Interventions for the management of mandibular fractures (Review)

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[Intervention Review]

Interventions for the management of mandibular fractures

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ABSTRACT

Background

Fractures of the mandible (lower jaw) are a common occurrence and usually related to interpersonal violence or road traffic accidents. Mandibular fractures may be treated using open (surgical) and closed (non-surgical) techniques. Fracture sites are immobilized with intermaxillary fixation (IMF) or other external or internal devices (i.e. plates and screws) to allow bone healing. Various techniques have been used, however uncertainty exists with respect to the specific indications for each approach.

Objectives

The objective of this review is to provide reliable evidence of the effects of any interventions either open (surgical) or closed (non-surgical) that can be used in the management of mandibular fractures, excluding the condyles, in adult patients.

Search methods

We searched the following electronic databases: the Cochrane Oral Health Group's Trials Register (to 28 February 2013), the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2013, Issue 1), MEDLINE via OVID (1950 to 28 February 2013), EMBASE via OVID (1980 to 28 February 2013), *meta*Register of Controlled Trials (to 7 April 2013), ClinicalTrials.gov (to 7 April 2013) and the WHO International Clinical Trials Registry Platform (to 7 April 2013). The reference lists of all trials identified were checked for further studies. There were no restrictions regarding language or date of publication.

Selection criteria

Randomised controlled trials evaluating the management of mandibular fractures without condylar involvement. Any studies that compared different treatment approaches were included.

Data collection and analysis

At least two review authors independently assessed trial quality and extracted data. Results were to be expressed as random-effects models using mean differences for continuous outcomes and risk ratios for dichotomous outcomes with 95% confidence intervals. Heterogeneity was to be investigated to include both clinical and methodological factors.

Main results

Twelve studies, assessed as high (six) and unclear (six) risk of bias, comprising 689 participants (830 fractures), were included. Interventions examined different plate materials and morphology; use of one or two lag screws; microplate versus miniplate; early and delayed mobilization; eyelet wires versus Rapid IMF™ and the management of angle fractures with intraoral access alone or combined with a transbuccal approach. Patient-oriented outcomes were largely ignored and post-operative pain scores were inadequately reported. Unfortunately, only one or two trials with small sample sizes were conducted for each comparison and outcome. Our results and conclusions should therefore be interpreted with caution. We were able to pool the results for two comparisons assessing one outcome. Pooled data from two studies comparing two miniplates versus one miniplate revealed no significant difference in the risk of post-operative infection of surgical site (risk ratio (RR) 1.32, 95% CI 0.41 to 4.22, P = 0.64, I^2 = 0%). Similarly, no difference in post-operative infection between the use of two 3-dimensional (3D) and standard (2D) miniplates was determined (RR 1.26, 95% CI 0.19 to 8.13, P = 0.81, I^2 = 27%). The included studies involved a small number of participants with a low number of events.

Authors' conclusions

This review illustrates that there is currently inadequate evidence to support the effectiveness of a single approach in the management of mandibular fractures without condylar involvement. The lack of high quality evidence may be explained by clinical diversity, variability in assessment tools used and difficulty in grading outcomes with existing measurement tools. Until high level evidence is available, treatment decisions should continue to be based on the clinician's prior experience and the individual circumstances.

PLAIN LANGUAGE SUMMARY

Treatments for fractures of the lower jaw

Review question

The lower jaw (also known as the mandible) is an important bone that shapes the face, holds the lower teeth in place and is used to move the mouth, for talking and chewing food. Fractures are most often found in the part of the lower jaw that supports teeth (known as the body), the part where the jaw curves upwards into the neck (the angle), or at the knobbly-shaped joint found at the very top of the jaw bone (the condyle). Available treatments align and stabilize the fracture, allowing the bone to heal in the proper position. Treatments may or may not involve surgery.

This review, produced by the Cochrane Oral Health Group, examines different methods for treating fractures of the body and angle of the mandible in existing research and studies.

Background

People of all ages can fracture their lower jaw, but fractures mainly occur as a result of violence (for example, being hit or punched in the jaw) or by being involved in an accident on the road (for example, car crashes or bicycle accidents). These fractures can be stabilized by physically binding the jaw shut with a system of bars, wires or elastic bands (intermaxillary fixation), or by using tiny screws or plates attached directly to the fractured sections of the lower jaw bone whilst still allowing the mouth to open (rigid fixation).

Study characteristics

The evidence on which this review is based is up to date as of 28 February 2013. Twelve studies with a combined total of 689 participants were included in this review. Participants ranged in age from 16 to 68 years and most participants (90%) were male. All of the studies compared different types of surgical treatments, and each study evaluated a different aspect of surgical treatment such as different types of plates, screws, or wires or how long the jaw was immobilized after surgery.

Key results

There were concerns about the design and quality of all the studies. All the studies evaluated different aspects of surgical treatment. None of the studies evaluated non-surgical treatments such as intermaxillary fixation and no study compared surgical treatment with non-surgical treatment. As a result there is no clear evidence to indicate which approach is the best to manage these fractures.

Quality of the evidence

The quality of the evidence found is poor. Recommendations are made for further well-conducted research studies in this area to be undertaken.

BACKGROUND

The mandible or lower jaw is a horse-shoe shaped bone which articulates with the base of the skull on each end. It is prone to fracture, with inherently weak areas including the condyle, the angle and parasymphysis.

Description of the condition

Aetiology and prevalence

Mandibular fractures are a common form of facial injury in adults and occur most frequently in males during the third decade of life (Adeyemo 2008). There is geographical variation in the causes of mandibular fractures in adults, with interpersonal violence considered the leading cause in Western Europe (Depprich 2007; Dimitroulis 1991); Australia (Schön 2001); USA (Ogundare 2003), and Canada (Sojot 2001). In Asia (Abbas 2003; Ansari 2004; Ba 1999; Klenk 2003) and Africa (Adeyemo 2008) the majority of mandibular fractures are related to road traffic accidents. Other causes include injury from contact sports, falls, work-related accidents, alcohol and drug abuse in addition to pathological and iatrogenic factors.

Fractures resulting from violence are most commonly associated with the angle region while those related to road traffic accidents usually involve the condyle, body and parasymphysis. Fractures not involving the condylar process of the mandible account for 65% to 75% of the total number of mandibular fractures (Ellis 2005). A minority of mandibular fractures (less than 1%) occur in edentulous patients and many of these involve the mandibular body (Bruce 1993). Mandibular fractures in elderly people are also more likely to be associated with falls (Nishiike 2002) but have also been reported in atrophic edentulous mandibles after the insertion of dental implants (Carls 1996). The majority of mandibular fractures occur at more than one site, typically bilaterally (Kubilius 2009; Ogundare 2003).

Signs and symptoms

Mandibular fractures may present with a variety of signs and symptoms such as pain, swelling, limited jaw movement, bleeding, tenderness and step deformity at the fracture site. Diminished or altered sensation to the lower lip (anaesthesia, hypoaesthesia or paraesthesia) resulting from damage to the inferior alveolar nerve, and associated soft tissue trauma including intraoral bruising, gingival lacerations and sublingual haematoma are also common. Dentoalveolar injuries are often observed with fractures involving the tooth-bearing regions of the mandible; occlusal derangement may also occur with its severity related to the site and degree of displacement of the fracture.

Description of the intervention

The intervention is aimed at realignment (reduction) of the fractured segments into their normal anatomic positions (Johnson 1999), and prevention of movement by immobilization (fixation) of the fractured bone thereby allowing osseous union to occur (Banks 2001). The ultimate goal is to restore occlusion (bite), mandibular anatomy and jaw function.

Treatment approaches range from conservative non-invasive management by 'closed' reduction and immobilization using intermaxillary fixation (IMF) to the more invasive surgical 'open' reduction with internal fixation approach. Several key factors can influence the management of mandibular fractures including the location of the fracture and the degree of displacement. In the dentate mandible, reduction must aim to restore good functional occlusion whereas less precise reduction may be acceptable if sections of the body of the mandible are edentulous or lack opposing teeth. In closed (non-surgical) reduction the bone ends or fragments are realigned either manually or using traction devices without surgically exposing the fracture site, whereas in an open (surgical) reduction the fracture site is surgically exposed during the procedure (Johnson 1999).

A range of options exist for internal fixation of the fractured mandibular segments (van den Bergh 2012). These include transosseous wiring, circum-mandibular wiring, compression plates, reconstruction plates, miniplates and lag screws (Ellis 1999). Other less commonly used methods include: intra- and extra- medullary K-wires, and metallic mesh (Chakraborty 2011) which may involve the simultaneous use of autogenous bone grafts (Basa 1997; Zię bowicz 2006). Titanium miniplates and screws are used extensively for internal fixation. During the last two decades bone plates made of resorbable materials (e.g. polylactic acid, polyglycolic acid, and polydioxanone) have also increased in popularity but are not used much in mandibular fractures. One of the main factors contributing to their popularity is biological degradation, eliminating the potential need for a second operation for plate removal. However, foreign body inflammatory responses have been described with polylactic and polyglycolic implants (Mohamed-Hashem 2000). In the edentulous or partially-dentate mandible adjunctive use of dentures, Gunning splints and external fixation appliances may be helpful to stabilize the fracture, although these methods may not be appropriate for grossly displaced fractures of the edentulous mandible, especially those that are atrophic (Barber 2001).

A number of patient and operator related factors may influence the approach to reduction and fixation of mandibular fractures. Patient factors include age, medical health, state of the dentition, degree of fracture displacement or comminution, and the presence and degree of associated trauma and infection. Important operator factors include surgical skills and experience, operating room facilities, and equipment. In addition, the cost of treatment may have direct implications for both patients and operator.

Protocols for managing mandibular fractures are evolving, with

traditional treatment involving intraoperative IMF in conjunction with rigid internal fixation. However non-compression miniplates, which provide only relative stability, have gained in popularity more recently. The importance of intraoperative IMF as an adjunct to facilitate the application of internal fixation has more recently been questioned (Bell 2008; Gear 2005). The use of a single miniplate on the superior border of the mandible is increasingly preferred for management of mandibular angle fractures among American and European surgeons (Gear 2005). Non-compression plates are also more widely advocated when large bone plates are placed along the inferior border of the mandible. In addition, design changes have been proposed to bone plates for rigid internal fixation to enhance biomechanical characteristics in the symphysis, parasymphysis and mandibular body (Lovald 2009; Madsen 2008). The aim of such systems is to enhance fracture stability, while minimizing the bulk of the implanted plates and improving patient comfort.

Post-operative complications

Nine possible post-operative complications in the management of mandibular fractures have been described by the American Association of Oral and Maxillofacial Surgeons and are often used as parameters of care (Meaders 1998):

- mobility at fracture site (non-union or fibrous union)
- malocclusion
- soft tissue deformity
- infection
- chronic pain
- neurosensory disturbances
- tooth loss or vitality loss
- inability to chew hard food
- need for alternative or additional treatment.

The likelihood of complications increases in older patients with fractures requiring longer stabilization and often accompanied by more post-operative complications particularly in those patients with a history of systemic health problems and in those treated with open (surgical) reduction. Inflammatory complications may also develop in the elderly more frequently than in other age groups (Pankratov 2000). There is also a higher incidence of non-union with severely atrophic mandibles. Additional complications which have been reported include fractured plates, persistent anaesthesia/dysaesthesia and osteomyelitis (Eyrich 1997; Luhr 1996).

How the intervention might work

The closed (non-surgical) reduction technique to a large extent relies on the restoration of the occlusion to achieve correct alignment of the fractured bone segments through IMF with bone or dental ligations or both (Toma 2003). In the open (surgical) technique, alignment of the bone segments can be accomplished by extraoral and transoral approaches to achieve exposure, followed by internal fixation (open reduction and internal fixation (ORIF)) carried out under direct vision (Shetty 2008). Direct exposure of the fracture site may be achieved via an intraoral incision overlying the fracture site; extraorally, via a submandibular (or Risdon) incision; or through an existing laceration where appropriate. A transbuccal approach combining a stab extraoral incision with intraoral exposure is widely used for mandibular angle fractures.
The mechanism of healing of a fracture depends on the method of immobilization used. With non-rigid fixation methods (e.g. IMF or transosseous wiring) a haematoma is formed in the fracture line, initially emanating from the marrow and later from the periosteum. The haematoma subsequently gives rise to a callus which is responsible for initial stability between the segments. Ultimately, the callus ossifies thereby restoring bony reunion. Rigid fixation methods, usually employed in conjunction with open (surgical) reduction, ensure close proximity of the fracture segments. Minimal callus formation is observed with rigid fixation and the bone heals primarily by remodelling.

Why it is important to do this review

Mandibular fractures are generally treated by either open (surgical) or closed (non-surgical) reduction techniques followed by external or internal fixation or both. There is still a lack of consensus on several aspects of the management of mandibular fractures i.e. whether and when to use open or closed reduction, the choice of specific fixation techniques or the appropriateness of surgical or non-surgical interventions for specific types of fractures (Bell 2008; Gear 2005). Patients also require adequate information on the effectiveness, risks, benefits and quality of life implications of each potential treatment option to facilitate informed decision making (Der-Martirosian 2006; Gironda 2006). We are unaware of the existence of a high quality comprehensive systematic review investigating the effects of interventions used in the management of mandibular fractures, without condylar involvement, in adults.

OBJECTIVES

The objective of this review is to provide reliable evidence of the effects of any interventions either open (surgical) or closed (non-surgical) that can be used in the management of mandibular fractures, excluding the condyles, in adult patients. This could include different techniques to perform the procedure or different products to facilitate the implementation of the procedure.

METHODS

Criteria for considering studies for this review

Types of studies

Only randomised controlled trials (RCTs) were considered in this review.

Types of participants

Adults with mandibular fractures excluding unilateral or bilateral condylar involvement, a clinical topic which has been addressed in a prior Cochrane review (Sharif 2010). Studies considering both types of mandibular fractures and reporting separate data for these fractures were included. Initially, subjects over 18 years were to be included but the threshold was reduced to 16 years as adults are usually defined as being over 16 years within health services (see Differences between protocol and review).

Types of interventions

Any form of open or closed reduction and fixation. Studies that compared any two or more methods of management of mandibular fractures were included, however those investigating intentional mandibular fractures i.e. carried out for orthognathic surgery or tumour resection were excluded.

Types of outcome measures

We categorized these as:

- patient-oriented (i.e. of principal interest to patients and reported by them),
- clinical (i.e. those which refer chiefly to the success of the intervention in terms of achieving union and healing of the fracture),
- process (i.e. complications occurring during surgery or those that might result in the surgery not being completed or both).

Primary outcomes

Patient-oriented

1. Restoration and, if reported, the degree of post-operative function including chewing, swallowing, speech and the ability to wear dentures, if relevant. Interpretation of these data would account for differences in treatment protocols (i.e. with or without IMF). We would consider any validated instruments to measure this outcome.
2. Facial appearance to include profile considerations, restoration of symmetry and post-operative scarring.
3. Impact on well-being and quality of life assessed using any validated instrument either generic (i.e. Oral Health-Related Quality of Life (OHRQoL), Oral Health Impact Profile (OHIP)), or specifically targeting patients with a fractured mandible.

Clinical

Proportion of participants with.

