Evidence report for closed treatment (without surgery) vs. open reduction (involving surgery) for fractures of the mandibular condyle

Prepared by EBSCO Health Innovations and EBM Development Department (in alphabetic order):

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*Note that each *section* of the report also has *section-specific* page numbering at the bottom-right corner of the page. The above page numbers refer to the *report-specific* page number, which appears in bolded and italicized font in the top-right corner of the page.

Evidence report for closed treatment (without surgery) vs. open reduction (involving surgery) for fractures of the mandibular condyle

Scoping

EBSCO Information Services

June 2, 2020
Amended July 9, 2020 to include infection and bleeding as descriptive responses and change FAQ 6 from "Will the surgery cause weakness in my face or scar?" to "What are the risks?"

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Abbreviations

General abbreviations that may appear in this report

CI – confidence interval
CrI – credible interval
HR – hazard ratio
IQR – interquartile range
MA – meta-analysis
MD – mean difference
NA, N/A – not applicable
NMA – network meta-analysis
NR – not reported
OR – odds ratio
RCT – randomized, controlled trial
RR – risk ratio, relative risk
RtR – rate ratio
SD – standard deviation
SE – standard error
SMD – standardized mean difference
SR – systematic review
SRMA – systematic review and meta-analysis

Abbreviations specific to this report that may appear in this report

AMSTAR-2 – A MeaSurement Tool to Assess systematic Reviews, 2nd version
IMF – intermaxillary fixation
MMF – maxillomandibular fixation

Methods

Using an established, structured template that delineates key elements for scoping (i.e., the population, interventions, and key outcomes to consider), we collaboratively agreed with UKSH on the scope of the present evidence report. Scoping was completed on June 2, 2020.

Where outcomes will be answered with systematic searches, critical appraisal, and evidence synthesis, we will state the intended approach after we state the outcome(s) of interest for that FAQ. For example, we might say: "The outcome of interest is all-cause mortality. We will obtain effect estimates from systematic reviews and meta-analyses of randomized, controlled trials or from individual trials if systematic reviews do not exist or meta-analysis is not the most appropriate method of synthesis." Otherwise, where we say: "We will include a description of", "We will include descriptive responses", or something similar, we will answer the FAQ with descriptive responses, which do not involve systematic evidence searches, critical appraisal, or evidence synthesis.

Results – Criteria Selection for Critical Appraisal

Population:

Inclusion criteria

Adults with unilateral or bilateral fractures of the mandibular condyles. Studies including populations of patients with mandibular fractures with condylar involvement and mandibular fractures without condylar involvement will be included if they reported data separately for the two populations.

Exclusion criteria

Patients ineligible for surgery due to health status or patients with absolute indications for surgery (e.g., central luxation, foreign object penetration).

Intervention and Comparator/Options:

The comparison we will address in this review is open reduction (involving surgery) vs. closed treatment (without surgery). A description of these two options is below.

Open reduction with internal fixation (surgery)

Open reduction with internal fixation is a surgical approach to management of mandibular condyle fracture. This is sometimes followed by a postoperative period of immobilization.

Closed treatment (no surgery)

Conservative/closed management can consist of either of the following:

- management by 'closed' reduction with immobilization using IMF
- no active intervention (other than soft diet, analgesics, and/or antibiotics)

Notes on comparisons:
Based on a preliminary scoping review of the available evidence, randomized or quasi-randomized trials comparing open reduction (surgery) vs. closed treatment (no surgery) have all used closed reduction and immobilization with IMF as the closed treatment (no surgery) option (ie, none used no active intervention). If we subsequently identify trials using no active intervention as the closed treatment option, we will also address the comparison of surgery vs. no active intervention, and we may address this comparison separately from the comparison of surgery vs. closed reduction and immobilization with IMF because these two approaches to non-surgical treatment may have different effects (and thus lead to heterogeneity of treatment effect).

Among 5 relevant randomized or quasi-randomized trials comparing open reduction (involving surgery) vs. closed treatment (without surgery) identified in preliminary scoping, Eckelt 2006/Schneider 2008[1] and Kotrashetti 2013 appear to have compared surgery alone vs. IMF alone, whereas Danda 2010, Singh 2010, and Shiju 2015 appear to have compared surgery plus IMF vs. IMF alone (although the IMF alone group uses a lengthier duration or more involved IMF compared to the IMF in the surgery group). This may be partly due to postoperative IMF being traditionally considered "a widely accepted dictum" (Saman 2014); however, some have questioned this traditional approach and whether it is helpful or necessary (Diaconu 2018, El-Anwar 2015A, El-Anwar 2015B, El-Anwar 2018, Saman 2014). If there is evidence of heterogeneity of treatment effect based on whether postoperative IMF is utilized, we may report the data separately in accordance with the more specific comparison they address.

Notes on study designs considered for this evidence review:
For comparing effects of the two treatment options, we will include both randomized trials and quasi-randomized trials. Although it would be preferable to limit focus to RCTs, it appears doing so may not yield sufficient evidence for the scoped outcomes, so we have extended consideration to quasi-randomized trials as well (such as treatment allocation by alternate assignment).

Note on Search and Selection for this evidence report:
We are aware of a pending update to the Cochrane reviews Sharif 2010 and Nasser 2013, which will be merged into one Cochrane review. Although this update is still unpublished as of June 3, 2020, the first and corresponding author of this pending Cochrane review (Mona Nasser) has provided us with an unfinished copy of the work they have done thus far on this Cochrane review. We will use the work Nasser and colleagues have done on the as-of-yet unpublished Cochrane review as a starting point for Search and Selection.

[1] Eckelt 2006 and Schneider 2008 were included as two separate trials in most SRs, but Sharif 2010 Cochrane confirmed after contacting investigators that these were two reports of the same trial.

Outcomes:

FAQ 1: What does the treatment involve?

We will include a description of the treatment or procedure, such as frequency of dosing, monitoring, and length of stay, as relevant.

Descriptive responses are acceptable, and this does not involve systematic evidence searches, critical appraisal, or evidence synthesis.

FAQ 2: Will the treatment help my teeth come together correctly when I bite down (for example, when I eat)?

The outcome of interest is patient-reported occlusal disturbance.

We will obtain estimates from randomized and quasi-randomized trials or systematic reviews thereof.

FAQ 3: Will the treatment increase how much I can open my mouth?

The outcome of interest is maximal mouth opening. This will be assessed by maximal interincisal opening.

We will obtain estimates from randomized and quasi-randomized trials or systematic reviews thereof.

FAQ 4: Will the treatment help me move my jaw in other ways?

The outcome of interest is range of motion of the injured joint together with the contralateral joint. This will be assessed by the extent of being able to move the jaw to the right or left, and to move it forward.

We will obtain estimates from randomized and quasi-randomized trials or systematic reviews thereof.

FAQ 5: Will the treatment reduce pain or discomfort in the temporomandibular joint?

The outcome of interest is patient-reported pain.

We will obtain estimates from randomized and quasi-randomized trials or systematic reviews thereof.

FAQ 6: What are the risks?

The outcomes of interest are proportion of patients treated surgically with facial nerve weakness or surgery scar.

We will obtain estimates from randomized and quasi-randomized trials or systematic reviews thereof.

After original completion of this evidence report, we also added infection and bleeding as surgical risks to be addressed via descriptive responses and changed this FAQ from “Will the surgery cause weakness in my face or scar?” to “What are the risks?”.

All outcomes above will be assessed at the 6-month follow-up point or at the timepoint nearest to the 6-month follow-up point if another timepoint is reported by the study(-ies) in question.

Danda AK, Muthusekhar MR, Narayanan V, Baig MF, Siddareddi A. Open versus closed treatment of unilateral subcondylar and condylar neck fractures: a prospective, randomized clinical study. J Oral Maxillofac Surg. 2010 Jun;68(6):1238-41. doi: 10.1016/j.joms.2009.09.042. Epub 2010 Mar 29. PubMed

Diaconu SC, McNichols CHL, Liang Y, Orkoulas-Razis D, Woodall J, Rasko YM, Grant MP, Nam AJ. Utility of Postoperative Mandibulomaxillary Fixation After Rigid Internal Fixation of Isolated Mandibular Fractures. J Craniofac Surg. 2018 Jun;29(4):930-936. doi: 10.1097/SCS.0000000000004368. PubMed

Eckelt U, Schneider M, Erasmus F, Gerlach KL, Kuhlisch E, Loukota R, Rasse M, Schubert J, Terheyden H. Open versus closed treatment of fractures of the mandibular condylar process-a prospective randomized multi-centre study. J Craniomaxillofac Surg. 2006 Jul;34(5):306-14. doi: 10.1016/j.jcms.2006.03.003. Epub 2006 Jun 15. PubMed

Schneider M, Erasmus F, Gerlach KL, Kuhlisch E, Loukota RA, Rasse M, Schubert J, Terheyden H, Eckelt U. Open reduction and internal fixation versus closed treatment and mandibulomaxillary fixation of fractures of the mandibular condylar process: a randomized, prospective, multicenter study with special evaluation of fracture level. J Oral Maxillofac Surg. 2008 Dec;66(12):2537-44. doi: 10.1016/j.joms.2008.06.107. PubMed.

El-Anwar MW, Sayed El-Ahl MA, Amer HS. Open Reduction and Internal Fixation of Mandibular Fracture without Rigid Maxillomandibular Fixation. Int Arch Otorhinolaryngol. 2015 Oct;19(4):314-8. doi: 10.1055/s-0035-1549154. Epub 2015 Mar 30. PubMed

El-Anwar MW. Changing Trends in the Treatment of Mandibular Fracture. Int Arch Otorhinolaryngol. 2018 Jul;22(3):195-196. doi: 10.1055/s-0037-1606645. Epub 2017 Oct 25. PubMed

Kotrashetti SM, Lingaraj JB, Khurana V. A comparative study of closed versus open reduction and internal fixation (using retromandibular approach) in the management of subcondylar fracture. Oral Surg Oral Med Oral Pathol Oral Radiol. 2013 Apr;115(4):e7-11. doi: 10.1016/j.oooo.2011.10.027. Epub 2012 Nov 10. PubMed

Nasser M, Pandis N, Fleming PS, Fedorowicz Z, Ellis E, Ali K. Interventions for the management of mandibular fractures. Cochrane Database Syst Rev. 2013 Jul 8;(7):CD006087. doi: 10.1002/14651858.CD006087.pub3. PubMed

Saman M, Kadakia S, Ducic Y. Postoperative maxillomandibular fixation after open reduction of mandible fractures. JAMA Facial Plast Surg. 2014 Nov-Dec;16(6):410-3. doi: 10.1001/jamafacial.2014.543. PubMed

Sharif MO, Fedorowicz Z, Drews P, Nasser M, Dorri M, Newton T, Oliver R. Interventions for the treatment of fractures of the mandibular condyle. Cochrane Database Syst Rev. 2010 Apr 14;(4):CD006538. doi: 10.1002/14651858.CD006538.pub2. Review. PubMed

Shiju M, Rastogi S, Gupta P, Kukreja S, Thomas R, Bhugra AK, Parvatha Reddy M, Choudhury R. Fractures of the mandibular condyle--Open versus closed--A treatment dilemma. J Craniomaxillofac Surg. 2015 May;43(4):448-51. doi: 10.1016/j.jcms.2015.01.012. Epub 2015 Jan 29. PubMed

Singh V, Bhagol A, Goel M, Kumar I, Verma A. Outcomes of open versus closed treatment of mandibular subcondylar fractures: a prospective randomized study. J Oral Maxillofac Surg. 2010 Jun;68(6):1304-9. doi: 10.1016/j.joms.2010.01.001. Epub 2010 Apr 3. PubMed

Evidence report for closed treatment (without surgery) vs. open reduction (involving surgery) for fractures of the mandibular condyle

Evidence Synthesis

EBSCO Information Services

July 1, 2020

Prepared by EBSCO Health Innovations and EBM Development Department (in alphabetic order):

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Methods

Where evidence is very limited, or the FAQ is scoped as a descriptive response, such that no evidence synthesis or processing is applied, the descriptive summary/-ies will be given.

For each FAQ for which evidence synthesis or processing is considered, we will summarize the key concepts (results and factors affecting certainty of the results) from the included studies that are most relevant to evidence synthesis; we will prefer using a tabular format for this summary in most cases, but depending on the circumstances, we may adopt a non-tabular form instead. For each outcome, we will then articulate the method selected for evidence synthesis and justification of that method; again, we will prefer a tabular approach in most cases, but we may articulate the justification in a non-tabular form depending on the circumstances. We will do this for the effect estimate (i.e., answering the question "Is there a difference between the intervention and comparator?") and results will be presented with GRADE-based certainty of evidence ratings related to the certainty of effect estimates. For FAQs which require noncomparative/option-specific responses (i.e., the FAQ is "What will happen with this option?" rather than "How do things change with this option?") the evidence synthesis process will be extended to include the method to produce noncomparative responses.

For summary statements representing a plain language summary of evidence appraisal and synthesis

We will include the following 2 items immediately after the summary statement as a parenthetical, regardless of whether they occur in the Summary of Findings section or the individual FAQs in the body of the Evidence Synthesis document:

- our certainty in the summary statement (categorized as High, Moderate, Low, or Very low), and
- the number and type of studies informing the statement, as well as a label for the studies in "[Author] [Year]" format.

If the study informing the summary statement is a systematic review and meta-analysis, then unless there are compelling reasons to proceed in a different manner, we will cite the systematic review and meta-analysis as the source. We will do this even if the result on which our summary statement is based comes from a subset of studies in that systematic review and meta-analysis (e.g., a meta-analysis of 5 out of 10 studies, because only 5 of the 10 reported on the outcome of interest). If EBSCO Information Services conducts its own meta-analysis of studies to inform a summary statement, we will list the individual studies.

For summary statements representing a plain language summary of a descriptive response/summary

Certainty rating and provision of details about contributing studies do not apply. Accordingly, we will not include a parenthetical at the end of the summary statement. However, when descriptive summaries appear in the Summary of Findings section, we will include a general parenthetical citation of applicable references. We will place this at the end of the relevant FAQ in the Summary of Findings section. For summary statements occurring in the body of the Evidence Synthesis document, placement will depend on the context.

