

Systematic Review

Systematic review of outcomes reported in trials of facial trauma

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Received 2 May 2026; accepted in revised form 8 May 2026 Available online 27 May 2026

Abstract

This study aimed to identify and collate outcomes reported in trials of facial trauma. Searches for randomised controlled trials on facial trauma containing 50 patients or more were conducted on Cochrane CENTRAL, Embase and Ovid MEDLINE on 9 October 2025. Additional studies were identified through review of the reference lists of relevant systematic reviews and included trials, as well as through text searches of Google Scholar. A manual search of clinicaltrials.gov and the International Standard Randomised Controlled Trial Number (ISRCTN) registry was also completed in line with Cochrane guidelines on 20 November 2025. A total of 3,695 studies were screened following PRISMA guidelines, with 131 articles included in the final analysis. Two reviewers (KC and NB) independently performed data extraction, and the outcomes reported were recorded verbatim and mapped on to the World Health Organization International Classification of Functioning, Disability and Health (WHO ICF) framework. A total of 151 distinct outcomes were identified, with a median of four outcomes per trial. Mapping to the WHO ICF yielded 102 outcome domains. Eighty-two studies involved the mandible only, 39 involved the midface only, nine involved the mandible and midface, and one involved the midface and frontal bone. In mandibular fracture trials, immunological system functions that would capture infections (56%), structure of the mouth (53%) and pain (41%), were most frequently reported. In midfacial fracture trials, pain was the most common domain (37%), followed by immunological system functions (31%). Seven patient-reported outcome measures (PROMs) were identified across 10 trials, most commonly the General Oral Health Assessment Index. Outcome reporting in facial trauma trials is highly heterogeneous, spanning all domains of the WHO ICF framework, with limited and inconsistent use of PROMs. Most available PROMs were not designed specifically for facial trauma, and no single instrument was used consistently across the studies. This lack of standardisation limits comparability between trials and hinders meaningful evidence synthesis. These findings support the need for the development of a consensus-based core outcome set for facial trauma to improve consistency, relevance, and quality of outcome reporting in future research.

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Keywords: Facial trauma; Mandibular fractures; Midfacial fractures; Core outcome sets; Systematic review; PRISMA; Patient-reported outcome measures

Introduction

Facial trauma is a common and clinically complex injury, encompassing fractures of the mandible, midface, orbit, and frontal bone, often due to falls, physical violence, and unintentional injury.¹ With an aging global population, the incidence of these injuries will be likely to increase, contributing substantially to the worldwide burden of disease. Facial fractures can result in a wide range of functional impairments, including altered bite, nasal obstruction, visual disturbances, and changes in facial sensation.² Additionally,

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<https://doi.org/10.1016/j.bjoms.2026.05.002>

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facial trauma often leads to aesthetic and structural issues such as facial asymmetry, contour deformities and visible scarring.^{3,4} Together, these complications result in long-term disability, with profound impacts on appearance, psychological wellbeing, and quality of life.¹

A core outcome set (COS) provides an agreed minimum standardised set of outcomes to be measured and reported. Currently, to our knowledge, no COS specifically for facial trauma has been established, representing a significant gap in standardised research reporting within this field. Furthermore, we know of only a limited number of randomised controlled trials evaluating outcomes in facial trauma, further restricting the evidence base and the ability to compare findings across studies. A systematic review on outcomes after facial trauma and subsequent development of a COS could identify the most relevant and consistently reported outcomes, and reduce heterogeneity across future studies, improving comparability and quality of evidence (see Table 1).

The primary objective of this systematic review was to identify outcomes reported in trials on facial trauma. The outcomes were then mapped on to domains of the World Health Organization (WHO) International Classification of Functioning, Disability and Health (ICF) framework,⁵ and outcome tools measuring surgeon or patient-reported outcomes (PROMs) were also assessed. Our methods were guided by recommendations from the COMET (Core Outcome Measures in Effectiveness Trials) initiative.⁶

Methods

Eligibility criteria

This study followed the COMET initiative methodology and Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines to identify, classify, and report outcomes reported in clinical trials.^{6,7} The systematic review was prospectively registered on the PROSPERO database (CRD420251149340).

