

Systematic Review Trauma

Late mandibular fracture occurring in the postoperative period after third molar removal: systematic review and analysis of 124 cases

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Abstract. Factors associated with the diagnosis, aetiology, and treatment of mandibular fractures occurring during the postoperative period following the removal of a lower third molar are discussed. The following databases were searched using specific key words: PubMed/MEDLINE, LILACS, Embase, and Scopus. The search yielded 124 cases. Sex, age, side, tooth position and angulation, bone impaction, relationship between the tooth and the inferior alveolar nerve, local pathological conditions, aetiology of the fracture, symptomatology, and time between surgery and fracture, as well as any displacement of the fracture and the treatment of the fracture, were evaluated. Data were tabulated and the χ^2 statistical test was applied ($P < 0.05$). Male patients aged >35 years, with teeth in positions II/III and B/C, complete bony impaction, and local bone-like alterations, were found to have a higher frequency of fracture and pericoronitis ($P < 0.05$). Late fractures generally occurred between the second and fourth postoperative weeks ($P < 0.05$). They were generally not displaced and the typical treatment was the non-surgical approach ($P < 0.05$). It is concluded that the risk of mandibular fracture after extraction is associated with excessive osteotomy and/or local alterations. At-risk patients should be thoroughly briefed on the importance of a proper postoperative diet.

Key words: third molar; mandibular fractures; fractures; spontaneous.

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The surgical removal of a lower third molar is a common procedure in the dental clinic. Potential complications include infection, bleeding, haemorrhage, lesion of

the inferior alveolar nerve, trismus, and mandibular angle fractures.^{1–8} A mandibular angle fracture is the most serious complication occurring during surgery;

however, this is very rare, with an incidence of 0.0034 to 0.0075%.¹ The incidence of late mandibular angle fracture occurring in the postoperative period after

the surgical removal of a lower third molar is less than 0.005%.^{2,3}

Factors contributing to the risk of mandibular angle fracture after the extraction of a third molar include the level of impaction on the bone around the tooth,³ the dental anatomy and the dental root characteristics,³ the side of the fracture,³ previous local infections,² age,³ sex,^{2,3} amount of time postoperative,^{2,3} bruxism,² and whether the patient is an active athlete.²

The choice of treatment depends on the fracture characteristics and the surgeon's preference, and includes more conservative approaches such as a soft diet,⁴⁻⁶ maxillomandibular fixation,^{5,7} and surgical treatment by means of reduction and fixation of the fracture.⁴

The aim of this systematic review was to report and discuss the factors associated with the aetiology and treatment of mandibular fractures in the postoperative period following lower third molar removal.

Methods

The PRISMA statement was followed for the systematic review,⁹ as well as models proposed in the literature.^{10,11} The articles were selected individually by two of the authors (WRP and JPB) and there was no disagreement in the selection of the articles.

Eligibility criteria

The studies selected for this systematic review met the criteria established by the PICO framework: (1) population: patients presenting for the extraction of a lower third molar; (2) intervention: patients undergoing lower third molar extraction; (3) comparison: patients presenting with mandibular angle fractures after lower third molar extraction; (4) outcome: the main outcome of the study was the relationship between lower third molar removal and the incidence of mandibular angle fracture.

Literature search strategy

An electronic search without date or language restriction was performed in January 2016 in the following electronic databases: PubMed/MEDLINE, LILACS, Embase, and Scopus.

The key words "Molar, Third" and "Mandibular Fractures" were selected, which are available in the medical subject headings (MeSH, PubMed). These search terms were then used in the following combinations: ("Molar, Third"[Mesh]) AND ("Mandibular Fractures"[Mesh]),

("Dental Extraction") AND ("Mandibular Fractures"), and ("Tooth Extraction") AND ("Mandibular Fractures") for the PubMed database; "Dental Extraction" AND "Mandibular Fractures", "Tooth Extraction" AND "Mandibular Fractures", and "Molar, Third" AND "Mandibular Fractures" for the Scopus database; "Dental Extraction" AND "Mandibular Fractures", "Tooth Extraction" AND "Mandibular Fractures", and "Molar, Third" AND "Mandibular Fractures" for the Embase database; (Dental Extraction) AND (Mandibular Fractures), (Tooth Extraction) AND (Mandibular Fractures), (Molar, Third) AND (Mandibular Fractures), (Exodontia) AND (Fratura mandibular), (Extracção dental) AND (Fratura mandibular), (Extracción dental) AND (fractura mandibular), and (Exodontia) AND (fractura mandibular) for the LILACS database.