Results – Summary of Findings

FAQ 1: What does the treatment involve?

Closed treatment (no surgery)

You will not have major surgery, but you will need a procedure to place equipment in your mouth. You may have to stay in the hospital for a few days. The equipment may include things like metal bars and rubber bands that help keep your jaw in the correct spot. You will likely need this equipment for several weeks. Then, you will work with your health care team over the next several weeks to remove the equipment from your mouth. Some people need the equipment longer, and some may need it for less time.

Initially, you will likely need to change your diet to softer foods. In some cases, you might need to have only liquids for a while. You can get back to eating what you normally eat over time.

Physical therapy is very important to make sure your jaw heals well.

Open reduction with internal fixation (surgery)

You will have surgery. You will likely be put to sleep for the surgery. How the surgery is done can vary a lot, because there are many ways to do the surgery. Some surgeons may try to do the surgery through your mouth if that is possible, but sometimes this cannot be done. You can decide with your health care team which surgery might be best for you. Before the surgery, you will have equipment like metal bars and rubber bands in your mouth that help keep your jaw in the correct spot. You may have to stay in the hospital for a few days. You may be advised to keep the equipment in your mouth for a while after surgery. If so, you will likely have the equipment in your mouth for a shorter time than if you treated your jaw without surgery.

Initially, you will likely need to change your diet to softer foods. In some cases, you might need to have only liquids for a while. You can get back to eating what you normally eat over time.

Physical therapy is very important to make sure your jaw heals well.

(Sources considered for these descriptive responses include: Al-Moraissi 2015, Boffano 2014, Choi 2012, Diaconu 2018, El-Anwar 2015A, El-Anwar 2015B, El-Anwar 2018, Eusterman 2012, Goldman 2018, Howlader 2019, Kuang 2019, Nasser ND, Saman 2014, Weis 2016)

FAQ 2: Will the treatment help how well my jaw works?

Closed treatment (no surgery) vs. open reduction with internal fixation (surgery)

Reasonable conclusion 1

How well you can use your jaw should get better as your jaw heals. There is not enough research to know if people who have treatment without surgery have worse functioning, better functioning, or similar functioning compared with people who have treatment with surgery.

Reasonable conclusion 2

How well you can use your jaw should get better as your jaw heals. It is possible that treatment with surgery could be somewhat better for some parts of how the jaw works for some people at 3 months or longer after treatment. But the research about this is not good, and if there is a difference, it may be very small or even too small to notice. We need better research to know if people who have treatment without surgery have worse functioning, better functioning, or similar functioning compared with people who have treatment with surgery.

(Very low certainty; based on 6 randomized trials [Asim 2019, Danda 2010, Eckelt 2006, Kotrashetti 2013, Rastogi 2015, Singh 2010])

FAQ 3: Will the treatment reduce pain or discomfort in my jaw?

Closed treatment (no surgery) vs. open reduction with internal fixation (surgery)

Reasonable conclusion 1

Pain should get better as your jaw heals. There is not enough research to know if people who have treatment without surgery have less pain, more pain, or the same amount of pain compared with people who have treatment with surgery.

Reasonable conclusion 2

Pain should get better as your jaw heals. It is possible that treatment with surgery could help some people have less pain at 3 months or longer after treatment. But the research about this is not good, and if there is a difference, it may be very small or even too small to notice. We need better research to know if people who have treatment without surgery have less pain, more pain, or the same amount of pain compared with people who have treatment with surgery.

(Very low certainty; based on 4 randomized trials [Danda 2010, Eckelt 2006, Kotrashetti 2013, Singh 2010])

FAQ 4: What are the risks?

Closed treatment (no surgery) vs. open reduction with internal fixation (surgery)

There is a risk that surgery will injure a nerve in your face. If this happens, it can make your face muscles weak. But most of the time, this does not happen. If the nerve is injured, people usually get the strength in their face back within 6 months or so.

Surgery can sometimes leave a scar. But depending on the type of surgery and how well the area heals, there may be no scar or only a very small scar.

As with any surgery, there is a risk of infection or bleeding, but these things are not common. Surgery may also have other risks, and you can talk about this more with your health care team.

(Certainty not assessed for these statements, but insufficient evidence from relevant sources formally included for evidence appraisal and synthesis [Asim 2019, Danda 2010, Kotrashetti 2013, Nasser ND, Rastogi 2015, and Singh 2010]; additional sources consulted as part of developing the above descriptive responses include Alyahya 2020, Al-Moraissi 2015, Ellis 2000, García-Guerrero 2018, Haug 2001, and Sharif 2010)

Search Summary

Number of articles screened and selected

	Screened	Selected*
Start with pending Cochrane review by Nasser and colleagues	1	1
1st-round (searching for randomized or quasi-randomized trials)	44†	1
2nd-round (citation tracing)	5	5
Total	*50*	*7*

*Number shown is after deduplication

†Also retrieved a publication describing an ongoing trial (underway since 2013) that has been impeded by several challenges (Rozeboom 2018)

	Articles selected for evaluation (Author Year)
Systematic reviews	1 (pending Cochrane review by Nasser and colleagues)
Randomized or quasi-randomized trials	6 (Asim 2019*, Danda 2010†, Eckelt 2006†, Kotrashetti 2013†, Rastogi 2015†‡, Singh 2010‡§)
Other article types	0

*Full summary in Critical Appraisal given it is not/not yet included in the pending Cochrane review by Nasser and colleagues

†We include only a brief entry for this study in Critical Appraisal as part of assessing for outcomes we scoped for inclusion but were not/not yet included in the pending Cochrane review by Nasser and colleagues

‡Also published as Shiju 2015

§Full summary in Critical Appraisal given it is not included in the pending Cochrane review by Nasser and colleagues (they excluded it due to its quasi-randomized design)

Of note, throughout Evidence Synthesis, we may refer to the ongoing Cochrane review by Nasser and colleagues as either “the Cochrane review”, “Nasser ND” (“ND” signifying “no date” given it is not yet published), or “the Cochrane review (Nasser ND)”.

Results – Synthesis Details

FAQ 1: What does the treatment involve?

Given the common sources used for both options for this FAQ, we give a single collective reference at the end of this FAQ.

Closed treatment (no surgery)

Descriptive Summary (pre-synthesis and synthesis efforts not applicable for descriptive summaries)

This approach attempts to align and stabilize the fracture to promote healing without surgery. This approach capitalizes on the anatomy of the affected area, with the surrounding musculature functionally serving as an *in-situ* splint and also ensuring sufficient vascular supply to the injured area. Arch bars, Ivy loops, or other devices permitting the use of elastics (or possibly wires in some cases) are used to achieve occlusal control.

When using elastics, patients are often advised to change them daily and to wear them continuously for the first several weeks. Removal for oral hygiene or physical therapy is permitted. Although the exact approach to progressive rehabilitation of the jaw may vary, after about 3 to 4 weeks, the patient may be able to progress toward removal of the elastics and hardware in a gradual fashion, with successive steps occurring at approximately weekly intervals. If there is a regression during this graduated approach (e.g., the patient's bite starts to drift out of place), the patient may return to the previous step of therapy; alternatively, the time in a given step may be prolonged based on a patient's needs (e.g., 2 weeks instead of 1 week). Comparably, the schedule can be expedited if a patient seems to be recovering more quickly.

Diet may be based on a patient's comfort level, but it often consists of a soft diet for at least the first few weeks.

Physical therapy is important for maximizing recovery (this is also true for surgical treatment). The physical therapy is simple and can be done within a person's home.

Based on a study of the National Inpatient Sample from 2005 to 2014, the mean (±SE) hospital stay for patients having a mandibular condyle fracture treated without surgery was 2.7 days (0.07 days) among 3,061 patients (Kuang 2019).

Descriptive Summary Results

You will not have major surgery, but you will need a procedure to place equipment in your mouth. You may have to stay in the hospital for a few days. The equipment may include things like metal bars and rubber bands that help keep your jaw in the correct spot. You will likely need this equipment for several weeks. Then, you will work with your health care team over the next several weeks to remove the equipment from your mouth. Some people need the equipment longer, and some may need it for less time.

Initially, you will likely need to change your diet to softer foods. In some cases, you might need to have only liquids for a while. You can get back to eating what you normally eat over time.

Physical therapy is very important to make sure your jaw heals well.

Open reduction with internal fixation (surgery)

Descriptive Summary (pre-synthesis and synthesis efforts not applicable for descriptive summaries)

This approach involves having surgery. There are different approaches to surgery, including extraoral (outside the mouth) and intraoral (inside the mouth) approaches. These approaches can also have variations. For instance, extraoral approaches may involve a preauricular (in front of the ear) approach or a sub- or retromandibular (below or behind the jaw) approach. Sometimes these approaches are used in concert. Even within a given approach, specifics about the tooling used can vary. For instance, with an intraoral approach using a mandibular vestibular incision, this may or may not involve using an endoscope. For patients opting for surgery, the approach used can be chosen as a function of the patient's clinical specifics, the surgeon's experience/expertise, and the patient's preference. Surgery is typically performed under general anesthesia, though for select patients, a protocol for surgery with only local anesthesia has been described. Understandably, an intraoral approach may be preferred by some surgeons when possible (e.g., this could reduce the potential for scarring).

Before surgery, occlusal control is typically achieved via some form of hardware, such as arch bars or Ivy loops [as discussed in the above section 'Closed treatment (no surgery)']. Although postoperative maxillomandibular fixation may be considered by some to be a standard of care, this stance has not gone without challenge; accordingly, the utilization of postoperative maxillomandibular fixation may vary from center to center and even from surgeon to surgeon within a given center. However, if/when postoperative maxillomandibular fixation it is utilized, it is often for a shorter period of time than the amount of time maxillomandibular fixation is used as part of closed reduction. Patients may need to alter their diet for a period of time after surgery, at least adjusting to a soft foods diet; however, patients may be advised to alter their diet more to limit movement of the jaw.

Physical therapy is important for maximizing recovery (this is also true for closed reduction). The physical therapy is simple and can be done within a person's home.

Based on a study of the National Inpatient Sample from 2005 to 2014, the mean (±SE) hospital stay for patients having surgery for mandibular condyle fracture was 3.73 days (0.08 days) among 8,437 patients (Kuang 2019).

Descriptive Summary Results

You will have surgery. You will likely be put to sleep for the surgery. How the surgery is done can vary a lot, because there are many ways to do the surgery. Some surgeons may try to do the surgery through your mouth if that is possible, but sometimes this cannot be done. You can decide with your health care team which surgery might be best for you. Before the surgery, you will have equipment like metal bars and rubber bands in your mouth that help keep your jaw in the correct spot. You may have to stay in the hospital for a few days. You may be advised to keep the equipment in your mouth for a while after surgery. If so, you will likely have the equipment in your mouth for a shorter time than if you treated your jaw without surgery.

Initially, you will likely need to change your diet to softer foods. In some cases, you might need to have only liquids for a while. You can get back to eating what you normally eat over time.

Physical therapy is very important to make sure your jaw heals well.

(Al-Moraissi 2015, Boffano 2014, Choi 2012, Diaconu 2018, El-Anwar 2015A, El-Anwar 2015B, El-Anwar 2018, Eusterman 2012, Goldman 2018, Howlader 2019, Kuang 2019, Nasser ND, Saman 2014, Weis 2016)

FAQ 2: Will the treatment help how well my jaw works?

Closed treatment (no surgery) vs. open reduction with internal fixation (surgery)

Evidence Review

In Scoping, we defined three different FAQs that relate to functioning:

- patient-reported occlusal disturbance (FAQ2)
- maximal interincisal opening (FAQ3)
- range of motion as assessed by the extent of being able to move the jaw (FAQ4)
    - to the right
    - to the left
    - forward

In reviewing our key source, the ongoing Cochrane review (Nasser ND), these outcomes were assessed separately under a broader Results section category that included multiple outcomes that assessed different aspects of functioning.

The specific outcomes that assessed different aspects of functioning are listed below; we list them in the order used by the Cochrane review (Nasser ND), and we include a sub-bullet describing the relationship of the outcome to the outcomes in Scoping:

- patient perception of overall mandibular impairment
    - we did not scope this outcome
        - however, we consider this patient-reported outcome an important outcome to consider and have added it to the Nasser ND summary and table below
- limitation of mandibular movement
    - we did not specifically scope this outcome
        - however, we interpreted it as a measure of overall range of motion and thus relevant to FAQ4
- maximum inter-incisal opening
    - FAQ3
- mandibular protrusion
    - FAQ4
- lateral excursion movement on fractured side
    - FAQ4 (although we scoped as “to the right” or “to the left” instead of “fractured side” or “non-fractured side”)
    - the Cochrane review did not report the data for this outcome (which it noted was still to be added) and therefore we extracted the data from each of the articles that reported this outcome as brief summaries including only this outcome data
- lateral excursion movement on non-fractured side
    - FAQ4 (although we scoped as “to the right” or “to the left” instead of “fractured side” or “non-fractured side”)

  - the Cochrane review did not report the data for this outcome (which it noted was still to be added) and therefore we extracted the data from each of the articles that reported this outcome as brief summaries including only this outcome data
- malocclusion
  - FAQ2

We reconsidered our initial splitting of functioning outcomes into separate FAQs and consider the Cochrane review's approach preferable from a clinical perspective, because the key outcome of interest for the patient would typically be an overall measure of functioning rather than some specific aspect of functioning. Also, including multiple measures of different aspects of functioning may complicate the decision-making process for patients. Therefore, for synthesis, we collapsed FAQs 2, 3, and 4 into a key outcome of overall functioning.

For estimating the strength and quality of the evidence for overall functioning, we first tabulated the trials contributing to the multiple outcomes that assessed different aspects of functioning as shown below (with the outcomes listed in the order they were reported in the ongoing Cochrane's results). The information below about the contributing trials, their outcomes, and their risk of bias have all been extracted from the Results text and tables of the ongoing Cochrane review, other than: (1) lateral excursion movement outcomes (these are still pending extraction in the ongoing Cochrane review, and (2) data for two trials that are not included in the ongoing Cochrane review. The two trials not included in the ongoing Cochrane review are Singh 2010 (quasi-randomized, and therefore not meeting the Cochrane review eligibility criteria) and Asim 2019 (had not yet been identified by the ongoing Cochrane review, as updated searches have not yet been run). For Singh 2010 and Asim 2019, we extracted data from the trial publications. We also conducted random checks of the data in the ongoing Cochrane review against the trial publications it includes.