The study protocol as part of the COMET initiative methodology will be available in a separate publication. Randomised and quasi-randomised controlled trials published in English from 1 January 2000 to the date of the search, which reported outcomes of facial hard tissue trauma, were included. Additional studies were identified through review of the reference lists of relevant systematic reviews and

included trials, as well as through text searches of Google Scholar. Studies with fewer than 50 participants were excluded to minimise the inclusion of underpowered and experimental trials, focusing the review on powered trials designed to assess the effectiveness and efficacy of interventions.

Search strategy

Searches were conducted on Ovid MEDLINE, Ovid EMBASE and the Cochrane Central Register of Controlled Trials (CENTRAL) on 9 October 2025 using the search strategy included in the [Supplementary Material](#). Additional studies were also identified through manual searches of the reference lists of the included trials and relevant systematic reviews. A text search on Google Scholar was conducted on 20 November 2025. A manual search of clinicaltrials.gov and the International Standard Randomised Controlled Trial Number (ISRCTN) registry was also completed in line with Cochrane guidelines on 20 November 2025.⁸

Two reviewers (KC and NB) independently screened all titles and abstracts identified by the search strategy to assess eligibility and inclusion. Full texts were reviewed independently to extract demographics, study design, and outcomes reported. Where consensus was not reached, a third reviewer was given a casting vote. A standardised template was used for data extraction. Rayyan⁹ was used for deduplication and screening.

Data extraction

Two reviewers (KC and NB) independently collected data from the reports. Demographics and study characteristics that were collected were: date of the trial, name of the first author, location, setting, funding source, condition studied, intervention, control, and number of participants in both the intervention and control groups. All outcomes reported in individual studies were extracted verbatim with no restriction. The names of PROMs were collected.

Synthesis methods

Outcomes were extracted verbatim from trials. The list of verbatim outcomes was then clustered with deduplication of identical outcome domains. The clustered domains were then mapped on to the WHO ICF framework using appropri-

Table 1
PICO framework eligibility criteria.

Population	Inclusion: Children (aged 0–17) and adults with trauma to facial bones, including the frontal, midfacial and mandibular bones. Exclusion: Isolated dental trauma. Injuries outside the facial skeleton (for example, fractures to the cranial vault or skull base, cervical spine fractures). Soft tissue injuries (for example, lacerations, scars, burns). Temporal bone fractures are typically considered outside the facial skeleton and are associated with vascular and otological issues. Studies involving intubation or anaesthetic agents focusing exclusively on anaesthesia-related outcomes.
Intervention	Any intervention studied with randomised controlled trial or systematic review.
Comparator	Not applicable, as the purpose of this review was to identify reported outcomes.
Outcome	All reportable outcomes.

ate 3 or 4-level codes (for example, s710 ‘Structure of head and neck region’, s7101 ‘Bones of face’), with additional digits indicating increasingly specific aspects of functioning. Composite outcomes (for example, PROMs or multidimensional scores) were identified and analysed separately. For multi-item scores, the original scores were obtained and mapped onto WHO ICF codes.

Data synthesis was performed by two reviewers (KC and NB) and agreed through consensus. Any discrepancies were resolved through consensus, with the senior author making the final decision.

All verbatim outcomes were tabulated in the review database using a standardised extraction form. Results are presented using tables of verbatim outcomes by study, and frequency tables showing how often each outcome domain was reported, WHO-ICF domain maps (where clustered outcomes are displayed within their assigned codes), and subgroup summaries stratified by anatomical region (for example, mandible, midface).

Risk of bias and certainty assessments

As the primary aim of this review was to identify and collate reported outcomes rather than to compare the effectiveness of interventions, a narrative synthesis was undertaken. For

this reason, no quantitative synthesis or formal effect measures were applied, and no analyses of heterogeneity or sensitivity were conducted. Formal assessments of reporting bias, risk of bias, or certainty of evidence were not performed, as outcomes were extracted independently of the relative internal or external validity of the included studies.

Results

Fig 1 shows the PRISMA flow diagram of included studies.

Our searches resulted in 3695 articles; this was reduced to 3151 articles after deduplication. A total of 717 full text articles were reviewed, and outcomes were extracted from 131 included trials. A summary of the characteristics of all the included trials can be found in the [Supplementary Material](#).