1. A requirement for additional open (surgical) or closed (non-surgical) interventions (beyond the primary planned treatment protocol) e.g. due to dislocation or failure of fixation. If data were available, these would be divided into minor and major additional treatment and analysed separately over a period of up to 1 year post-intervention.
2. Duration and intensity of post-operative pain assessed with any recognised and validated pain rating scale to include change from baseline to clinically relevant post-operative time points. Pain relief and its impact (e.g. type, number and frequency of analgesic consumption to reduce pain/discomfort post-intervention).
3. Post-operative adverse events and complications. If data were available, these would be categorised according to their impact on daily life (i.e. major, moderate and minor), and analysed separately over up to 1 year post-intervention.

As an outcome 'status of the occlusion', if adequately achieved should restore the individual's ability to chew and speak, in addition to improving facial appearance. Therefore, it should be considered a surrogate outcome and was not included as one of the primary outcomes for this review.

Secondary outcomes

Process

1. Intraoperative complications. Subject to availability of data, we would differentiate between complications resulting in a change, or those resulting in no change to the treatment protocol.
2. Drop-out rate due to protocol deviation.

Search methods for identification of studies

Electronic searches

To identify studies to be included or considered for this review, detailed search strategies were developed for each database. These were based on the search strategy developed for MEDLINE (Appendix 1) but revised appropriately for each database.

We searched the following databases:

- Cochrane Oral Health Group's Trials Register (to 28 February 2013) (Appendix 2)
- Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2013, Issue 1) (Appendix 3)
- MEDLINE via OVID (1950 to 28 February 2013) (Appendix 1)
- EMBASE via OVID (1980 to 28 February 2013) (Appendix 4).

The MEDLINE search strategy was combined with the Cochrane Highly Sensitive Search Strategy (CHSSS) for identifying randomised trials in MEDLINE: sensitivity maximising version (2008 revision) as referenced in Chapter 6.4.11.1 and detailed in box 6.4.c of the*Cochrane Handbook for Systematic Reviews of Interventions*, Version 5.1.0 (updated March 2011) (Higgins 2011). The search of EMBASE was linked with the Cochrane Oral Health Group's search strategy for identifying randomised controlled trials in EMBASE (Appendix 4).

Searching other resources

The reference lists of relevant articles were examined and the investigators of included studies were contacted by electronic mail for details of additional published and unpublished trials.

Handsearches

Handsearching was conducted as part of the Cochrane Worldwide Handsearching programme (see the Cochrane Masterlist for details of journals currently being searched).

Ongoing trials

We searched the following trials registries for ongoing trials:

- The *meta*Register of Controlled Trials on http://www.controlled-trials.com/ (up to 7 April 2013)
- ClinicalTrials.gov: http://www.clinicaltrials.gov/ (up to 7 April 2013)
- The WHO International Clinical Trials Registry Platform: http://who.int/ictrp/en/ (up to 7 April 2013).

Language

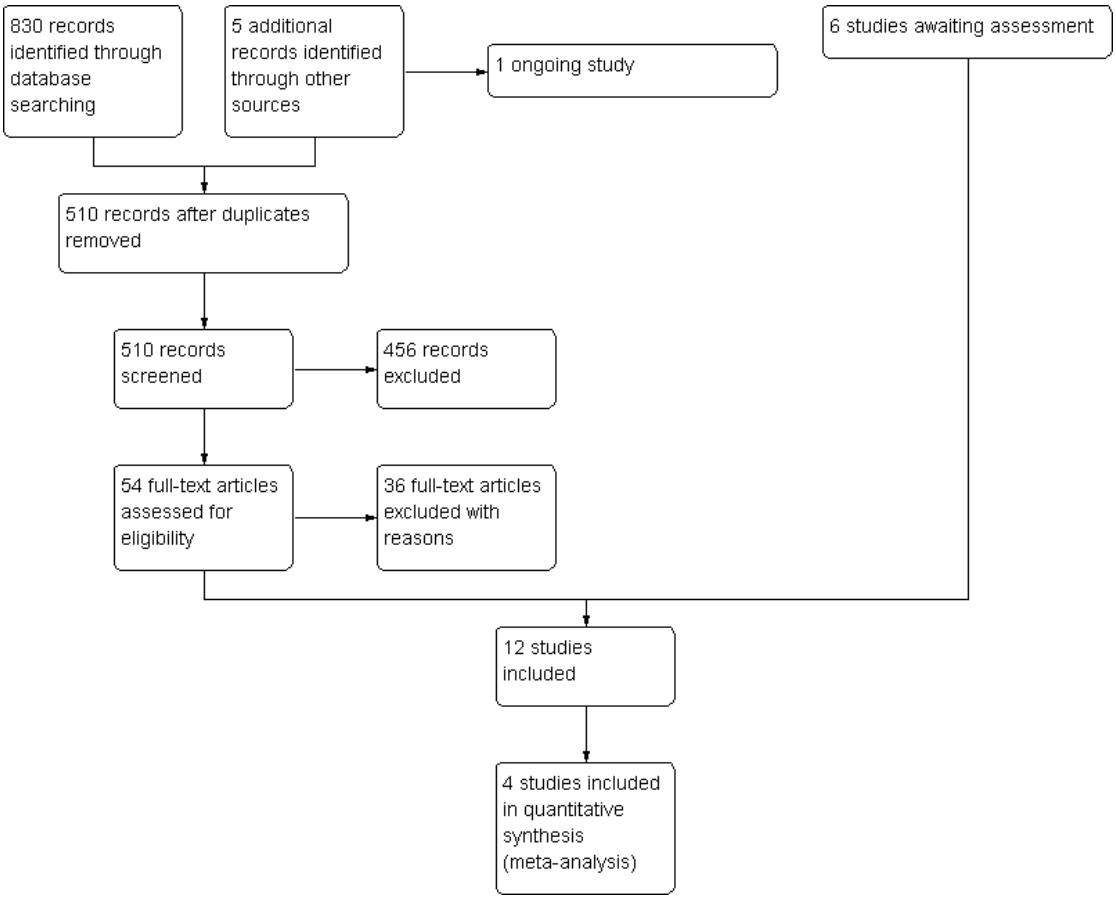
There were no language restrictions on studies for inclusion. Translation of non-English language papers was carried out by the authors or with assistance.

Data collection and analysis

Selection of studies

Four review authors (Nikolaos Pandis (NP), Padhraig S Fleming (PSF), Kamran Ali (KA) and Mona Nasser (MN)), independently assessed the abstracts of studies resulting from the searches in duplicate. Full copies were obtained of all relevant and potentially relevant studies, those appearing to meet the inclusion criteria, or for which there were insufficient data in the title and abstract to make a clear decision. The full-text papers were assessed independently by the review authors and any disagreement on the eligibility of included studies was resolved by discussion or in consensus or both with two other review authors (MN, Zbys Fedorowicz (ZF)). All irrelevant records were excluded and the details and the reasons for their exclusion are outlined in the Characteristics of excluded studies section of the review. For further details see study flow diagram (Figure 1).

Figure 1. Study flow diagram.



Data extraction and management

Study details and outcome data were collected independently and in duplicate by four review authors (NP, ZF, MN, PSF) using a predetermined form designed for this purpose and were entered into the Characteristics of included studies tables in RevMan 5.2 (RevMan 2012). Disagreements were discussed and data were only included if there was an independently reached consensus.
The following details were extracted if reported.

1. Trial methods: method of allocation, masking of participants and outcomes, exclusion of participants after randomisation and proportion of losses to follow-up.
2. Participants: country of origin and study setting, sample size, age, sex, inclusion and exclusion criteria.
3. Intervention: type, duration and length of time of follow-up.
4. Control: any comparisons between different methods of management.
5. Outcomes: as described in the Types of outcome measures section of this review.
6. Sources of funding.

The review authors used this information to help them assess heterogeneity and the external validity of the included trials.

Assessment of risk of bias in included studies

Three review authors (NP, PSF, MN) independently assessed risk of bias in the included trials in duplicate using the Cochrane Collaboration's tool for assessing risk of bias as described in section 8.5 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). The gradings were compared and inconsistencies in the assessments between the review authors were discussed and resolved. The following domains were graded as being at low, high or unclear risk of bias:

1. sequence generation;
2. allocation concealment;

3. blinding (of participants, personnel and outcome assessors);
4. incomplete outcome data addressed;
5. free of selective outcome reporting;
6. free of other bias.

These assessments are reported in the risk of bias table for each individual study in the Characteristics of included studies section of the review. See also Figure 2 and Figure 3.

The overall risk of bias of each of the included studies was categorised and reported as follows:

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

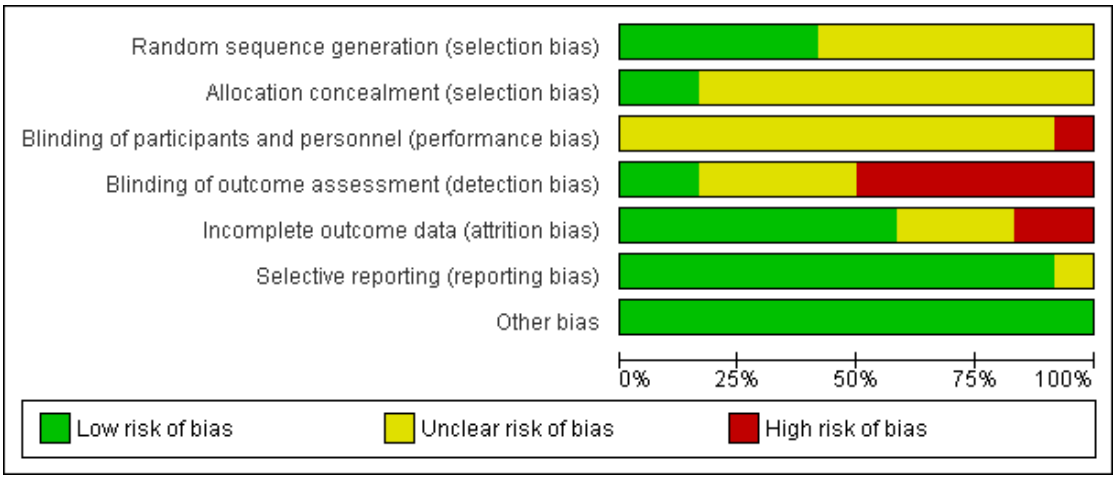
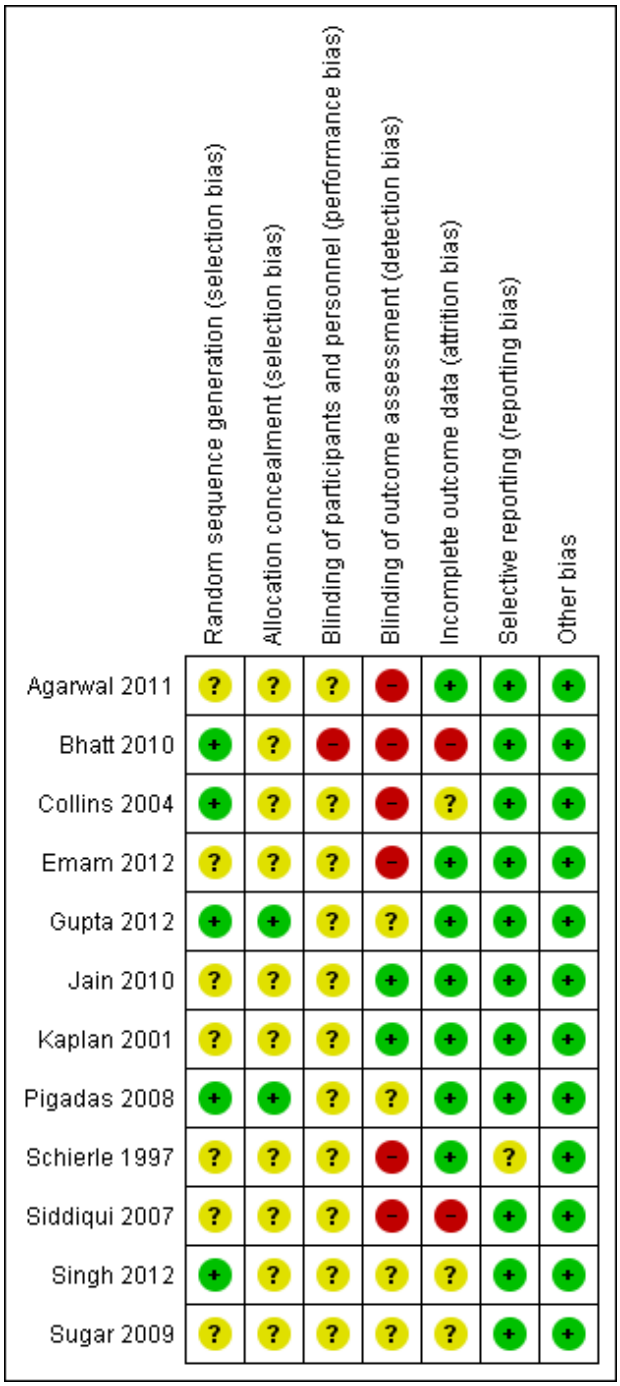


Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



- low risk of bias (plausible bias unlikely to seriously alter the results) if all criteria were met;
- unclear risk of bias (plausible bias that raises some doubt about the results) if one or more criteria were assessed as unclear; or
- high risk of bias (plausible bias that seriously weakens confidence in the results) if one or more criteria were not met.

See Risk of bias in included studies section of the review.

Measures of treatment effect

Risk ratios and 95% confidence intervals were calculated for all dichotomous primary and secondary outcomes and mean differences with 95% confidence intervals for continuous data.

Unit of analysis issues

We anticipated that some of the included studies may present data from repeated and/or multiple site observations on participants which may lead to unit of analysis errors, if so we followed the advice provided in section 9.3.4 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

Dealing with missing data

In studies where data were unclear or missing the principal investigators were contacted. If data were unavailable we followed the advice given in section 16.1.2 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We had concerns about missing data in two studies (Bhatt 2010; Siddiqui 2007); these issues were discussed in the review.

Assessment of heterogeneity

Given that the review question is broad, we expected a degree of clinical diversity between the studies included in this review. Clinical heterogeneity was assessed by examining the characteristics of the studies, the similarity between the types of participants, interventions and outcomes as specified in the criteria for included studies. Statistical heterogeneity was assessed using the I^2 statistic (Higgins 2003) using the following values for the interpretation of results:

- 0% to 40%: might not be important;
- 30% to 60%: may represent moderate heterogeneity;
- 50% to 90%: may represent substantial heterogeneity;
- 75% to 100%: considerable heterogeneity.

However, we recognize that this is a general guide to interpreting the results and inconsistency will depend on a number of other factors.

Assessment of reporting biases

If a sufficient number of studies evaluating similar interventions had been identified for inclusion in this review (> 10) we planned to assess publication bias according to the recommendations on testing for funnel plot asymmetry (Egger 1997) as described in section 10.4.3.1 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). If asymmetry was identified, we would attempt to assess other possible causes exploring these in the discussion section, if appropriate.

Data synthesis

If future updates include a sufficient number of studies (> 2) investigating similar interventions allowing pooling of outcome data, we plan to implement fixed-effect and random-effects models, as appropriate. If we establish heterogeneity between the studies, a random-effects model will be used, however if the heterogeneity between the studies is more significant, we will explore the data to explain this and may not undertake a meta-analysis (section 9.5 of the *Cochrane Handbook for Systematic Reviews of Interventions* 5.1.0 (Higgins 2011)). If sufficient data were available, we calculated a pooled estimate of effect of specific interventions together with their corresponding 95% confidence intervals (CI).