Outcome	Study	Timepoint of assessment	Open group findings	Closed group findings	Comparative statistics	Risk of bias (elements only listed if they are high or unclear)*
patient perception of overall mandibular impairment†	Eckelt 2006	6 months	mean 2.47 (SD 4.6), n = 36	mean 10.53 (SD 12.1), n = 30	MD -8.06 (95% CI -12.42 to -3.7) p < 0.001	• blinding of participants and personnel (high) • blinding of outcome assessors (unclear) • incomplete outcome data addressed (high) • free of selective outcome reporting (high)
limitation of mandibular movement	Kotrashetti 2013‡	3 months	0% (0/10)	33.3% (4/12)	ARD -33% (95% CI -61% to 1%)	• allocation concealment (high) • blinding of participants and personnel (high) • blinding of outcome assessors (high) • incomplete outcome data addressed (high)
		6 months	0% (0/10)	33.3% (4/12)	ARD -33% (95% CI -61% to 1%)	

Outcome	Study	Timepoint of assessment	Open group findings	Closed group findings	Comparative statistics	Risk of bias (elements only listed if they are high or unclear)*
	Rastogi 2015§	6 months	0% (0/25)	72% (18/25)	ARD -72% (95% CI -86% to -48%)	• blinding of participants and personnel (high) • blinding of outcome assessors (unclear) • free of selective outcome reporting (high)
	Asim 2019¶	6 months	mean 0.48 mm (SD 0.99 mm), n = 31	mean 1.09 mm (SD 1.60 mm), n = 35	MD -0.61 mm (95% CI -1.27 mm to 0.05 mm) p = 0.068	• random sequence generation (unclear) • allocation concealment (unclear) • incomplete outcome data (unclear) • blinding of patients, personnel, and outcome assessors (high)
	Singh 2010¶	6 months	mean 0.38 mm (SD 0.84 mm), n = 18	mean 1.18 mm (SD 1.29 mm), n = 22	MD NR/NC p = 0.03	• random sequence generation (high) • allocation concealment (high) • incomplete outcome data (unclear) • blinding of patients and personnel (high)
maximum inter-incisal opening**	Danda 2010	22.5 months (mean; range 4 to 42 months)	mean 42.125 mm (SD NR), n = 16	mean 40.062 mm (SD NR), n = 16	MD 2.06 mm (95% CI NR/NC) p > 0.05 per publication; estimated at 0.95	• blinding of participants and personnel (high)
	Eckelt 2006	6 months	mean 46.47 mm (SD 5.3 mm), n = 36	mean 40.93 mm (SD 6.8 mm), n = 30	MD 5.54 mm (95% CI 2.56 mm to 8.52 mm) p = 0.001	• blinding of participants and personnel (high) • blinding of outcome assessors (unclear) • incomplete outcome data addressed (high) • free of selective outcome reporting (high)
	Kotrashetti 2013 (proportion with opening <40 mm)††	3 months	20% (2/10)	58.3% (7/12)	ARD -38% (95% CI -65% to 2%)	• allocation concealment (high) • blinding of participants and personnel (high) • blinding of outcome assessors (high) • incomplete outcome data addressed (high)
		6 months	10% (1/10)	41.7% (5/12)	ARD -32% (95% CI -59% to 6%)	

Outcome	Study	Timepoint of assessment	Open group findings	Closed group findings	Comparative statistics	Risk of bias (elements only listed if they are high or unclear)*
	Asim 2019	6 months	mean 36.39 mm (SD 4.72 mm), n = 31	mean 33.74 mm (SD 4.72 mm), n = 35	MD 2.65 mm (95% CI 0.32 mm to 4.98 mm) p = 0.027	• random sequence generation (unclear) • allocation concealment (unclear) • incomplete outcome data (unclear) • blinding of patients, personnel, and outcome assessors (high)
	Singh 2010	6 months	mean 39.61 mm (SD 2.22 mm), n = 18	mean 33.54 mm (SD 1.89 mm), n = 22	MD NR/NC p = 0.00‡‡	• random sequence generation (high) • allocation concealment (high) • incomplete outcome data (unclear) • blinding of patients and personnel (high)
mandibular protrusion (forward excursion movement)	Danda 2010	22.5 months (mean; range 4 to 42 months)	mean 7.37 mm (SD NR), n = 16	mean 6.93 mm (SD NR), n = 16	MD 0.44 mm (95% CI NR/NC) p > 0.05 per publication; estimated at 0.69	• blinding of participants and personnel (high)
	Eckelt 2006	6 months	mean 7.33 mm (SD 2.0), n = 36	mean 4.7 mm (SD 2.5), n = 30	MD 2.63 mm (95% CI 1.52 mm to 3.73 mm) p = 0.001	• blinding of participants and personnel (high) • blinding of outcome assessors (unclear) • incomplete outcome data addressed (high) • free of selective outcome reporting (high)
	Singh 2010	6 months	mean 5.94 mm (SD 1.10 mm), n = 18	mean 4.13 mm (SD 0.77 mm), n = 22	MD NR/NC p = 0.00‡‡	• random sequence generation (high) • allocation concealment (high) • incomplete outcome data (unclear) • blinding of patients and personnel (high)
lateral excursion movement						
lateral excursion movement on fractured side	Danda 2010	22.5 months (mean; range 4 to 42 months)	mean 8 mm (SD NR), n = 16	mean 6.5 mm (SD NR), n = 16	MD 1.5 mm (95% CI NR/NC) p > 0.05; estimated at 0.69	• blinding of participants and personnel (high)

Outcome	Study	Timepoint of assessment	Open group findings	Closed group findings	Comparative statistics	Risk of bias (elements only listed if they are high or unclear)*
	Rastogi 2015	6 months			NR/NC p > 0.05§§	• blinding of participants and personnel (high) • blinding of outcome assessors (unclear) • free of selective outcome reporting (high)
lateral excursion movement on non-fractured side	Danda 2010	22.5 months (mean; range 4 to 42 months)	mean 8.06 mm (SD NR), n = 16	mean 7.56 mm (SD NR), n = 16	MD 0.5 mm (95% CI NR/NC) p > 0.05; estimated at 0.71	• blinding of participants and personnel (high)
	Rastogi 2015	6 months	NR	NR	p > 0.05§§	• blinding of participants and personnel (high) • blinding of outcome assessors (unclear) • free of selective outcome reporting (high)
lateral excursion movement as sum of movement to left and to right	Eckelt 2006	6 months	mean 17.5 mm (SD 5.1 mm), n = 36	mean 13.33 mm (SD 4.97 mm), n = 30	MD 4.17 mm (95% CI 1.68 mm to 6.66 mm) p = 0.001	• blinding of participants and personnel (high) • blinding of outcome assessors (unclear) • incomplete outcome data addressed (high) • free of selective outcome reporting (high)
	Singh 2010	6 months	mean 12.55 mm (SD 1.33 mm), n = 18	mean 9.86 mm (SD 1.64 mm), n = 22	MD NR/NC p = 0.00‡‡	• random sequence generation (high) • allocation concealment (high) • incomplete outcome data (unclear) • blinding of patients and personnel (high)
malocclusion	Kotrashetti 2013	6 months	0% (0/10)	8.3% (1/12)	ARD -8.3% (95% CI NR/NC, but clearly imprecise based on 1 event among 22 participants)	• allocation concealment (high) • blinding of participants and personnel (high) • blinding of outcome assessors (high) • incomplete outcome data addressed (high)

Outcome	Study	Timepoint of assessment	Open group findings	Closed group findings	Comparative statistics	Risk of bias (elements only listed if they are high or unclear)*
	Rastogi 2015	6 months	0% (0/25)	4% (1/25)	ARD -4% (95% CI NR/NC, but 95% CI for risk ratio reported as 0.01 to 7.81; only 1 event among 50 participants)	• blinding of participants and personnel (high) • blinding of outcome assessors (unclear) • free of selective outcome reporting (high)
	Asim 2019¶¶	6 months	mean 1.10 (SD 0.30), n = 31	mean 1.17 (SD 0.38), n = 35	MD -0.07 (95% CI -0.24 to 0.10) p = 0.386	• random sequence generation (unclear) • allocation concealment (unclear) • incomplete outcome data (unclear) • blinding of patients, personnel, and outcome assessors (high)
		6 months	9.7% (3/31)	17.1% (6/35)	ARD -7.4% (95% CI NR/NC) p = 0.48	
	Singh 2010***	6 months	mean 1.11 (SD 0.47), n = 18	mean 1.09 (SD 0.29), n = 22	MD NR/NC p = 0.86	• random sequence generation (high) • allocation concealment (high) • incomplete outcome data (unclear) • blinding of patients and personnel (high) • blinding of outcome assessors (unclear)
		6 months			ARD 4% (95% CI NR/NC, but only 3 events among 40 participants)	

ARD = absolute risk difference

NA = not applicable (commonly used when a specific measure of effect was not used, so an estimate for that measure of effect would not be reported, such as a trial reporting the results of an outcome on a continuous scale and not a dichotomous scale, so the 'Absolute risk difference (95% CI)' entry would be 'NA')

NR = not reported

NR/NC = not reported/not calculated (typically used when data such as a measure of effect or p-value could be calculated based on the outcome but was not reported, such as a trial using mean difference as outcome but only reporting a p-value for between group comparisons; the 'not calculated' portion refers to the fact that EBSCO Information Services calculated certain estimates based on available data but did not do this for all outcomes)

*Because it is typically difficult to rule out selective outcome reporting without a review of the trial protocol, we only include 'free of selective outcome reporting' domain for the 2 trials for which it was rated 'high' risk of bias (Eckelt 2006, Rastogi 2015; reasons for judgment are in Critical Appraisal) and not for the other trials for which it was rated 'unclear'

†As assessed by the 17-item mandibular function impairment questionnaire, with answers to each question being on a scale from 0 (no difficulty) to 4 (very difficult or impossible without help); the final score is a simple sum from 0 (best) to 68 (worst)

‡Measure used to assess outcome was movement limitations in all directions. This outcome was assessed dichotomously ("Restricted" vs. "Normal"), and it is not clear (1) whether this outcome was investigator-assessed or patient-reported or (2) what constituted a rating of "Restricted" vs. "Normal". This raises questions about the meaningfulness of this outcome (for instance, the presence of minor or trivial limitations could still be counted as "Restricted"), especially in the context of concerns about blinding.

¶Measure used to assess outcome was deviation of mouth opening (i.e., how far the jaw involuntarily moves laterally during movement intended to be purely vertical)

**Rastogi 2015 reported measuring maximum interincisal opening but did not report the results

††No justification for the choice of 40 mm as a cutoff is provided, and this dichotomization could lead to people with very small differences (such as 41 mm vs. 39 mm being considered 'adequate' vs. 'inadequate', respectively)
‡‡Per publication; no recalculated at EBSCO given the information would not impact evidence synthesis because the difference is of questionable meaningfulness anyway
§§Rastogi 2015 only reported "...At 6 months, there was no significant difference between the two groups with regard to ... movement of jaw toward the ipsilateral and contralateral sides..."
¶¶ Reported as both a continuous and dichotomous outcome. The continuous assessment is based on a scale from 1 to 3, with 1 being pre-trauma occlusion, 2 being mild malocclusion that required occlusal adjustment by spot grinding of teeth, and 3 being gross malocclusion that required reoperation. The dichotomous assessment amounted to those with "occlusal disturbances", all of which were "mild [and] managed by chairside occlusal adjustment".
***Reported as both a continuous and dichotomous outcome. The continuous assessment is based on a scale from 1 to 5, with 1 being identical to pretraumatic, 2 being slight difference, 3 being functional malocclusion, 4 being requiring occlusal adjustment, and 5 being gross malocclusions. The dichotomous assessment did not provide clear explanation of assessment and thus raises the possibility of people with slight abnormality (i.e., a rating of 2 on the continuous assessment) being counted as 'events'.

Evidence Synthesis Process

For the outcome of functioning, most trials measured outcomes at 6 months, but this varied somewhat across the trials and ranged from a minimum of 3 months to a maximum of almost 2 years.

We consider the available evidence from 6 randomized or quasi-randomized trials to be extremely limited. Five had multiple risk of bias domains assessed as high or unclear; the sixth (Danda 2010) was only at high risk in the domain of patient blinding. All trials were relatively small, and results were typically imprecise. Although we did not explicitly rate the overall certainty for each trial, we would probably consider the 5 trials with multiple high or unclear risk of bias domains to be Very low certainty and the Danda 2010 trial to be Low certainty. In cases where function outcomes were measured dichotomously, the way the outcome was assessed was often very unclear, and this was typically coupled with imprecision of the estimate; this gives us serious reservation about suggesting any direction of effect from these outcomes, regardless of the magnitude of the point estimate for some of the dichotomous measures; additionally, focusing on the dichotomous measures to the exclusion of the continuous outcomes would be akin to a form of selective outcome reporting and thus at high risk of bias. For outcomes assessed continuously, even where statistically-significant differences existed, the point estimates were of highly questionable clinical relevance and/or had confidence intervals compatible with differences of highly questionable clinical relevance. All these limitations raise serious questions about any attempt to assess 'consistency' of findings among the trials. However, we do note that the trial with the least risk of bias (Danda 2010) also showed no significant differences for any of the above outcomes (whereas the other trials had varying degrees of outcomes showing a statistical difference even if they are of questionable clinical relevance).