Study selection

Inclusion criteria encompassed the following: systematic reviews that included new cases, randomized studies, prospective studies, retrospective studies, clinical cases, case series, letters to editor, and expert opinions on late fractures after lower third molar extraction, with no restrictions on age or sex.

Articles that reported fractures without specification of the time of occurrence (preoperative or postoperative period) and those that did not report any of the data required for this review were excluded.

The selection of studies was conducted independently by two calibrated examiners (WRP and JPB). The inter-examiner (kappa) test was used to evaluate the selection of titles and abstracts and full-texts for reading and interpretation, resulting in concordance test values of $\kappa = 1$, 1 for PubMed/MEDLINE, $\kappa = 1$, 1 for LILACS, $\kappa = 1$, 1 for Embase and $\kappa = 1$, 1 for Scopus. Finally, a total of 36 articles were considered eligible for this review.

Data items

The following data, when available, were extracted from the studies included in the final analysis: year, number of cases, sex, age, side of the extracted tooth (fracture side), tooth position (Pell and Gregory classification¹²), tooth angulation (Winter classification), degree of impaction (partial or complete bony impaction), relationship of the tooth to the mandibular canal (adjacent or superimposed), local pathological conditions, fracture aetiology,

symptomatology, time between surgery and the fracture, and fracture displacement and treatment.

Risk of bias in individual studies

The selected manuscripts were analyzed according to the clinical evidence. The manuscripts were separated into the following categories: systematic review/case series, case series, case report, retrospective study, letter to the editor, and expert opinion on a case series. The systematic review/cases series, case series, cases report, and retrospective studies were sorted according to their level of evidence, as proposed by the National Health and Medical Research Council of Australia (NHMRC).¹³

With regard to summary measures, the relationships between the frequency of fractures and the following parameters were analyzed: the kind of inclusion, the aetiology of the fracture, the side of the fracture, age, and the time between surgery and the fracture.

Risk of bias across studies

A few studies reported mandibular fractures occurring through an external trauma during the postoperative period following third molar extraction. Thus, it was not possible to claim that these fractures occurred entirely due to the tooth extraction, since the external trauma would be an aetiological factor.¹⁴

Statistical analysis

Data were tabulated in Microsoft Excel 2013 and analyzed by descriptive statistics (distribution frequency). Associations between the occurrence of fracture and other sample factors, such as age, sex, and third molar position, were analyzed by χ^2 test, considering a significance level of 5% ($P < 0.05$). These tests were run using the statistical software SigmaPlot 12.3 (Systat Software Inc., San Jose, CA, USA).

Results

The database search returned 476 articles after the removal of duplicates. Following the screening of titles and abstracts, 423 records were excluded. Fifty-three full-text articles were assessed for eligibility (Fig. 1). Finally, 36 articles were selected; these articles included 124 clinical cases associated with mandibular fracture after the removal of a lower third molar (Table 1).^{2-8,15-43}



