

LUANA CARDOSO CABRAL

**Avaliação fisiopatológica de indivíduos afetados com fratura
condilar: Revisão Sistemática com Metanálise, Análise
Epidemiológica, Clínica e Tomográfica**

*Pathophysiological evaluation of individuals affected with condylar
fracture: Systematic Review with Meta-Analysis, Epidemiological, Clinical
and Tomographic Analysis*

Tese apresentada a Faculdade de Odontologia
da Universidade Federal de Uberlândia, para
obtenção do título de Doutor em Odontologia na
Área de Clínica Odontológica Integrada.

Uberlândia – MG

2020

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Orientador: Prof. Dr. Paulo César Simamoto Júnior

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DEDICATÓRIA

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por ter abençoado todos os dias da minha vida, por iluminar meu caminho e me dar forças para seguir sempre em frente.

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*“Não é sobre ter todas as pessoas do mundo pra si,
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“A tarefa não é tanto ver aquilo que ninguém viu, mas pensar o que ninguém ainda pensou sobre aquilo que todo mundo vê.”

Arthur Schopenhauer

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RESUMO

As injúrias mandibulares é o trauma facial mais comum com prevalência entre 26% a 57% envolvendo a região condilar. A etiologia está associada a fatores externos como acidentes de trânsito, agressões físicas, atividades esportivas, quedas da própria altura e acidentes industriais. As abordagens terapêuticas são realizadas de forma aberta (cirúrgica) ou fechada (conservadora). Contudo, devido à complexidade anatômica da região, existem complicações inerentes aos tratamentos como a presença de disfunção temporomandibular (DTM), alterações oclusais, dor, anquilose, deformidades condilares, desvio mandibular e injúrias ao nervo facial. Tendo em vista a alta prevalência das fraturas condilares e a importância do restabelecimento funcional, o objetivo geral deste trabalho foi avaliar por meio de estudos clínicos e revisão sistemática da literatura os parâmetros determinantes para a longevidade e previsibilidade das terapias adotadas em indivíduos afetados com fratura condilar. Este estudo envolveu três objetivos específicos. **Objetivo específico 1:** avaliar a dinâmica mandibular e articular e presença de complicações associadas ao tratamento cirúrgico e não-cirúrgico das fraturas condilares. **Objetivo específico 2:** analisar retrospectivamente as características epidemiológicas como prevalência, tipo e modalidades de tratamento das fraturas condilares mandibulares em dois diferentes centros. **Objetivo específico 3:** avaliar o efeito da redução aberta e fixação interna ou fixação maxilomandibular na função da mandíbula e componentes da articulação temporomandibular. Os métodos utilizados foram: desenvolvimento da revisão de literatura com metanálise, seguindo o *Preferred Reporting Items for Systematic Reviews and Meta-Analyses* (PRISMA Checklist). Posteriormente, levantamento epidemiológico multicêntrico. E por fim, aplicação do *Research Diagnostic Criteria for Temporomandibular Disorders* (RDC/TMD) e realização de exame tomográfico para associação da presença da desordem temporomandibular e tratamento proposto. Frente as análises conclui-se que as fraturas apresentaram prevalência no gênero masculino, na faixa etária entre 21-30 anos. O principal fator etiológico são os acidentes de trânsito. Ambos as terapias mostraram previsibilidade e longevidade. Os principais parâmetros para análise desses fatores são os movimentos mandibulares e presença de

comorbidades. Os resultados foram satisfatórios para mobilidade mandibular a longo prazo. Entretanto, complicações como má-oclusão, dor e desvio mandibular foram observadas com prevalência no tratamento fechado.

Palavras-chave: Côndilo mandibular, Fratura, Tratamento.

ABSTRACT

Mandibular injuries are the most common facial trauma with prevalence between 26% to 57% involving the condylar region. The etiology is associated with external factors such as traffic accidents, physical aggressions, sports activities, falls and industrial accidents. Therapeutic approaches are performed in an open (surgical) or closed (conservative) manner. However, due to the anatomical complexity of the region, there are complications inherent to treatments such as the presence of temporomandibular disorder (TMD), occlusal changes, pain, ankylosis, condylar deformities, mandibular deviation and injuries of the facial nerve. In view of the high prevalence of condylar fractures and the importance of functional restoration, the general objective of this paper was to evaluate, through clinical studies and systematic review, the parameters that determine the longevity and predictability of therapies adopted in affected individuals with condylar fracture. This study involved three specific objectives. **Specific objective 1:** to evaluate the mandibular and joint dynamics and the presence of complications associated with surgical and nonsurgical treatment of condylar fractures. **Specific objective 2:** to retrospectively analyze the epidemiological characteristics such as prevalence, type and treatment modalities of mandibular condylar fractures in two different centers. **Specific objective 3:** to assess the effect of open reduction internal fixation (ORIF) or maxillomandibular fixation (MMF) on function jaw and components of temporomandibular joint. The methods used were literature review with meta-analysis, following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA Checklist). Subsequently, multicenter epidemiological survey. And finally, application of the Research Diagnostic Criteria for Temporomandibular Disorders (RDC / TMD) and tomographic examination to associate the presence of the disorder temporomandibular and proposed treatment. In view of the analyzes, it is concluded that the fractures were prevalent in the male gender, in the age group between 21-30 years. The main etiological factor is traffic accidents. Both therapies showed predictability and longevity. The main parameters for analyzing these factors are mandibular movements and the presence of comorbidities. The results were satisfactory for long-term mandibular mobility. However, complications such as malocclusion,

pain and mandibular deviation were observed with prevalence in closed treatment.