Given all these concerns, we rate the overall certainty of the evidence as Very low. Overall, the evidence is currently insufficient to establish whether closed treatment or open reduction is associated with better functioning. However, it is not unreasonable to consider that the available data – extremely limited as they are in both quantity and quality – might still suggest it is possible surgery could be somewhat better than treatment without surgery for some outcomes and some patients, but that the effect may be very small or unnoticeable and that the research is of very low quality. We emphasize additional, better-quality research is very much needed in this domain. Clinical impressions sometimes suggest the type of fracture may play a role in whether surgery yields better outcomes than closed reductions vs. whether closed reduction might be preferred, whereas others may favor closed reductions unless surgery is absolutely indicated. The suggestion that there may be heterogeneity for treatment effect based on the specifics of the fracture is a potentially useful observation from clinical expertise that could be further explored in future research efforts. Nevertheless, and as noted by the international Medical College of Münster, Germany (as of July 9, 2020): "Die Therapie der Gelenkfortsatzfrakturen ist umstritten. Eine große Vielzahl von Meinungen und von Therapiemaßnahmen werden in der Literatur angeboten." (roughly "Treatment of articular process fractures is controversial. A wide variety of opinions and therapeutic measures are offered in the literature."), and other than patients who have ≥1 absolute indication for surgery (and thus would fall outside the population of interest for this evidence report) "Zwischen den beschriebenen Indikationen gibt es eine breite Vielzahl von klinischen Situationen, für die keine konkreten therapeutischen Indikationen basierend auf stichhaltigen wissenschaftlichen Kriterien, erhältlich sind" (roughly "There is a wide variety of clinical situations between the described [absolute] indications, for which no specific therapeutic indications based on sound scientific criteria are available"). Regardless of these considerations, we consider it reasonable to state jaw function should improve as the jaw heals regardless of the treatment approach. This is the natural expectation with healing irrespective of treatment approach (even without comparison against no treatment at all, which would arguably be impractical and unethical).

Lastly, we acknowledge our conclusions may seem in contrast to those offered by other systematic reviews, such as Alyahya 2020, which is actually a systematic review of systematic reviews. Alyahya 2020 includes the systematic reviews Al-Moraissi 2015 and Chrcanovic 2015, and Alyahya 2020 base

their conclusions on these systematic reviews. However, we note both these systematic reviews include a mixture of observational and randomized studies, and we prespecified using randomized or quasi-randomized trials for this evidence report (see Scoping). Additionally, although we did not comprehensively evaluate Al-Moraissi 2015 or Chrcanovic 2015 given they are out of scope, an abridged inspection of Chrcanovic 2015 raises concern about its meta-analytic technique; as a simple example, for the outcomes of protrusion and laterotrusion shown in Figures 7 and 8, it appears Chrcanovic 2015 includes the same outcome from the same study reported at different time points as though it came from separate studies. This can obviously introduce serious bias in the results and raises questions about the quality/validity of Chrcanovic 2015 as a whole, so we do not consider it any further here. With Al-Moraissi 2015, it appears at least some of the findings suggestive of a 'difference' that 'favors' surgery are again limited by some of the issues we highlight in the existing trial evidence. For instance, we still have very serious concern about the opaque way dichotomous outcomes were assessed in the available evidence (let alone the choice to measure those outcomes dichotomously *per se*) and the spurious appearance of 'difference' this could bring; relatedly, outcomes measured on a continuous scale again demonstrate findings of questionable clinical relevance. For example, Al-Moraissi 2015 reports a statistically significant 'benefit' for maximal interincisal opening, but this is based on a meta-analytic mean difference of 3.32 mm (95% CI 2.42 mm to 4.04 mm); one sees similar findings for laterotrustive (1.14 mm; 95% CI 0.73 mm to 1.55 mm) and protrustive movement (0.99 mm; 95% CI 0.70 mm to 1.29 mm). These arguably marginal findings are perhaps noteworthy given the possibility for observational studies to bias effect estimates upward.

We emphasize that a conclusion of a modality being 'better' than another must not rest on whether one modality shows a statistical difference from another modality, but whether that difference is meaningful for patients.

Evidence Synthesis Results

Reasonable conclusion 1

How well you can use your jaw should get better as your jaw heals. There is not enough research to know if people who have treatment without surgery have worse functioning, better functioning, or similar functioning compared with people who have treatment with surgery.

Reasonable conclusion 2

How well you can use your jaw should get better as your jaw heals. It is possible that treatment with surgery could be somewhat better for some parts of how the jaw works for some people at 3 months or longer after treatment. But the research about this is not good, and if there is a difference, it may be very small or even too small to notice. We need better research to know if people who have treatment without surgery have worse functioning, better functioning, or similar functioning compared with people who have treatment with surgery.

(Very low certainty; based on 6 randomized trials [Asim 2019, Danda 2010, Eckelt 2006, Kotrashetti 2013, Rastogi 2015, Singh 2010])

FAQ 3: Will the treatment reduce pain or discomfort in my jaw?

(Note our simplification from the formally scoped "… in the temporomandibular joint?" to "… in my jaw?". This is solely for ease of comprehension.)

Closed treatment (no surgery) vs. open reduction with internal fixation (surgery)

Evidence Review

Two trials included in the ongoing Cochrane review (Nasser ND) reported pain as a dichotomous outcome (Kotrashetti 2013, Danda 2010) and one as a continuous outcome (Eckelt 2006). The quasi-randomized trial (Singh 2010, excluded from the ongoing Cochrane review) reported pain as both a continuous and dichotomous outcome. Asim 2019, which was identified in our searches to update the Cochrane review's searches, did not report on pain as an outcome. The data pertinent to synthesis are shown in the table below.

Study (no. patients)	Time point of assessment	Open group findings	Closed group findings	Comparative statistics	Risks of bias (elements only listed if they are high or unclear)*
Kotrashetti 2013 (n = 22)†	3 months	0% (0/10)	33.3% (4/12)	ARD -33.3% (95% CI -60.9% to 0.6%) p = 0.1430	• allocation concealment (high) • blinding of participants and personnel (high) • blinding of outcome assessors (high) • incomplete outcome data addressed (high)
	6 months	0% (0/10)	33.3% (4/12)	ARD -33.3% (95% CI -60.9% to 0.6%) p = 0.1430	
Danda 2010 (n = 32)†	22.5 months mean (range 4 to 42 months)	12.5% (2/16)	37.5% (6/16)	ARD -25.0% (95% CI -50.5% to 5.2%) p > 0.05	• blinding of participants and personnel (high)
Eckelt 2006‡ (n = 66)	6 months	mean 2.89 (SD 6.52), n = 36	mean 13.53 (SD 17.14), n = 30	MD -10.64 (95% CI -16.82 to -4.46) p = 0.003	• blinding of participants and personnel (high) • blinding of outcome assessors (unclear) • incomplete outcome data addressed (high) • free of selective outcome reporting (high)
Singh 2010†‡ (n = 40)	6 months	mean 1.11 (SD 3.30), n =18	mean 5.27 (SD 5.43), n = 22	MD -4.16 (95% CI NR/NC) p = 0.00	• sequence generation (high) • allocation concealment (high) • blinding of participants and personnel (high) • blinding of outcome assessors (high) • incomplete outcome data addressed (unclear)
	6 months	11.1% (2/18)	54.5% (12/22)	-43.4% (95% CI -63.6% to -14%)	

*Because it is typically difficult to rule out selective outcome reporting without a review of the trial protocol, we only include 'free of selective outcome reporting' domain for the trial reporting pain for which it was rated 'high' risk of bias (Eckelt 2006; reasons for judgment are in Critical Appraisal) and not for the other 3 trials for which it was rated 'unclear'.

†Measured pain dichotomously with little to no description (Kotrashetti 2013 as "present" or "absent", Danda 2010 as the proportion of patients who "had joint pain", and Singh 2010 as the proportion who had "no pain", which we inverted in the table to represent the proportion who had "any pain"). The manner in which these trials assessed pain dichotomously raises questions about the meaningfulness of the outcome; for instance, minor or trivial pain – such as a pain rating of 4 on a 0 to 100 visual analogue scale – could possibly still be counted as pain being "present".

‡Measured pain on a visual analogue scale from 0 to 100

Evidence Synthesis Process

Most trials reporting on pain or discomfort provided an outcome assessment at 6 months, but this varied somewhat and ranged from a minimum of 3 months to a maximum of almost 2 years.

We consider the available evidence from randomized or quasi-randomized trials to be extremely limited. Three of the 4 trials reporting on this outcome have 4 to 5 risk of bias domains at high or unclear risk (Danda 2010 has only one domain of concern, namely blinding of participants and personnel).

Danda 2010, Kotrashetti 2013, and Singh 2010 all measured pain dichotomously with little to no description, which raises questions about the meaningfulness of these outcomes; for instance, minor or trivial pain – such as a pain rating of 4 on a 0 to 100 visual analogue scale – could possibly still be counted as "pain". These effect estimates are also based on very few events (8 events out of 32 people in Danda 2010, 4 events among 22 people in Kotrashetti 2013, and 14 events out of 40 people in Singh 2010). It is unsurprising, therefore, that the results for 'pain' measured dichotomously were imprecise, though Singh 2010 technically reached conventional statistical significance (Singh 2010 also had the highest number of risk of bias domains that were assessed as high or unclear). We would consider it tenuous to place any emphasis on the point estimate for the absolute risk difference, and we would have serious reservation about inferring any 'direction' of effect given how limited the data are. Eckelt 2006 and Singh 2010 both assessed pain on a 0 to 100 visual analogue scale; although they showed a statistical difference favoring open reduction, both estimates also had considerable imprecision, and one could question the importance of the point estimates as well (again, however, we would have reservation about any emphasis on the point estimate for these data).

Given the multiple risks of bias across the body of evidence, the lack of detail in outcome definition for some outcomes, and the imprecision in the results, we have rated this outcome as Very low. Overall, the evidence is currently insufficient to establish whether closed treatment or open reduction is associated with better pain outcomes. However, it is not unreasonable to consider that the available data – extremely limited as they are in both quantity and quality – might still suggest it is possible surgery could be somewhat better than treatment without surgery for pain for some patients, but that the effect may very small or unnoticeable and that the research is of very low quality. We also reiterate our considerations in FAQ 2 (Will the treatment help how my jaw works?) regarding: the need for additional, better-quality research; the clinical impressions that offer variable suggestion of a possibility for heterogeneity of treatment effect based on the type of fracture and that this could be investigated in future research efforts; and the controversy and uncertainty that exists in the treatment of mandibular condyle fractures without an absolute indication for surgery, as well-emphasized by the International Medical College of Münster, Germany. Regardless of these considerations, we consider it reasonable to state that pain should get better as the jaw heals regardless of the treatment approach. This is the natural expectation with healing irrespective of treatment approach and is also at least indirectly supported by the low mean pain scores in both groups in the studies that assessed pain on a continuous scale and the majority of people not having pain at 3 months of follow-up or longer in the studies that assessed pain dichotomously (we note Singh 2010 had a >50% rate of 'any' pain in the control group at follow-up, but we also note this study is methodologically the weakest of the studies; thus, we do not consider it to provide sufficient evidence to the contrary, especially given how tenuous the dichotomous definitions of pain seem to be).

Similar to the function outcome (see FAQ 2: Will the treatment help how well my jaw works?), we acknowledge our conclusions may seem in contrast to those offered by other systematic reviews, such as Alyahya 2020, which is actually a systematic review of systematic reviews. Alyahya 2020 includes the systematic reviews Al-Moraissi 2015 and Chrcanovic 2015, and Alyahya 2020 base their conclusions on these systematic reviews. However, we

note both these systematic reviews include a mixture of observational and randomized studies, and we prespecified using randomized or quasi-randomized trials for this evidence report (see Scoping). Additionally, although we did not comprehensively evaluate Al-Moraissi 2015 or Chrcanovic 2015 given they are out of scope, we do not address Chrcanovic 2015 in any detail for this FAQ given the concerns we highlight in FAQ 2. With Al-Moraissi 2015, it appears at least some of the findings suggestive of a 'difference' that 'favors' surgery are again limited by some of the issues we highlight in the existing trial evidence. For instance, we still have very serious concern about the opaque way pain was assessed dichotomously in the available evidence (let alone the choice to measure it dichotomously *per se*) and the spurious appearance of 'difference' this could bring; relatedly, pain measured on a continuous scale again demonstrates findings of questionable clinical relevance. For example, Al-Moraissi 2015 reports a dichotomous measure of "TMJ Pain and Clicking", but it is not clear how this outcome was assessed (e.g., Did patients need to have both pain and clicking or just one or the other? Was 'any' pain and/or 'any' clicking sufficient to be counted as a patient with the event?). It is also unclear why Al-Moraissi 2015 would combine pain and clicking as a composite outcome (e.g., it seems unlikely that patients care equally about pain and clicking). Al-Moraissi 2015 also reports a statistically significant 'benefit' for surgery for the outcome of pain on the visual analogue scale. However, they conduct their meta-analysis using the standardized mean difference, which is unnecessary given both Singh 2010 and Eckelt 2006 (the only studies contributing to their meta-analysis) measured pain on a 0 to 100 visual analogue scale, as noted in our evidence review table. We also note Al-Moraissi 2015 report their results show a reduction in pain in the surgery group amounting to "0.74 mm on VAS; 95% CI, 1.07 to 0.41 mm on VAS". This is incorrect, because the effect measure of their meta-analysis is the standardized mean difference, so the results are in standard deviation units, not mm. They also say these findings "do not reach statistical significance" when they in fact do. In any case, the data presented by Al-Moraissi 2015 for Singh 2010 and Eckelt 2006 are identical to those we present in our evidence review table. Accordingly, one can infer effects in a more straightforward manner from those data than from Al-Moraissi 2015's meta-analysis of the standardized mean difference.

As with the function outcome, we emphasize that a conclusion of a modality being 'better' than another must not rest on whether one modality shows a statistical difference from another modality, but whether that difference is meaningful for patients.

Evidence Synthesis Results

Reasonable conclusion 1

Pain should get better as your jaw heals. There is not enough research to know if people who have treatment without surgery have less pain, more pain, or the same amount of pain compared with people who have treatment with surgery.

Reasonable conclusion 2

Pain should get better as your jaw heals. It is possible that treatment with surgery could help some people have less pain at 3 months or longer after treatment. But the research about this is not good, and if there is a difference, it may be very small or even too small to notice. We need better research to know if people who have treatment without surgery have less pain, more pain, or the same amount of pain compared with people who have treatment with surgery.

(Very low certainty; based on 4 randomized trials [Danda 2010, Eckelt 2006, Kotrashetti 2013, Singh 2010])

FAQ 4: What are the risks?