A total of 151 distinct WHO ICF outcomes were identified, with a median number of four reported per trial (interquartile range 2 to 7). These outcomes were subsequently mapped onto relevant level 3 and 4 ICF codes across the four components of the ICF framework (body function, body structures, activities and participation, and environmental factors).⁵ Non-patient-related outcomes were categorised separately. This resulted in 102 outcome domains, comprising 35 body function (b), nine structural (s), 24 activity and participation (d), nine environmental

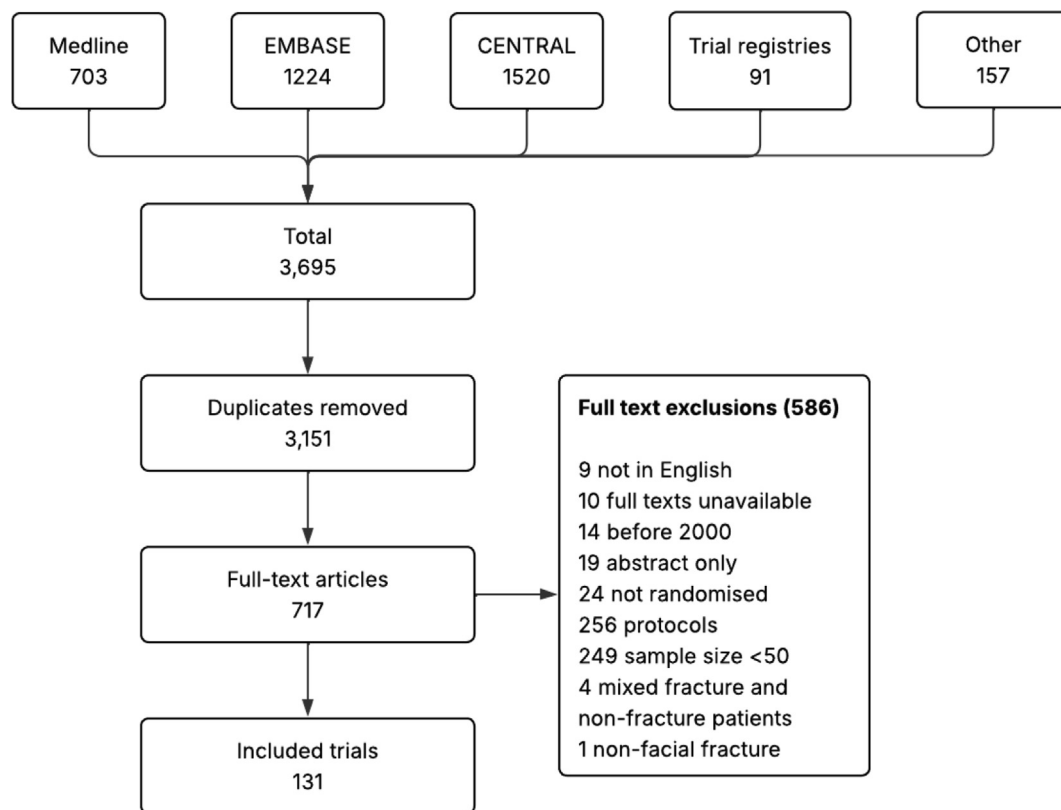


Fig. 1. PRISMA flow diagram.

(e), and 25 non-patient-related domains. Appendix C in the [Supplementary Material](#) shows a table displaying the frequencies of level 4 codes and their classification into level 3 codes in further detail.

Studies were split into subgroups based on Level 1 of the Arbeitsgemeinschaft für Osteosynthesefragen Cranio-Maxillofacial Surgery (AO CMF)¹⁰ classification of facial fractures. Eighty-two studies involved the mandible only, 39 involved the midface only, nine involved the mandible and midface, and one involved the midface and frontal bone. [Table 2](#) presents WHO ICF outcome domains reported in more than 10% of the included trials, showing their frequency across all facial trauma studies and within mandibular and midfacial fracture subgroups.

In the 91 trials involving mandibular fractures, the most frequently reported domain was ‘Immunological system functions’ (b435, 56.0%). Most of these represent postoperative infection. In the 49 trials involving midfacial fractures, the most frequently reported domain was ‘Sensation of pain’ (b280, 36.7%), most commonly measured using a visual analogue scale (VAS). In addition, we identified four critical non-clinical outcomes that were measured in over 10% of trials: operating time, hardware failure, reoperation, and length of hospital stay.