Keywords: Mandibular condyle, Fracture, Treatment.

INTRODUÇÃO E REFERENCIAL TEÓRICO

1. INTRODUÇÃO E REFERENCIAL TEÓRICO

A mandíbula é um tecido ósseo ímpar que se articula com o crânio por meio da articulação temporomandibular (ATM), apresentando distribuição de tensão variável ⁽¹⁾. No serviço de cirurgia oral e traumatologia, é a segunda região facial mais lesionada e a décima comumente afetada do corpo ^(2, 3).

A prevalência do sítio anatômico preciso da fratura na mandíbula é variável ⁽⁴⁾, mas aproximadamente um terço envolve o processo condilar ⁽⁵⁾. Os levantamentos epidemiológicos das fraturas do côndilo mandibular são consistentemente influenciados pela densidade populacional, área geográfica, condição socioeconômica, status da amostra estudada, diferenças culturais e período de investigação ⁽⁶⁾.

O principal fator etiológico associado a fratura condilar são os acidentes de trânsito ⁽⁷⁾. Os motociclistas é o grupo mais acometido ⁽⁸⁾. Outras causas do macrotrauma mencionadas na literatura incluem agressões físicas, quedas, atividades esportivas ⁽⁹⁾ e acidentes de trabalho ⁽¹⁰⁾. Além disso, 80% dos casos ocorrem principalmente na faixa etária entre 20 a 39 anos e a proporção de homens para mulheres é 6:1 ⁽²⁾.

O diagnóstico é baseado em investigações clínicas e radiológicas apropriadas. Os achados clínicos observados são dor, edema na região pré-auricular, má-oclusão, distúrbios oclusais, assimetria facial, trismo e desvio na abertura mandibular para o lado fraturado. Além da avaliação dos sinais e sintomas clínicos, a solicitação de exames complementares é essencial para obtenção de informações para diagnóstico inicial, plano de tratamento e preservação ⁽¹¹⁾.

As radiografias representam a primeira técnica de escolha em pacientes com lesão traumática. A radiografia com vista antero-posterior angular chamada vista Towne, é útil em caso de deslocamento de fragmentos condilares ⁽¹²⁾. Outro exame indicado é a radiografia panorâmica que abrange toda a mandíbula apresentando sensibilidade maior do que a mencionada anteriormente para detecção de fraturas. Entretanto, devido às suas duas dimensões, pode resultar em sobreposição de estruturas ósseas, dificultando a interpretação. Desta forma, o resultado da captura da imagem é dependente da posição da linha da fratura e da comunicação dos fragmentos ⁽¹³⁾. A introdução da tomografia

computadorizada tornou-se padrão ouro na imaginologia. Com o advento da reconstrução tridimensional (3D), as imagens podem ser visualizadas sem a interferência de estruturas anatômicas permitindo uma resolução precisa da área analisada ⁽¹⁴⁾.

Associado aos exames clínico e complementar, vários sistemas de classificação que descrevem a fratura condilar têm sido publicados, essencialmente desde o desenvolvimento de protocolos de tratamento para essas lesões ⁽¹⁵⁾. Desta forma, quanto a localização da fratura, classifica-se como fratura da cabeça condilar, pescoço ou base (subcondilar). A fratura da cabeça condilar tem essencialmente a maioria dos componentes ou a totalidade contida dentro da cápsula articular, a fratura do colo localiza-se na região abaixo do nível da cabeça do côndilo e a fratura subcondilar inicia-se na incisura sigmóide e estende-se até a borda posterior da mandíbula ⁽¹⁶⁾.

O objetivo primordial do manejo das fraturas envolvendo o côndilo é restaurar a simetria, oclusão e função mandibular prevenindo futuras complicações pós-operatórias ⁽¹⁷⁾. Vale ressaltar que a longevidade e previsibilidade da conduta terapêutica dependem do caráter biológico, capacidade adaptativa do sistema mastigatório e da idade do paciente. Os métodos de tratamento descritos na literatura ainda permanecem controversos, principalmente em razão da complexidade anatômica da região e das complicações inerentes aos procedimentos ⁽¹⁸⁾. Nesse contexto, as estratégias de tratamento são categorizadas em abordagem conservadora (redução fechada) ou abordagem cirúrgica (redução aberta e fixação interna).