PRISMA 2009 Flow Diagram

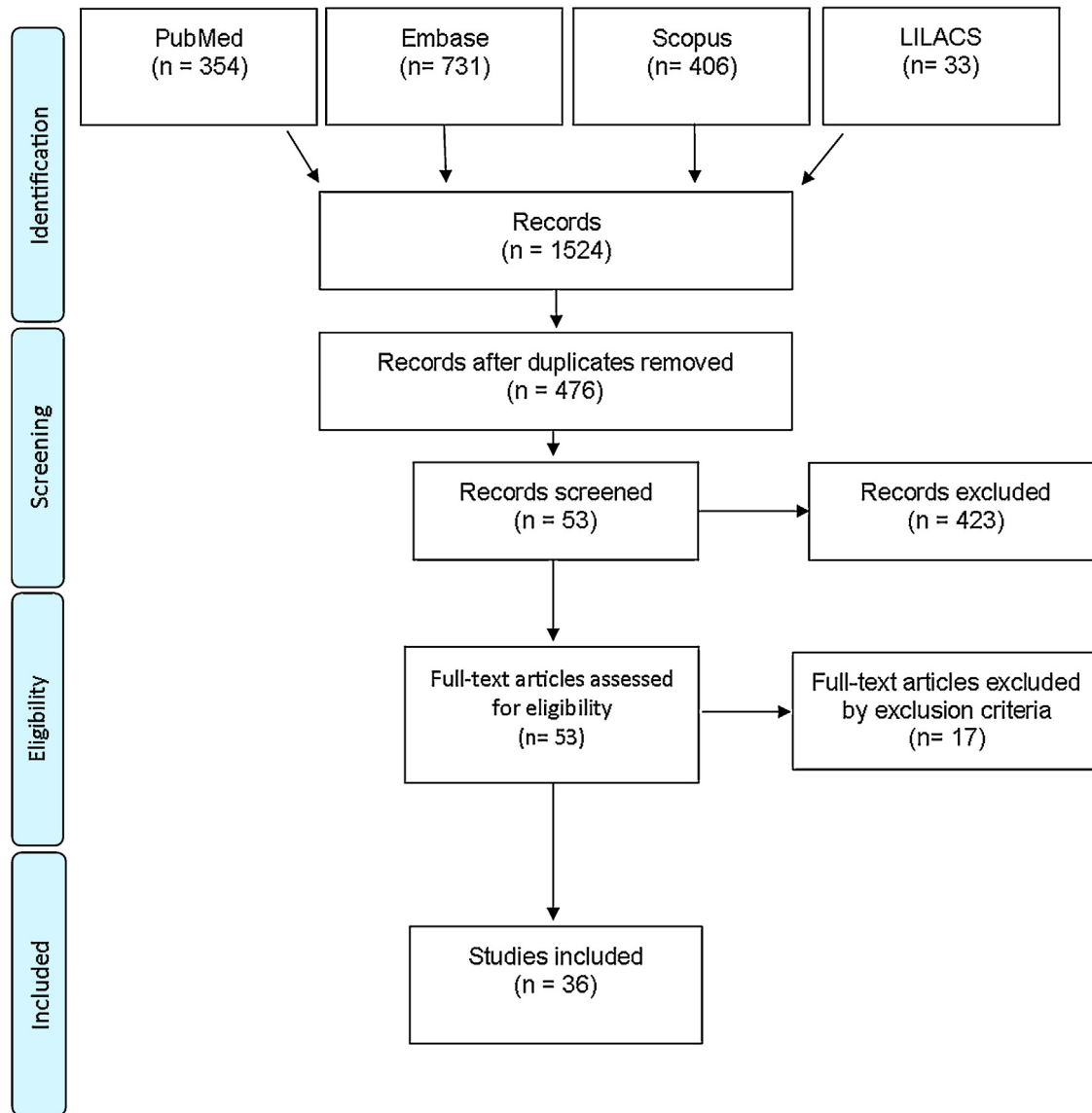


Fig. 1. Flow diagram of the study selection for the systematic review.

Sex and age

The patient's sex was documented for 80 of the 124 cases and the exact age for 102 of them. Fifty-nine cases involved male patients (73.7%) and 21 involved female patients (26.2%) ($P < 0.001$). Patients between the ages of 46 and 60 years were the most affected, comprising 34.3% of the 102 cases ($P < 0.05$) (Table 2).

Local factors associated with the risk of fracture

The side of the mandibular fracture was documented in 67 cases. The left side

was affected in 35 cases (52.2%) and the right side in 30 cases (44.8%) ($P = 0.16$) (Table 3).

The tooth position was recorded using the Pell and Gregory classification system in 39 cases. Classes II and III, and classes B and C accounted for higher proportions of cases than class I and class A ($P < 0.05$) (Table 3).

The tooth angulation was reported in 75 cases. The most frequent angulation was mesioangular, with 27 cases (36%), followed by vertical (33.3%), horizontal (18.7%), and distoangular (12.0%) (Table 3). There was no statistical difference

between the mesioangular and vertical categories ($P > 0.05$).

The degree of bony impaction was reported in 54 cases; 35 (64.8%) were completely impacted and 19 (35.2%) were partially impacted (Table 3) ($P < 0.05$).