Subgroup analysis and investigation of heterogeneity

If a sufficient number of studies (> 3) examining similar interventions had been included with moderate, substantial or considerable heterogeneity (Assessment of heterogeneity), we planned to investigate heterogeneity carrying out subgroup analyses based on:

1. severity of the fracture;
2. location of the fracture;
3. gender and age;
4. socioeconomic status of the participants.

Sensitivity analysis

We had planned to conduct sensitivity analyses to assess the robustness of the overall results by repeating the analyses with the following adjustments:

1. exclusion of trials with unclear or high risk of bias for allocation concealment;
2. exclusion of trials with unclear or a high risk of bias for blinding; and
3. adjusting for missing data or difficulties encountered in data extraction.

If a sufficient number of studies were included, consideration would be given to undertaking sensitivity analyses to examine the effect of completeness of follow-up using best-worst and worst-best case scenarios.

RESULTS

Description of studies

Results of the search

The electronic searches retrieved 830 studies (510 records after de-duplication). The titles and abstracts were examined for eligibility and those not matching the inclusion criteria were eliminated. We obtained full-text articles of the 54 remaining studies and subjected them to further evaluation. After further assessment, we eliminated 36 of these studies; the reasons for their exclusion are reported in the Characteristics of excluded studies table. In six studies, several key methodological features were not reported and it was unclear whether they were randomised controlled trials. We also identified one ongoing study on the Clinical Trials Registry website. We contacted the authors for further information and categorized them as awaiting assessment and ongoing studies until a response is received. Details are available at Characteristics of studies awaiting classification and Characteristics of ongoing studies. Twelve studies were therefore included overall.
For further details see study flow diagram (Figure 1).

Included studies

Twelve studies were included in this review (Characteristics of included studies table).

Characteristics of the trial settings and investigators

All of the studies were carried out by consultants or specialists based in university hospitals' oral maxillofacial departments or specialised units in India (six), UK (two), USA (two), Germany (one) and Egypt (one). Recruitment and enrolment of participants took place over time periods ranging from 1 to 6 years. Study end-points varied from 1 week to 6 months: 1 week to 2 months (Emam 2012), 6 weeks (Collins 2004), 2 months (Bhatt 2010 and Jain 2010), 3 months (Agarwal 2011; Siddiqui 2007; Sugar 2009 and Singh 2012), and 6 months (Gupta 2012; Kaplan 2001 and Schierle 1997). However, one study was confined to the intraoperative time period only (Pigadas 2008).

Characteristics of the participants

A total of 689 participants with ages ranging from 16 to 68 years with 830 fracture sites were included. The gender distribution was not given in one study (Gupta 2012); however, there were (618 males and 51 females in the other studies). Three studies (Agarwal 2011; Pigadas 2008 and Singh 2012) did not report separate details for specific fracture sites; in a further study a distinction was not made between symphyseal and parasymphyseal fractures (Gupta 2012). In the remaining studies fractures of the angle (346/547 = 63.3%) were the most common, followed by the parasymphysis (115/547 = 21.0%), body (36/547 = 6.6%), symphysis (11/547 = 2.0%) and other associated fractures (39/547 = 7.1%).

Characteristics of the interventions

All of the included studies evaluated different types of open interventions against each other. There were no studies comparing different types of closed interventions with one another or comparing open and closed interventions.
Specific interventions assessed for the management of mandibular fractures excluding the condyle included:

- 2 mm locking titanium plates versus 2 mm non-locking titanium plates (Agarwal 2011; Collins 2004)
- 2 mm titanium plates versus 2.5 mm bioresorbable plates (Bhatt 2010)
- two lag screws versus one lag screw (Emam 2012)
- 3-dimensional (D) miniplates versus standard Champys plates (Jain 2010; Singh 2012)
- microplate versus miniplate (Gupta 2012)
- immediate mobilization versus 2 weeks delayed mobilization in patients with 2 mm titanium miniplates (Kaplan 2001)
- intraoperative Rapid IMF™ versus eyelet wire ties (following open reduction) (Pigadas 2008).

Interventions considered for the management of fractures of the angle of the mandible only were:

- two miniplates versus one miniplate and two screws (Schierle 1997; Siddiqui 2007)
- one transbuccal miniplate combined with an intraoral approach versus intraoral alone approach (Sugar 2009).

All studies with the exception of Gupta 2012 and Schierle 1997 used some form of external fixation. In several studies this was applied solely as intraoperative temporary IMF (Jain 2010; Kaplan 2001; Siddiqui 2007); in the remainder it was used for extended post-operative periods, although it was used for just 5 days by Singh 2012. IMF was used in conjunction with elastics for 7 to 10 days in Agarwal 2011, and archbars were used with IMF for 2 weeks in the resorbable plate group in Bhatt 2010. External fixation with arch bars and IMF was used in the single lag screw group in Emam 2012, and Rapid IMF™ or eyelet wiring in one of each of the intervention groups in Pigadas 2008. Although both intervention groups underwent IMF for 4 weeks in Collins 2004, the method used to achieve fixation was not reported.

Characteristics of the outcomes

One of the included studies (Bhatt 2010) evaluated all nine complications described by the American Association of Oral and Maxillofacial Surgeons (Meaders 1998) related to the management of mandibular fractures. Many of the key outcomes for this review

such as infection, swelling, nerve injury, segmental mobility, non-union, malocclusion, plate exposure and removal, and assessment of the need for further surgical intervention, were common across the studies although they were assessed at varying points in time and frequently reported merely as present or absent, without describing the nature and severity of the specific complication.
Post-operative follow-up periods varied; in most of the studies weekly follow-up was undertaken for the first 2 months up to a maximum end-point of 6 months (Gupta 2012; Kaplan 2001; Schierle 1997). In three studies (Collins 2004; Schierle 1997 and Siddiqui 2007) there were no intermediate post-operative assessments, and one study (Pigadas 2008) reported intraoperative assessments only.

Primary outcomes

Patient-oriented

1. Restoration of function and, if reported, the degree of function re-established (seven studies). Inability to chew was assessed in one study (Bhatt 2010); malocclusion and occlusal discrepancies in six studies (Agarwal 2011; Bhatt 2010; Emam 2012; Schierle 1997; Siddiqui 2007; Sugar 2009). Surrogate outcomes of bite force measurement assessed in Agarwal 2011; Gupta 2012 and interincisal mouth opening in Sugar 2009.
2. Facial appearance to include profile, post-operative scarring and cosmetic appearance (two studies: Bhatt 2010; Siddiqui 2007).
3. Impact on well-being and quality of life assessed using any validated instrument (no studies).

Clinical

Proportion of participants with.

1. A requirement for additional surgical or closed (non-surgical) interventions (seven studies: Bhatt 2010; Collins 2004; Jain 2010; Kaplan 2001; Schierle 1997; Siddiqui 2007; Sugar 2009).
2. Post-operative pain (four studies: Agarwal 2011; Bhatt 2010; Emam 2012 and Kaplan 2001), however the methods of assessment, other than reference to a standard VAS, were not clearly described. Assessments of pain were not carried out in the remaining studies.
3. Post-operative adverse events and complications (11 studies). These were assessed in all studies except Pigadas 2008.

Secondary outcomes

Process

1. Intraoperative complications (three studies: Bhatt 2010; Emam 2012; Pigadas 2008).
2. Drop-out rate due to protocol deviation (Collins 2004).

Excluded studies

Thirty-six studies were excluded. The reasons for their exclusion are reported in the Characteristics of excluded studies table.
A further six studies are awaiting classification.

Risk of bias in included studies

None of the 12 studies met all of the criteria, across all of the domains, that would permit a judgement of low risk of bias. In the overall rating of the risk of bias, half of the studies (Gupta 2012; Jain 2010; Kaplan 2001; Pigadas 2008; Singh 2012; Sugar 2009) were categorised as at 'unclear risk' (plausible bias that raises some doubt about the results) because one or more criteria were assessed as unclear. The remaining studies (Agarwal 2011; Bhatt 2010; Collins 2004; Emam 2012; Schierle 1997; Siddiqui 2007) were judged to be at 'high risk' of bias as one or more of the criteria were not met. Further details of these assessments are given in the risk of bias table corresponding to each study in the Characteristics of included studies tables. Overall ratings are also presented in the risk of bias graph (Figure 2) and the risk of bias summary (Figure 3).

Allocation

The methods used to generate the allocation sequence and the method of concealing the sequence, such that participants and investigators enrolling participants could not foresee the upcoming assignment, are the most important and sensitive indicators for minimising bias in a clinical trial (Schulz 1995). The method of sequence generation was reported adequately in only five of the 12 trials; in the remainder it was not described at all or was, at best, unclear. Concealment of the allocation sequence was reported adequately in only two trials (Gupta 2012; Pigadas 2008).

Blinding

Whilst the challenges of blinding participants and personnel to the interventions considered in this review are recognised, few of the studies attempted to ensure that the outcome assessments were independent of the investigators. Consequently, in most of the studies, it was unclear if foreknowledge of the allocated interventions by participants and personnel could have been prevented during the study (performance bias), therefore the judgement given for this domain was 'unclear' with the exception of one (Bhatt 2010). In the latter study, it was explicitly stated that "blinding was not used", therefore a judgement of 'high risk' of bias was given. As

the investigators in most of the studies were the outcome assessors and were generally not 'blinded' to the allocated interventions (detection bias) a judgement of 'high risk' of bias was given for this domain in six of the studies, with a further four judged 'unclear' (Gupta 2012; Pigadas 2008; Singh 2012 and Sugar 2009) and only the remaining two scored as 'low risk' (Jain 2010 and Kaplan 2001).

Incomplete outcome data

In the majority of studies incomplete outcome data appear to have been adequately addressed; missing data were reasonably well-balanced across intervention groups with similar reasons for absent data across groups. However, in two studies (Bhatt 2010; Siddiqui 2007) there were substantial losses to follow-up and the explanation and reporting of missing outcome data were largely inadequate, therefore these studies were adjudged to be at 'high risk' of bias for this domain.

Selective reporting

Although study protocols were unavailable for any of the studies, in general the outcomes listed in the 'Methods' section were comparable to the reported results.

Other potential sources of bias

There did not appear to be any reason for concern about other potential sources of bias in any of the included studies.

Effects of interventions

All 12 studies included in this review evaluated the effects of open (surgical) interventions to manage mandibular fractures, the majority used some form of external fixation (i.e. IMF, eyelet wiring with or without archbars and elastics). Three (Schierle 1997; Siddiqui 2007; Sugar 2009) of the 12 studies evaluated the effects of interventions in which only the mandibular angle was involved, eight included participants with fractures at multiple sites, some of which included the angle, and one study was confined to analysis of symphyseal and parasymphyseal fractures (Gupta 2012).

Comparisons of interventions for the management of multiple mandibular fractures not involving the condyles

1. Locking titanium plates versus non-locking titanium plates

Two studies compared the effects of these interventions (Agarwal 2011; Collins 2004).

Primary outcomes

Patient-oriented

- Restoration and, if reported, the degree of function to include chewing, swallowing, speech and the ability to wear dentures

Although one of the studies (Agarwal 2011) reported bite force measurements as an outcome, this related to the ability of the plates to withstand masticatory loads during function and, although not directly relevant to this outcome, constitutes a surrogate or proxy outcome. The investigators indicated that functional occlusion was achieved in all participants in both intervention groups, however the measurement of this outcome was not clearly reported.

- Facial appearance

Nothing reported in either of the included studies.

- Impact on well-being and quality of life

Nothing reported in either of the included studies.

Clinical

- Requirement for additional open (surgical) or closed (non-surgical) interventions

Only one of the studies (Collins 2004) provided data for this outcome; 6/122 participants had minor complications (three in each group): five required surgical removal of the locking plates, and one post-operative malocclusion was managed with elastic traction and occlusal equilibration.

- Post-operative pain (duration and intensity) and pain relief (including impact)

Agarwal 2011 indicated that there was a significant decrease in pain measured as visual analogue scale (VAS) scores from week 1 to follow-up at 3 months and, although they reported that there was no difference between the groups at the follow-up visits, no data were presented in support of these conclusions.

- Post-operative adverse events and complications

In Agarwal 2011 at 3-week follow-up, paraesthesia occurred in one participant in the non-locking plate group although this resolved at 3 months. No paraesthesia was noted in the locking plate group. Infection rates were similar in each group at 6 weeks and at 3 months, and post-operative swelling persisted in 20% of participants in both groups at weeks 1 and 3, reducing to 10% in the locking plate group at 3 months. The intergroup differences for these complications were not reported as being significant. The investigators indicated that there was no significant difference in the mobility of fracture segments between the groups but provided no supporting data. At the 6-week follow-up in Collins 2004 there

was no reported difference in risk of infection, between the intervention groups (odds ratio (OR) = 0.90, 95% confidence interval (CI) 0.1 to 7).

Secondary outcomes

Only one of the studies (Collins 2004) comparing these interventions reported data for one of the secondary outcomes prespecified for this review.

Process

- Drop-out rate due to protocol deviation

Early, from hours up to 2 weeks, premature removal of IMF was reported in 13 of the 90 participants analysed. However, the report provided limited details other than the participants themselves releasing their IMF or indicating "the wires fell off" (Collins 2004).

2.Titanium plates versus bioresorbable plates

One study compared these interventions (Bhatt 2010). Substantial (38%) and unbalanced losses to follow-up at the 2-month recall provided data that were largely unusable and should be considered unreliable, therefore we report only the assessments obtained 1 month post-operatively.

Primary outcomes

Patient-oriented

- Restoration and, if reported, the degree of function to include chewing, swallowing, speech and the ability to wear dentures

At the first month follow-up visit 17/20 (85%) patients per group returned for assessment and there was no difference between the intervention groups in the proportion of participants 3/17 (risk ratio (RR) = 1, 95% CI 0.23 to 4.27) in each group unable to chew hard food. It was not clear whether a validated tool was used to assess this outcome.

- Facial appearance

Not reported.

- Impact on well-being and quality of life

Not reported.

Clinical

- Requirement for additional open (surgical) or closed (non-surgical) interventions

Plate removal was statistically more likely in the titanium group (Fisher's exact test: $P < 0.05$) with infection leading to plate removal in one participant in the titanium group 2 months post-operatively. A further 4/21 (19%) participants, with six fracture sites, in the same intervention group required re-operation for plate removal. Additional surgery was not required in any participant in the resorbable group, although two participants required maxillo-mandibular fixation (MMF) for an additional 2 weeks.

- Post-operative pain (duration and intensity) and pain relief (including impact)

Although there were some losses to follow-up, 4/21 (19.0%) in the titanium group and 2/19 (10.5%) in the resorbable group, at the 1-month recall, we were able to re-analyse the individual patient data provided by the investigators. The proportion of participants with no pain was 7/21 (33.3%) and 8/19 (42.1%) in the titanium and resorbable groups, respectively (RR = 1.26, 95% CI 0.57 to 2.82) . Mild pain occurred in 9/21(42.9%) participants in the titanium group compared to 6/19 (31.6%) in the resorbable group (RR = 0.74, 95% CI 0.32 to 1.68). Moderate pain was experienced in 1/21(4.8%) in the titanium and 2/19 (10.5%) in the resorbable group (RR = 2.9, 95% CI 0.22 to 22.5). Severe pain was unique to participants in the resorbable group 1/19 (5.3%) (Additional Table 1). However, the investigators did not accurately report the methods used to evaluate pain severity in their studies. Consequently we are unable to speculate on the reliability of the pain assessment techniques. Therefore, the outcome data reported in this review are restricted to the proportion of participants with residual pain (of any degree of severity) at the 1-month recall visit.

