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Shears E, Armitstead CP

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TABLE OF CONTENTS

[Intervention Review]

Surgical versus conservative management for odontoid fractures

Emma Shears[1], Christopher P Armitstead[2]

[1]Spinal Unit, Royal Orthopaedic Hospital, Birmingham, UK. [2]Department of Orthopaedics, Royal Orthopaedic Hospital, Birmingham, UK

Contact: Emma Shears, Spinal Unit, Royal Orthopaedic Hospital, Bristol Road, Northfield, Birmingham, West Midlands, B31 2AP, UK. shears@doctors.org.uk.

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ABSTRACT

Background

Fractures of the odontoid process of the second cervical vertebra can result in instability, neurological damage and death. Treatment includes conservative management (external immobilisation devices) or surgical treatment (internal fixation by posterior fusion or anterior screw fixation).

Objectives

To compare surgical with conservative treatment for fractures of the odontoid process.

Search methods

We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (September 2010), the Cochrane Central Register of Controlled Trials (*The Cochrane Library* 2010, Issue 3), MEDLINE (1950 to August Week 5 2010), EMBASE (1980 to 2010 Week 35), LILACS (September 2010), reference lists of articles and registries of ongoing trials.

Selection criteria

Randomised and quasi-randomised controlled trials comparing surgical versus conservative treatment of odontoid fractures.

Data collection and analysis

Two review authors independently examined the search results to identify trials for inclusion.

Main results

We identified an interm report of one study which appeared to meet our inclusion criteria but are awaiting further details from the trial authors before making a final judgment. We excluded one registered study comparing surgery and conservative treatment which does not involve randomisation of treatment allocation.

Authors' conclusions

There is no evidence available from adequately controlled trials to inform the decision on whether the surgical treatment of odontoid fractures gives a better outcome. A sufficiently powered good quality multicentre randomised controlled trial comparing surgery versus conservative treatment is warranted.

PLAIN LANGUAGE SUMMARY

Surgical versus conservative management for an odontoid fracture (a serious neck injury)

The seven bones making up the neck region of the backbone are called the cervical vertebrae. The first vertebra, called the atlas, supports the skull. Underneath this is the axis or second vertebra, which has a upward pointing process called the odontoid process around which the atlas can rotate, enabling the head to be turned. Fracture of the odontoid process is a serious injury and is often fatal. In survivors there is a risk of ongoing damage to the spinal cord and paralysis. People with these fractures are often treated conservatively, which entails stabilisation of the neck in devices such as a 'Halo' (external frame) and/or rigid collar for several months. Another option is surgical stabilisation of the fractured parts. The review aimed to examine the evidence from randomised controlled trials comparing surgical versus conservative treatment for these fractures to find if either approach gave a better outcome. Despite a comprehensive search, the review authors found no evidence from completed randomised controlled trials to inform the choice between surgical and conservative management.

BACKGROUND

Description of the condition

The odontoid process (also called the peg) is a bony projection of the second cervical vertebra (C2), around which the ring-shaped first cervical vertebra (atlas or C1) can rotate. Behind the odontoid process runs a strong ligament, the transcervical ligament of the axis, which separates it from the spinal cord. This unique arrangement, which allows rotational movement of the head, is known as the atlanto-axial complex.

Odontoid fractures typically result from flexion (i.e. anterior movement of the head on the neck) injury, and occasionally from extension (posterior head movement) injury. Due to the proximity of vital neural structures, fracture of the odontoid process may result in fatal damage to the cervical spine, as the fracture is highly unstable. Some 25% to 40% of fractures are estimated to be immediately fatal (Greenberg 2001). Amongst survivors, failure of the fracture to unite is frequently associated with progressive neurological damage (Crockard 1993).

Odontoid fractures have been classified by Anderson and D'Alonzo into three main categories (Anderson 1974). Type I is an oblique (slanting) fracture through the upper portion of the odontoid process, and is considered relatively stable. The most unstable injuries, type II fractures involve the base of the odontoid peg at the junction with the C2 body. A sub-classification added by Hadley 1988 is the type IIa fracture, which is a comminuted (fragmented) type II fracture. Type III fractures are odontoid fractures which extend into the body of C2, and are considered more stable than type II lesions.