O tratamento conservador pode ser desenvolvido por meio de técnicas passivas como analgésicos, dieta macia, terapia funcional ou técnicas ativas como a fixação maxilomandibular (FMM) e o uso de aparelhos ortodônticos. A FMM, em muitos casos é realizada por meio da elasticoterapia. Os elásticos permitem que o paciente guie sua mordida para posição de máxima intercuspidação ^(19,20). A duração da imobilização varia entre 2 a 6 semanas ⁽²¹⁾. A abordagem não invasiva consequentemente resulta em muito pouco ou nenhum dano ao nervo facial ⁽²²⁾. Atualmente é indicada para fraturas condilares intracapsulares, presença de oclusão estável e fraturas em crianças. Essa última indicação se justifica pela capacidade de remodelação do tecido nessa faixa etária, atingindo resultados satisfatórios a longo prazo ⁽²³⁾. Este protocolo

também é aplicável a fraturas bilaterais nas quais os segmentos fraturados não são deslocados ⁽²⁴⁾. Historicamente essa terapia foi considerada padrão para as fraturas condilares. A suposição que a redução fechada resultaria em menores complicações a tornou procedimento comum. No entanto, estudos observaram resultados imprevisíveis longitudinalmente em indivíduos adultos ⁽²⁵⁾. As complicações potenciais do tratamento conservador são má oclusão (principalmente mordida aberta), redução do ramo mandibular, assimetria facial e mobilidade mandibular reduzida ⁽²⁶⁾.

Devido a essas limitações do tratamento fechado e a introdução de melhores materiais para a osteossíntese, a abordagem cirúrgica tornou-se uma opção de tratamento ^(27, 28). Como regra geral, a necessidade para redução anatômica em fraturas complexas é uma razão para empregar a redução aberta e fixação interna. Alguns estudos discutem os melhores resultados do tratamento cirúrgico para oclusão, morfologia óssea, função da ATM ^(29, 30), capacidade de mobilidade mandibular imediata do paciente, redução do tempo requerido da FMM e diminuição do risco de anquilose ⁽²⁴⁾. Outros, no entanto, argumentam que o acesso cirúrgico ao côndilo mandibular, aumentaria a chance de injúrias no nervo facial e alterações estéticas como a presença de cicatrizes ⁽³¹⁾.

Diante desse contexto, parece oportuno analisar as diferentes formas de tratamento para o macrotrauma e as comorbidades associadas à essas terapias, no intuito de desenvolver protocolos baseados em evidências científicas, para aqueles pacientes que apresentam complicações pós-tratamento da fratura condilar.

OBJETIVOS

2. OBJETIVOS

Objetivo Geral

Avaliar por meio de estudos clínicos e revisão sistemática da literatura os parâmetros determinantes para a longevidade e previsibilidade das terapias adotadas em indivíduos afetados com fratura condilar.

Objetivos Específicos

Objetivo Específico 1

Capítulo 1: Changes in mandibular and articular dynamics associated with surgical versus nonsurgical treatment of mandibular condylar fractures: A systematic review with meta-analysis

Este objetivo específico avaliou a dinâmica mandibular e articular e presença de complicações associadas ao tratamento cirúrgico e não-cirúrgico das fraturas condilares.

Objetivo Específico 2

Capítulo 2: Analysis of patterns, etiology and treatment strategies for mandibular condyle fractures: epidemiological and multicenter study, 9 years follow-up

Este objetivo específico analisou retrospectivamente as características epidemiológicas como prevalência, tipo e modalidades de tratamento das fraturas condilares mandibulares em dois diferentes centros.

Objetivo Específico 3

Capítulo 3: Are temporomandibular disorders an outcome after treatment of condylar fractures?

Este objetivo específico investigou o efeito da redução aberta e fixação interna ou fixação maxilomandibular na função da mandíbula e componentes da articulação temporomandibular.

CAPÍTULOS

3.1 Capítulo 1

Changes in mandibular and articular dynamics associated with surgical versus nonsurgical treatment of mandibular condylar fractures: A systematic review with meta-analysis

Artigo publicado no periódico Oral Surgery, Oral Medicine, Oral Pathology and Oral Radiology

Title: Changes in mandibular and articular dynamics associated with surgical versus nonsurgical treatment of mandibular condylar fractures: A systematic review with meta-analysis

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Changes in mandibular and articular dynamics associated with surgical versus nonsurgical treatment of mandibular condylar fractures: a systematic review with meta-analysis



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Objective. The aim of this study was to evaluate the mandibular and articular dynamics and the presence of complications associated with surgical or nonsurgical treatments of condylar fractures.

Study Design. Clinical trials that compared open reduction internal fixation and maxillomandibular fixation in patients with condylar fractures were included. We performed an electronic search of PubMed, Scopus, Cochrane Library, Web of Science, and LILACS (Latin American and Caribbean Health Sciences) databases starting from February 2017 and updated in January 2019 and found 467 articles. We evaluated methodologic quality by using the criteria from Cochrane's Collaboration Tool.

Results. After independent screening of abstracts, we assessed the full texts of 88 articles; 9 studies were included for qualitative synthesis; but only 8 were included for the meta-analysis. Four studies were considered to have high risk of bias, and 5 were considered to have low risk. The risk ratio (RR = 0.20; 95% confidence interval [CI] 0.13–0.32) was observed for complications. The quality of evidence, using GRADE software, was considered low for maximum mouth opening and protrusive movement and moderate for lateral excursion movement and complications.