- Post-operative adverse events and complications

Dehiscence occurred in 3/32 (9.4%) sites in the titanium group and 5/25 (20%) in the resorbable group within the first few weeks post-operatively, although this resolved with antibiotic therapy and local measures. Outcomes for several parameters of care according to the American Association of Oral and Maxillofacial Surgeons were measured (Additional Table 2 and Table 3). In the immediate post-operative period, mental nerve paraesthesia occurred in 18/32 (56.3%) titanium sites and 21/25 (84%) sites in the resorbable group. Neurosensory disturbances, reported at the 1-month post-operative recall, decreased slightly with 13/32 (40.6%) versus 18/25 (72.0%) in the titanium and resorbable groups affected, respectively (Additional Table 2).
At 1-month post-operatively, the risk of mobility expressed as the risk difference (RD) was 17.8%, and moderate soft tissue deformity (RD = 12.5%) were higher in the resorbable group, whereas the risk of chronic infection (RD = -3.1%) was higher in the titanium group. Small differences in risk of malocclusion (2.0%) or inability to chew hard foods (1.5%) were observed between the intervention groups. Additionally, no complications necessitating

re-operation and need for alternative treatment in either group were reported 1 month post-operatively (Additional Table 3).

Secondary outcomes

Process

No data were reported for these outcomes.

3. Two lag screws versus one lag screw

Only one study compared these interventions (Emam 2012).

Primary outcomes

Patient-oriented

- Restoration and, if reported, the degree of function to include chewing, swallowing, speech and the ability to wear dentures

The investigators stated that the restoration of the original occlusion, as assessed visually, was similar in both groups (P > 0.05). Occlusal correction was not achieved in just one participant in the two lag screws group. This is not a directly patient relevant outcome. It is a surrogate/proxy outcome that provides indirect evidence on the effect on the patient-oriented outcomes.

- Facial appearance

Not reported.

- Impact on well-being and quality of life

Not reported.

Clinical

- Requirement for additional open (surgical) or closed (non-surgical) interventions

Not reported.

- Post-operative pain (duration and intensity) and pain relief (including impact)

Only "average pain scores", rated "using a scale of 1 to 10", were reported as 6.6 in the two lag screws group and 6.4 in the one lag screw with archbars group at the first week follow-up visit. After 2 weeks these values were: 2.5 (two lag screws group) and 2.1 (one lag screw group). Confidence intervals were not reported.

- Post-operative adverse events and complications

Three participants in the two lag screws group experienced post-operative complications: malocclusion (one) and paraesthesia of the mental nerve (two) which resolved after 3 months. There were no reports of post-operative complications in the one lag screw group.

Secondary outcomes

Process

- Intraoperative complications

Drill bit fracture occurred during preparation in one participant in the two lag screws group.

- Drop-out rate due to protocol deviation

Not reported.

4. 3D miniplates versus standard plates

Two studies compared these interventions and provided very limited data for few of the outcomes (Jain 2010; Singh 2012).

Primary outcomes

Patient-oriented

- Restoration and, if reported, the degree of function to include chewing, swallowing, speech and the ability to wear dentures

Nothing was reported other than that all participants in both groups in Jain 2010 had "satisfactory post-operative occlusion". It is not clear whether this outcome was measured using a validated tool.

- Facial appearance

Not reported.

- Impact on well-being and quality of life

Not reported.

Clinical

- Requirement for additional open (surgical) or closed (non-surgical) interventions

In Jain 2010 surgical site infection in 2/20 participants in the 3D miniplates group required wound debridement, drainage, antibiotic therapy and IMF for a 3-week period; however, no infection was recorded for any of the patients in the standard fixation group. In Singh 2012, the number of patients who required post-operative MMF were recorded. The trialists waited 24 hours and then

assessed the occlusion. Patients with any occlusal discrepancy received IMF for 5 days. In the 3D miniplates group, eight out of 25 patients (32%) required MMF and in the conventional miniplates group 17 out of 25 patients (68%) required IMF (RR = 0.47, 95% CI 0.25 to 0.88, P = 0.01).

- Post-operative pain (duration and intensity) and pain relief (including impact)

Singh 2012 evaluated post-operative pain using VAS during the first week, fourth week, eighth week and third month after treatment. They reported no significant difference in pain experienced between the groups although details are not provided to verify this.

- Post-operative adverse events and complications

In the 3D miniplates group (Jain 2010) a number of participants experienced post-operative events: infection (two), segmental mobility (two), proximity to mental nerve or roots of teeth (two), and based on radiological assessment unsatisfactory reduction (one), and unsatisfactory fixation (four). In the standard miniplate group, only one participant had unsatisfactory fixation. The only statistically significant difference between the groups observed was in relation to fixation (t test: P = 0.03). In the Singh 2012 study, two patients in the 3D plate group and three patients in the conventional plate group developed infection. In addition, two complications occurred in the 3D plate group and three in the conventional group.

Pooling of data for post-operative infection from both studies showed no significant differences between the 3D miniplate and conventional intervention groups (RR 1.26, 95% CI 0.19 to 8.13, P = 0.81, I^2 = 27%). However, the studies involved only a small number of participants with a low number events. Therefore, these results should be interpreted with caution (Analysis 1.1).

Secondary outcomes

Process

Nothing was reported for any of these outcomes.

5. Immediate versus delayed mobilization after open reduction

One study compared this approach following open reduction (Kaplan 2001).

Primary outcomes

Patient-oriented

- Restoration and, if reported, the degree of function to include chewing, swallowing, speech and the ability to wear dentures

Limited data were provided; at the conclusion of the study all participants indicated that they had returned to their '"baseline bite".

- Facial appearance

Not reported.

- Impact on well-being and quality of life

Not reported.

Clinical

- Requirement for additional open (surgical) or closed (non-surgical) interventions

In the IMF intervention group, one (7.7%) participant had a wound infection and plate exposure leading to its subsequent removal 4 months post-operatively.

- Post-operative pain (duration and intensity) and pain relief (including impact)

Pain was assessed (scale 1 to 10, 1 = no pain, 10 = the worst) and reported as minor in both treatment groups throughout the study, with no significant differences found at any of the three time points (Additional Table 4).

- Post-operative adverse events and complications

One wound separation and one case of infection was reported in the immobilization intervention group. Assessment (scale 1 to 3, 1 = normal, 3 = absent sensation) of the status of the inferior alveolar nerve was undertaken at each post-operative visit. No statistically significant difference was noted between the intervention groups at the 6-week (P = 0.76), 3-month (P = 0.87), or 6-month (P = 0.99) evaluations. Data for the subjective assessments of trismus (scale 1 to 10, 1 = no problems, 10 = severe) indicated no difference between the two intervention groups at the 6-week, 3- and 6-month time points (Additional Table 5). Trismus based on recordings of the interincisor distance showed gradual improvement in both groups and was reported as not statistically significant between the groups at the 6-week (P < 0.43), and 6-month (P < 0.99) time points.

Secondary outcomes

None of the secondary outcomes for this review were considered by the investigators in this study.

6. Rapid IMF™ versus eyelet wire ties

Only one study involved comparison of these interventions (Pigadas 2008). Although the principal objective was to assess the incidence of surgical glove perforation between the two interventions, the investigators also recorded other intraoperative complications associated with the interventions.

Primary outcomes

None of the primary outcomes were addressed.

Secondary outcomes

Process

- Intraoperative complications

In the rapid IMF group, there were 15/60 intraoperative complications; loosening or fracture of the anchorage ties (11), minor gingival lacerations (two), crown dislodgement (one), and fracture of the power chain (one).
Intraoperative complications in the eyelet wire group (6/60) included minor gingival lacerations (five) and loosening of the eyelet wires (one). The investigators reported that although the incidence of complications was significantly lower in the eyelet group (RR = 2.6, 95% CI 1.0 to 7.0, P = 0.036) these did not appear to affect the surgical outcome.

7. One microplate + one miniplate versus two miniplates

Only one study compared the efficacy and stability of one microplate in conjunction with one miniplate versus two miniplates in patients with isolated mandibular fractures in the interforaminal region (Gupta 2012). However, the data reported in the trial did not satisfy our inclusion criteria.

Comparisons of interventions for the management of fractures of the angle of the mandible only

1. Two miniplates (transbuccal) versus one miniplate + two screws (intraoral at external oblique)

Two studies compared these interventions (Schierle 1997; Siddiqui 2007).

Primary outcomes

Patient-oriented

- Restoration and, if reported, the degree of function to include chewing, swallowing, speech and the ability to wear dentures

Only one study(Siddiqui 2007) reported this outcome as subjective and objective assessments of malocclusion, although the methods used in the assessment and the scale used to rate the degree of malocclusion were not reported. Subjective assessments of malocclusion were reported for 3/36 (8.3%) participants in the single miniplate group and 1/26 (3.8%) in the two-miniplate group (RR = 2.17, 95% CI 0.24 to 19.68). Objective assessment demonstrated malocclusion in 1/36 (2.8%) and 1/26 (3.8%) in the single and two miniplates groups, respectively (RR = 0.72, 95% CI 0.05 to 11.02). This is a surrogate outcome providing indirect evidence on the effect of the interventions on important patient-oriented outcomes.

- Facial appearance

Facial scarring, as a result of access through the transbuccal route, occurred in two participants in the two-miniplate group (Siddiqui 2007).

- Impact on well-being and quality of life

Nothing was reported in either study.

Clinical

- Requirement for additional open (surgical) or closed (non-surgical) interventions

Schierle 1997 reported infection in one participant in both the single (6.3%) and two (6.7%) miniplates group, leading to surgical removal of hardware after 43 and 47 days, respectively (P = 0.74). Plate removal was necessary in 2/36 (5.6%) in the single miniplate compared with 3/26 (11.5%) in the two-miniplate group (P = 0.66) in Siddiqui 2007. The pooled estimate from the two studies did not demonstrate a difference in respect of additional surgical interventions (RR = 0.78, 95% CI 0.19 to 3.11).

- Post-operative pain (duration and intensity) and pain relief (including impact)

Neither study reported on this outcome.

- Post-operative adverse events and complications

The only complications reported in Schierle 1997 were infection in one participant (6.3%) in the single miniplate group, and one (6.7%) in the two-miniplate group with no significant differences between intervention groups (P = 0.74). There were no reports of post-operative malocclusion or delayed or non-union of fractures.

In Siddiqui 2007 22/36 (61%) participants in the single miniplate group had one or more complications and 14/26 (54%) in the two-miniplate group. Lip numbness was assessed both subjectively and objectively. Subjective assessments of numbness constituted 15/36 (41.7%) in the single miniplate group compared to 10/26 (38.5%) in the two-miniplate group (P = 0.82), and objective assessments revealed 16/36 (44.4%) compared to 8/26 (31.7%), respectively (P = 0.29).

The risk of infection as reported was 4/36 (11.1%) participants in the single miniplate group compared to 4/26 (15.4%) in the two-miniplate group (P = 0.75); these responded to incision and drainage and antibiotic therapy. Pooling of data for post-operative infection from both studies revealed no significant differences between the single and two miniplates intervention groups (RR 1.32, 95% CI 0.41 to 4.22; P = 0.64; I^2 = 0%). However, the studies involved only a small number of participants with a low number events. Therefore, these results should be interpreted with caution (Analysis 2.1).

Secondary outcomes

None of the secondary outcomes were reported in either study.

2. Transbuccal miniplate combined with an intraoral approach versus intraoral alone approach

Only one study investigated these comparisons (Sugar 2009).

Primary outcomes

Patient-oriented

- Restoration and, if reported, the degree of function to include chewing, swallowing, speech and the ability to wear dentures

Persistence of malocclusion and its impact on restoration of function was minimal and was reported in one participant in each intervention group at the 3-month follow-up. There was minimal difference in the mean degree of interincisor assessed mouth opening at 3 months between the intervention groups; in the combined approach 37.68 mm (range: 17 to 50 mm) and 38.19 mm (range: 22 to 60 mm) in the intraoral alone. These are surrogate/proxy outcomes providing indirect evidence on the effect of the interventions.

- Facial appearance

The investigators reported that no patients were "recorded as having an unsatisfactory scar" but it was unclear how, when and by whom these assessments were made.

- Impact on well-being and quality of life

Nothing was reported.

Clinical

- Requirement for additional open (surgical) or closed (non-surgical) interventions

Plate removal within the first 90 days was required in 17/84 (20%) in the combined approach group compared to 20/56 (36%) in the intraoral only approach group (RR = 0.57, 95% CI 0.33 to 0.98, P = 0.042). Reasons for removal included: infection in 14/17 (82.4%), and non-union in 3/17 (17.6%) of the participants in the combined approach group. In the intraoral alone group removal was due to infection in 17/20 (85.0%), due to loose screws in 1/20 (5.0%) and due to non-union in 2/20 (10.0%).

- Post-operative pain (duration and intensity) and pain relief (including impact)

Nothing was reported.

- Post-operative adverse events and complications

There was no statistical difference in infection rates between the respective groups with 8/84 (9%) treated with the combined approach and 11/54 (20%) with the intraoral approach having persistent infection at 3 months subsequent to the procedure (RR = 0.47, 95% CI 0.20 to 1.09, P = 0.071). The rate of non-union was found to be identical in both groups (3.6%) with 3/84 in the combined group and 2/56 in the intraoral group failing to unite (RR = 1, 95% CI 0.17 to 5.79). One week following the procedure, wound dehiscence was more frequent in the intraoral only group (9/54: 16.7%) than in the combined approach group (10/84: 12%), although this difference was not of statistical significance (RR = 1.4, 95% CI 0.61 to 3.22, P = 0.43). At the end of the first month the rate of dehiscence increased to 25% (14/54) in the intraoral group and 15% (13/84) in the combined approach group (RR = 1.68, 95% CI 0.85 to 3.28, P = 0.13). By the third month, 21% (12/54) of the intraoral alone group had wound dehiscence or granulation tissue or both compared to 9% (8/84) of the combined approach group (RR = 2.33, 95% CI 1.02 to 5.33, P = 0.039).

Secondary outcomes

Nothing was reported for either of the secondary outcomes.

DISCUSSION

The management of mandibular fractures without condylar involvement may be influenced by a range of local conditions and factors which include the degree of displacement, the extent of associated problems and the anatomic location of the fracture.

However, in view of the wide range of possible interventions, a number of technical and surgical controversies persist. Although there is a lack of consensus as to whether surgical interventions can give better results than closed (non-surgical) treatment, there are certain types of fracture that do not lend themselves to treatment by closed (non-surgical) methods. Consequently, randomised trials comparing all types of mandibular fractures cannot be justified; albeit for the majority of situations (i.e. single fractures, undisplaced fractures or multiple fractures without complications outside the maxillofacial region), randomised controlled trials are the preferred study design to assess the best approach to treatment.