Description of the intervention

In view of the potentially fatal nature of the injury, treatment aims to re-establish stability of the atlanto-axial complex by restoring the odontoid process. This may be achieved by conservative or surgical approaches. Conservative approaches include the application of a cervical collar (with or without prior traction) or the use of an external immobilisation device (the 'Halo' or 'Minerva' devices). Use of the cervical collar alone has been shown in case series to yield fusion rates approaching 100% in type I fractures, approximately 55% in type II, and 50% to 60% in type III injuries. The use of traction has been demonstrated to increase the fusion rate in type III fractures to around 80% (with no discernable difference in types I or II) (Hadley 2002). The rate of non-union in type II fractures is related to age, with non-union rates 21 times higher in the over than in the under fifties (Lennarson 2000); and also to displacement of the dens fragment (86% non-union when there is more than six millimetres of displacement, compared with 18% when there is less) (Greene 1997).

Surgical options include posterior fusion of the C1 and C2 vertebrae using wire/cable instrumentation. This prevents subluxation (slippage) of the C1 vertebra on C2, and case series have demonstrated fusion rates of 87% and 100% for type II and III fractures respectively. Fusion may also be performed with screws via a posterior approach (Campanelli 1999). This procedure has a reported morbidity and mortality rate of between 2% and 4%. Specific complications include vertebral artery injury and new onset neurological deficit. C1 to C2 fusion also causes atlantoaxial movement to be lost, leaving the patient unable to rotate their head. Screw fixation of the odontoid peg itself is an alternative surgical option. This involves placing screws through the body of C2 via an anterior approach which is more technically challenging and may be precluded by body habitus (a person's physique) or fracture geometry. Case series have demonstrated success rates of 90% to 95% for type ll fractures, and 100% for type III. Two screw, rather than one screw, fixation may produce a slightly higher fusion rate (Jenkins 1998). These techniques have a significant complication rate, including retropharyngeal wall injury (resulting in airway compromise), infection, implant breakage, loosening and misplacement causing neurovascular injury, although atlantoaxial motion is preserved.

How the intervention might work

The following consensus has been reached in contemporary clinical practice based on retrospective case series (Hadley 2002): conservative management in all instances initially, with consideration of surgical fixation in type II fractures in the over fifties, type IIa (comminuted) fractures, type II and III fractures with displacement over five millimetres, and failed conservative management. It is also widely acknowledged that aggressive surgical management in elderly patients may not be in their best interests.

Why it is important to do this review

Odontoid fracture is a potentially devastating injury. It is clearly important to confirm whether surgical management is superior to conservative management for such injuries. We aimed to review the literature systematically to identify and evaluate the evidence from randomised controlled trials comparing surgical and conservative interventions for odontoid fractures.

OBJECTIVES

This review aimed to compare the relative effects of surgical versus conservative treatment in all classes of acute (i.e. not failed management cases), isolated (i.e. not combined with other cervical vertebral fractures) odontoid fracture in all patient groups (paediatric, adult and elderly age groups), irrespective of any co-morbidities). We planned to assess treatment effects primarily in terms of neurological injury resulting from spinal instability, rates of radiographic bony fusion, complications of conservative and surgical management, and pain and function.

METHODS

Criteria for considering studies for this review

Types of studies

Any randomised or quasi-randomised (methods of allocating participants to a treatment which are not strictly random: e.g. by date of birth, hospital record number, alternation) controlled trials comparing surgical versus conservative management of odontoid fractures.

Types of participants

All people with radiologically confirmed acute and isolated (i.e. not combined with other cervical vertebral fractures) fractures of the odontoid process.

Types of interventions

Surgical internal fixation of odontoid fractures: including posterior fusion (using wire, transarticular screw or other methods) and anterior peg fixation (single or double screw techniques or other methods). The control or comparison intervention is conservative management: i.e. immobilisation in a collar or external fixation device.