A total of seven PROMs were reported in 10 trials. [Table 3](#) shows the characteristics of the PROMs identified. The General Oral Health Assessment Index (GOHAI),¹¹ a 12-item

questionnaire designed to measure the impact of oral health on quality of life was the most frequently reported PROM overall, followed by the Mandibular Function Impairment Questionnaire (MFIQ) and the Quality of Recovery-40 (QoR-40) survey. The MFIQ was reported in two studies to assess physical function. Health-related quality of life was evaluated using the Quality of Recovery-40 (QoR-40) survey in two studies and the Nutrition Quality of Life Tool in one study. A self-reported questionnaire, designed to assess outcomes following third molar surgery and described by Savin and Ogden,¹² which comprised domains such as eating, speech, appearance, and quality of life, was used in two studies. Additional PROMs included the Oral Health Impact Profile-14 (OHIP-14), used in one study to assess oral health-related quality of life, and the Self-rating Anxiety Scale (SAS), a measure of emotional function, reported in one study. The distribution of PROMs used in facial trauma trials is presented in [Table 3](#).^{11–17}

Discussion

This systematic review has identified substantial heterogeneity in outcome reporting across randomised and quasi-randomised controlled trials on facial trauma. Of 131 included trials, 151 distinct outcomes were mapped onto 102 outcome domains across the WHO ICF framework. Despite the wide range of outcomes identified, the median

Table 2
Distribution of outcome domains across facial trauma trials. Data are number (%).

WHO ICF code	Frequency across all facial trauma trials (n = 131)	Frequency across mandibular fracture trials (n = 91)	Frequency across midfacial fracture trials (n = 49)
b435 Immunological system functions	61 (46.6)	51 (56.0)	15 (30.6)
b280 Sensation of pain	54 (41.2)	37 (40.7)	18 (36.7)
s320 Structure of mouth	50 (38.2)	48 (52.8)	–
s710 Structure of head and neck region	46 (35.1)	34 (37.4)	13 (26.5)
b510 Ingestion functions	43 (32.8)	34 (37.4)	12 (24.5)
b265 Touch function	36 (27.5)	25 (27.5)	11 (22.4)
Operating time	31 (23.7)	27 (29.7)	5 (10.2)
Hardware failure	28 (21.4)	25 (27.5)	–
b152 Emotional functions	20 (15.3)	13 (14.3)	8 (16.3)
s8100 Skin of head and neck region	16 (12.2)	12 (13.2)	5 (10.2)
b820 Repair functions of the skin	14 (10.7)	–	5 (10.2)
b7100 Mobility of a single joint	–	13 (14.3)	–
b5350 Sensation of nausea	–	–	7 (14.3)
b440 Respiration functions	–	–	6 (12.2)
b134 Sleep functions	–	–	5 (10.2)
b210 Seeing functions	–	–	5 (10.2)
b430 Haematological system functions	–	–	5 (10.2)
s220 Structure of eyeball	–	–	5 (10.2)
Reoperation	–	–	5 (10.2)
Length of hospital stay	–	–	5 (10.2)

Table 3

Frequency of patient-reported outcome measures (PROMs) identified across facial trauma trials.

PROM and reference	Total frequency	Mandible	Nasal bone	Orbital bone	Maxilla	Items	Original construct
Mandibular Function Impairment Questionnaire (MFIQ) ¹³	2	2	0	0	0	17	Physical function
Quality of Recovery-40 (QoR-40) survey ¹⁴	2	0	1	1	0	40	HRQoL
Nutrition Quality of Life Tool ¹⁵	1	1	0	0	1	50	
General Oral Health Assessment Index (GOHAI) questionnaire ¹¹	3	3	0	0	0	12	Oral HRQoL
Self-report questionnaire described by Savin and Ogden ¹²	2	2	0	0	0	17	Oral HRQoL
Oral Health Impact Profile-14 (OHIP-14) questionnaire ¹⁶	1	1	0	0	1	14	Oral HRQoL
Self-rating Anxiety Scale (SAS) ¹⁷	1	0	0	1	0	20	Emotional function

HRQoL: health-related quality of life.

number of outcomes reported ($n = 4$) was relatively low with inconsistent outcome selection. This suggests a lack of standardisation in outcome reporting within facial trauma research and underscores the need for the development of a COS to improve comparability across future studies.