The objectives of this systematic review were to undertake a complete analysis of outcomes both from an objective viewpoint and with respect to patient reports. Given that assessment of key parameters (e.g. occlusion, facial symmetry or nerve function) prior to the event leading to the fracture is impossible, final assessments from a patient's perspective are often essential to gauge the response to interventions. Unfortunately, many of these patient-reported outcomes were poorly or incompletely described in the included studies or were assessed in a number of different ways. While it is important that future studies do consider patient-centred outcomes, there is also an onus on investigators to provide consistent and standardised reporting.

The sparsity of evidence identified in this review may reflect a range in the diversity and questionable reliability of the traditional, normative predictors of success. For example, a major outcome in many studies was the need for secondary surgery; an outcome of this nature is likely to be subjective, with different clinicians having individual thresholds for further treatment. In addition, causes of further treatment may vary, ranging from major complications such as non-union or malunion to minor problems (e.g. infection necessitating plate removal). Furthermore, given that the aetiology of mandibular fractures, particularly multiple fractures, is typically related to significant traumatic episodes, robust analysis can be compromised by difficulty in separating the response to surgery from extraneous physical and psychological injury. Consequently, assessment of pain scores and other patient-reported outcomes can be complex, and may be confounded by other clinical parameters. Use of strict selection criteria with omission of certain subtypes or causes of injury (e.g. maxillofacial trauma with multiple non-facial injuries) is therefore important during the conduct of future research.

There is wide agreement that factors, such as the degree of surgical complexity and the possibility of post-operative complications with either open (surgical) or closed (non-surgical) treatment, may influence clinical decisions. This review illustrates that there is currently insufficient high quality evidence to support a single approach, either open (surgical) or closed (non-surgical), in the management of the fractured mandible without condylar involvement. Therefore, until more robust evidence in the form of well-designed randomised controlled trials is available, treatment decisions will continue to be based on individual circumstances and clinical experience.

Summary of main results

Twelve studies, six of which were assessed as high and six as unclear risk of bias were included. A total of 689 participants aged 16 to 68 years with 830 fractures were investigated. Unfortunately, there were very limited numbers of trials with small sample sizes conducted for each comparison and outcome. Therefore, our results and conclusions should be interpreted with caution.

Interventions and comparisons considered were open reduction involving differing plate materials and morphology (i.e. use of one or two lag screws; early and delayed mobilization; eyelet wires versus Rapid IMF™ and management of angle fractures with intraoral or transbuccal approaches). Patient-oriented outcomes appear to have been largely ignored and post-operative pain scores were either unavailable or inadequately reported in the majority of the included studies.

Pooled data for post-operative infection in two studies indicated no significant difference between the single and two miniplates groups (RR = 1.32, 95% CI 0.41 to 4.22, P = 0.64, I^2 = 0%). Likewise, no difference in post-operative infection between use of two 3D and standard (2D) miniplates was determined (RR = 1.26, 95% CI 0.19 to 8.13, P = 0.81, I^2 = 27%). However the studies involved a small number of participants with a low number of events. Surgical site infection was also reported in other studies but no significant differences were identified.

Overall completeness and applicability of evidence

Although a relatively large number of studies were included in this review, these were of moderate or low quality and reporting of outcome data was suboptimal. Consequently, the overall quality of the evidence was considered to be low, precluding clearcut conclusions in relation to the relative merits of one technique over another. In addition, while there is an increasing emphasis on patient-reported measures of outcome in health care generally, there was limited consideration given to patient relevant outcomes in the studies included in this review.

Quality of the evidence

Limitations in study design and implementation

Although the overall clinical design of the included studies appeared to be adequate, our assessments of risk of bias revealed limitations in the quality of the studies covering most of the interventions.

There was considerable variation in the reporting of these studies and in particular the methods used to generate the sequence, to conceal the allocation, and the measures taken to blind investigators and participants. These factors, allied to unsuccessful attempts to contact many of the investigators for additional information, created difficulties in making accurate assessments of the risk of bias in some of the included studies.

The inability to blind investigators and outcomes assessors to the interventions, which is considered a valuable step in reducing bias, presented challenges in the design of many of the studies. Data for losses to follow-up and the final disposition of missing participants, where failure was a key outcome, were additional indicators of a likelihood of biased assessment of the intervention effect. Independent post-operative evaluation could have helped to limit the effects of subjectivity in the assessment of these outcomes.

Indirectness of the evidence

The objectives of this review were broad, namely to compare the effects of any intervention (open/surgical or closed/non-surgical) in the management of mandibular fractures without condylar involvements. Some difficulties were encountered in terms of addressing a restricted version of the main review question with regard to criteria including population, intervention, comparator and outcomes. In particular, adolescent patients were included in some studies, there was also a preponderance of males in most studies.

Both mandibular fractures with and without condylar involvement were reported in some randomised controlled trials. Attempts were made to omit these data from the analysis.

In addition, data were absent for many patient-preferred outcomes, with patient-centred outcomes largely overlooked and the total absence of any assessments of the impact of interventions on quality of life in the included studies. In certain cases, only surrogate/proxy outcome measurements related indirectly to our patient-oriented outcomes were reported. One of the included studies evaluated the extent of mouth opening using the interincisor measurement which is a surrogate/proxy outcome of a patient-oriented outcome on restoration of function (i.e. chewing and speaking). However, the research settings were in general considered appropriate and relevant to the majority of treatment centres undertaking management of mandibular fractures.

Inconsistency of results

The presence of clinical heterogeneity, although to a certain degree expected under the broad scope of the review, and the inability to extract much usable data, made it difficult to further assess the consistency of the results between the studies.

Imprecision of results

The rather limited number of studies, albeit of adequate sample size and duration and examining similar interventions, that were included in this review did not permit any substantive assessment of the degree of precision of effect.

Publication bias

Every effort was made to identify additional published studies. The low number of studies comparing similar interventions did not permit a funnel plot assessment of publication bias (Higgins 2011).

Potential biases in the review process

Strident attempts were made to limit bias in the review process by ensuring a comprehensive search for potentially eligible studies. The authors' independent assessments of eligibility of studies for inclusion in this review and the extraction of data minimised the potential for additional bias beyond that detailed in the risk of bias tables.

Agreements and disagreements with other studies or reviews

While this review only considered randomised controlled trials, a recent systematic review and meta-analysis (Andreasen 2008) compared healing with open and closed techniques but no randomised controlled trials were included. All of the studies were retrospective and thus their conclusions need to be viewed within the context of being at risk of bias. In addition, the investigators in these studies did not appear to have considered or included any patient-reported outcomes in their assessments. Consequently, higher complication rates with open techniques are likely to be have been confounded by the use of open techniques in the management of more displaced and complex fractures.

A further review, which included both retrospective and prospective studies, compared outcomes with resorbable plates and screws and involved both traumatic and planned mandibular fractures (e.g. during orthognathic surgery) (Agarwal 2009). A comparison of five outcomes following rigid fixation and mono-cortical fixation of mandibular fractures were reported in Regev 2010 but both retrospective and prospective studies were included and combined in the meta-analysis with consideration of outcomes relating to mandibular angle fractures only.

AUTHORS' CONCLUSIONS

Implications for practice

There is a shortage of high quality evidence relevant to treatment modalities considered in this review; the effectiveness of interven-

tions for management of mandibular fractures without condylar involvement remains unclear. Clinical decisions regarding the most appropriate management of these cases must be based on clinical experience, and the nature of the presentation taking into account patients' preferences and choices.

Implications for research

While it is accepted that for practical reasons, trials testing surgical interventions are generally less common than therapeutic drug trials, there would appear to be a continuing need for further trials to evaluate the effectiveness of open reduction versus closed treatment of fractured mandibles without condylar involvement. Currently, most of the outcome measurements used in clinical trials are not standardised patient-oriented outcome measurements. Trialists should first develop a standardised set of patient-oriented outcomes before conducting further clinical trials. It is important that future trials are robust, well-designed and reported according to the CONSORT statement (http://www.consort-statement.org/) or the extensions of the CONSORT statement. They should also carefully consider the IDEAL recommendations for clinical trials evaluating surgical interventions (Ergina 2009; McCulloch 2009). Clear conduct and reporting will enable appraisal and interpretation of results, and accurate judgements to be made about the risk of bias, and the overall quality of the evidence. Although it is uncertain whether reported quality mirrors the true conduct of the study, it is noteworthy that studies with unclear methodology have been shown to produce biased estimates of treatment effects (Schulz 1995). Adherence to guidelines, such as the CONSORT statement, would promote transparent, better and more complete reporting.

A significant drawback of most published studies is that fractures in various locations throughout the mandible are included. It is known that some fractures, for instance those involving the angle of the mandible, have a higher risk of complications than in other locations. Restricting the inclusion criteria in future studies to fractures in specific regions of the mandible will yield more meaningful information. It would also be beneficial if future randomised controlled trials could focus more closely on comparisons of rigid fixation utilising strong plates (the AO technique) with one of the other commonly reported methods (e.g. closed reduction, miniplates or midsized plates).

Other variables that should be controlled or investigated in future studies include: infected and non-infected fractures, single fractures and multiply-fractured mandibles, and simple linear or comminuted fractures. Each of these criteria is important to control or analyse or both as they influence the decision to use either closed or open approaches to treatment, the amount of internal fixation hardware required, and timing of interventions.

For further research recommendations based on the EPICOT format (Brown 2006) see Additional Table 6.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Agarwal 2011

Methods	Randomised controlled trial Setting: Faculty of Dental Science, CSMMU, Lucknow, India Duration: January 2007 to January 2008
Participants	N = 20, male (19), female (1) Age range: lower limit unclear < 60 years, 16 to 30 years (60%) Cause of fractures: road traffic accident (65%) FRACTURE SITES: 34 (parasymphysis most common, no other data) INCLUSION CRITERIA: • non-comminuted mandibular fractures at any site EXCLUSION CRITERIA: • other facial fractures • local infection • history of diabetes • prolonged steroid therapy • compromised immunity • associated bone pathology BASELINE CHARACTERISTICS: none reported
Interventions	INTERVENTION: Synthes 2 mm locking titanium miniplates CONTROL: Synthes non-locking titanium miniplates Elastic intermaxillary fixation for 7 to 10 days
Outcomes	• Pain (VAS 1 to 10)* • Swelling* • Infection* • Paraesthesia* • Hardware failure (plate fracture)* • Mobility of fracture fragments* • Bite force at incisor, right molar, and left molar regions Outcome assessments and follow-up: 1, 3, and 6 weeks and 3 months *Denotes pre-specified outcome
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "The patients were randomly divided into 2 equal groups" Comment: Insufficent information to

Agarwal 2011 (*Continued*)

		make a clear decision
Allocation concealment (selection bias)	Unclear risk	No information reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not discussed not feasible Comment: Unclear if lack of blinding is likely to influence outcome
Blinding of outcome assessment (detection bias) All outcomes	High risk	Comment: Blinding of participants and assessors possible, lack of blinding is likely to exert an influence on outcome measurement
Incomplete outcome data (attrition bias) All outcomes	Low risk	No losses to follow-up Comment: Probably low risk of bias
Selective reporting (reporting bias)	Low risk	Although the protocol was unavailable there was no evidence of selective reporting. Outcomes listed in the methods section were comparable to those reported albeit with minimal data
Other bias	Low risk	The study appears to be free of other sources of bias

Bhatt 2010

Methods	Randomised controlled trial Setting: outpatient clinics Department of Oral and Maxillofacial Surgery, All India Institute of Medical Sciences, New Delhi, India Duration: October 2007 to December 2008
Participants	N = 40, male (38), female (2) Age range 18 to 48 years. Mean age 28.7 years Cause: assault (37%), falls (32%), road traffic (26%), sports injuries (5%) FRACTURE SITES: 57 (parasymphysis 9, symphysis 1, angle 10, body 3, combined angle-parasymphysis 34) INCLUSION CRITERIA: • linear fracture of the mandibular symphysis, parasymphysis, body, or angle EXCLUSION CRITERIA: • paediatric participants • major systemic diseases • infected or comminuted fractures • associated condyle or midface fractures RANDOMISED: 40 WITHDRAWALS/LOSSES TO FOLLOW-UP: • bioresorbable (1) reallocated to titanium group, lost to follow-up (1). Participants analysed (18) = 24 fracture sites • titanium (1) allocated from bioresorbable group, lost to follow-up (8).

	Participants analysed (13) = 19 fracture sites BASELINE CHARACTERISTICS: fracture sites: • titanium group: male 20, female 1; symphysis (1), parasymphysis (2), body (2), angle (5), combined with angle-parasymphysis (22). Displaced fractures (12); nerve paraesthesia (14) sites • bioresorbable group: male 18, female 1; symphysis (0), parasymphysis (7), body (1), angle (5) combined angle-parasymphysis (12). Displaced fractures (8) nerve paraesthesia (10) sites
Interventions	INTERVENTION: (21 titanium group) 2 mm locking plates screws (Synthes GmBh, Oberdorf, Switzerland) COMPARISON: (19 bioresorbable group) 2.5 mm plating system (Inion, Tempere, Finland); amorphous copolymer of L-lactide, D-lactide, and trimethylene carbonate. Parasymphysis fractures, a single plate in the intermental foramen region plus archbar and IMF for 2 weeks Post-operative: amoxicillin with clavulanate and metronidazole for 7 days
Outcomes	Nine complications based on the American Association of Oral and Maxillofacial Surgeons guidelines parameters of care (Meaders 1998): • mobility at fracture site* • malocclusion* • soft tissue deformity • infection* • chronic pain* • neurosensory disturbances* • tooth loss or vitality loss • inability to chew hard food* • need for alternative treatment (fixation system failure, persistent mobility of segments in post-op/follow-up, extended IMF period* Other complications: • need for repeat surgery for plate removal* • mobility at the site graded (in 1 or 2 planes, or with rotational mobility) • soft tissue deformity (mild, moderate, or severe) • chronic pain VAS: mild < 3, moderate < 7, or severe 7 to 10* Outcome assessments and follow-up: 1, 2, 4, 6 and 8 weeks *Denotes pre-specified outcome
Notes	Principal investigator provided IPD which was re-analysed by the review authors

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "allocated to either the titanium group or bioresorbable group using a computer-generated randomisation table" (page 1844) Comment: Probably done

Bhatt 2010 (*Continued*)

Allocation concealment (selection bias)	Unclear risk	No information reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "blinding was not used" (page 1844) Comment: Blinding of participants and personnel was not feasible. Both participants and personnel were outcome assessors
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "blinding was not used" Outcomes assessed: • participant-assessed pain • personnel-assessed clinical evaluation Comment: Lack of blinding is likely to exert an influence on outcome measurement. High Risk of bias
Incomplete outcome data (attrition bias) All outcomes	High risk	Inconsistent reporting of outcomes data Email communication with principal investigator: Data set provided and re-analysed Available case analysis at 2 months, incomplete data for 8/21 (38%) titanium group, 1/19 bioresorbable group Comment: Substantial losses and imbalance across intervention groups, reasons unreported High risk of bias
Selective reporting (reporting bias)	Low risk	Although the study protocol was unavailable there was no evidence of selective reporting. Outcomes listed in the methods section were comparable to those reported, albeit with minimal data
Other bias	Low risk	The study appears to be free of other sources of bias