Types of outcome measures

- Rates of radiological bony fusion (see below)
- Rates of neurological injury resulting from spinal instability (i.e. non-union) (Crockard 1993)
- Complications attributable to conservative management techniques (local bleeding & infection, pressure sores, failure to tolerate the device)
- Complications attributable to surgical management techniques, comprising complications common to any operative procedure (e.g. infection, bleeding, deep vein thrombosis, pulmonary embolism, complications of anaesthesia) and complications attributable to specific procedures, such as neurovascular injuries from surgery (see 'Background')
- Pain, function and activities of daily living
- Death

Radiological bony fusion was selected as the main outcome measure as it is widely considered and quoted as representing successful treatment. Expert opinion suggests a minimum of 18 months follow-up to confirm whether or not this has taken place (Julien 2000). Interobserver variation exists, and various criteria have been suggested (but not uniformly adopted) for diagnosing radiological non-union on standard 3-view plain cervical radiography (Greenberg 2001). Prompted by editorial feedback on the review, we added pain, function and activities of daily living, and death.

Search methods for identification of studies

Electronic searches

We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (September 2010), the Cochrane Central Register of Controlled Trials (*The Cochrane Library* 2010, Issue 3), MEDLINE (1950 to August Week 5 2010), EMBASE (1980 to 2010 Week 35), and the Latin American and Caribbean Health Sciences Database (LILACS) (September 2010). Current Controlled Trials and the WHO International Clinical Trials Registry were also searched for ongoing and recently completed trials (September 2010).

In MEDLINE (OvidSP) a subject-specific strategy was combined with all three phases of the Cochrane highly sensitive search strategy for identifying reports of randomised controlled trials (Higgins 2006) (*see* Appendix 1). Details of search strategies for EMBASE (OvidSP), *The Cochrane Library* (Wiley InterScience) and LILACS are also shown in Appendix 1.

There were no restrictions based on language or publication status.

Searching other resources

We searched reference lists of articles.

Data collection and analysis

Selection of studies

From the title, abstract, or descriptors, two review authors independently reviewed literature searches to identify potentially relevant trials for full review. Searches of bibliographies and texts were conducted to identify additional studies. Two authors planned to independently assess the full reports of potentially eligible trials for inclusion.

Data extraction and management

Data will be independently extracted by review authors using a data extraction form. Disagreement will be resolved by consensus, or third party adjudication.

Assessment of risk of bias in included studies

All included trials will be independently assessed by two review authors for methodological quality. Differences will be resolved by discussion or independent assessment by a third party.

Methodological quality will be assessed using a Risk of Bias table as detailed in the Cochrane Handbook (Higgins 2008). This tool addresses allocation sequence generation; allocation concealment; blinding of participants, personnel and outcome assessors; completeness of outcome data; selective outcome reporting; and other sources of bias.

Data synthesis

Statistical analysis will be carried out using Review Manager (RevMan 2008). For dichotomous data, the individual and pooled statistics will be calculated using the fixed-effect model and will be reported as risk ratios (RR) with 95% confidence intervals (95% CI). For continuous data (reporting means and standard deviations or standard errors of the mean), pooled mean differences (MD) with 95% confidence intervals will be calculated. Heterogeneity will be assessed by visual examination of the forest plots, in conjunction with the I-squared statistic, and the standard test for heterogeneity. If there is a suggestion that heterogeneity is important then the studies will be further examined for any potential causes. The results of both the fixed-effect and random-effects models will be examined with and without studies deemed to be different to decide which results should be presented, or if no pooling should be done.

Subgroup analysis and investigation of heterogeneity

Data allowing, we will perform subgroup analyses for older adults (over 50) and paediatric (under 16) participants, as case series have suggested that differences in response to management may be present in these groups. In addition and if the data allow, we will perform subgroup analysis for different classes of fracture, as case series have suggested that different fractures respond differently to conservative or surgical management.

Sensitivity analysis

Where appropriate, we will perform sensitivity analyses investigating the effects of allocation concealment, exclusion/inclusion of ambiguous studies, and substitution of a reasonable range of data if data are missing or unclear.