Conclusions. This review suggested that open reduction internal fixation and maxillomandibular fixation are effective. However, surgical treatment presented higher objective parameters. Nonsurgical treatment presented a high index of complications, such as malocclusion, pain and deviation. (Oral Surg Oral Med Oral Pathol Oral Radiol 2020;129:311–321)

A mandibular condyle fracture is one of the most common fractures of the mandible, with prevalence rates between 26% and 57%.^{1,2} The main causes of fractures are car accidents, violence, industrial hazard, falls, sport injuries, and gunshot wounds.^{3–5}

Treatment of condylar fractures consists of open reduction and internal fixation (ORIF) and closed treatment.^{6,7} The latter therapy can be performed by either passive techniques (i.e., analgesics, soft diet, and functional therapy) or active techniques, such as maxillomandibular fixation (MMF), orthodontic appliances, and functional therapy.⁸ Most cases are treated with MMF, followed by the use of elastic bands to guide the mandible for maximum intercuspitation.^{9–11}

Because of the anatomic complexity of the area, treatments have inherent complications.^{12,13} Nonsurgical treatments may result in increased displacements, condylar deformities, open bite, deviation during opening of the mouth, habitual dislocation of the temporomandibular joint (TMJ), and malocclusion.¹⁴ Conversely, in surgical treatments, we can observe such complications as temporary or permanent paresis, infection, transient salivary fistula, ankylosis, osteosynthesis failure, pseudoarthrosis, occlusal disorders or malocclusion, and the need for a new surgery.¹⁵

The ideal option for the management of condylar fractures is still being debated among oral and maxillofacial surgeons. Despite an abundance of literature on the subject, no consensus has been reached, and surgeons continue to determine a treatment plan based on clinical experience and individual preferences.¹⁶

The aim of this study was to evaluate the mandibular and articular dynamics and the presence of complications associated with surgical (ORIF) or nonsurgical

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Statement of Clinical Relevance

The surgical and nonsurgical treatments for condylar mandibular fractures present predictability and longevity. However, the risk of postoperative complications is greater in conservative treatment. The main complications include pain, mandibular deviation and malocclusion.

Changes in mandibular and articular dynamics associated with surgical versus nonsurgical treatment of mandibular condylar fractures: A systematic review with meta-analysis

Abstract

Objective: To evaluate the mandibular and articular dynamics and the presence of complications associated with surgical or nonsurgical treatment of condylar fractures.

Study Design: Clinical trials that compared open reduction internal fixation (ORIF) and maxillomandibular fixation (MMF) in patients with condylar fractures were included. We performed an electronic search of PubMed, Scopus, Cochrane Library, Web of Science, and Latin American and Caribbean Health Sciences (LILACS) databases starting from February 2017 and updated in January 2019 and found 467 articles. The authors evaluated the methodological quality using criteria from Cochrane's Collaboration tool. **Results:**

After independent screening of abstracts, we assessed 88 articles in full text; 9 studies were included for qualitative synthesis; but 8 were included for the meta-analysis. Four studies were considered to have high risk of bias and five were considered to have low risk. The risk ratio [RR=0.20; 95% confidence interval (CI)=0.13 to 0.32] was observed for complications. The quality of evidence, using GRADE software, was considered low for maximum mouth opening and protrusive movement, and moderate for lateral excursion movement and complications. **Conclusion:** This review suggests that MMF and ORIF are effective. However, surgical treatment presented better objective parameters. The nonsurgical treatment presented a high index of complications, such as malocclusion, pain, and deviation.

Clinical Relevance: The surgical and nonsurgical treatment for condylar mandibular fractures present predictability and longevity. However, the risk of postoperative complications is superior in conservative treatment. The main complications include pain, mandibular deviation and malocclusion.

Keywords: mandibular condyle; fractures, bone; closed fracture reduction; open fracture reduction.

Introduction

A mandibular condyle fracture is one of the most common fractures of the mandible, with a prevalence between 26% and 57% ^{1,2}. The main causes of the fracture are car accident, violence, industrial hazard, a fall, sports, and gunshot wound ^{3,4,5}.

The treatment of condylar fractures consists of open reduction and internal fixation (ORIF) or closed treatment ^{6,7}. The latter therapy can be performed by either passive techniques (i.e., analgesics, soft diet, and functional therapy) or active techniques, such as maxillomandibular fixation (MMF), orthodontic appliances, and functional therapy ⁸. In MMF, most cases consist of MMF followed by the use of elastic bands to guide the mandible for maximum intercuspitation ^{9,10,11}.

Due to the complexity of the area, there are inherent complications to the treatments ^{12,13}. Nonsurgical treatments may result in increased displacements, condylar deformities, open bite, deviation during opening of the mouth, habitual dislocation of the temporomandibular joint (TMJ), and malocclusion ¹⁴. Conversely, in surgical treatments, we can observe complications such as temporary or permanent paresis, infection, transient salivary fistula, ankylosis, osteosynthesis failure, pseudoarthrosis, occlusal disorders or malocclusion, and the need for a new surgery ¹⁵.

The options for management of condyle fractures remain a debate among oral and maxillofacial surgeons. Despite an abundance of literature on the subject, no consensus has been reached and surgeons continue to determine a treatment plan based on clinical experience and personal beliefs ¹⁶.