Closed treatment (no surgery) vs. open reduction with internal fixation (surgery)

Evidence Review

Facial nerve function

Two trials (Danda 2010, Kotrashetti 2013) included in the ongoing Cochrane review (Nasser ND) reported facial nerve weakness/loss of facial nerve function (both as a dichotomous outcome), and the quasi-randomized Singh 2010 trial (excluded from the ongoing Cochrane review) reported outcomes on motor function as continuous outcome. Singh 2010 also reported on sensory function, but sensory function to the face is served by the trigeminal nerve rather than the facial nerve, so we did not carry it forward to Evidence Synthesis (though both groups had no deficit in sensory function). Asim 2019, which was identified in our searches to update the Cochrane searches, did not report on facial nerve weakness/loss of facial nerve function. The data pertinent to synthesis are shown in the table below.

Study (no. patients)	Time point of assessment	Open group findings	Closed group findings	Absolute difference (95% CI)	Risks of bias (elements only listed if they are high or unclear)
Kotrashetti 2013 (n = 22)	3 months	10% (1/10)	0% (0/12)	10% (-15.6% to 40.4%)	• allocation concealment (high) • blinding of participants and personnel (high) • blinding of outcome assessors (high) • incomplete outcome data addressed (high)
	6 months	10% (1/10)	0% (0/12)	10% (-15.6% to 40.4%)	
Danda 2010 (n = 32)	1 month	12.5% (2/16)	0% (0/16)	12.5% (-8.9% to 36.0%)	• blinding of participants and personnel (high)
Singh 2010* (n = 40)	6 months	mean 1.00 (SD 0.00), n = 18	mean 1.00 (SD 0.00), n = 22	None†	• sequence generation (high) • allocation concealment (high) • blinding of participants and personnel (high) • blinding of outcome assessors (high) • incomplete outcome data addressed (unclear)

*Based on a patient-reported 5-category scale, with 1 being no deficit and 5 being complete absence of function

†Could not be determined statistically because the mean and SD of both groups were 1 and 0, respectively, thus signaling no difference (more specifically, the mean and SD indicate there was no deficit in any patient)

Scarring

Data from randomized or quasi-randomized trials are extremely limited for the outcome of scarring. We found only Kotrashetti 2013 and Rastogi 2015 to report on scarring, and only in an extremely limited manner. Kotrashetti 2013 also assessed scar as "conspicuous, inconspicuous, or hypertrophic". Out of 10 patients treated with surgery, 1 (10%) had a scar rated as conspicuous. They do not provide data for other scar ratings. These findings are only reported in their Discussion section. Rastogi 2015 noted "…at the 6th-month evaluation, none of the patients [treated with surgery] developed any complications, such as facial nerve damage, parotid fistula, or an unsightly scar."

Infection and bleeding

These outcomes were added for descriptive summaries after original completion of this evidence report and thus were not part of systematic evidence searches, critical appraisal, or evidence synthesis. We address these outcomes below.

Synthesis Process

Of note, facial nerve injury and scar are both considered to be outcomes associated with open reduction (surgery) rather than being associated with either closed or open reduction (Alyahya 2020, Nasser ND, Rastogi 2015, Sharif 2010). Additionally, although these outcomes were scoped to be addressed with randomized or quasi-randomized trials (or systematic reviews thereof), we note that the evidence that does exist is extremely limited. The relative infrequency of these outcomes and that fact that facial nerve weakness may not be permanent and scarring may improve over time (thus possibly needing longer follow-up time to ascertain fully) led us to consider additional sources for information on these outcomes.

In a systematic review of systematic reviews, Alyahya 2020 noted "facial nerve injury could be the main reason that many surgeons choose non-surgical treatment for condylar fractures"; Alyahya 2020 cite the systematic review and meta-analysis of mixed study types by Al-Moraissi 2015 as reporting an incidence of postoperative facial nerve injury of 8.3%, with only 2.2% still having an issue at 6 months. In line with our concern immediately above, Alyahya 2020 also discuss follow-up, noting "it is generally accepted that at least one year of follow-up is required to report a permanent nerve injury". We examined Al-Moraissi 2015 and found these results reported only in their Discussion section. Of note, Al-Moraissi 2015 incorrectly report the percentage of people with postoperative facial nerve injury as 5.83%; Al-Moraissi 2015 report this outcome occurred in 22 of 265 patients (≈ 8.3%, in line with what Alyahya 2020 report), and Al-Moraissi 2015 also note only 6 had persistent issues at 6 months (≈ 2.3%; Alyahya 2020 report 2.2%). We also note these estimates are the result of simple summation of numerators and denominators across studies rather than an actual meta-analysis of single proportions; given Al-Moraissi 2015 allude to possible heterogeneity in the estimates (describing a range from 0% to 21% across studies), it is important to note a simple summation as they did (and as Alyahya 2020 repeated) would fail to capture between-study variance and is thus at considerable risk of yielding falsely-precise estimates.

Al-Moraissi 2015 also note "Data about unacceptable scarring were limited, but in most studies, the scar was described as imperceptible and acceptable by the patient"; no quantification accompanies this statement, and the citation provided for this statement is a single non-randomized study of 178 patients (93 receiving surgery, 85 receiving closed reduction; Ellis 2000). Alyahya 2020 also note "Although facial scarring is well concealed with the contemporary approaches to condylar fracture, scarring is the most frequent complaint from patients"; however, the reference provided for this claim is to a single non-randomized study of 20 patients (10 receiving surgery, 10 receiving closed reduction; Haug 2001).

A more recent systematic review (García-Guerrero 2018) found essentially comparable results for facial nerve injury (8.6%, with resolution in 8.3%) and reported inclusion of studies with follow-up durations longer than 6 months. However, we have serious concerns about the quality of this review (shared by Alyahya 2020, who excluded it from consideration due to rating its quality as being "Critically low" per the AMSTAR-2 rating system).

García-Guerrero 2018 also report on other complications from surgery, including hemorrhage and infection. Our concerns about García-Guerrero 2018 hold in full (i.e., for the entire systematic review), but they note risks of 0.60% and 0.17% for infection and hemorrhage, respectively. Although out of

scope, they also note other possible complications, such as seroma and salivary fistula. Of note, Al-Moraissi 2015 also discuss these complications, but only as a consideration within their discussion section.

Given the above considerations, we feel it is reasonable to state: (1) facial nerve injury may occur with surgery, but that most probably do not experience this, (2) that persistent facial nerve weakness is even more uncommon, (3) surgery may produce a scar, but this may improve over time or even be unnoticeable depending on how the surgery is done and how well the incision site heals, (4) that infection and bleeding are potential complications of surgery but are not common, and (5) that there may be other risks from surgery that patients can discuss with their health care team. We do not provide quantification for these statements, but we do give qualitative ideas of frequency/commonality.

Descriptive Summary Results

There is a risk that surgery will injure a nerve in your face. If this happens, it can make your face muscles weak. But most of the time, this does not happen. If the nerve is injured, people usually get the strength in their face back within 6 months or so.

Surgery can sometimes leave a scar. But depending on the type of surgery and how well the area heals, there may be no scar or only a very small scar.

As with any surgery, there is a risk of infection or bleeding, but these things are not common. Surgery may also have other risks, and you can talk about this more with your health care team.

(Certainty not assessed for these statements, but insufficient evidence from relevant sources formally included for evidence appraisal and synthesis [Asim 2019, Danda 2010, Kotrashetti 2013, Nasser ND, Rastogi 2015, and Singh 2010]; additional sources consulted as part of developing the above descriptive responses include Alyahya 2020, Al-Moraissi 2015, Ellis 2000, García-Guerrero 2018, Haug 2001, and Sharif 2010)

Evidence report for closed treatment (without surgery) vs. open reduction (involving surgery) for fractures of the mandibular condyle

Search and Selection

EBSCO Information Services

June 8, 2020

Prepared by EBSCO Health Innovations and EBM Development Department (in alphabetic order):

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Methods

Approach to search and selection for this evidence report:
In line with Scoping for this evidence report, in contrast to our typical approach to search and selection (retained below for completeness and transparency), we began our search and selection process (first-round searching) with an as-of-yet unpublished Cochrane review that directly addresses the intended scope of this evidence report. This Cochrane review is considered unfinished according to the lead and corresponding author, Mona Nasser, but she kindly shared the preliminary content of the Cochrane review to benefit our preparation of this evidence report. Of note, this pending Cochrane review subsumes and supplants two prior Cochrane reviews that were prepared separately for mandibular condyle fracture and fractures of the mandible not involving the condyle (Nasser 2013, Sharif 2010).

When this Cochrane is published, it will then become the most current systematic review on this topic. Accordingly, it would seem unhelpful to search for more current systematic reviews (as is typically part of our second-round search process). Accordingly, we planned to search as follows: (1) we would search PubMed/MEDLINE® for randomized or quasi-randomized trials to confirm there are no trials that are not/not yet included in the pending Cochrane review, and (2) we would conduct citation tracing from included sources as/if needed.

Typical approach to search and selection, retained here for completeness and transparency:
First-round searching will consist of searching DynaMed Plus summaries pertinent to the topic. The search starts with DynaMed Plus because DynaMed Plus content is based on a thorough, systematic search and active literature surveillance system.

> Systematic literature surveillance (SLS) has been a cornerstone of creating DynaMed content since its inception. Currently, the SLS team works closely with members of McMaster University's Department of Health Research Methods, Evidence, and Impact to define and refine optimal search strategies, utilizing search terms for methodology and for clinical concepts (especially diagnosis and treatment) for each journal. These filters for PubMed searches are derived from PubMed Clinical Queries, McMaster University Hedges system, and DynaMed search filters and were found to capture >95% of relevant valid articles for use in DynaMed.[1]
> [1]Alper BS, Iorio A. Optimising search filters for active literature surveillance: a concordance study. Global Evidence Summit. Cape Town, South Africa; September 2017.
>
> The SLS team, in collaboration with McMaster University, continually evaluates and improves these filters to keep abreast of the ever-changing medical literature landscape. PubMed searches are performed daily. Each article is assessed by an external screener for clinical relevance, then reviewed by internal staff for both clinical relevance and validity. Any disagreements are settled by the Deputy Editor of the SLS team.
> In addition, the SLS team continually monitors the Journal source list against the list of journals catalogued in MEDLINE and existing DynaMed content to determine the set of journals that provide the highest yield for valid, clinically relevant content. As of November 2018, 507 Journals are systematically searched (see http://dynamed.com/home/content/content-sources). The journal selection threshold leads to routine adjustments to the number of journals selected.

Second-round searching will involve PubMed/MEDLINE® searches for intervention-specific systematic reviews or guidelines that involve a systematic review that are more recent than those identified in first-round searching.

Third-round searching will involve searches for original evidence reports. Such searching will be limited to areas considered insufficiently addressed by earlier searches, such as focused concepts published after search dates in systematic reviews.

Fourth-round searching will involve citation tracing from sources found in the preceding rounds of searching. This may be done to identify additional evidence sources if the results from the preceding rounds of searching are insufficient.

Additional selective searching, such as tracing citations from articles found or seeking related articles, may be done for additional concepts discovered.

Additional evidence updates may also be added continuously from feedback from any source.

FAQ Summary

Results

Use of preliminary results from a pending Cochrane review

Nasser M, Dorri M, Pandis N, Sharif MO, Fleming PS, Ali K, Ellis E, Elango NM. Interventions for managing mandibular fractures. *Pending Cochrane Review, provided by Nasser M.*

First-round searching – searching for randomized or quasi-randomized trials not included/not yet included in the pending Cochrane review by Nasser and colleagues (Nasser ND)

Database	Search string	Number of search results	Number of unique references included
PubMed June 8, 2020	((mandibular OR mandible) AND (condyle OR condylar) AND fracture) AND (randomized controlled trial OR quasi-randomized OR quasi-randomised OR quasi-random) NOT (systematic[sb] OR meta-analysis[ti]) AND ("2013/01/01"[EDAT] : "3000/12/31"[EDAT])	44	1 (Asim 2019)*

*Also retrieved a publication describing an ongoing trial (underway since 2013) that has been impeded by a number of challenges (Rozeboom 2018)

PARSE Mapping

PARSE Name	Search string	Number of search results	Number of new references selected for inclusion
Mandibular condyle fracture first round string #1	((mandibular OR mandible) AND (condyle OR condylar) AND fracture) AND (randomized controlled trial OR quasi-randomized OR quasi-randomised OR quasi-random) NOT (systematic[sb] OR meta-analysis[ti]) AND ("2013/01/01"[EDAT] : "3000/12/31"[EDAT])	39*	Not applicable for first run

*The discrepancy from the count in the above search is due to the cutover to the new PubMed/MEDLINE® (PARSE still uses the previous version of PubMed/MEDLINE®).

Second-round searching – citation tracing

Source	Tracing	Number of unique references included
Nasser pending Cochrane review (Nasser ND)	Tracing for randomized or quasi-randomized trials	5 (Danda 2010*, Eckelt 2006*, Kotrashetti 2013*, Rastogi 2015*†, Singh 2010‡)

*We include only a brief entry for this study in Critical Appraisal as part of assessing for outcomes we scoped for inclusion but were not yet included in the pending Cochrane review by Nasser and colleagues

†Also published as Shiju 2015

‡Full summary in Critical Appraisal given it was not included in the pending Cochrane review by Nasser and colleagues (it was excluded due to its quasi-randomized design)

Search summary:

Number of articles screened and selected

	Screened	Selected*
Start with pending Cochrane review by Nasser and colleagues	1	1
1st-round (searching for randomized or quasi-randomized trials)	44†	1
2nd-round (citation tracing)	5	5
Total	*50*	*7*

*Number shown is after deduplication

†Also retrieved a publication describing an ongoing trial (underway since 2013) that has been impeded by several challenges (Rozeboom 2018)

	Articles selected for evaluation (Author Year)
Systematic reviews	1 (pending Cochrane review by Nasser and colleagues)
Randomized or quasi-randomized trials	6 (Asim 2019*, Danda 2010†, Eckelt 2006†, Kotrashetti 2013†, Rastogi 2015†‡, Singh 2010‡§)
Other article types	0

*Full summary in Critical Appraisal given it is not/not yet included in the pending Cochrane review by Nasser and colleagues

†We include only a brief entry for this study in Critical Appraisal as part of assessing for outcomes we scoped for inclusion but were not/not yet included in the pending Cochrane review by Nasser and colleagues

‡Also published as Shiju 2015

§Full summary in Critical Appraisal given it is not included in the pending Cochrane review by Nasser and colleagues (they excluded it due to its quasi-randomized design)

Evidence report for closed treatment (without surgery) vs. open reduction (involving surgery) for fractures of the mandibular condyle

Critical Appraisal

EBSCO Information Services

June 29, 2020

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Methods

For each study selected for critical appraisal, we assessed for criteria needed for Level 1 [likely reliable] evidence ratings in DynaMed's Levels of Evidence criteria in which evidence quality is labeled in 1 of 3 levels:

- **(level 1 [likely reliable] evidence)** for studies with clinical outcomes and minimal risk of bias;
- **(level 2 [mid-level] evidence)** for studies with clinical outcomes and significant methodological or statistical limitations; and
- **(level 3 [lacking direct] evidence)** for reports that do not include scientific analysis of clinical outcomes or for study types that do not include comparisons between groups.