RESULTS

Description of studies

Results of the search

We screened 101 citations up to September 2010 from the Cochrane Bone, Joint and Muscle Trauma Group's Specialised Register, *The Cochrane Library,* MEDLINE, EMBASE and LILACS, and two citations from the WHO International Clinical Trials Registry. Searches for trials were also conducted via Current Controlled Trials, which yielded no trials, and the US National Institute of Health trials registry, which identified the same two trials as the WHO registry. We identified one interim report of an RCT which appears to meet our inclusion criteria (Hurlbert 2007). Until further information has been obtained from the trial authors, this study has been placed into 'Characteristics of studies awaiting classification'. We excluded one registered study (Vaccaro 2008) comparing surgery and conservative treatment because it does not involve randomisation of treatment allocation.

Risk of bias in included studies

There are no included studies in this review.

Effects of interventions

There are no included studies in this review.

DISCUSSION

Our comprehensive search failed to identify any completed randomised controlled trials to inform the choice between surgical and conservative management of these fractures. This is consistent with the findings of others, such as Maak 2006, who have conducted literature reviews on the treatment of these fractures. The published literature to date consists of retrospective case series and case-control studies. While we may have missed unpublished trials, randomised trials comparing surgery versus conservative treatment can be challenging to do and we do not think that a successfully performed trial would have gone unnoticed.

We identified an abstract report of a randomised controlled trial addressing type II fractures only (Hurlbert 2007). Hurlbert 2007 presented an interim analysis of 29 patients and reported on non-union and subsequent surgery. They concluded that a further 20 patients were required to meet the sample size target. It is hoped that the sample size target will be met by the time of our next update.

We identified one meta-analysis of the available evidence with regard to type II fractures only (Nourbakhsh 2009). This concluded that operative treatment provides a significantly better fusion rate than external immobilisation in older patients (over 55 years), posteriorly displaced fractures, and fractures displaced over 4-6 millimetres. We also identified one prospective, non-randomised trial comparing conservative and surgical management in type II odontoid peg fractures in the elderly which is currently recruiting patients (Vaccaro 2008). This two-centre study aims to recruit 166 patients in five years, ending in August 2009.

AUTHORS' CONCLUSIONS

Implications for practice

There is no evidence from randomised controlled trials to inform the choice between surgical and conservative management of acute isolated odontoid fracture.

Implications for research

There is a need for reliable evidence to clarify best practice in this area. As odontoid fractures are relatively uncommon, and patient recruitment may be slow, a pragmatic multi-centre randomised controlled trial is required. Such a trial needs to have a minimum of two years follow-up and record bony fusion, complications resulting from spinal instability and treatment, pain and function, including activities of daily living of survivors.

ACKNOWLEDGEMENTS

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The authors acknowledge the valuable contribution to the protocol and early drafts of this review made by Alan James Watkins.

Jayne Beevers, Damian Griffin, Kate Rowntree and Marc Swiontkowski are acknowledged for valuable comments during the protocol stage.

REFERENCES

References to studies excluded from this review

Vaccaro 2008 *{published data only}*

Vaccaro A, Kopjar B, Yoon T. Comparing surgical to conservative management in the treatment of type II odontoid fractures among the elderly. www.clinicaltrials.gov/ct2/show/NCT00283998?term=odontoid&rank=1 (accessed January 2008).

References to studies awaiting assessment

Hurlbert 2007 *{published data only}*

Hurlbert RJ, Fox R, Casha S, Broad R, Jiang H, DuPlessis S. Interim analysis on a prospective randomized odontoid fracture clinical trial. *Canadian Journal of Surgery* 2007;**50**(3 Suppl):S10-11.

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Campanelli M, Kattner KA, Stroink A, Gupta K, West S. Posterior C1-C2 transarticular screw fixation in the treatment of displaced type II odontoid fractures in the geriatric population - review of seven cases. *Surgical Neurology* 1999;**51**(6):596-600; discussion 600-1.

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Hadley 1988

Hadley MN, Browner CM, Liu SS, Sonntag VK. New subtype of acute odontoid fractures (type IIA). *Neurosurgery* 1988;**22**(1 Pt 1):67-71.