The aim of this study was to evaluate the mandibular and articular dynamics and the presence of complications associated with surgical (ORIF) or nonsurgical treatments (MMF) of mandibular condylar fractures through a systematic review with meta-analysis.

Materials and Methods

Inclusion criteria

This systematic review adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement ¹⁷. The protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO) under the number CRD42017052346. The acronym PICOS was used to formulate the focused

question of the study, of which: Population, patients with mandibular condyle fracture; Intervention, open treatment and internal fixation (ORIF); Comparison/control, maxillomandibular fixation (MMF); Primary outcome, mandibular movement; Secondary outcome, articular movement and complications; Study type, clinical trials. Articles in English and Portuguese were included. There were no limitations regarding the time of publication. A minimum period of 6 months was considered short term, and follow-up was over 2 years long.

Exclusion criteria

The following exclusion criteria were applied: articles that did not evaluate individuals; if the diagnostic criteria for the patient group were not clearly reported; studies in which the sample included children or teenagers (less than 18 years of age); studies that had less than 6 months of follow-up time; and reviews, case reports, protocols, personal opinions, letters, posters, conference abstracts, or laboratory research.

Information Sources and Study Selection

Appropriate word combinations and truncations were developed for each of the following bibliographic databases: PubMed, Scopus, Cochrane, Web of Science, and Latin American and Caribbean Health Sciences (LILACS). Open Thesis and Open Grey databases were searched to capture the 'grey literature'. A manual search was performed in the reference lists of the eligible articles. The main search strategy was developed for PubMed and then adapted for the other databases. The full strategy for PubMed is provided in Table 1.

Two of the authors (LCC and GMA) independently reviewed the titles and abstracts of the identified articles. If one reviewer deemed an abstract as potentially relevant, it was retained for full-text assessment. All potentially eligible studies were then retrieved, and full-text articles were reviewed to determine whether they met the inclusion criteria. Two of the authors (LCC and GMA) then formed review pairs where each reviewer independently assessed these full-text articles to determine whether or not they should be included. Any disagreement within the pair was resolved by including the third reviewer in arbitration (PCSJ). The study authors were contacted in cases of missing information.

Risk of Bias in Individual Studies

Two authors (LCC, GMA) independently assessed the risk of bias in the clinical trials included using the Cochrane's Collaboration tool for assessing risk of bias¹⁸. The classifications were compared, and the inconsistencies in the evaluations among the review authors were discussed and resolved. The following domains were classified as low, high, or uncertain risk of bias: random sequence generation, concealment of allocation, blinding of participants and professionals, blinding of outcome assessors, incomplete outcomes, reporting of selective outcome, and other sources of bias.

The quality of the evidence for the primary and secondary outcomes measure was assessed according to the GRADE system (Table 2). The table was generated using online software (GRADEproGDT; the GRADE Working Group).

Statistical analysis

The intervention effects were compared to the following outcomes: maximum mouth opening (MMO ≥ 30 mm), lateral excursion movement (≥ 10 mm), protrusive movement (≥ 10 mm), and presence of complications. The mandibular movements were analyzed qualitatively. Dichotomous data (complications) were analyzed using the risk ratio (RR) at 95% confidence interval (CI). Heterogeneity was assessed with the I^2 statistic, and a meta-analysis of the results was performed using Review Manager 5.3 software; the Cochrane Collaboration ($p < 0.05$).

Results

Study selection

In phase 1 of the study selection, we identified 590 articles across the five electronic databases. After removing the duplicates, 467 articles remained. Twenty-five articles were found in the grey literature. After title and abstract reading, 87 studies were selected. In addition, one study was added through manual search. From these remaining studies, 79 were later excluded. Thus, nine studies remained for qualitative synthesis and eight for quantitative synthesis. The flowchart of the process of identification, inclusion, and exclusion of studies is shown in Figure 1.

Study characteristics

Clinical trials included 196 patients treated with MMF and 199 treated with ORIF. The participants' ages ranged from 27 to 36 years, and the follow-up time ranged from 6 months to 2 years. For both treatments, no oral opening limitation was observed (41.24 mm MMF and 43.36 mm ORIF). When evaluating the protrusion movement, the mean was 5.94 mm for the nonsurgical and 6.85 mm for the surgical treatment. The values of the lateral excursion movement were 10.02 mm and 11.79 mm, respectively. Considering the complications, the nonsurgical treatment presented a higher prevalence of complications when compared with the open treatment. The main complications observed were malocclusion, pain, and mandibular deviation. Table 3 summarizes the descriptive characteristics of the studies.

Risk of bias within studies

Following the procedures outlined in the assessment of risk of bias in the included studies, we wrote a summary of 'Risk of bias' assessment for each outcome, according to Cochrane's tool. Four studies were deemed as having high risk of bias and others as having low risk of bias. The decisions on individual domains within the tool are shown in Figure 2.

Synthesis of results

A meta-analysis was performed within eight of the selected studies. Differences in the overall odds of complications favor the intervention group (RR=0.20; 95% CI=0.13, 0.32). Despite the presence of heterogeneity (I^2 45%), the direction and magnitude of the studies were considered similar (Figure 3).