The proximity of the tooth to the inferior alveolar nerve was reported in 38 cases. The tooth was superimposed on the nerve in 19 cases (50%) and was adjacent to the nerve in 19 cases (50%) (Table 3) ($P > 0.05$).

The history of infection was reported in 41 cases. Pericoronitis was the most

Table 1. Reports of mandibular fracture after the removal of a lower third molar.

Authors	Year	Number of cases	Article type	Level of evidence ^a	
Belvéze ¹⁵	1954	1	Case report	IV	Poor
Nyul ¹⁶	1959	1	Case report	IV	Poor
Lautenbach ¹⁷	1966	1	Case report	IV	Poor
Haunfelder and Tetsch ¹⁸	1972	2	Case series	IV	Poor
Berlin ¹⁹	1977	1	Case series	IV	Poor
Borea et al. ²⁰	1977	2	Case report	IV	Poor
Einrauch et al. ²¹	1980	4	Case series	IV	Poor
Schneider ²²	1980	1	Case report	IV	Poor
Roth ²³	1981	1	Case report	IV	Poor
Cantaloube et al. ²⁴	1982	1	Case report	IV	Poor
de Silva ²⁵	1984	1	Case report	IV	Poor
Litwan and Götzfried ²⁶	1987	4	Case series	IV	Poor
Härtel et al. ²⁷	1988	2	Case series	IV	Poor
Dunstan and Sugar ²⁸	1997	2	Case series	IV	Poor
Iizuka et al. ⁶	1997	12	Retrospective study	III-3	Satisfactory
Becktor and Schou ²⁹	1998	1	Case report	IV	Poor
Perry and Goldberg ⁷	2000	28	Expert opinion	IV	Poor
Krimmel and Reinert ³⁰	2000	6	Retrospective study	III-3	Satisfactory
Libersa et al. ³¹	2002	10	Retrospective study	III-3	Satisfactory
Tamashiro-Higa and Inclán ³²	2003	1	Case series	IV	Satisfactory
Arrigoni et al. ³³	2004	7	Retrospective study	III-3	Satisfactory
Wagner et al. ⁵	2005	14	Retrospective study	III-3	Satisfactory
Werkmeister et al. ³⁴	2005	1	Retrospective study	III-3	Satisfactory
Komerik and Karaduman ³⁵	2006	1	Case report	IV	Poor
Wagner et al. ³⁶	2007	1	Case report	IV	Poor
Khan et al. ³⁷	2009	1	Letter to the editor	IV	Poor
Chrcanovic and Custódio ²	2010	1	Case report	IV	Poor
Kao et al. ³⁸	2010	1	Case report	IV	Poor
Grau-Manclús et al. ⁴	2011	4	Retrospective study	III-3	Satisfactory
Tieghi et al. ³⁹	2011	1	Case report	IV	Poor
Ishii et al. ⁴⁰	2012	1	Case report	IV	Poor
Ethunandan et al. ⁴¹	2012	3	Systematic review/case series	I	Satisfactory
Duarte et al. ⁴²	2012	1	Case series	IV	Poor
Cutilli et al. ³	2013	3	Case series	IV	Poor
Andrade et al. ⁴³	2013	1	Case report	IV	Poor
Corrêa et al. ⁸	2014	1	Letter to the editor	IV	Poor
Total		124			

^a Level of evidence according to the National Health and Medical Research Council.¹³

frequent infection, with 28 cases (68.3%) (Table 3) ($P < 0.05$).

The presence (or absence) of an associated pathological process was reported in 52 cases. In 28 cases (53.8%) there was no pathological process associated with the tooth, and in 24 cases (46.2%) there was an associated pathology ($P > 0.05$). There were 10 cases of a follicular cyst (19.2%), and an expanded dental follicle was present in nine cases (17.3%) (Table 3) ($P > 0.05$).

Table 2. Sex and age of patients with late fracture after removal of a lower third molar.

Variable	Number of cases	%
Sex		
Male	59	73.7
Female	21	26.2
Age (years)		
<25	10	9.8
26–35	22	21.6
36–45	26	25.5
46–60	35	34.3
>60	9	8.8

Factors related to the diagnosis, characteristics, and treatment of the fracture

The aetiology of the fracture was reported in 46 cases, and the most common was mastication (35 cases, 76.1%) ($P < 0.05$) (Table 4). External traumas were reported in four cases. Amongst these, two fractures were due to sports traumas, one to a fall, and one to a car crash trauma. It was not possible to ascertain whether the mandibular fracture occurred as a result of the tooth extraction. Nevertheless, its frequency was not statistically significant ($P > 0.05$).