Hadley 2002

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Higgins 2006

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Jenkins 1998

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Julien 2000

Julien TD, Frankel B, Traynelis VC, Ryken TC. Evidence-based analysis of odontoid fracture management. *Neurosurgical Focus* 2000;**8**(6):Article 1.

Lennarson 2000

Lennarson PJ, Mostafavi H, Traynelis VC, Walters BC. Management of type II dens fractures: a case control study. *Spine* 2000;**25**(10):1234-7.

Maak 2006

Maak TG, Grauer JN. The contemporary treatment of odontoid injuries. *Spine* 2006;**31**(11 Suppl):S53-60.

Nourbakhsh 2009

Nourbakhsh A, Shi R, Vannemreddy P, Nanda A. Operative versus nonoperative management of acute odontoid Type II fractures: a meta-analysis. *Journal of Neurosurgery: Spine* 2009;**11**(6):651-8.

RevMan 2008 [Computer program]

The Nordic Cochrane Centre, The Cochrane Collaboration. Review Manager (RevMan). Version 5.0 for Windows. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2008.

CHARACTERISTICS OF STUDIES

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Vaccaro 2008	Non-randomised comparison

Characteristics of studies awaiting assessment *[ordered by study ID]*

Hurlbert 2007

Methods	Randomised trial: randomisation stratified for age, smoking status and neurologic deficit Two centres: Alberta and Calgary, Canada
Participants	Patients with type II odontoid fractures less than 14 days old Exclusion criteria: contraindications to either intervention; other spinal fractures Reported in interim analysis: 29 participants, 17 of whom were aged 65 years or older; 9 smokers; none with neurologic deficits
Interventions	Anterior screw fixation versus halo vest immobilisation
Outcomes	Clinical and radiographic outcomes Treatment failure was reported in the interim analysis: 2 patients ("13%" = 2/16) with anterior screw fixation versus 4 patients ("31%" = 4/13) with halos required revision surgery for non-union
Notes	Abstract report only of an interim analysis of 29 patients. Report concluded that 20 more patients were required to meet sample size target. We will attempt to contact the trial authors for more information.

APPENDICES

Appendix 1. Search strategies

MEDLINE (OvidSP)

1 Odontoid Process/
2 Axis/
3 or/1-2
4 odontoid$.tw.
5 (C2 or axis or epistropheus).tw.
6 (dens or peg or process).tw.
7 and/5-6
8 or/4,7
9 or/3,8
10 Spinal Fractures/
11 exp Fracture Fixation/
12 fractur$.tw.
13 or/10-12
14 and/9,13
15 randomized controlled trial.pt.
16 controlled clinical trial.pt.
17 Randomized Controlled Trials/
18 Random Allocation/
19 Double Blind Method/
20 Single Blind Method/
21 or/15-20
22 Animals/ not Humans/

23 21 not 22
24 clinical trial.pt.
25 exp Clinical Trials as topic/
26 (clinic$ adj25 trial$).tw.
27 ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).tw.
28 Placebos/
29 placebo$.tw.
30 random$.tw.
31 Research Design/
32 or/24-31
33 32 not 22
34 33 not 23
35 Comparative Study.pt.
36 Evaluation Studies.pt.
37 Follow Up Studies/
38 Prospective Studies/
39 (control$ or prospectiv$ or volunteer$).tw.
40 or/35-39
41 40 not 22
42 41 not (23 or 34)
43 23 or 34 or 42
44 14 and 43 (319 records from date of last update to present)

EMBASE (OvidSP)

1 Odontoid Process Fracture/
2 odontoid$.tw.
3 (C2 or axis or epistropheus).tw.
4 (dens or peg or process).tw.
5 and/3-4
6 or/2,5
7 exp Fracture Treatment/
8 fractur$.tw.
9 or/7-8
10 and/6-9
11 or/1,10
12 exp Randomized Controlled trial/
13 exp Double Blind Procedure/
14 exp Single Blind Procedure/
15 exp Crossover Procedure/
16 Controlled Study/
17 or/12-16
18 ((clinical or controlled or comparative or placebo or prospective$ or randomi#ed) adj3 (trial or study)).tw.
19 (random$ adj7 (allocat$ or allot$ or assign$ or basis$ or divid$ or order$)).tw.
20 ((singl$ or doubl$ or trebl$ or tripl$) adj7 (blind$ or mask$)).tw.
21 (cross?over$ or (cross adj1 over$)).tw.
22 ((allocat$ or allot$ or assign$ or divid$) adj3 (conditions$ or experiment$ or intervention$ or treatment$ or therap$ or control$ or group $)).tw.
23 or/18-22
24 or/17,23
25 limit 24 to human
26 and/11,25 (155 records from date of last update to present)