The specific concepts we critically assessed are fully mapped to cover all the criteria used in GRADE. We summarized key concerns identified that reduce the certainty of evidence in categories used for GRADE methods (i.e., risks of bias, indirectness, imprecision, inconsistency, and other considerations if relevant). In the study-level summaries inconsistency assessment was applied to consistency of within-study results – this applies to consistency across related outcomes for both original studies and for systematic reviews, and also applies to consistency across studies when applied to systematic reviews.

FAQ Summary

Results

Characteristics and Results of Critically Appraised Studies/Sources

ASIM 2019

Asim MA, Ibrahim MW, Javed MU, Zahra R, Qayyum MU. Functional Outcomes Of Open Versus Closed Treatment Of Unilateral Mandibular Condylar Fractures. J Ayub Med Coll Abbottabad. 2019;31(1):67-71. PubMed

Relevant to FAQ2, FAQ3, FAQ4

- **Study design:** randomized trial
- **Population:** adults with unilateral condylar neck or subcondylar fractures (head fractures excluded) with either or both of following
    - moderately displaced
        - ≥2 mm but <15 mm calculated on orthopantomogram
    - deviated
        - ≥10° but <45° calculated on reverse townes or PA mandible radiograph
- **Intervention:** open reduction and internal fixation
    - with miniplates
    - using either extraoral or intraoral approach
        - only 6 cases utilized an intraoral approach (remainder used preauricular, submandibular, or retromandibular approaches)
- **Comparison:** closed treatment with immobilization
    - with maxillomandibular fixation for 3 to 5 weeks

- **Study inclusion criteria:**
    - treated from June 2011 to December 2015

- **Number of participants:** 80 met the inclusion criteria and were included in study, 40 in each group
    - 14 patients dropped out because they were not able to maintain the follow up for 6 months post operatively
        - 9 in open treatment
        - 5 in closed treatment
- **Duration of follow-up:** outcomes assessed after 6 months of follow-up

- **Results:**

Clinical results at 6 months after surgery

Outcome	Open reduction (n = 31) mean (SD)	Closed treatment (n = 35) mean (SD)	P-value comparing groups	Mean difference (95% CI)*	Certainty (downgrade)[1]
maximum interincisal opening (mm)	36.39 (4.72)	33.74 (4.72)	0.027	2.65 (0.32 to 4.98)	Very low (risk of bias, imprecision)
deviation on opening (mm)†	0.48 (0.99)	1.09 (1.60)	0.068	-0.61 (-1.27 to 0.05)	Very low (risk of bias, imprecision)
occlusion‡	1.10 (0.30)	1.17 (0.38)	0.386	-0.07 (-0.24 to 0.10)	Very low (risk of bias, imprecision)

*Estimated by EBSCO Information Services (given sample size, calculations use a t distribution, though a z distribution would yield a comparable estimate here; homoscedasticity vs. heteroscedasticity makes little meaningful difference here, but results shown are under the condition of homoscedasticity)

†Assessed by calculating the midline discrepancy during mouth opening (i.e., how far the jaw involuntarily moves laterally during movement intended to be purely vertical)

‡Means are based on a 3-category scale: 1: pre-trauma occlusion; 2: mild malocclusion that required occlusal adjustment by spot grinding of teeth; 3: gross malocclusion, that required reoperation. The Results text also reported this outcome as the proportion of patients with occlusal disturbances, which was 17.1% (6/35) patients with closed treatment and 9.7% (3/31) patients with open treatment (p value not reported but calculated to be 0.48); all occlusal disturbances were classified as mild and comparative statistics were not reported for a comparison of these proportions.

[1]All outcomes were downgraded twice for risk of bias due to unclear risk of bias for random sequence generation, allocation concealment, and incomplete outcome data, and high risk of bias for blinding.

Risk of bias assessment

sequence generation	allocation concealment	blinding of participants and personnel	blinding of outcome assessors	incomplete outcome data addressed	free of selective outcome reporting
unclear*	unclear*	high†	high†	unclear‡	unclear

*Reported to be "randomized control trial" but description of method does not include information about sequence generation or allocation concealment "Selection of patients for either open or closed treatment group was done randomly by lottery method."

†There was no mention of blinding of either patients or outcome assessors, and if this were done, it probably would have been mentioned.

‡Although the overall proportion of dropouts was not high, there was differential dropouts across groups (ie, 9/40 in open and 5/40 in closed) which may increase the risk of bias.

DANDA 2010
Danda AK, Muthusekhar MR, Narayanan V, Baig MF, Siddareddi A. Open versus closed treatment of unilateral subcondylar and condylar neck fractures: a prospective, randomized clinical study. J Oral Maxillofac Surg. 2010;68(6):1238-1241. PubMed

Relevant to FAQ4

We extracted data for all but 2 outcomes from the Nasser ND Cochrane review. The only outcomes relevant to our scoped outcomes that the Cochrane review did not report the data for were (1) scar, and (2) lateral excursion movement (the latter of which the Cochrane review noted was still to be added). Lateral excursion movement is 1 of 2 pre-specified outcomes we included as part of our 'FAQ 4: Will the treatment help me move my jaw in other ways?' (the other was mandibular protrusion which was included in the Cochrane review and extracted from there). Therefore, we extracted data on scar and lateral excursion movement from each of the articles that reported this outcome as brief summaries including only this information. Danda 2010 did not report on scar.

Comparison of open vs. closed on lateral excursion movement on fractured side and nonfractured side

Outcome	Duration of follow-up (months)	Open		Closed		P-value comparing groups	Mean difference (95% CI)
		no.	mean (SD)	no.	mean (SD)		
lateral excursion movement on fractured side	22.5 mean (range 4 to 42 months)	16	8 mm (NR)	16	6.5 mm (NR)	> 0.05; estimated at 0.69*	1.5 mm (not estimated†)
lateral excursion movement on nonfractured side	22.5 mean (range 4 to 42 months)	16	8.06 mm (NR)	16	7.56 mm (NR)	> 0.05; estimated at 0.71*	0.5 mm (not estimated†)

*Estimated by EBSCO Information Services from the reported t statistics (0.4 for fractured side, 0.37 for nonfractured side) and degrees of freedom (30)
†Quantified estimates would require knowledge of the SDs in each of the groups or alternative methods to estimate the CI based on the available information; alternatively, for purposes of this evidence report, one might instead reasonably infer from the data that the CI might not have a substantive impact on overall conclusions (despite the absence of a CI technically precluding quantitative inference about the extent to which the data might be compatible with meaningful differences).

ECKELT 2006
Eckelt U, Schneider M, Erasmus F, et al. Open versus closed treatment of fractures of the mandibular condylar process-a prospective randomized multi-centre study. J Craniomaxillofac Surg. 2006;34(5):306 314. PubMed

Relevant to FAQ4

We extracted data for all but 2 outcomes from the Nasser ND Cochrane review. The only outcomes relevant to our scoped outcomes that the Cochrane review did not report the data for were (1) scar, and (2) lateral excursion movement (the latter of which the Cochrane review noted was still to be added). Lateral excursion movement is 1 of 2 pre-specified outcomes we included as part of our 'FAQ 4: Will the treatment help me move my jaw in other ways?' (the other was mandibular protrusion which was

included in the Cochrane review and extracted from there). Therefore, we extracted data on scar and lateral excursion movement from each of the articles that reported this outcome as brief summaries including only this information. Eckelt 2006 did not report on scar. As shown in the table below, Eckelt 2006 reported lateral excursion movement on the left and right and the sum of both. In Scoping, we specified lateral excursion movement irrespective of the side of fracture. Because the unclear utility of reporting excursion to the right and left as separate outcomes, we only progressed the sum of both excursions to Evidence Synthesis.

Lateral movement outcomes at 6-month follow-up point

Outcome	Open (n = 36) mean (SD)	Closed (n = 30) mean (SD)	P-value comparing groups	Mean difference (95% CI)*
Left lateral excursion (mm)	8.44 (3.02)	6.33 (2.7)	0.004	2.11 (0.69 to 3.53)
Right lateral excursion (mm)	9.06 (2.7)	7 (2.7)	0.004	2.06 (0.73 to 3.39)
Sum of both excursions (mm)	17.5 (5.1)	13.33 (4.97)	0.001	4.17 (1.68 to 6.66)

*Estimated by EBSCO Information Services (given sample size, calculations use a t distribution, though a z distribution would yield a comparable estimate here; homoscedasticity vs. heteroscedasticity makes little meaningful difference here, but results shown are under the condition of homoscedasticity)

KOTRASHETTI 2013

Kotrashetti SM, Lingaraj JB, Khurana V. A comparative study of closed versus open reduction and internal fixation (using retromandibular approach) in the management of subcondylar fracture. Oral Surg Oral Med Oral Pathol Oral Radiol. 2013;115(4):e7-e11. PubMed

Relevant to FAQ4, FAQ6

We extracted data for all but 2 outcomes from the Nasser ND Cochrane review. The only outcomes relevant to our scoped outcomes that the Cochrane review did not report the data for were (1) scar, and (2) lateral excursion movement (the latter of which the Cochrane review noted was still to be added). Lateral excursion movement is 1 of 2 pre-specified outcomes we included as part of our 'FAQ 4: Will the treatment help me move my jaw in other ways?' (the other was mandibular protrusion which was included in the Cochrane review and extracted from there). Therefore, we extracted data on scar and lateral excursion movement from each of the articles that reported this outcome as brief summaries including only this information.

Kotrashetti 2013 reported in Methods that lateral excursion movement would be evaluated (ie, "...movements (protrusive, laterospective-right, -left),..." but we did not find outcome data for these outcomes reported individually; rather, the authors appear to adopt an aggregate evaluation of these movements (as "mandibular movements" in Table III) with evaluation occurring as a dichotomous determination of "Restricted" vs. "Normal" (without further specification of how these assessments were made. This "mandibular movements" outcome in Table III had already been extracted into the ongoing Cochrane review and is included in our summary of the Cochrane.

Kotrashetti 2013 also assessed scar as "conspicuous, inconspicuous, or hypertrophic". Out of 10 patients treated with surgery, 1 (10%) had a scar rated as conspicuous. They do not provide data for other scar ratings. These findings are only reported in their Discussion section.

NASSER ONGOING COCHRANE REVIEW (NASSER ND)

This is an ongoing Cochrane review which includes trials evaluating interventions for the treatment of fractures of the mandibular with or without condylar involvement. Once published, it will update and replace two earlier Cochrane reviews – one specific to fractures of the mandibular with condylar involvement (Sharif 2010) and the other specific to fractures of the mandibular without condylar involvement (Nasser 2013). Although it is ongoing, it includes characteristics, outcomes, and risk of bias assessments for 4 out of the 5 trials comparing open vs. closed that we had identified as relevant during our scoping efforts. The fifth trial we identified (Singh 2010, summarized separately) was a quasi-randomized trial, a study design which had been pre-specified as not eligible for the Cochrane review but eligible for our evidence report (we decided to include quasi-randomized trials because of the overall thin level of randomized trial evidence). We also identified a trial that is not/not yet included in the Cochrane review (Asim 2019, summarized separately). The only outcomes relevant to our scoped outcomes that the Cochrane review did not report the data for were (1) scar, and (2) lateral excursion movement (the latter of which the Cochrane review noted was still to be added). We prepared separate abbreviated summaries for these outcomes as reported in the respective studies. During crosschecks of the data in Nasser ND vs. the original trial publications, we discovered Nasser ND appear to have misinterpreted the data tables in Kotrashetti 2013, so all data appearing below are from the original Kotrashetti 2013 publication.