The majority of trials involved mandibular fractures: 82 of 131 trials (62.6%) involved mandibular fractures only, compared with 39 (29.8%) that focused on midfacial fractures only, nine (6.9%) that included both mandibular and midfacial fractures, and a single trial (0.8%) that involved the frontal bone and midfacial bones. This largely reflects the real-world epidemiology of facial trauma, with mandibular fractures being most common followed by midfacial fractures,^{18,19} frequently managed using standardised techniques, and therefore relatively suited to randomised trial design. In comparison, frontal bone fractures are more uncommon, accounting for 5–15% of facial fractures, and often occur as a result of critical injuries,²⁰ limiting the feasibility of randomised trials.

One limitation of this study is the use of the Level 1 AO CMF classification to categorise facial fractures. This high-level anatomical grouping may obscure important differences between fractures involving specific subregions of the face, particularly within the midface. Fractures affecting different midfacial subunits can result in distinct functional consequences, such as enophthalmos and diplopia in orbital fractures, or airway obstruction and breathing difficulties in nasal and maxillary fractures. Consequently, outcomes that are particularly important for specific midfacial fractures may be under-represented. Future subgroup analysis using the Level 2 AO CMF classification may allow for more in-depth anatomical differentiation and more precise capture of condition-specific outcomes.

Across both mandibular and midfacial fractures, outcomes relating to body functions and body structures, were most frequently reported. For both, outcomes such as infection, union, malocclusion, pain, ingestion functions, and wound dehiscence were most frequently reported. These findings suggest that current trials focus more on short-

term clinical and surgical endpoints. However, even within trials focusing on mandibular fractures, outcomes such as speech, social interaction and return to daily activities were rarely reported. Similarly, in midfacial fractures, outcomes relating to respiratory function and vision-related outcomes were rarely reported. Furthermore, no outcome was measured in more than 50% of trials across all anatomical regions, with the exception of b435 ‘Immunological system functions (infection)’ and s320 ‘Structure of mouth’ in mandibular fractures. This finding emphasises the substantial heterogeneity between trials, and demonstrates a serious need for a COS for facial trauma.

The use of PROMs was particularly limited. Only 10 trials incorporated them, employing seven distinct instruments. Of these, only the Mandibular Function Impairment Questionnaire (MFIQ) was developed to assess functional impairment related to facial bone dysfunction.¹³ The remaining instruments were designed to assess outcomes after third molar surgery,¹² emotional wellbeing,¹⁷ oral hygiene,¹¹ postoperative recovery,¹⁴ and nutritional status.¹⁵ No PROM was used consistently across trials, and none comprehensively captured the multidimensional impact of facial trauma across physical function, appearance, emotional wellbeing, and social participation.

This review has several limitations. It was restricted to randomised controlled trials with 50 or more patients, and therefore may risk excluding important outcomes reported in smaller trials, or trials with a non-randomised design, such as cohort or case-controlled studies. Additionally, non-English studies were excluded due to a lack of translation resources. While this study has identified outcomes reported in the trials, further input from relevant stakeholders, such as clinicians and patients is required to fully develop a complete set of outcomes for facial trauma.

Conclusion

In conclusion, there is substantial heterogeneity in outcome reporting in trials on facial trauma across all areas of the

WHO ICF framework. A limited number of PROMs is available, with the majority not specifically designed for use in facial trauma, and their use in clinical trials is infrequent and inconsistent. This variability limits comparability between studies and restricts the ability to synthesise evidence and draw meaningful conclusions regarding the effectiveness of treatment. These findings highlight a clear need for the development of a consensus-based COS for facial trauma that incorporates both clinician-reported and patient-prioritised outcomes. Establishing a COS will promote standardisation in outcome selection, improve the quality and relevance of future research, and ensure that outcomes of importance to patients are consistently captured in clinical trials.

Based on the findings of this review, a preliminary COS for facial trauma research should include infection, pain, and restoration of anatomical structure, in particular the mouth and occlusion. These three domains were the most frequently reported across studies, suggesting they represent key clinical priorities by trialists.

Conflict of interest

We have no conflicts of interest.

Ethics statement/confirmation of patients permission

Ethics approval was not required for systematic review and meta-analysis. No patients were involved in this study.

Data availability

The data that supports the findings for this study are available to other researchers from the corresponding author upon reasonable request.

Funding

No funding.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.bjoms.2026.05.002>.

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