Confidence in cumulative evidence

In addition, the confidence in cumulative evidence was considered low for maximum mouth opening and protrusion and moderate for lateral movement and complications due to the risk of bias and heterogeneity observed within the included studies. The summary of these findings is provided in Table 2.

Discussion:

This review shows that the success rate ranges from 78% to 100% for ORIF and from 32% to 75% for MMF. The choice of surgical versus nonsurgical treatment for fractures of the condylar process remains a controversial issue ^{19, 20, 21, 22}. Historically, nonsurgical treatment by MMF was standard practice, especially in children, who showed a high potential for adaption and spontaneous regeneration ^{23, 24}. However, the development of better materials for osteosynthesis, such as wires, miniplates, and lag screws, have made open surgical treatments more advantageous ²⁵.

The ideal outcome of a condylar fracture treatment is restoration of occlusion and unrestricted range of motion (ROM) of the mandible, while minimizing the risk of joint ankylosis and injury to surrounding structures ^{26, 27, 28}. In this context, the analysis of mandibular and articular alterations after ORIF or MMF is critical to clarify some aspects such as ROM, muscular and masticatory activity, and bite force, as well as indicating the therapy that presents the fewest complications.

In general, the findings of this study showed acceptable results for functional parameters (i.e., MMO, lateral excursion, protrusive movement) for both treatment options ^{29, 30, 31, 32}. The reason why there were no significant differences between groups is probably associated with improvement in occlusion in some patients due to muscular retraining and compensation by the contralateral joint ²⁵. However, according to the study of Eckelt et al ²⁹ and Singh et al ³¹, in which they compared operative and conservative treatments of displaced condylar fractures, operative treatment was superior in all objective and subjective functional parameters. ORIF ideally returns the condylar process to its pre-traumatic position, restoring skeletal continuity, re-establishing normal mandibular position, and bringing the teeth into their own relationship ³⁰. When evaluating MMO and protrusive movement, it should be emphasized that these conclusions be interpreted with caution. The studies yielded low quality of evidence given the inconsistency of the results of the included articles.

Concerning the results of the present meta-analysis, the complications outcome showed a statistically significant difference between groups when analyzed as dichotomous outcome (95% CI, 0.13 to 0.32, $p < 0.01$), favoring surgical treatment. These data are similar to other studies that observed improvements in the reduction of postoperative pain and occlusion in patients treated in an open manner¹³. Early or delayed complications such hemorrhage or infection, auriculotemporal nerve paresthesia,

malocclusion, loss of ramus height, related facial and mandibular asymmetry, unsightly scar, ankylosis, anterior open bite, pain, reduced mandibular function, crepitation, hypomobility, deviation in mouth opening, and facial nerve injury have been reported ^{25, 33}.

Malocclusion is one of the main postoperative complications emerging after either MMF or ORIF ^{30, 31, 34, 35, 36}. The studies included showed moderate quality evidence for these data. In the study by Worsaae *et al* ³⁶, who compared clinical findings between open and closed reduction, they concluded that 39% of the individuals had occlusal alterations in the nonsurgical treatment and 4% in the surgical treatment. These findings are similar to those found in the studies by Eckelt *et al* ²⁹ and Landes *et al* ³⁵, in which prevalence rates of 23% and 13%, respectively, were observed. The prevalence of occlusal disturbance in MMF is attributed to the reduction in ramus height or to condyle dislocation from the fossa. In the long term, incomplete anatomical restoration with a remaining reduced ramus height in nonsurgical treatment can cause facial asymmetry and inclination of the occlusal plane, as well as functional occlusal problems, such as premature contact in protrusion and lateral movements ³⁷.

Another post-treatment complication is muscular or articular pain³⁸. In the study by Kotrashetti *et al* ³⁴ evaluating 22 patients with subcondylar fractures, they observed a prevalence of symptomatology in the conservative group (33%) over the surgical group, which presented no symptoms. This result is consistent with other studies ²⁹, which observed that patients who underwent surgical treatment also reported better results in terms of less pain and discomfort. In the case of the nonsurgical treatment group, it is suggested that the pain is caused by muscle spasms resulting from MMF; and in the surgical treatment group, the pain is due to the invasive surgical procedure³⁹.

Another relevant complication was deviation. Some studies ^{29, 31, 34} found that a greater number of deviations in mouth opening in patients treated with nonsurgical therapy. Shiju *et al* ³⁰ and Rastogi *et al* ²⁵ found that 70% of the patients in the conservative group presented mouth-opening deviation, which was statistically significant. As the lateral pterygoid function is diminished on the injured side due to malposition of the condyle, the contralateral lateral pterygoid pulls the condylar head anteriorly more vigorously, thus compensating for the injured side. This imbalance causes the chin to deflect to the injured side on mouth opening ^{30, 34, 40}.

Regarding complications associated with ORIF, facial nerve injury was reported in 22% (2/8) of the studies ^{32, 34}. Kotrashetti *et al* ³⁴, when evaluating 22 patients, observed

the presence of this complication in the surgical group (10%). Facial nerve function was assessed at regular intervals, and aggressive physiotherapy was provided. Recovery was significant after 6 months. In a meta-analysis that reviewed up to 20 studies, randomized controlled trials, and non-randomized case series, including the results of 1186 patients treated with ORIF, it was reported that only 6% of the study population showed facial nerve affection⁴¹.