Relevant to FAQ2, FAQ3, FAQ4, FAQ5, FAQ6

- **Study design:** systematic review of randomized trials
    - quasi-randomized trials were excluded
- **Population:** patients with fractures of the mandibular condyle
    - review included fractures of the mandible with or without condylar involvement, but we were only interested in the trials on mandibular condyle fracture
- **Intervention:** open reduction (involving surgery)
    - review included all interventions, but we were only interested in the trials comparing open vs. closed
- **Comparison:** closed treatment (without surgery)
    - review included all interventions, but we were only interested in the trials comparing open vs. closed
- **Study inclusion criteria:** no additional

- **Number of studies:** 4
    - 4 included studies addressed our comparison of interest
        - open reduction and internal fixation vs. closed treatment and maxillomandibular fixation
            - no included studies compared open reduction and internal fixation vs. no active intervention as the closed treatment option
- **Number of participants:**
    - total from 4 included studies
        - Danda 2010, n = 32
        - Eckelt 2006, n = 88
            - 66 patients (75%) completed the 6-month follow-up and were analyzed
            - 22 patients (25%) - treatment had not been completed, missed the follow-up examinations, or data files were incomplete so not analyzed

  - Kotrashetti 2013, n = 22
  - Rastogi 2015, n = 50
- **Duration of follow-up:** see Results tables below

- **Results and Certainty:**

patient perception of overall mandibular impairment*

Studies	Time point of outcome assessment (months)	Open		Closed		P-value comparing groups	Mean difference (95% CI)†
		no.	mean (SD)	no.	mean (SD)		
Eckelt 2006	6	36	2.47 (4.6)	30	10.53 (12.1)	< 0.001	-8.06 (-12.42 to -3.7)

*As assessed by the 17-item mandibular function impairment questionnaire, with answers to each question being on a scale from 0 (no difficulty) to 4 (very difficult or impossible without help); the final score is a simple sum from 0 (best) to 68 (worst)
†Estimated by EBSCO Information Services (given sample size, calculation uses a t distribution, though a z distribution would yield a comparable estimate here; homoscedasticity vs. heteroscedasticity makes little meaningful difference here, but results shown are under the condition of homoscedasticity)

malocclusion at 6 months

Study	Open % (events/total)	Closed % (events/total)	Risk ratio (95% CI)	Absolute risk difference*
Kotrashetti 2013†	0% (0/10)	8.3% (1/12)	NR	-8.3%
Rastogi 2015	0% (0/25)	4% (1/25)	0.33 (0.01 to 7.81)	-4%

NR = not reported
*CIs not estimated given clear imprecision in the data based on sample size and number of events; this can also be inferred from the reported risk ratio for Rastogi 2015 (with 1 event among 50 participants) and the smaller sample size for Kotrashetti 2013 (also with 1 event)
†Nasser ND report this as having no events in either arm, but this is not accurate. Nasser ND's reporting appears to be based on a misinterpretation of the data tables in Kotrashetti 2013.

maximal interincisal opening

Two trials reported this outcome as continuous (Danda 2010, Eckelt 2006), 1 reported this outcome as dichotomous (Kotrashetti 2013), and 1 (Rastogi 2015) reported measuring maximum interincisal opening but did not report the results.

as continuous

Studies	Duration of follow-up* (months)	Open		Closed		P-value comparing groups	Mean difference (95% CI)
		no.	mean (SD)	no.	mean (SD)		
Danda 2010	22.5 mean (range 4 to 42 months)	16	42.125 mm (NR)	16	40.062 mm (NR)	> 0.05 per publication; estimated at 0.95†	2.06 (not estimated)‡
Eckelt 2006	6	36	46.47 mm (5.3)	30	40.93 mm (6.8)	0.001	5.54 (2.56 to 8.52)§

NR = not reported
*Original trial reports were checked to determine if "duration of follow-up" (as provided in Cochrane Review Results tables) is the same as the time point for outcome assessment. For Eckelt 2006, it was confirmed that the outcome was assessed at 6 months; for Danda 2010 it was not explicitly stated that the "follow-up" time reported is the number of months of follow-up at time of outcome assessment although it was assumed that this was the case.
†Estimated by EBSCO Information Services from the t statistic (0.0689) and degrees of freedom (30) in the original publication.
‡Quantified estimates would require knowledge of the SDs in each of the groups or alternative methods to estimate the CI based on the available information; alternatively, for purposes of this evidence report, one might instead reasonably infer from the data that the CI might not have a substantive impact on overall conclusions (despite the absence of a CI technically precluding quantitative inference about the extent to which the data might be compatible with meaningful differences).
§Estimated by EBSCO Information Services (given sample size, calculation uses a t distribution, though a z distribution would yield a comparable estimate here; homoscedasticity vs. heteroscedasticity makes little meaningful difference here, but results shown are under the condition of homoscedasticity)

as dichotomous (Kotrashetti 2013)

Timing of assessment	Inadequate* opening in group, % (n/N)		Absolute risk difference (95% CI)†
	open	closed	
3 months	20% (2/10)	58.3% (7/12)	-38.3% (-64.9% to 2.4%)
6 months	10% (1/10)	41.7% (5/12)	-31.7% (-59.3% to 6.1%)

*Inadequate defined as < 40 mm; no justification for this dichotomization is provided, and of note, could lead to people with very small differences (such as 41 mm vs. 39 mm being considered 'adequate' vs. 'inadequate', respectively)
†Estimated by EBSCO Information Services with the method 10 in Newcombe 1998 (which is also recommended in Altman 2000) given 'traditional' methods can underperform with certain data.

range of motion

Two trials reported overall limitation of mandibular movement (Kotrashetti 2013, Rastogi 2015), 2 reported mandibular protrusion (Danda 2010, Eckelt 2006), and data for lateral excursion movement (on fractured and non-fractured sides) was not reported but there was a note that this was still to be added.

overall limitations of mandibular movement

Studies	Timing of assessment	Measure used to assess outcome	Open % (n/N)	Closed % (n/N)	Absolute risk difference (95% CI)*
Kotrashetti 2013	3 months	movement limitations in all directions†	0% (0/10)	33.3% (4/12)	-33.3% (-60.9% to 0.6%)
	6 months		0% (0/10)	33.3% (4/12)	-33.3% (-60.9% to 0.6%)
Rastogi 2015	6 months	deviation of mouth opening‡	0% (0/25)	72% (18/25)	-72.0% (-85.7% to -48.3%)

*Estimated by EBSCO Information Services with the method 10 in Newcombe 1998 (which is also recommended in Altman 2000) given 'traditional' methods can underperform with certain data.
†This outcome was assessed dichotomously ("Restricted" vs. "Normal"), and it is not clear (1) whether this outcome was investigator-assessed or patient-reported or (2) what constituted a rating of "Restricted" vs. "Normal". This raises questions about the meaningfulness of this outcome (for instance, the presence of minor or trivial limitations could still be counted as "Restricted"), especially in the context of concerns about blinding.
‡The same concerns as expressed for Kotrashetti 2013 in the '†' footnote above apply for this outcome from Rastogi 2015, with the only major difference being that Rastogi 2015 assessed deviation on mouth opening dichotomously (as present or absent).

mandibular protrusion

Studies	Duration of follow-up (months)	Open		Closed		P-value comparing groups	Mean difference (95% CI)
		no.	mean (SD)	no.	mean (SD)		
Danda 2010	22.5 mean (range 4 to 42 months)	16	7.37 mm (NR)	16	6.93 mm (NR)	> 0.05 per publication; estimated at 0.69*	0.44 (not estimated)†
Eckelt 2006	6	36	7.33 mm (2.0)	30	4.7 mm (2.5)	0.001	2.63 (1.52 to 3.73)‡

NR = not reported
*Estimated by EBSCO Information Services from the t statistic (0.4) and degrees of freedom (30) in the original publication.
†Quantified estimates would require knowledge of the SDs in each of the groups or alternative methods to estimate the CI based on the available information; alternatively, for purposes of this evidence report, one might instead reasonably infer from the data that the CI might not have a substantive impact on overall conclusions (despite the absence of a CI technically precluding quantitative inference about the extent to which the data might be compatible with meaningful differences).
‡Estimated by EBSCO Information Services (given sample size, calculation uses a t distribution, though a z distribution would yield a comparable estimate here; homoscedasticity vs. heteroscedasticity makes little meaningful difference here, but results shown are under the condition of homoscedasticity)

pain

as dichotomous

Studies	Time point of outcome assessment (months)	Open % (n/N)	Closed % (n/N)	P-value comparing groups	Absolute risk difference (95% CI)*
Kotrashetti 2013†	3	0% (0/10)	33.3% (4/12)	0.1430	-33.3% (-60.9% to 0.6%)
	6	0% (0/10)	33.3% (4/12)	0.1430	-33.3% (-60.9% to 0.6%)
Danda 2010†	22.5 mean (range 4 to 42 months)	12.5% (2/16)	37.5% (6/16)	> 0.05	-25.0% (-50.5% to 5.2%)

*Estimated by EBSCO Information Services with the method 10 in Newcombe 1998 (which is also recommended in Altman 2000) given 'traditional' methods can underperform with certain data.
†Each trial measured pain dichotomously with little to no description (Kotrashetti 2013 as "present" or "absent" and Danda 2010 as proportion of patients who "had joint pain"), which raises questions about the meaningfulness of the outcome; for instance, minor or trivial pain – such as a pain rating of 4 on a 0 to 100 visual analogue scale – could possibly still be counted as pain being "present".

as continuous (visual analog scale [range 0 to 100])

Studies	Time point of outcome assessment (months)	Open		Closed		P-value comparing groups	Mean difference (95% CI)*
		no.	mean (SD)	no.	mean (SD)		
Eckelt 2006	6	36	2.89 (6.52)	30	13.53 (17.14)	0.003	-10.64 (-16.82 to -4.46)

*Estimated by EBSCO Information Services (given sample size, calculation uses a t distribution, though a z distribution would yield a comparable estimate here; homoscedasticity vs. heteroscedasticity makes little meaningful difference here, but results shown are under the condition of homoscedasticity)

facial nerve weakness or surgery scar

facial nerve weakness/loss of facial nerve function

Studies	Time point of outcome assessment (months)	Open % (n/N)	Closed % (n/N)	Absolute risk difference (95% CI)*
Kotrashetti 2013	3	10% (1/10)	0% (0/12)	10% (-15.6% to 40.4%)
	6	10% (1/10)	0% (0/12)	10% (-15.6% to 40.4%)
Danda 2010	1	12.5% (2/16)	0% (0/16)	12.5% (-8.9% to 36.0%)

*Estimated by EBSCO Information Services with the method 10 in Newcombe 1998 (which is also recommended in Altman 2000) given 'traditional' methods can underperform with certain data.

scar – the ongoing Cochrane review reports no studies reported on this outcome, but we found that Kotrashetti 2013 and Rastogi 2015 both provide some information (albeit extremely limited) on scarring; we address this in the separate summaries for these studies

Risk of bias assessments of trials comparing open vs. closed in patients with fractures of the mandibular with condylar involvement

study	sequence generation	allocation concealment	blinding of participants and personnel	blinding of outcome assessors	incomplete outcome data addressed	free of selective outcome reporting	free of other bias
Danda 2010	low	low	high	low	low	unclear	NR
Eckelt 2006	low	low	high	unclear	high*	high†	low
Kotrashetti 2013	low	high	high	high	high	unclear	NR
Rastogi 2015	low	low	high	unclear	low	high‡	NR

NR = not reported

*The authors of the 2010 Cochrane review specific to mandibular condyle fractures (Sharif 2010) reported that this was the only trial that appeared initially to meet their inclusion criteria, but that they subsequently excluded it after further examination found substantial losses to follow-up (25%). Sharif 2010 contacted the trial investigators, but very few additional details were provided about these participants. It was unclear to which intervention they were allocated, the reason for the losses to follow-up, or the time during follow-up, and the data were not analyzed according to the intention-to-treat principle. The trial is included in the ongoing Cochrane review (into which Sharif 2010 was merged), in which it was assigned an 'unclear' risk of bias for this domain; we have rated this as 'high' (this was the only instance where we considered a different risk of bias assessment from that reported in the ongoing Cochrane).

†Outcomes were measured at 6 weeks and 6 months, but only the latter was reported.

‡Cochrane review authors assigned a 'high' risk of bias because trial publications did not report some pre-specified time points and pre-specified endpoints (including maximum interincisal distance).

RASTOGI 2015
Rastogi S, Sharma S, Kumar S, Reddy MP, Niranjanaprasad Indra B. Fracture of mandibular condyle—to open or not to open: an attempt to settle the controversy. Oral Surg Oral Med Oral Pathol Oral Radiol. 2015;119(6):608-613. PubMed

Relevant to FAQ4, FAQ6

We extracted data for all but 2 outcomes from the Nasser ND Cochrane review. The only outcomes relevant to our scoped outcomes that the Cochrane review did not report the data for were (1) scar, and (2) lateral excursion movement (the latter of which the Cochrane review noted was still to be added). Lateral excursion movement is 1 of 2 pre-specified outcomes we included as part of our 'FAQ 4: Will the treatment help me move my jaw in other ways?' (the other was mandibular protrusion which was included in the Cochrane review and extracted from there). Therefore, we extracted data on scar and lateral excursion movement from each of the articles that reported this outcome as brief summaries including only this information.

Trial publication reported only the following (without numerical results):

"...At 6 months, there was no significant difference between the two groups with regard to ... movement of jaw toward the ipsilateral and contralateral sides..."

and

"…at the 6th-month evaluation, none of the patients [treated with surgery] developed any complications, such as facial nerve damage, parotid fistula, or an unsightly scar."

SINGH 2010
Singh V, Bhagol A, Goel M, Kumar I, Verma A. Outcomes of open versus closed treatment of mandibular subcondylar fractures: a prospective randomized study. J Oral Maxillofac Surg. 2010;68(6):1304-1309. PubMed

Relevant to FAQ2, FAQ3, FAQ4, FAQ5, FAQ6

- **Study design:** quasi-randomized trial
    - Nasser ongoing Cochrane review authors determined this study was quasi-randomized after communicating with the investigator
- **Population:** adults with unilateral subcondylar fractures of the mandible and one or both of following
    - degree of displacement of the condylar fragment in the coronal plane between 10° and 35°
    - shortening of the height of the ascending ramus of the mandible > 2 mm
- **Intervention:** closed treatment consisting of MMF with elastics for period of 7 to 35 days (mean, 20 days)
    - following period of MMF, guiding elastics were used for variable period in most cases to maintain proper occlusion and to enable mouth opening
    - postoperative instructions regarding mouth opening exercises and physiotherapy were given to patients in both groups

- **Comparison:** open reduction and internal fixation, with MMF with light elastics kept for 3 to 5 days postoperatively
    - standardized surgical treatment by 2 surgeons of consultant grade
    - retromandibular, anteroparotid approach for surgical access was used
    - fractures were fixed with 2 mm titanium miniplates
    - postoperative instructions regarding mouth opening exercises and physiotherapy were given to patients in both groups

- **Study inclusion criteria:**
    - patients treated between November 2007 and March 2009
    - no severe pre-traumatic dysgnathia
    - no condylar head or neck fractures

- **Number of participants:** 40 analyzed (22 closed group, 18 open group)
    - number allocated to each treatment group not reported
- **Duration of follow-up:** 6 months
    - relevant outcomes assessed at 6 months

- **Results:**

Clinical results at 6 months after surgery

Outcome	Open reduction (n = 18) mean (SD)	Closed reduction (n = 22) mean (SD)	P-value comparing groups	Certainty (downgrade)[1]
maximum interincisal opening (mm)	39.61 (2.22)	33.54 (1.89)	p = 0.00	Low (risk of bias)
lateral excursion (sum of both sides in mm)	12.55 (1.33)	9.86 (1.64)	p = 0.00	Low (risk of bias)
protrusive movement (mm)	5.94 (1.10)	4.13 (0.77)	p = 0.00	Low (risk of bias)
deviation on opening (mm)*	0.38 (0.84)	1.18 (1.29)	p = 0.03	Low (risk of bias)
motor function†	1.00 (0.00)	1.00 (0.00)	-‡	Very low (risk of bias, imprecision)
sensory function§	1.00 (0.00)	1.00 (0.00)	-‡	Very low (risk of bias, imprecision)
pain (visual analog scale 0 [no pain] to 100 [strongest pain or discomfort])¶	1.11 (3.30)	5.27 (5.43)	p = 0.00	Very low (risk of bias)
occlusion**	1.11 (0.47)	1.09 (0.29)	p = 0.86	Very low (risk of bias, imprecision)

*The Results text also reported this outcome as the proportion of patients for whom deflection/terminal lateral shifts were observed, which was 54% (12/22) in the closed group and 22% (4/18) in the open group; comparative statistics were not reported for a comparison of these proportions.
†Means are based on a patient-reported 5-category scale: 1: no deficit; 2: mild weakness; 3: moderate weakness; 4: severe weakness; 5: absence of function.
‡Could not be determined statistically because the SD of both groups was zero; no practical difference existed.
§Means are based on a patient-reported 5-category scale: 1: full sensation; 2: can distinguish cotton/wood/pin; 3: not full but not distracting; 4: can discern pressure; 5: profoundly numb.

