories of effectiveness (definitions)

Rank	Category	Definition
1	Beneficial	Interventions for which effectiveness has been demonstrated by clear evidence from randomised controlled trials, and for which expectation of harms is small compared with the benefits.
2	Likely to be beneficial	Interventions for which effectiveness is less well established than for those listed under "beneficial".
3	Trade off between benefits and harms	Interventions for which clinicians and patients should weigh up the beneficial and harmful effects according to individual circumstances and priorities.
4	Unknown effectiveness	Interventions for which there is currently insufficient data or data of inadequate quality.
5	Unlikely to be beneficial	Interventions for which lack of effectiveness is less well established than for those listed under "likely to be ineffective or harmful"
6	Likely to be ineffective or harmful	Interventions for which ineffectiveness or harmfulness has been demonstrated by clear evidence.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. Search strategy for *The Cochrane Library* (Wiley InterScience)

#1 MeSH descriptor Radius Fractures explode all trees in MeSH products
#2 MeSH descriptor Wrist Injuries explode all trees in MeSH products
#3 (#1 OR #2)
#4 ((distal near radius) or (distal near radial)) in Title, Abstract or Keywords in all products
#5 (colles or smith or smiths) in Title, Abstract or Keywords in all products
#6 wrist* in Title, Abstract or Keywords in all products
#7 (#4 OR #5 OR #6)
#8 fractur* in Title, Abstract or Keywords in all products
#9 (#7 AND #8)
#10 (#3 OR #9)

Appendix 2. Search strategy for MEDLINE (OVID-WEB)

1. exp Radius Fractures/
2. Wrist Injuries/
3. (((distal adj3 (radius or radial)) or wrist or colles or smith$2) adj3 fracture$).ti,ab.
4. or/1-3

Appendix 3. Search strategies for CINAHL and EMBASE (OVID-WEB)

CINAHL	EMBASE
1. Radius Fractures/	1. (((distal adj3 (radius or radial)) or wrist or colles$2 or smith$2) adj3 fracture$).tw.
2. Wrist Injuries/	2. Colles Fracture/ or Radius Fracture/ or Wrist Fracture/ or Wrist Injury/
3. or/1-2	3. or/1-2
4. (((distal adj3 (radius or radial)) or wrist or colles or smith$2) adj3 fracture$).ti,ab.	4. exp Randomized Controlled trial/
5. or/3-4	5. exp Double Blind Procedure/
6. exp Clinical Trials/	6. exp Single Blind Procedure/
7. exp Evaluation Research/	7. exp Crossover Procedure/
8. exp Comparative Studies/	8. or/4-8
9. exp Crossover Design/	9. ((clinical or controlled or comparative or placebo or prospective$ or randomi#ed)adj3 (trial or study)).tw.
10. clinical trial.pt.	10. (random$ adj7 (allocat$ or allot$ or assign$ or basis$ or divid$ or order$)).tw.
11. or/6-10	11. ((singl$ or doubl$ or trebl$ or tripl$) adj7 (blind$ or mask$)).tw.
12. ((clinical or controlled or comparative or placebo or prospective or randomi#ed)adj3 (trial or study)).tw.	12. (cross?over$ or (cross adj1 over$)).tw.
13. (random$ adj7 (allocat$ or allot$ or assign$ or basis$ or divid$ or order$)).tw.	13. ((allocat$ or allot$ or assign$ or divid$) adj3 (condition$ or experiment$ or intervention$ or treatment$ or therap$ or control$ or group$)).tw.
14. ((singl$ or doubl$ or trebl$ or tripl$) adj7 (blind$ or mask$)).tw.	14. or/9-13
15. (cross?over$ or (cross adj1 over$)).tw.	15. or/8,14
16. ((allocat$ or allot$ or assign$ or divid$) adj3 (condition$ or experiment$ or intervention$ or treatment$ or therap$ or control$ or group$)).tw.	16. Animal/ not Human/
17. or/12-16	17. 15 not 16
18. or/11,17	

(*Continued*)

19. and/5,18	18. and/3,17

WHAT'S NEW

25 July 2008	Amended	Converted to new review format.

HISTORY

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DECLARATIONS OF INTEREST

None known

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External sources

- No sources of support supplied