Collins 2004

Methods	Randomised controlled trial Setting: Harborview Medical Center (Seattle, WA) Duration: January 2002 to February 2003
Participants	N = 94, male (86), female(8) Age range: 14-58 years, mean 25.9 $\pm$ 6.7years Majority were Caucasian, followed by African American, Hispanics and Asians Cause: majority related to assaults

	FRACTURE SITES: 122 (parasymphysis 56, angle 50, body 16) INCLUSION CRITERIA: • non-comminuted mandibular fractures excluding condyle and coronoid process • no other facial fractures • no intracapsular condyle fracture • dentition to enable Erich archbars EXCLUSION CRITERIA: • unspecified WITHDRAWALS/LOSSES TO FOLLOW-UP: 4 participants no further details reported BASELINE CHARACTERISTICS: average number of days from injury to treatment: 3.9 $\pm$ 2.2 (range: 2 hours to 18 days)
Interventions	INTERVENTION: (64 sites) 2.0 mm locking Synthes plates (Synthes USA, Paoli, PA) CONTROL: (58 sites) 2.0 mm standard Synthes plates (Synthes USA, Paoli, PA) Identical surgical technique except that a locking drill guide used with the locking plates. Transoral approach, except angle fractures treated with a transbuccal trochar system Post-operative care: IMF 4 weeks post-operatively
Outcomes	PRIMARY OUTCOMES: • major complications: non-union and/or infection requiring debridement and re-application of a larger plate (2.4 mm)* • minor complications: localized infection with complete bony healing requiring hardware removal only; minor occlusal discrepancies treated with elastics* SECONDARY OUTCOMES: • operative time Outcome assessments and follow-up: minimum at 6 weeks post-operatively *Denotes pre-specified outcome
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "Patients were randomly assigned to receive .....according to a computer-generated randomiser" (page 1393) Comment: Probably done
Allocation concealment (selection bias)	Unclear risk	No information reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported Comment: Unclear if lack of blinding is likely to influence outcome

Collins 2004 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	High risk	Comment: Blinding of participants and personnel was not feasible; lack of blinding is likely to exert an influence on outcome measurement
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	4 participants lost to follow-up with per protocol analysis Comment: Low attrition rate, reasons for losses unreported
Selective reporting (reporting bias)	Low risk	Although the study protocol was unavailable, there was no evidence of selective reporting Outcomes listed in the methods section were comparable to those reported, albeit with minimal data
Other bias	Low risk	The study appears to be free of other sources of bias

Emam 2012

Methods	Randomised controlled trial Setting: oral and maxillofacial surgery department, Cairo University Faculty of Oral and Dental Medicine, Egypt, Duration: not stated
Participants	N = 20, male (20), female (0) Age range: 15 to 45 years, mean 28.3 $\pm$ 2.78 FRACTURE SITES: 25 parasymphysis (+ associated 4 subcondylar, 1 angle) INCLUSION CRITERIA: • unilateral anterior mandibular fractures with or without further mandibular fractures EXCLUSION CRITERIA: • systemic disease • infection • local pathology in the mandible • inadequate dentition BASELINE CHARACTERISTICS: • intervention: male 10, female 0. Fracture site: left symphysis (6), right symphysis (4), associated mandibular injuries (4) • control: male 10, female 0. Fracture site: left symphysis (6), right symphysis (4), associated mandibular injuries (1), subcondylar (3)
Interventions	INTERVENTION: 2 lag screws - 1 screw placed several mm above inferior mandibular border, other 5 mm below the tooth apices Archbars used for IMF removed after lag screw placement CONTROL: 1 lag screw placed several mm above the inferior mandibular border. The archbar crossing the fracture line used in intermaxillary fixation was left in place

Emam 2012 (*Continued*)

	Post-operative care: 3 gm of Unasyn and 8 mg of dexamethasone intravenously. IMF for 3 weeks
Outcomes	• Wound dehiscence* • Infection • Segmental mobility* • Post-operative occlusion* • Significant post-operative complications* • Radiological evaluation of reduction, and fixation • Operative time Outcome assessments and follow-up: 1, 2, 4, 6 weeks and 2 months *Denotes pre-specified outcome
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "The treatment method was randomised among all patients, with no preference given in the selection of treatment method among the study subjects" (page 2) Comment: Insufficient information to make a clear decision
Allocation concealment (selection bias)	Unclear risk	No information reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported but not feasible Comment: Unclear if lack of blinding is likely to influence outcome
Blinding of outcome assessment (detection bias) All outcomes	High risk	Comment: Blinding of assessors is not mentioned, this is likely to exert an influence on outcome measurement
Incomplete outcome data (attrition bias) All outcomes	Low risk	No losses to follow-up Comment: Probably low risk of bias
Selective reporting (reporting bias)	Low risk	Although the study protocol was unavailable there was no evidence of selective reporting Outcomes listed in the methods section were comparable to those reported, albeit with minimal data
Other bias	Low risk	The study appears to be free of other sources of bias

Gupta 2012

Methods	Randomised controlled trial Setting: Department of Oral and Maxillofacial Surgery, CMS Medical University, Chandigarh, India Duration: 1 year
Participants	N= 20 patients, gender not reported Age range: not reported FRACTURE SITES: isolated mandibular fractures of the interforaminal region INCLUSION CRITERIA: • isolated mandibular fractures of the interforaminal region EXCLUSION CRITERIA: • comminuted fracture of the mandible • infection • concomitant midface and dentoalevolar fractures BASELINE CHARACTERISTICS: no specific data reported
Interventions	INTERVENTION: Osteosynthesis using the combination of 1 microplate (Lieblinger 1.2 mm titanium system (Stryker, Freiburg, Germany), subapical) and 1 miniplate (Lieblinger 2.0 mm titanium system (Stryker, Freiburg, Germany)) CONTROL: Osteosynthesis using 2 miniplates (Lieblinger 2.0 mm titanium system (Stryker, Freiburg, Germany))
Outcomes	PRIMARY OUTCOMES: • bite force: measured using a bite force recorded SECONDARY OUTCOMES: • complications: infection reported in 2 patients; no mention of any other complications. Infections at fracture site are not differentiated from infection at implant sites
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The randomisation was done using sealed opaque envelopes with the treatment allocation inside each envelope" (page 1904) Comment: Probably low risk of bias
Allocation concealment (selection bias)	Low risk	"The randomisation was done using sealed opaque envelopes with the treatment allocation inside each envelope" (page 1904) Comment: Probably low risk of bias

Gupta 2012 (*Continued*)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported Comment: Unclear if lack of blinding is likely to influence outcome
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcomes were participant and investigator assessed Blinding of participants and outcome assessors feasible but not done Comment: Unclear risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	No losses to follow-up Comment: Probably low risk of bias
Selective reporting (reporting bias)	Low risk	Although the study protocol was unavailable, the outcomes listed in the methods section were comparable to the reported results Comment: Low risk of bias
Other bias	Low risk	The study appears to be free of other sources of bias

Jain 2010

Methods	Randomised controlled trial Setting: Department of Oral and Maxillofacial Surgery, Sri Hasanamba Dental College and Hospital, Karnataka, India Duration: May 2008 to April 2009
Participants	N = 40, male (35), female(5) age range 28 to 34 years Cause: majority road traffic accident FRACTURE SITES: 40 (parasymphysis 18, symphysis 8, angle 4, body 10) INCLUSION CRITERIA: • 20 to 50 years of age • isolated mandibular fracture EXCLUSION CRITERIA: • local pre-operative infection • medically-compromised patients • unwilling to return for follow-up BASELINE CHARACTERISTICS: • intervention: male (18), female (2). Fracture site: symphysis (4), para symphysis (9), body (5), angle (2) • control: male 17, female 3. Fracture site: symphysis (4), para symphysis (9), body (5), angle (2) (90%) dentate, (10%) partially dentate Mean interval from trauma to surgery: 62.6 hours (range 1 to 152 hours)

Interventions	INTERVENTION: (20) 3D 2 mm stainless steel plates CONTROL: (20) standard miniplate Champy's system Post-operative care: prophylactic antibiotic cefotaxime 2 gm intravenously , and 1 gm orally bd for 4 days
Outcomes	• Wound dehiscence • Infection evaluated by criteria (Johnson 1984) • Segmental mobility • Post-operative occlusion • Post-operative complications Outcome assessments and follow-up: 1, 2, 4, 6 weeks and 2 months
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"...divided into 2 groups by lottery method and were matched for fracture site and age" (page 1569). However, in the results it is reported that there were a number of drop-outs with only 20 patients in each group for analysis. Depending on the timing and number of drop-outs, the randomisation may have been compromised
Allocation concealment (selection bias)	Unclear risk	No information reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: Blinding of participants and personnel was not feasible Both participants and personnel were outcome assessors
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "by a blinded senior oral surgeon for .." (page 1570) Comment: Low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	No losses to follow-up Comment: Low risk of bias
Selective reporting (reporting bias)	Low risk	Although the study protocol was unavailable, the outcomes listed in the methods section were comparable to the reported results Comment: Low risk of bias

Jain 2010 (*Continued*)

Other bias	Low risk	The study appears to be free of other sources of bias

Kaplan 2001

Methods	Randomised controlled trial Setting: level I trauma centre in the USA Duration: January 1997 to March 2000
Participants	N = 29, male (29), female (0) mean age 26.98 years FRACTURE SITES: 40 (parasymphysis 12, symphysis 2, angle 19, body 7) INCLUSION CRITERIA: • isolated mandibular fractures EXCLUSION CRITERIA: • comminuted fractures • concomitant maxillary or midface injuries • involvement of the ramus, condyle, coronoid process, alveolus, or dentition BASELINE CHARACTERISTICS: • intervention group: fracture sites (20): parasymphysis (6), angle (8), body (4), symphysis (2) • control: fracture sites (20): parasymphysis (6), angle (11), body (3)
Interventions	All participants: 2 mm titanium miniplates (Synthes Ltd, Paoli, PA craniofacial system) INTERVENTION: immediate mobilization CONTROL: 2 weeks (IMF) archbars with 24 gauge wire
Outcomes	• Occlusion (subjective rated 1 to 10) and objective* • Trismus (subjective and objective) 1 = no difficulties to 10 = severe problems* • Status of the inferior alveolar nerve* • Weight loss • Wound status* • Dentition • Infection* • Oral hygiene • Pain (rated 1 to 10, 10 = worst pain possible)* Outcome assessments and follow-up: 1, 2, 3, and 6 weeks and 3 and 6 months *Denotes pre-specified outcome
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "Patients meeting the inclusion criteria were randomly assigned to one of two treatment arms, either immediate mobilization or 2 weeks of IMF" (page 1521)

Kaplan 2001 (*Continued*)

		Comment: Insufficient information to make a decision
Allocation concealment (selection bias)	Unclear risk	No information reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Single blind (assessor only) Comment: Unclear if lack of blinding is likely to influence outcome
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "with one of the senior authors serving as the primary surgeon for each case and the other as the "blinded" examiner" . .. "the last three visits included a "blinded" examination by the nonoperating surgeon" (page 1521) Comment: Probably done, low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	No losses to follow-up Comment: Probably low risk of bias
Selective reporting (reporting bias)	Low risk	Although the study protocol was unavailable there was no evidence of selective reporting Outcomes listed in the methods section were comparable to those reported albeit with minimal data
Other bias	Low risk	The study appears to be free of other sources of bias

Pigadas 2008

Methods	Randomised controlled trial Setting: maxillofacial units of 3 university hospitals in UK Duration: November 2002 to November 2004
Participants	N = 120, male (112) female (8), age/gender unspecified but balanced across treatment arms and centres FRACTURE SITES: 173 no further details other than number of sites 1 (68), 2 (51), 3 (1), in each participant INCLUSION CRITERIA: • > 18 years • dentate • fracture requiring open reduction and internal fixation • temporary intraoperative IMF possible with either Rapid IMF or wiring technique EXCLUSION CRITERIA: • fractures requiring post-operative IMF or elastic traction • unco-operative patients RANDOMISED: 120

	WITHDRAWALS/LOSSES TO FOLLOW-UP: none BASELINE CHARACTERISTICS: • intervention: 24.2 ± 7.3 years • control: 24.6 ± 9 years
Interventions	INTERVENTION: IMF with Rapid IMF (60) CONTROL: eyelet wire ties and intermaxillary wires (60)
Outcomes	PRIMARY: • incidence of glove perforations per operation SECONDARY: • number and types of exposure by operators • incidence of unnoticed glove perforations • time and degree of difficulty for IMF application • intraoperative and post-operative complications* Outcome assessments and follow-up: only intraoperative assessments with no further time points *Denotes pre-specified outcome
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "Simple randomisation, stratified by centre, was used to allocate 20 patients to each group in each centre. Twenty forms for IMF with Rapid IMFTM and 20 forms for IMF with eyelet wires were generated for each centre and were placed within sealed envelopes. These were mixed, numbered and opened by the surgeon prior to the procedure in order to determine which technique was to be used" (page 717) This is in keeping with restricted, stratified randomisation as allocation was balanced Comment: Probably done and acceptable
Allocation concealment (selection bias)	Low risk	"Sealed envelopes" Comment: Probably done and acceptable
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No blinding Comment: Insufficient information to permit a clear judgement of the risk of bias
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No blinding Comment: Insufficient information to permit a clear judgement of the risk of bias

Pigadas 2008 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Low risk	No losses to follow-up Comment: Low risk of bias
Selective reporting (reporting bias)	Low risk	Although the study protocol was unavailable, the outcomes listed in the methods section were comparable to the reported results Comment: Low risk of bias
Other bias	Low risk	The study appears to be free of other sources of bias

Schierle 1997

Methods	Randomised controlled trial Setting: Department of Maxillofacial Surgery, University of Hanover, Germany Duration: unspecified
Participants	N = 31, male (23), female (8), age range: 19 to 52 years FRACTURE SITES: 38 mandibular angle. 7 participants with associated fractures: parasymphysis (5), condylar (2) INCLUSION CRITERIA: • mandibular angle fracture EXCLUSION CRITERIA: • other facial fractures • loss of more than 1 area of dental support • comminuted and infected fractures BASELINE CHARACTERISTICS: • intervention: 4 associated fractures, 1 third molar in fracture line • control: 3 associated fractures, 4 third molars in fracture line
Interventions	INTERVENTION: bicortical 2.0 mm titanium miniplate (Synthes Co, Switzerland) at the inferior border of the buccal cortex of the mandible CONTROL: monocortical fixation in the area of the external oblique line of the mandible, using a single 6-hole 2.0 mm titanium miniplate (Synthes Co, Switzerland) Third molars in fracture line removed IMF not used
Outcomes	• Infection* • Malocclusion correctable by minor grinding* • Delayed union or non-union* • Nerve injury, secondary to surgical manipulation* Outcome assessments and follow-up: minimum 6 months, no other time points specified *Denotes pre-specified outcome
Notes	
Risk of bias	