¶The Results text also reported this outcome as the proportion of patients with no pain, which was 45.5% (10/22) in the closed group and 88.9% (16/18) in the open group. Comparative statistics were not reported for a comparison of these proportions.
**Means are based on a patient-reported 5-category scale: 1: identical to pretraumatic; 2: slight difference; 3: functional malocclusion; 4: requires occlusal adjustment; 5: gross malocclusions. The Results text also reported this outcome as the proportion of patients with occlusal disturbances, which was 9% (2/22) in the closed group and 5% (1/18) in the open group. Although comparative statistics were not reported for a comparison of these proportions, these data do not provide convincing evidence of a meaningful difference.
[1] All outcomes were downgraded at least twice for risk of bias due to inadequate randomization and unclear completeness of outcome data. Motor function, sensory function, pain, and occlusion were additionally downgraded for risk of bias because lack of patient blinding may bias these patient-reported outcomes and/or imprecision for outcomes that did not show significant difference.

Risk of bias assessment

sequence generation	allocation concealment	blinding of participants and personnel	blinding of outcome assessors	incomplete outcome data addressed	free of selective outcome reporting
high[1]	high[1]	high	low for provider-assessed outcomes; high for patient reported outcomes[2]	unclear[3]	unclear

[1]The article described randomization as follows: "To ensure randomization and avoid any bias, selection of 1 of the 2 treatment modalities for any of these patients was done by opening lots in sealed envelopes". If the envelopes were sealed, opaque, and sequentially numbered, this would be a form of randomization associated with a low risk of bias. However, the Cochrane review authors excluded this trial and their "Reason for exclusion:" was the following: "After communicating with investigator it was concluded that randomisation was by alternate assignment." Because we had found that this Cochrane review was clear and accurate in comparing its descriptions against the trial reports, we accepted the Cochrane review authors' conclusion that this study is 'Quasi-randomized' and therefore assigned risk of bias as 'high' for both 'sequence generation' and 'allocation concealment'. (As noted at the beginning of the Nasser ongoing Cochrane review summary, while the Cochrane review pre-specified excluding quasi-randomized trials, we pre-specified including them in our scoping for this evidence report.)
[2]The article notes that the outcomes were recorded by two oral and maxillofacial surgery residents who were not involved in the treatment of the patients and were thus blinded to the treatment the patient had received. For provider-measured outcomes (eg, maximum interincisal opening [mm], lateral excursion [sum of both sides in mm]), we judged a low risk of bias because of this blinding. However, for patient-reported outcomes (ie, pain, motor nerve function, occlusal disturbances), even if those outcomes were collected by the surgery residents (eg, asking patients to rate their pain from 0 to 100), we judged a high risk of bias because the patients were not blinded.
[3]The article did not report the number of patients allocated to each treatment or number of patients who dropped out or were lost to follow-up, so it is unclear whether the number of patients analyzed (ie, 40 total with 22 closed and 18 open) is the same as the number of patients randomized.

Evidence report for closed treatment (without surgery) vs. open reduction (involving surgery) for fractures of the mandibular condyle

Reference list

EBSCO Information Services

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ALTMAN 2000
Altman DG, Machin D, Bryant TN, Gardner MJ. Statistics with Confidence. 2nd ed. 2000. BMJ Books.

ALYAHYA 2020
Alyahya A, Bin Ahmed A, Nusair Y, Ababtain R, Alhussain A, Alshafei A. Mandibular condylar fracture: a systematic review of systematic reviews and a proposed algorithm for management. Br J Oral Maxillofac Surg. 2020 Mar 31:S0266-4356(20)30099-1. doi: 10.1016/j.bjoms.2020.03.014. Epub ahead of print. PubMed

AL-MORAISSI 2015
Al-Moraissi EA, Ellis E 3rd. Surgical treatment of adult mandibular condylar fractures provides better outcomes than closed treatment: a systematic review and meta-analysis. J Oral Maxillofac Surg. 2015 Mar;73(3):482-93. doi: 10.1016/j.joms.2014.09.027. Epub 2014 Oct 12. PubMed

ASIM 2019
Asim MA, Ibrahim MW, Javed MU, Zahra R, Qayyum MU. Functional Outcomes Of Open Versus Closed Treatment Of Unilateral Mandibular Condylar Fractures. J Ayub Med Coll Abbottabad. 2019;31(1):67-71. PubMed

BOFFANO 2014
Boffano P, Benech R, Gallesio C, Arcuri F, Benech A. Current opinions on surgical treatment of fractures of the condylar head. Craniomaxillofac Trauma Reconstr. 2014 Jun;7(2):92-100. doi: 10.1055/s-0034-1371772. Epub 2014 Mar 11. PubMed

CHOI 2012
Choi KY, Yang JD, Chung HY, Cho BC. Current Concepts in the Mandibular Condyle Fracture Management Part II: Open Reduction Versus Closed Reduction. Arch Plast Surg. 2012 Jul;39(4):301-8. doi: 10.5999/aps.2012.39.4.301. Epub 2012 Jul 13. PubMed

DANDA 2010
Danda AK, Muthusekhar MR, Narayanan V, Baig MF, Siddareddi A. Open versus closed treatment of unilateral subcondylar and condylar neck fractures: a prospective, randomized clinical study. J Oral Maxillofac Surg. 2010 Jun;68(6):1238-41. doi: 10.1016/j.joms.2009.09.042. Epub 2010 Mar 29. PubMed

DIACONU 2018
Diaconu SC, McNichols CHL, Liang Y, Orkoulas-Razis D, Woodall J, Rasko YM, Grant MP, Nam AJ. Utility of Postoperative Mandibulomaxillary Fixation After Rigid Internal Fixation of Isolated Mandibular Fractures. J Craniofac Surg. 2018 Jun;29(4):930-936. doi: 10.1097/SCS.0000000000004368. PubMed

ECKELT 2006
Eckelt U, Schneider M, Erasmus F, Gerlach KL, Kuhlisch E, Loukota R, Rasse M, Schubert J, Terheyden H. Open versus closed treatment of fractures of the mandibular condylar process-a prospective randomized multi-centre study. J Craniomaxillofac Surg. 2006 Jul;34(5):306-14. doi: 10.1016/j.jcms.2006.03.003. Epub 2006 Jun 15. PubMed

Schneider M, Erasmus F, Gerlach KL, Kuhlisch E, Loukota RA, Rasse M, Schubert J, Terheyden H, Eckelt U. Open reduction and internal fixation versus closed treatment and mandibulomaxillary

fixation of fractures of the mandibular condylar process: a randomized, prospective, multicenter study with special evaluation of fracture level. J Oral Maxillofac Surg. 2008 Dec;66(12):2537-44. doi: 10.1016/j.joms.2008.06.107. PubMed.

EL-ANWAR 2015A
El-Anwar MW, Sayed El-Ahl MA, Amer HS. Open Reduction and Internal Fixation of Mandibular Fracture without Rigid Maxillomandibular Fixation. Int Arch Otorhinolaryngol. 2015 Oct;19(4):314-8. doi: 10.1055/s-0035-1549154. Epub 2015 Mar 30. PubMed

EL-ANWAR 2015B
El-Anwar MW. Changing Trends in the Treatment of Mandibular Fracture. Int Arch Otorhinolaryngol. 2018 Jul;22(3):195-196. doi: 10.1055/s-0037-1606645. Epub 2017 Oct 25. PubMed

ELLIS 2000
Ellis E 3rd, McFadden D, Simon P, Throckmorton G. Surgical complications with open treatment of mandibular condylar process fractures. J Oral Maxillofac Surg. 2000 Sep;58(9):950-8. doi: 10.1053/joms.2000.8734. PubMed

EUSTERMAN 2012
Eusterman VD. Chapter 5: Mandibular Trauma. In Brennan JA, Holt GR, Connor MP, Donald PJ, Eusterman VD, Hayes DK, Kellman RM, Morehead JM, Packer MD, Pafford WA, Ramsey MJ, Salinas NL, Sniezek JC, Stallworth CL, Stevens MS, Thomas RW (eds.). Resident Manual of Trauma to the Face, Head, and Neck. 1st ed. 2012. Available at https://www.entnet.org/sites/default/files/Trauma-Chapter-5.pdf.

GARCÍA-GUERRERO 2018
García-Guerrero I, Ramírez JM, Gómez de Diego R, Martínez-González JM, Poblador MS, Lancho JL. Complications in the treatment of mandibular condylar fractures: Surgical versus conservative treatment. Ann Anat. 2018 Mar;216:60-68. doi: 10.1016/j.aanat.2017.10.007. Epub 2017 Dec 6. PubMed

GOLDMAN 2018
Goldman KE, Meyers AD. Mandibular condylar and subcondylar fractures. Last reviewed/updated November 19, 2018. Accessed June 19, 2020. Available at https://emedicine.medscape.com/article/870075-print.

HAUG 2001
Haug RH, Assael LA. Outcomes of open versus closed treatment of mandibular subcondylar fractures. J Oral Maxillofac Surg. 2001 Apr;59(4):370-5; discussion 375-6. doi: 10.1053/joms.2001.21868. PubMed

HOWLADER 2019
Howlader D, Ram H, Mohammad S, Singh V, Gamit J, John RS. Surgical Management of Mandibular Subcondylar Fractures Under Local Anesthesia: A Proposed Protocol. J Oral Maxillofac Surg. 2019 May;77(5):1040.e1-1040.e9. doi: 10.1016/j.joms.2019.01.010. Epub 2019 Jan 14. PubMed

KOTRASHETTI 2013
Kotrashetti SM, Lingaraj JB, Khurana V. A comparative study of closed versus open reduction and internal fixation (using retromandibular approach) in the management of subcondylar fracture. Oral

Surg Oral Med Oral Pathol Oral Radiol. 2013 Apr;115(4):e7-11. doi: 10.1016/j.oooo.2011.10.027. Epub 2012 Nov 10. PubMed

KUANG 2019
Kuang SJ, He YQ, Zheng YH, Zhang ZG. Open reduction and internal fixation of mandibular condylar fractures: A national inpatient sample analysis, 2005-2014. Medicine (Baltimore). 2019 Sep;98(37):e16814. doi: 10.1097/MD.0000000000016814. PubMed

NASSER ND
Nasser M, Dorri M, Pandis N, Sharif MO, Fleming PS, Ali K, Ellis E, Elango NM. Interventions for managing mandibular fractures. Cochrane Database Syst Rev. *Pending Cochrane review, shared by Nasser M.*

NASSER 2013
Nasser M, Pandis N, Fleming PS, Fedorowicz Z, Ellis E, Ali K. Interventions for the management of mandibular fractures. Cochrane Database Syst Rev. 2013 Jul 8;(7):CD006087. doi: 10.1002/14651858.CD006087.pub3. PubMed

NEWCOMBE 1998
Newcombe RG. Interval estimation for the difference between independent proportions: comparison of eleven methods. Stat Med. 1998 Apr 30;17(8):873-90. doi: 10.1002/(sici)1097-0258(19980430)17:8<873::aid-sim779>3.0.co;2-i. Erratum in: Stat Med 1999 May 30;18(10):1293. PubMed

RASTOGI 2015
Rastogi S, Sharma S, Kumar S, Reddy MP, Niranjanaprasad Indra B. Fracture of mandibular condyle—to open or not to open: an attempt to settle the controversy. Oral Surg Oral Med Oral Pathol Oral Radiol. 2015;119(6):608-613. PubMed

SAMAN 2014
Saman M, Kadakia S, Ducic Y. Postoperative maxillomandibular fixation after open reduction of mandible fractures. JAMA Facial Plast Surg. 2014 Nov-Dec;16(6):410-3. doi: 10.1001/jamafacial.2014.543. PubMed

SHARIF 2010
Sharif MO, Fedorowicz Z, Drews P, Nasser M, Dorri M, Newton T, Oliver R. Interventions for the treatment of fractures of the mandibular condyle. Cochrane Database Syst Rev. 2010 Apr 14;(4):CD006538. doi: 10.1002/14651858.CD006538.pub2. Review. PubMed

SHIJU 2015
Shiju M, Rastogi S, Gupta P, Kukreja S, Thomas R, Bhugra AK, Parvatha Reddy M, Choudhury R. Fractures of the mandibular condyle--Open versus closed--A treatment dilemma. J Craniomaxillofac Surg. 2015 May;43(4):448-51. doi: 10.1016/j.jcms.2015.01.012. Epub 2015 Jan 29. PubMed

SINGH 2010
Singh V, Bhagol A, Goel M, Kumar I, Verma A. Outcomes of open versus closed treatment of mandibular subcondylar fractures: a prospective randomized study. J Oral Maxillofac Surg. 2010 Jun;68(6):1304-9. doi: 10.1016/j.joms.2010.01.001. Epub 2010 Apr 3. PubMed

WEISS 2016
Weiss JP, Sawhney R. Update on mandibular condylar fracture management. Curr Opin Otolaryngol Head Neck Surg. 2016 Aug;24(4):273-8. doi: 10.1097/MOO.0000000000000272. PubMed