This study has presented some limitations. First, the sample size and the follow-up periods varied. Second, some necessary information was not mentioned in the articles evaluated. The authors were contacted systematically to retrieve additional information or clarifications, but no additional information was returned. It was not possible to define the direction and force of the recommendation characterizing a technical report in health since the approach adopted for condylar fractures was general. Finally, the available data may suggest that ORIF is at least as good, if not better, than MMF. However, it was impossible to assess different surgical approaches and techniques.

In conclusion, the present review suggests that MMF and ORIF are effective treatments options for condylar fractures of the mandible. However, surgical treatments present better objective parameters. The nonsurgical treatment presented a high index of complications, with associated complications such as malocclusion, pain, and deviation.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Table 1. List of terms used in the bibliographic search

Search	Query
#1	"Mandibular Condyle"[Mesh] OR "Condyle, Mandibular" OR "Condyles, Mandibular" OR "Mandibular Condyles"
#2	"Fractures, Bone"[Mesh] OR "Broken Bones" OR "Bone, Broken" OR "Bones, Broken" OR "Broken Bone" OR "Bone Fractures" OR "Bone Fracture" OR "Fracture, Bone"
#3	"Therapy" [Subheading] OR "treatment" OR "disease management"
#4	"Complications" [Subheading] OR "associated disease" OR "coexistent conditions" OR "sequels" OR "concomitant conditions" OR "concomitant disease" OR "sequelae" OR "associated conditions" OR "coexistent disease"
#5	#1 AND #2 AND #3 AND #4

Table 2. GRADE summary of findings

Quality Assessment							N° Participants		Effect			
No. of Studies	Study Design	Risk of Bias	Inconsistency	Indirectness	Imprecision	Other Considerations	Open Treatment	Closed Treatment	Relative (95% CI)	Absolute (95% CI)	Quality	
RR for Maximum mouth opening (assessed with millimeter ≥ 30mm)												
3	RCTs	serious ^a	serious ^b	not serious	not serious	none	63	60	RR 5.81 (4.64 to 6.98)	Not estimative		LOW
RR for Protrusive movement (assessed with millimeter ≥ 10mm)												
3	RCTs	serious ^a	serious ^b	not serious	not serious	none	63	60	RR 1.83 (1.31 to 2.35)	Not estimative		LOW
RR for Lateral excursion movement (assessed with millimeter ≥ 10mm)												
2	RCTs	serious ^a	not serious	not serious	not serious	none	27	30	RR 2.40 (1.53 to 3.26)	Not estimative		MODERATE
RR for complications												
8	RCTs	serious ^a	not serious	not serious	not serious	none	163	166	RR 0.19 (0.12 to 0.31)	Not estimative		MODERATE

CI, confidence interval; GRADE, Grading of Recommendations Assessment, Development and Evaluation; RR, relative risk; a Lack of masking of evaluators; b Magnitude and statistical heterogeneity across studies.