The most frequent symptom at the time of the fracture was crackling, followed by pain and oedema. Crackling was reported in 45 cases (50.6%) (Table 4) ($P < 0.05$).

The time between surgery and the fracture was reported in 61 cases. A late fracture was most likely to occur in the second week after surgery (32.8%), followed by the third (27.9%) and fourth weeks (18.0%) (Table 4). There was no statistical

difference between the second and third weeks ($P = 0.04$); however fractures occurred significantly more frequently in these weeks than in the others ($P < 0.05$).

The degree of displacement was recorded in 49 cases. The majority of patients did not experience displacement (39 cases, 79.6%) (Table 4) ($P < 0.05$).

The treatment procedure was reported in 96 cases. The majority of patients were treated only with maxillomandibular fixation (43 cases, 44.8%), followed by open reduction and internal fixation (27 cases, 28.1%) (Table 4) ($P < 0.05$).

Risk of bias within studies

In the assessment of the level of evidence, 27 articles were classified as being 'poor' and nine as being 'satisfactory'.

Discussion

The most commonly retained teeth are the lower third molars and their presence is

Table 3. Local factors that could be associated with the risk of mandibular fracture.

Variable	Number of cases	%
Side		
Left	35	52.2
Right	30	44.8
Bilateral	2	3.0
Localization (Pell and Gregory)		
Anteroposterior		
I	4	10.2
II	24	61.5
III	11	28.2
Vertical		
A	2	5.1
B	16	41.0
C	21	53.8
Angulation		
Distoangular	9	12
Horizontal	14	18.7
Mesioangular	27	36
Vertical	25	33.3
Degree of impaction		
Complete	35	64.8
Partial	19	35.2
Relationship to IAN		
Adjacent	19	50
Superimposed	19	50
History of infection		
None	11	26.8
Pericoronitis	28	68.3
Periodontal pocket	2	4.9
Pathological association		
None	28	53.8
Expanded dental follicle	9	17.3
Follicular cyst	10	19.2
Stafne defect	3	5.8
Odontogenic tumour	1	1.9
Reabsorption	1	1.9

IAN, inferior alveolar nerve.

linked to a higher probability of mandibular angle fracture.⁴² The fractures associated with these teeth are not just related to postoperative factors, like the cases presented in this review, but also to intraoperative factors such as surgical malpractice⁴⁴ and the angulation of the third molar, where the mesioangular angulation is associated with the highest risk.⁴⁵

Regarding the risk factors associated with a mandibular fracture after lower third molar extraction, some studies have reported that female patients represent around 60% of mandibular angle fracture cases associated with complications of lower third molar removal.^{46,47} However, in the present study, it was found that 73.7% of the cases were in male patients, similar to the results of Perry and Goldberg,⁷ who reported that 78% of cases were in male patients. Men usually have a greater bite force than women,⁴⁸ and thus would be more likely to experience mandibular fractures after tooth extraction. Patient age was also a significant risk

factor, and the most affected age bracket was 46–60 years, comprising 34.3% of the cases. No fractures occurred in subjects aged <20 years and 68.6% of the fractures occurred in patients older than 36 years. Since almost 90% of third molar surgeries are done in patients younger than 35 years,⁴⁶ it is evident that the postoperative fracture risk increases with age. The decrease in bone elasticity and occurrence of osteoporosis in elderly patients are possible explanations for this trend.⁶ In the same vein, the narrowing of the periodontal ligament and the incidence of ankylosis also increase with age,^{5,30} which can hamper tooth removal, generating a considerable need for osteotomies.

The side of the fracture is less discussed as a relevant risk factor. In the present study, fractures on the left side made up 52.2% of the cases. In the study by Wagner et al.,⁵ fractures on the left side comprised 70% of the cases. This could be related to the fact that right-handed surgeons have a better view of the right operative field, which results in a less extensive osteotomy.⁵ In the present study, there were two cases of bilateral mandibular angle fracture; however, these had car and sporting accidents as aetiological factors.