Schierle 1997 (*Continued*)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "prospective randomised study" (page 163) Comment: Insufficient information to make a clear decision
Allocation concealment (selection bias)	Unclear risk	Insufficient information to make a clear judgement
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	This intervention/control involved surgical procedures, which precluded blinding at the surgeon level Comment: Unclear if lack of blinding is likely to influence outcome
Blinding of outcome assessment (detection bias) All outcomes	High risk	Comment: Blinding of assessors was not mentioned, lack of blinding is likely to exert an influence on outcome measurement
Incomplete outcome data (attrition bias) All outcomes	Low risk	No losses to follow-up mentioned Comment: Probably low risk of bias
Selective reporting (reporting bias)	Unclear risk	Although the protocol was unavailable there was no evidence of selective reporting. Outcomes listed in the methods section were comparable to those reported, albeit with minimal data
Other bias	Low risk	The study appears to be free from other sources of bias

Siddiqui 2007

Methods	Randomised controlled trial Setting: Faculty of Dental Science, CSMMU, Lucknow, India, Duration: November 1995 to May 2001
Participants	N = 85, male (57), female (5) age range: 17 to 57 years FRACTURE SITES: 85 angle only INCLUSION CRITERIA: • mandibular angle • dentate • age 16 to 60 years EXCLUSION CRITERIA: • local sepsis • comminuted fractures requiring rigid fixation and/or extraoral access • multiple trauma

	• maxillary fractures • admitted to intensive care unit WITHDRAWALS/LOSSES TO FOLLOW-UP: • intervention: 15 • control: 8 Reasons and timing unreported BASELINE CHARACTERISTICS: no details reported
Interventions	INTERVENTION: 2-miniplate group, patients had a second plate inserted transbuccally, as near as possible to the mandibular angle CONTROL: single-miniplate group, a 2 mm titanium plate intraoral approach at the external oblique ridge with 2 secure screws either side of the fracture line Post-operative care: metronidazole, cefuroxime, and erythromycin intravenously perioperatively and < 24 hours post-operatively
Outcomes	• Malocclusion* • Infection* • Malunion, non-union, delayed union* • Lip numbness and weakness • Tooth damage • Scars • Need for plate removal* • Neurosensory deficits tested with von Frey hairs and recorded on Semme-Weinstein scale Outcome assessments and follow-up: 3 months post-operatively, no other time points specified *Denotes pre-specified outcomes
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "The patients were randomly allocated to the single- or two miniplate groups" (page 224) Comment: Insufficient information to make a clear decision No response from principal investigator
Allocation concealment (selection bias)	Unclear risk	Not reported. Insufficient information to make a clear decision
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported, not feasible Comment: Unclear if lack of blinding is likely to influence outcome

Siddiqui 2007 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	High risk	Comment: Blinding of participants and assessors possible, lack of blinding is likely to exert an influence on outcome measurement
Incomplete outcome data (attrition bias) All outcomes	High risk	Losses to follow-up: intervention 15 (37%) , control 8 (18%) Comment: Substantial and unbalanced between groups, high risk of bias
Selective reporting (reporting bias)	Low risk	Although the study protocol was unavailable there was no evidence of selective reporting Outcomes listed in the methods section were comparable to those reported albeit with minimal data
Other bias	Low risk	The study appears to be free of other sources of bias

Singh 2012

Methods	Randomised controlled trial Setting: Department of Oral and Maxillofacial Surgery, Postgraduate Institute of Dental Sciences, Pt. B.D. Sharma University of Health Sciences, Rohtak, Haryana, India Duration: 14 months, from August 2010 to September 2011
Participants	N = 50, male (46), female (4) age range: 17 to 46 years, average age 30.43 ± 8.23 years Causes of fractures: 21 road traffic accidents, 11 assaults, 8 fall/sport injury FRACTURE SITES: 56 fracture sites were included (28 in each group) INCLUSION CRITERIA: isolated mandibular fractures involving symphysis/parasymphysis and angle fractures without pre-existing infection and comminution EXCLUSION CRITERIA: no further information BASELINE CHARACTERISTICS: they did not report any comparison of the baseline characteristics between the 2 groups
Interventions	INTERVENTION: 28 fracture sites were treated with 2.0 mm titanium 3D plates CONTROL: 28 sites were treated with 2.0 mm titanium conventional miniplates
Outcomes	• Duration of the surgery (from the beginning of incision to surgical closure) • Pain (VAS) • Requirement for maxillomandibular fixation • Infection, paraesthesia, hardware failure (plate fracture), mobility between fracture fragments, occlusion
Notes	

Risk of bias

Singh 2012 (*Continued*)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Computer generated randomisation was used" (page 451) Comment: Probably low risk of bias
Allocation concealment (selection bias)	Unclear risk	Not reported. Insufficient information to make a clear decision
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported Comment: Unclear if lack of blinding is likely to influence outcome
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcomes were participant and investigator assessed Blinding of participants and outcome assessors feasible but not done Comment: Unclear risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No losses to follow-up Comment: Probably low risk of bias
Selective reporting (reporting bias)	Low risk	Although the study protocol was unavailable, the outcomes listed in the methods section were comparable to the reported results Comment: Low risk of bias
Other bias	Low risk	The study appears to be free of other sources of bias

Sugar 2009

Methods	Randomised controlled trial Setting: Maxillofacial Unit at University Hospital Wales UK Date of study unspecified, duration of follow-up 3 months
Participants	N = 140, male (132), female (8) age: mean 24 years range 16 to 68 years FRACTURE SITES: 140 INCLUSION CRITERIA: • 16 years or older (unclear how many < 18 years) • fractures of mandibular angle requiring open reduction and fixation EXCLUSION CRITERIA: • not possible to establish an occlusion with own natural teeth • comminuted fractures • frank infection RANDOMISED: 140 (intervention 84; control 56) WITHDRAWALS/LOSSES TO FOLLOW-UP:

	• 1 self discharge and no follow-up, 1 missing initial data and no follow-up • intervention: male (80), female (4) side of fracture: 58% left, 37% right, 4% bilateral • control: male (52), female (4) side of fracture: 59% left, 37% right, 4% bilateral
Interventions	INTERVENTION: single miniplate placed from a combined transbuccal and intraoral approach CONTROL: single miniplate placed intraorally alone
Outcomes	PRIMARY OUTCOMES: • uncomplicated bony union without deformity or malocclusion* • complication requiring further intervention* • wound dehiscence or presence of granulation tissue at wound site* • infection with sinus and pus* • plate exposure* • malocclusion* • interincisal mouth opening • need and reason for plate removal* SECONDARY OUTCOMES: • total operative time • dry socket (if third molar removed) • facial nerve weakness* • external scar in the intervention group (self reported patient opinion)* • questionnaire to surgeons regarding technique preferences Outcome assessments and follow-up: 1 week, 1 month and 3 months *Denotes pre-specified outcomes
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "Randomisation was accomplished by consecutive sealed envelopes containing allocation to one of the two study groups" (page 242) Comment: Insufficent information to permit a clear judgement Email communication with investigators: "The randomisation was done from a randomisation table... envelopes arranged in the order of the allocation from the randomisation table... envelope was numbered 1 to 150 with an A or B, corresponding to the table" Principal investigator admitted to confusion in the randomisation process with incorrect allocation of some participants con-

Sugar 2009 (*Continued*)

		tributing to the imbalance between intervention (84 patients) and control groups (56 patients) Comment: Random sequence generation probably correctly done, however errors in implementation result in unclear risk of bias
Allocation concealment (selection bias)	Unclear risk	See random sequence generation Comment: Allocation concealment probably successful, however errors in implementation represent 'unclear risk' of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Method of blinding unreported. This intervention/control involved surgical procedures which will not allow blinding at least at the surgeon level Comment: Probably no blinding, unclear risk of bias
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcomes were participant and investigator assessed Blinding of participants and outcome assessors feasible but not done Comment: Unclear risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	It appears that at least 2 patients were excluded after surgery; however, this low rate of attrition is unlikely to lead to bias. Statistical analysis was undertaken on a per protocol basis Comment: Insufficient information to permit a clear judgement of risk of bias
Selective reporting (reporting bias)	Low risk	Although the study protocol was unavailable, the outcomes listed in the methods section were comparable to the reported results Comment: Low risk of bias
Other bias	Low risk	This study was supported by a grant from the AO Research Fund of the AO Foundation, Dübendorf, Switzerland Comment: Low risk of bias

IMF = intermaxillary fixation; IPD = individual patient data; VAS = visual analogue scale

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

Study	Reason for exclusion
Al-Belasy 2005	Investigator confirmed that study was not randomised
Ayman 2003	No control
Ayoub 2003	None of the outcomes corresponded with the pre-specified outcomes for this review (i.e. "time required for applying each method of fixation, the needle-stick injuries that occurred during their application, and the periodontal damage that followed interdental immobilization")
Beriashvili 2006	Translated from the Russian by Dr V Vlassov no evidence of randomisation
Bilkay 1997	Comparative study, non-RCT
Borys 2004	Observational study patients selected "depending on the treatment method" not randomised to either study group
Buijs 2012	Small proportion of the sample consisted of patients with mandibular fractures. No breakdown of outcomes for mandibular fracture cases
Danda 2010	Includes both subcondylar and condylar fractures without clear distinction in the report
Ehrenfeld 1996	No response from investigators
Ferretti 2008	Prospective non-randomised study
Ghanem 2011	Non-RCT
Hsu 2012	CCT
Knauf 1998	Conference abstract no subsequent full-text publication, investigators contact details unavailable
Landes 2005	Condylar and subcondylar fractures, unclear differentiation, no separate data
Laverick 2012	Non-RCT as allocation was determinate: "Patients were randomised to having their angle fractures treated with an intraorally placed ridge plate, or a plate placed transbuccally. Randomisation was by the patient's year of birth, odd or even indicating the treatment they were to have"
Lee 2010	CCT
Leonhardt 2008	Initially planned to be randomised, however on occasion, unavailability of the required plating system did not allow random allocation
Masureik 1997	No response from investigators
Molloy 2004	Abstract to conference proceedings limited reporting. No response from investigators

(*Continued*)

Osmola 1996	No response from investigators
Rai 2012	The study included patients with maxillary and mandibular fractures without separating the data
Schmelzeisen 1992	No control
Shetty 2008	Randomisation according to hospital identification number. Quasi-randomised CCT
Sindet-Pedersen 1992	No control
Singh 2010	After communicating with investigator it was concluded that randomisation was by alternate assignment. Quasi-randomised CCT
Singh 2011a	After communicating with investigator, it was concluded that randomisation was by alternate assignment. Quasi-randomised CCT
Singh 2011b	Non-RCT
Tseng 1999	Retrospective cohort study
Uglesić 1993	Full text indicated non-RCT
Villarreal 2000	Retrospective cohort
Wen 2004	No information in the text indicating any form of randomisation
Widmark 1991	Non-RCT
Widmark 1996	No concurrent control
Worsaae 1994	Non-RCT
Yerit 2005	Age range outside inclusion criteria, participants 5 to 69 years
Yoshioka 2012	The focus of the study is orthognathic surgery

CCT = controlled clinical trial; RCT = randomised controlled trial

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

Adeyemi 2012

Methods	Reported to be an RCT but the methodological details to evaluate this are lacking
Participants	Minimally-displaced mandibular fracture in tooth-bearing area
Interventions	2-week period of IMF and 4 to 6 weeks of IMF
Outcomes	Healing time, post-operative infection, paraesthesia, maximal interincisal opening
Notes	

Channar 2011

Methods	It is unclear whether it is an RCT or CCT. In one part of the article, they state "The confounding variables like age, sex, duration of injury and site of fracture were adjusted by paired sampling". In another section, the authors state that "Patients were divided in two groups by using random number table"
Participants	Patients with gun shot injury
Interventions	Open reduction and internal fixation versus closed reduction and maxillomandibular fixation
Outcomes	Post-operative infection, malocclusion, non-union/malunion of fracture fragments, facial asymmetry, plate exposure, sequestration of devitalised bone
Notes	

Jain 2012

Methods	Reported to be an RCT but the methodological details to evaluate this are lacking
Participants	Isolated non-comminuted mandibular fractures located between both mental foramens (interforaminal fractures)
Interventions	2.0 mm titanium 3D locking plates versus 2.0 mm titanium standard miniplates
Outcomes	Duration of the procedure, mobility between fracture fragments, occlusion, need for maxillomandibular fixation, radiological evaluation of reduction and fixation, infection, paraesthesia, hardware failure (plate fracture)
Notes	We contacted authors for further information

Moe 2012

Methods	Reported to be an RCT but the methodological details to evaluate this are lacking
Participants	Participants with mandibular fractures
Interventions	Open reduction and internal fixation with small titanium plates versus large plates
Outcomes	Total cost of treatment, operating room cost, hardware cost, LOS cost and cost of treating complications
Notes	This was a conference abstract, further details were not available. We contacted authors for further information

Rai 2011

Methods	Reported to be an RCT but the methodological details to evaluate this are lacking
Participants	Patients with minimally-displaced mandibular fractures
Interventions	Stainless steel screws and miniplates (Orthomax Shreerang Apartments, Kothi, Baroda, India) with or without open reduction versus Erich archbar (Dentaurum's Barres Eaich Arch Bars; KG Marburg Cenavisa SA Combiphrar CSC Pharmaceuticals, Marburg, Germany)
Outcomes	Mean working time for placement, plaque deposition, occlusal disturbance, glove perforation, soft tissue trauma, trauma to operators' fingers
Notes	We contacted authors for further information

Vineeth 2013

Methods	Reported to be an RCT but the methodological details to evaluate this are lacking
Participants	Patients with mandibular angle fractures
Interventions	Single 2.0 mm conventional titanium miniplate versus 3D titanium miniplate
Outcomes	Inadequate mouth opening, post-injury/pre-operative inferior alveolar nerve sensory disturbance, infections
Notes	We contacted authors for further information

CCT = controlled clinical trial; RCT = randomised controlled trial; IMF = intermaxillary fixation

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

Brown 2013

Trial name or title	Comparison of orthodontic and conventional wire IMF in the open and closed management of mandibular fractures: a 2-centre randomised trial (ISRCTN31051582)
Methods	It is reported to be a randomised controlled trial to compare orthodontic fixation treatment in jaw fractures, details are not available
Participants	150 patients 75 from this site. Included are all patients with a mandibular lower jaw fracture, over 16, no pre-existing dental disease, attending Whipps Cross NHS or Barts and the London NHS Trust
Interventions	Patients randomised into 2 groups: open or closed management of fractures using 2 different types of fixings, patient satisfaction questionnaire/VAS pain scores
Outcomes	To evaluate the 2 forms of treatment for cost benefit to the NHS. Outcome measures: theatre time, length of stay, amount of follow-up, patient satisfaction and pain experienced
Starting date	1 June 2004
Contact information	Dr Geraldine Brown SSR Orthodontics Whipps Cross University Hospital Trust Whipps Cross Road, London, E11 1NR, UK dhmail@doh.gsi.org.uk +44 (0)20 7307 2622
Notes	We found the study on the Current Controlled Trials website. We were unable to access the full report of this study yet

IMF = intermaxillary fixation; VAS = visual analogue scale

DATA AND ANALYSES

Comparison 1. 3D miniplates versus standard plates

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Post-operative infection	2	90	Risk Ratio (M-H, Random, 95% CI)	1.26 [0.19, 8.13]

Comparison 2. 2 miniplates versus 1 miniplate + 2 screws

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Post-operative infection	2	93	Risk Ratio (M-H, Random, 95% CI)	1.32 [0.41, 4.22]

Analysis 1.1. Comparison 1 3D miniplates versus standard plates, Outcome 1 Post-operative infection.