The Cochrane Central Register of Controlled Trials (Wiley Online Library)

#1 MeSH descriptor Odontoid Process, this term only
#2 MeSH descriptor Axis, this term only
#3 (#1 or #2)
#4 (odontoid):ti,ab,kw
#5 (c2 or axis or epistropheus) :ti,ab,kw
#6 (dens or peg or process) :ti,ab,kw
#7 (#5 and #6)
#8 (#3 or #4 or #7)

#9 MeSH descriptor Spinal Fractures, this term only
#10 MeSH descriptor Fracture Fixation explode all trees
#11 (fractur*):ti,ab,kw
#12 (#9 or #10 or #11)
#13 (#8 and 12) (7 records)

LILACS (Bireme)

Mh Odontoid Process or Mh Axis or Tw odontoid or ((Tw C2 or Tw axis or Tw epistropheus) and (Tw dens or Tw peg or Tw process)) [Palavras] and (Mh Fracture Fixation or Mh Spinal Fractures or Tw fractur*) [Palavras] and ((Pt randomized controlled trial OR Pt controlled clinical trial OR Mh randomized controlled trials OR Mh random allocation OR Mh double-blind method OR Mh single-blind method) AND NOT (Ct animals AND NOT (Ct human and Ct animal)) OR (Pt clinical trial OR Ex E05.318.760.535$ OR (Tw clin$ AND (Tw trial$ OR Tw ensa$ OR Tw estud$ OR Tw experim$ OR Tw investiga$)) OR ((Tw singl$ OR Tw simple$ OR Tw doubl$ OR Tw doble$ OR Tw duplo$ OR Tw trebl$ OR Tw trip$) AND (Tw blind$ OR Tw cego$ OR Tw ciego$ OR Tw mask$ OR Tw mascar$)) OR Mh placebos OR Tw placebo$ OR (Tw random $ OR Tw randon$ OR Tw casual$ OR Tw acaso$ OR Tw azar OR Tw aleator$) OR Mh research design) AND NOT (Ct animals AND NOT (Ct human and Ct animals)) OR (Ct comparative study OR Ex E05.337$ OR Mh follow-up studies OR Mh prospective studies OR Tw control$ OR Tw prospectiv$ OR Tw volunt$ OR Tw volunteer$) AND NOT (Ct animals AND NOT (Ct human and Ct animals))) [Palavras] (0 records)

WHAT'S NEW

Date	Event	Description
5 October 2010	New search has been performed	For this update, published in Issue 11, 2010, the search was updated to September 2010 and an interim report of an RCT identified and placed into 'Studies awaiting classification' pending further information from the trial authors.

HISTORY

Protocol first published: Issue 1, 2005
Review first published: Issue 4, 2008

Date	Event	Description
13 March 2008	Amended	Converted to new review format

CONTRIBUTIONS OF AUTHORS

Both authors undertook searches, screened search results and revised successive drafts of the review.

Emma Shears also revised the previous work of Alan James Watkins, which formed the foundation of the current review. Emma Shears is the guarantor of this review.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- The Royal Orthopaedic Hospital, Birmingham, UK.

  Access to library facilities
- The John Radcliffe Hospital, Oxford, UK.

  Access to library facilities

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Prompted by editorial feedback on the review, we added pain, function and activities of daily living, and death to the list of outcomes.

INDEX TERMS

Medical Subject Headings (MeSH)

Fracture Fixation [*methods]; Odontoid Process [*injuries]; Spinal Fractures [surgery] [*therapy]

MeSH check words

Humans