With regard to angulation, the distoangular position is generally considered the most technically difficult in relation to the others and requires more extensive bone removal.² In the present study, however, the mesioangular and vertical angulations were associated with the highest incidence of fracture, despite these being the easiest positions to operate on and requiring less bone removal. This is probably because the mesioangular and vertical angulations are more prevalent in the general population.⁴⁹

In terms of dental position, cases of class II and III, and B and C were found to have higher incidences of mandibular fracture than cases of class I and A. This is likely linked to a higher degree of difficulty of extraction and to more extensive bone removal.⁵ There was also a higher incidence of mandibular fracture for completely impacted teeth (64.8%) compared to teeth that were partially impacted. When the tooth is completely covered by bone, it generally occupies a greater proportion of the mandibular angle and requires more bone removal during surgery. Postoperatively, this results in less remaining cortical bone and thus a more fragile mandibular angle, which can be an important causal factor in late fracture.⁷ In the present study, it was found that the proximity of the tooth to the inferior alveolar nerve had no effect on the incidence of late mandibular fracture.

Table 4. Factors related to the diagnosis, characteristics, and treatment of the fracture.

Variable	Number of cases	%
Aetiology		
Mastication	35	76.1
Yawn	3	6.5
Sport	2	4.3
Exercise	1	2.2
Fall	1	2.2
Car accident	1	2.2
Osteomyelitis	3	6.5
Symptomatology		
Crackling	45	50.6
Pain	26	29.2
Oedema	11	12.3
Occlusal alteration	2	2.2
Trismus	3	3.4
Unnoticed	1	1.1
Bleeding	1	1.1
Time (weeks)		
1	7	11.5
2	20	32.8
3	17	27.9
4	11	18.0
5	2	3.3
≥6	4	6.5
Displacement		
None	39	79.6
Minor	4	8.2
Yes	6	12.2
Treatment		
Soft diet	17	17.7
MMF	43	44.8
ORIF	27	28.1
ORIF + MMF	5	5.2
ORIF + mandibular reconstruction	2	2.1
None	2	2.1

MMF, maxillomandibular fixation; ORIF, open reduction and internal fixation.

There was a significant relationship between a history of pericoronitis (68.3%) and the incidence of late mandibular fracture, as shown previously in other studies.^{6,7} This could be related to the fact that recurring infections, chronic or deep, can contribute to decalcification and therefore a higher probability of fracture.^{4,6,7} Comparing the percentage of pericoronitis cases (68.3%) with partial impaction cases (35.2%) seems contradictory, since pericoronitis affects partially impacted teeth. An explanation for this could be that the data calculations were done separately and the existence of a relationship with some kind of infection was considered in only 41 out of the 124 cases; of these 41 cases, 68.3% reported previous pericoronitis. The degree of bone impaction was reported for 54 out of the 124 cases reported. Of these 54 cases, 64.8% reported complete bone impaction. As many authors did not specify whether the teeth were partially covered by bone

and soft tissue or only by soft tissue, pericoronitis could not be classified as partial bony impaction.

The number of radiolucent pathological bone alterations was recorded in a few cases in this study. These lesions occupied space in the bone, causing the bone to weaken, particularly in the mandibular angle region.^{4,6,30}

It is of considerable interest that 76.1% of the fractures occurred during mastication. The masticatory force needed to break down food before deglutition can generate a considerable amount of stress in the bone region, which already has less volume due to the tooth removal and probable ostectomy. The study by Perry and Goldberg reported that the fractures occurred while the patients were eating solid food, such as nuts, meat, ribs, bacon, and frozen chocolate bars, which require a considerable masticatory force.⁷ Mandibular fractures also occurred during yawning due to the elevated muscular force associated with this process.⁵⁰ The fractures related to falls and sports and car accidents probably occurred due to a high impact trauma in the mandible region. This region was the most vulnerable to fracture due to a reduced bone volume. However, it is necessary to consider that these traumas can cause mandibular fractures even if no previous tooth extraction has been performed. Nevertheless, third molar removal leading to bone impairment and, consequently, increasing the risk of bone fracture in this region should be considered as a cause.