Review: Interventions for the management of mandibular fractures

Comparison: 1 3D miniplates versus standard plates

Outcome: 1 Post-operative infection

Study or subgroup	3D miniplates n/N	Standard plates n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Jain 2010	2/20	0/20		31.5 %	5.00 [0.26, 98.00]
Singh 2012	2/25	3/25		68.5 %	0.67 [0.12, 3.65]
Total (95% CI)	**45**	**45**		**100.0 %**	**1.26 [0.19, 8.13]**

Total events: 4 (3D miniplates), 3 (Standard plates)

Heterogeneity: $Tau^2 = 0.57$; $Chi^2 = 1.37$, df = 1 (P = 0.24); $I^2 = 27\%$

Test for overall effect: Z = 0.24 (P = 0.81)

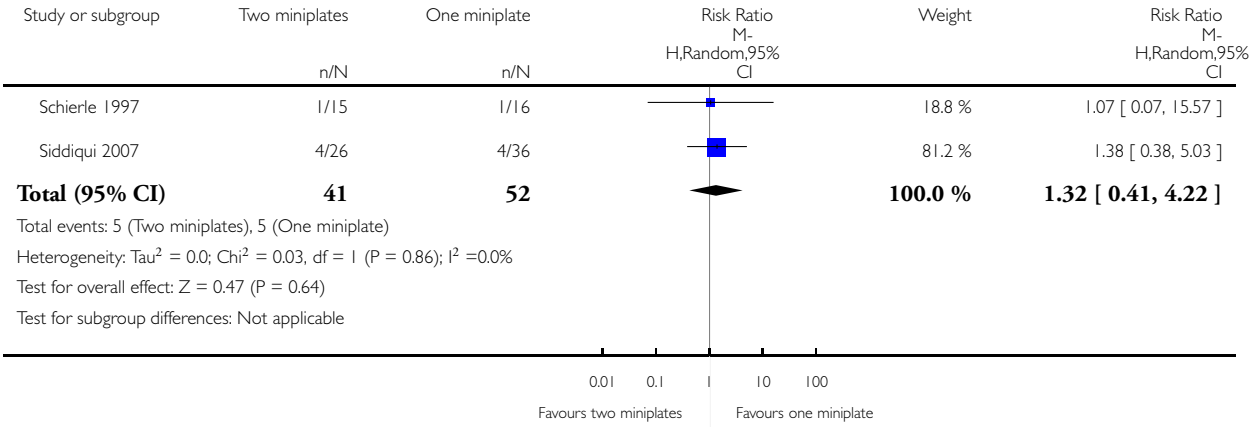
Test for subgroup differences: Not applicable

Analysis 2.1. Comparison 2 2 miniplates versus 1 miniplate + 2 screws, Outcome 1 Post-operative infection.

Review: Interventions for the management of mandibular fractures

Comparison: 2 2 miniplates versus 1 miniplate + 2 screws

Outcome: 1 Post-operative infection



ADDITIONAL TABLES

Table 1. Chronic pain scores (month 1) at participant level (Bhatt 2010)

Pain level	**No pain n (%)**	**Mild n (%)**	**Moderate n (%)**	**Severe n (%)**
Titanium group*	7/21(33.3%)	9/21 (42.9%)	1/21 (4.8%)	0/21(0.0%)
Resorbable group	8/19 (42.1%)	6/19 (31.6%)	2/19 (10.5%)	1/19 (5.3%)
RR (95% CI)	**1.26 (0.57 to 2.82)**	**0.74 (0.32 to 1.68)**	**2.9 (0.22 to 22.5)**	**n/a**
RD (95% CI)	**8.8% (-21.2% to 39. 87%)**	**-11.3% (-41.0% to 18. 5%)**	**6.35% (-10.7 to 22.2%)**	**5.3% (-4.7% to 15.3%)**
P value	0.70	0.62	0.61**	0.49**

CI = confidence interval; RD = risk difference; RR = risk ratio

* referent

** P value based on Fisher's exact test, otherwise based on Pearson Chi^2 test

Table 2. Post-operative neurosensory disturbances per site (Bhatt 2010)

		Immediate	1 month
		n (%)	n (%)
Neurosensory disturbances	Titanium group*	18/32 (56.3%)	13/32 (40.6%)
	Resorbable group	21/25 (84.0%)	18/25 (72.0%)
	RR (95% CI)	1.49 (1.05 to 2.12)	1.77 (1.09 to 2.88)
	RD (95% CI)	27.7% (5.3% to 50.1%)	31.4% (6.9% to 55.8%)
	P value	0.34	0.20
Dehiscence	Titanium group *	3/32 (9.4%)	n/a
	Resorbable group	5/25 (20.0%)	n/a
	RR (95% CI)	2.13 (0.56 to 8.08)	n/a
	RD (95% CI)	10.6% (-8.0% to 29.3%)	n/a
	P value	0.46**	n/a

CI = confidence interval; RD = risk difference; RR = risk ratio

* referent

** P value based on Fisher's exact test, otherwise based on Pearson Chi^2 test

Table 3. Complications AAOMS parameters (Bhatt 2010)

Complications	Intervention group	1 month			
		n (%)	RR (95% CI)	RD (95% CI)	P value
Mobility (per site)	Titanium	2/32 (6.3%)	referent	referent	
	Resorbable	6/25 (24.0%)	3.84 (0.85 to 17.4)	17.8% (-0.1% to 36.5%)	0.70*
Malocclusion (per participant)	Titanium	4/21 (19.1 %)	referent	referent	
	Resorbable	4/19 (21.1%)	1.1 (0.32 to 3.82)	2.0% (-22.9% to 26.9%)	1*
Moderate soft tissue deformity (per site)	Titanium	1/32 (3.1%)	referent	referent	

Table 3. Complications AAOMS parameters (Bhatt 2010) (*Continued*)

	Resorbable	5/25 (15.6%)	6.4 (0.80 to 51.3)	12.5% (0.08% to 33.7%)	0.09*
Chronic infection (per site)	Titanium	1/32 (3.1%)	referent	referent	
	Resorbable	-	n/a	(-3.1%)	
Inability to chew hard food (per participant)	Titanium	3/21 (14.3%)	referent	referent	
	Resorbable	3/19 (15.8%)	1.1 (0.25 to 4.83)	1.5% (-20.7% to 23.7%)	1*
Need for re-operation (per site)	Titanium	-	-	-	
	Resorbable	-	-	-	
Need for alternative treatment (per participant)	Titanium	-	-	-	
	Resorbable	-	-	-	

CI = confidence interval; RD = risk difference; RR = risk ratio

Table 4. Pain assessments (Kaplan 2001)

	Immediate release VAS (rated 1 to 10)	**IMF VAS (rated 1 to 10)**
6 weeks	1.55	1.20
3 months	1.00	2.64
6 months	1.30	2.71
95% confidence interval was not reported.		

IMF = intermaxillary fixation; VAS = visual analogue scale (VAS 1 = no pain, 10 = severe pain)

Table 5. Subjective trismus (Kaplan 2001)

	Immediate release VAS (rated 1 to 10)	**IMF VAS (rated 1 to 10)**
6 weeks	2.00	1.90
3 months	2.00	1.14

Table 5. Subjective trismus (Kaplan 2001) (*Continued*)

6 months	1.60	1.29

IMF = intermaxillary fixation; VAS = visual analogue scale (VAS 1 = no problems, 10 = severe problems)

Table 6. Research recommendations based on a gap in the evidence of effectiveness of interventions for the management of mandibular fractures

Core elements	Issues to consider	Status of the research for this review and recommendations for future research
Evidence (**E**)	What is the current status of the evidence?	This systematic review includes 12 RCTs on nine comparisons
Population (**P**)	Diagnosis, disease stage, comorbidity, risk factor, sex, age, ethnic group, specific inclusion or exclusion criteria, clinical setting	Further studies need to transparently report and analyse patients based on the type and severity of fractures. Most of the included studies involved male patients; future studies might consider stratification based on sex
Intervention (**I**)	Type, duration, prognostic factor	There is limited evidence on different open (surgical) treatments for management of mandibular fractures. There is a need for more research on any type of intervention for the management of mandibular fractures. However, the most fundamental unanswered question remains 'Which approach is most effective open treatment with internal fixation or closed management?'
Comparison (**C**)	Type, duration, prognostic factor	Rigid fixation versus functionally stable (non-rigid) fixation The role of post-operative IMF after ORIF Intraoral versus extraoral surgical approach Locking versus non-locking screw/plate systems
Outcome (**O**)	Which clinical or patient-related outcomes will the researcher need to measure, improve, influence or accomplish? Which methods of measurement should be used?	Patient satisfaction Return to pre-trauma lifestyle Occlusal outcome Requirement for second intervention
Time stamp (**T**)	Date of literature search or recommendation	February 2013 (however, there are six trials awaiting assessment)
Study type	What is the most appropriate study design to address the proposed question?	RCT (adequately powered/multicentred) Methods: concealment of allocation sequence Blinding: not possible for patients or operators, however blinding of outcomes assessors and data analysts is important Setting: hospital/university or general practice with adequate follow-up

Table 6. Research recommendations based on a gap in the evidence of effectiveness of interventions for the management of mandibular fractures (*Continued*)

IMF= intermaxillary fixation; ORIF = open reduction and internal fixation; RCTs = randomised controlled trials

APPENDICES

Appendix 1. MEDLINE (OVID) search strategy

1. Mandibular fractures/
2. Jaw fractures/
3. ((mandib$ or "lower jaw$") adj5 fractur$).mp.
4. or/1-3
5. (fix$ or plat$ or screw$ or stabilis$ or stabiliz$ or titanium or miniplate$ or "mini plate$" or mini-plate$ or "bone graft$" or mesh$ or splint$).mp.
6. (treat$ or manag$).mp.
7. or/5-6
8. 4 and 7

The above subject search was linked to the Cochrane Highly Sensitive Search Strategy (CHSSS) for identifying randomised trials in MEDLINE: sensitivity maximising version (2008 revision) as referenced in Chapter 6.4.11.1 and detailed in box 6.4.c of the*Cochrane Handbook for Systematic Reviews of Interventions* version 5.1.0 [updated March 2011] (Higgins 2011).

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. placebo.ab.
5. drug therapy.fs.
6. randomly.ab.
7. trial.ab.
8. groups.ab.
9. or/1-8
10. exp animals/ not humans.sh.
11. 9 not 10

Appendix 2. Cochrane Oral Health Group's Trials Register search strategy

((mandib* or "lower jaw*") AND fracture*)

Appendix 3. CENTRAL search strategy

#1 MeSH descriptor Mandibular fractures this term only
#2 MeSH descriptor Jaw fractures this term only
#3 ((mandib* in All Text near/5 fractur* in All Text) or ("lower jaw*" in All Text near/5 fractur* in All Text))
#4 (#1 or #2 or #3)
#5 (fix* in All Text or plat* in All Text or screw* in All Text or stabilis* in All Text or stabiliz* in All Text or titanium in All Text or miniplate* in All Text or "mini plate*" in All Text or mini-plate* in All Text or "bone graft*" in All Text or mesh* in All Text or splint* in All Text)
#6 (treat* in All Text or manag* in All Text)
#7 (#5 or #6)
#8 (#4 and #7)

Appendix 4. EMBASE (OVID) search strategy

1. Mandibular fracture/
2. Jaw fracture/
3. ((mandib$ or "lower jaw$") adj5 fractur$).mp.
4. or/1-3
5. (fix$ or plat$ or screw$ or stabilis$ or stabiliz$ or titanium or miniplate$ or "mini plate$" or mini-plate$ or "bone graft$" or mesh$ or splint$).mp.
6. (treat$ or manag$).mp.
7. or/5-6
8. 4 and 7

The above subject search was linked to the Cochrane Oral Health Group filter for EMBASE via OVID:
1. random$.ti,ab.
2. factorial$.ti,ab.
3. (crossover$ or cross over$ or cross-over$).ti,ab.
4. placebo$.ti,ab.
5. (doubl$ adj blind$).ti,ab.
6. (singl$ adj blind$).ti,ab.
7. assign$.ti,ab.
8. allocat$.ti,ab.
9. volunteer$.ti,ab.
10. CROSSOVER PROCEDURE.sh.
11. DOUBLE-BLIND PROCEDURE.sh.
12. RANDOMIZED CONTROLLED TRIAL.sh.
13. SINGLE BLIND PROCEDURE.sh.
14. or/1-13
15. ANIMAL/ or NONHUMAN/ or ANIMAL EXPERIMENT/
16. HUMAN/
17. 16 and 15
18. 15 not 17
19. 14 not 18

WHAT'S NEW

Last assessed as up-to-date: 28 February 2013.

Date	Event	Description
4 July 2013	New citation required but conclusions have not changed	Changes to title and review authors Scope of review extended to include all fractures of the mandible but excluding condylar fractures Amended to include participants under 18 years (Differences between protocol and review)
4 July 2013	New search has been performed	Searches updated February 2013

HISTORY

Protocol first published: Issue 3, 2006

Review first published: Issue 1, 2007

Date	Event	Description
1 August 2008	Amended	Converted to new review format

CONTRIBUTIONS OF AUTHORS

Mona Nasser (MN) and Zbys Fedorowicz (ZF), Nikolaos Pandis (NP) and Padhraig Fleming (PSF) were responsible for:

- data collection for the review
- screening search results, also including Kamran Ali (KA)
- screening retrieved papers against inclusion criteria
- appraising quality of papers
- extracting data from papers
- obtaining and screening data on unpublished studies
- entering data into RevMan
- analysis of data
- interpretation of data also including Edward Ellis (EE)
- writing the review.

NP and ZF was responsible for:

- organising retrieval of papers

- writing to authors of papers for additional information
- providing additional data about papers.

MN, ZF and NP were responsible for:

- designing the review
- co-ordinating the review
- data management for the review.

DECLARATIONS OF INTEREST

There are no financial conflicts of interest and the review authors declare that they do not have any associations with any parties who may have vested interests in the results of this review.

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Internal sources

- None, Not specified.

External sources

- Cochrane Oral Health Group Global Alliance, UK.

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- National Institute for Health Research (NIHR), UK.

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Disclaimer:
The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the NIHR, NHS or the Department of Health.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The previous version of this review which only considered fractures of the edentulous atrophic mandible failed to identify any eligible randomised trials (Nasser 2007), and therefore the scope of the review was widened to include all fractures of the mandible but excluding those of the condyle. We will provide evidence for a wider clinical question and also indirect evidence to inform the original question on the management of fractured edentulous atrophic mandible.

Although we initially planned to limit participants to18 years and over, several of the identified studies included a small number of participants under 18 years. For practical purposes when the second molars are erupted the mandible can be considered adult and the open or closed approaches are both similar to those used in the adult mandible. Based on content expert advice received, we included these studies under the following conditions:

- the focus of the study was on adults and most of the participants were over 18 years of age;
- the outcome measurements are unlikely to be affected by the addition of this age group.

If adequate data are available in future updates we will conduct a subgroup analysis to explore any potential differences based on a threshold of 18 years of age on the effect of interventions.

INDEX TERMS

Medical Subject Headings (MeSH)

Atrophy; Fracture Fixation [*methods]; Mandible [pathology]; Mandibular Fractures [*therapy]; Mouth, Edentulous [*complications]

MeSH check words

Aged; Humans; Middle Aged