By the end of the second postoperative week, patients who have undergone surgical removal of a third molar feel better.³¹ This false sense of security, due to the disappearance of postoperative symptoms, can convince the active athlete patients to return to their sports routine, increasing the risk of a mandibular fracture in the weak spot of the mandibular angle region. The risk of maxillofacial fractures is considerably greater in popular contact sports that do not use facial protection.⁵¹ Thus, as observed in this review, there is a relevant risk for mandibular fracture until the fourth postoperative week. Patients undergoing third molar removal should maintain a liquid and soft diet and should expect to return to their regular physical activities after 4 weeks.

Iizuka et al. reported that the highest incidence of fracture occurred during the first week after surgery⁶; however, Libersa et al. only reported fractures in the third week after surgery.³¹ According to Perry and Goldberg, the greatest risk period is during the second and third

postoperative weeks,⁷ as during this period the granulation tissue in the alveolus is being substituted by connective tissue.⁵² In the present study, postoperative fractures were also observed to occur most often during the second and third weeks. However, fractures still occurred up until the sixth week postoperative. Fractures generally occur during the period when the patient is no longer experiencing any unpleasant postoperative symptoms and so proceeds to place excessive mastication force on a weakened mandibular angle. This period is generally between the second and fourth weeks (78.7% of the cases).

In the diagnosis of late mandibular angle fracture related to the removal of the lower third molar, the clinical examination takes precedence over the radiographic examination. Generally, the patient reports that they heard a snap during mastication or when yawning; this could have been followed by pain, oedema, trismus, or occlusal alterations. Iizuka et al. reported that the radiographic diagnosis is not as simple.⁶ The fractures are not always immediately apparent, so a negative radiographic diagnosis does not completely exclude the possibility of a fracture. Therefore, a patient-reported snap should be considered as a possible indication of fracture even if the fracture cannot initially be detected radiographically.⁵³ In cases where the radiographic finding is negative but a non-displaced mandibular fracture is suspected, computed tomography should be utilized. This imaging modality offers a superior anatomical view and is capable of generating images in the sagittal, coronal, and axial planes, eliminating the superimposition of the anatomical structures.⁵⁴⁻⁵⁶

The treatment options for this type of fracture are diverse and include conservative treatment,⁷ a postoperative diet of soft food for 45 days⁴³ to 3 months,⁴ maxillo-mandibular fixation with elastics, and open reduction with internal fixation.⁵ The objectives of treatment are to restore the mandibular contour, dental occlusion, and temporomandibular joint function.⁵⁷ The most applied treatment is intermaxillary fixation with elastics, generally for 45 days,³ followed by open reduction and internal fixation. In the present study, 79.6% of the cases had a non-displaced fracture and just one case presented with occlusal alteration.

In studies that prescribed a diet of soft food for patients with non-displaced fractures, the treatment was successful and bone repair was observed radiographically.^{4-6,43} Krimmel and Reinert reported six

cases of non-displaced late fractures that were treated by intraoral open reduction and stabilization with rigid internal fixation.³⁰ Champy's principle was used in four of these cases, and osteosynthesis with bicortical screws was performed in the other two cases.

The high number of studies showing a poor level of evidence in this review can be explained by the high numbers of case reports and case series included. Nevertheless this literature review examined the individual cases reported in these articles. Therefore, despite these studies presenting a poor level of evidence, they contributed significantly to this review, sometimes providing more information than those that presented a satisfactory level of evidence.

From the results obtained, it is possible to conclude that the risk of post-extraction mandibular fracture is mainly associated with excessive ostectomy and/or local alterations. At-risk patients should be thoroughly briefed on the importance of diet choices during the postoperative period. Finally, the non-surgical treatment plan seems to be the most suitable approach to non-displaced fractures for cooperative patients.

This systematic review makes it evident that new clinical studies should be performed, such as randomized or prospective studies with longitudinal follow-up, since most currently available data come from case series and retrospective studies. Nevertheless, with the assessment of the cases in this review, it was possible to clearly identify that there were no late postoperative fractures in patients under 20 years of age. This fact should be shared with third party payers, who are now denying authorization for the removal of asymptomatic third molars that will never be in function.

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Competing interests

No conflict of interest exists between any of the authors or their academic institution and other people or organizations.

Ethical approval

Not required.

Patient consent

Not required.

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