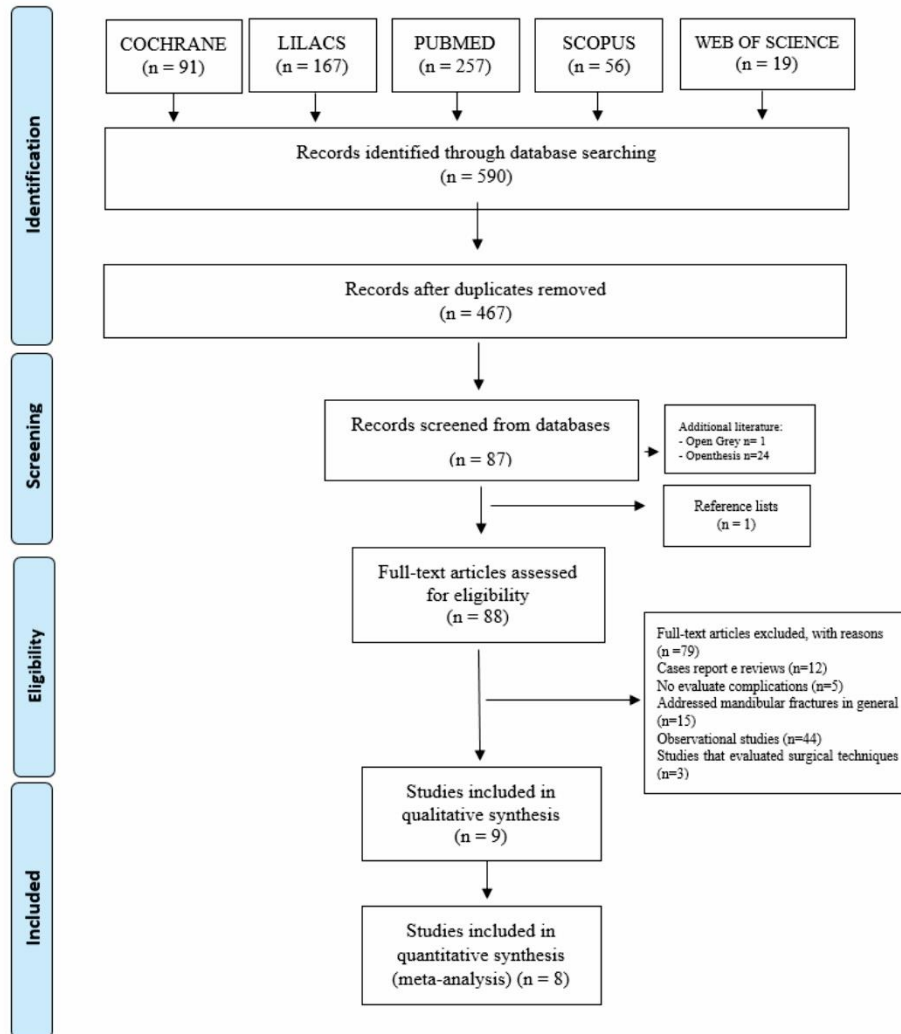


Figure 1. Flow Diagram of literature search and selection criteria

Table 3. Summary of descriptive characteristics of included articles (n=9)

Year	Author	Age (Mean)	Sample	Types of treatment	Fracture region	Types of evaluation	Follow-up (Mean)	Complications
1994	Worsaae et al	36	52	<p>Closed reduction (Rigid MMF. After training elastics and jaw exercises)</p> <p>n= 28</p> <p>Open reduction and transosseous wire osteosynthesis combined with rigid MMF followed training elastics and physiotherapy</p> <p>n=24</p>	Subcondylar	<p>Range of motion</p> <p>Closed: MMO- 50mm</p> <p>P- 7mm</p> <p>L- 8mm</p> <p>Open: MMO- 46mm</p> <p>P- 7mm</p> <p>L- 9.5mm</p> <p>Scars</p> <p>Pain</p> <p>Masticatory function</p> <p>Panoramic and posteroanterior radiographs</p>	2 years	<p>Closed treatment:</p> <ul style="list-style-type: none"> Mandibular Asymmetry: 10.7% Malocclusion: 28.6% Reduced interincisal opening (< 35 mm): 10.7% Persistent headache: 7.1% Pain: 21.4% Impaired masticatory function: 21.4% <p>Open treatment:</p> <ul style="list-style-type: none"> Malocclusion: 4.1% Pain: 4.1% Impaired masticatory function: 4.1%
2006	Eckelt et al	32	66	<p>Closed treatment group consisted of short-term elastic maxillomandibular immobilization applied to arch bars</p> <p>n=30</p>	Condylar base, in the condylar neck region, or in the condyle itself	<p>Range of motion</p> <p>Closed: MMO- 40.9 mm</p> <p>P- 4.7 mm</p> <p>L- 13mm</p> <p>Open: MMO- 46.5mm</p> <p>P- 7.3mm</p>	6 months	<p>Closed treatment:</p> <ul style="list-style-type: none"> Deflection: 66% (3.1 mm) Occlusal disturbances: 23% Pain: 56.6% (VAS 13.5) <p>Open treatment:</p> <ul style="list-style-type: none"> Deflection: 19% (2.6mm) Occlusal disturbances: 9% Pain: 22.2% (VAS 2.9)

				Open reduction and internal fixation n=36		L- 16mm Malocclusion Deviation or deflection Pain (VAS) Panoramic and posteroanterior radiographs		
2008	Landes et al	Closed reduction: 31 Open reduction: 27	17	Closed reduction by means elastic training n=8 Open reduction and internal fixation n=9	Head and upper neck	Range of motion Closed: MMO- 41mm P- 7.5mm L- 8mm Open: MMO- 39 mm P- 6.1mm L- 8.1mm Topographies and Towne views Local inflammation Scarring Condyle translation Pain Facial nerve function Asymmetry	1 year	Closed Treatment: <ul style="list-style-type: none">• Malocclusion: 13%• Insufficient translations on opening: 25% Open Treatment: <ul style="list-style-type: none">• Pain: 22%• Deflection: 22%• Insufficient translations on opening: 22%
2008	Schneider et al	-	66	Closed reduction (Elastic MMF)	Head or Neck or Subcondylar	Range of motion		<ul style="list-style-type: none">• Pain: Closed treatment subcondylar fracture: 12mm

				<p>n=30</p> <p>Open reduction and internal fixation</p> <p>n=36</p>		<p>Closed:</p> <p>- Subcondylar: MMO- 42mm</p> <p>P- 5.7mm</p> <p>L- 15mm</p> <p>- Neck: MMO- 40mm</p> <p>P- 5.3mm</p> <p>L-12mm</p> <p>- Head: MMO- 45mm</p> <p>P- 5.4mm</p> <p>L- 16mm</p> <p>Open:</p> <p>- Subcondylar: MMO- 45mm</p> <p>P- 7.4mm</p> <p>L- 18mm</p> <p>- Neck: MMO- 47mm</p> <p>P- 8mm</p> <p>L- 15mm</p> <p>- Head: MMO- 49mm</p> <p>P- 7mm</p> <p>L- 17mm</p> <p>Pain (VAS)</p>	6 months	<p>Closed treatment neck fracture:10 mm</p> <p>Closed treatment head fracture: 7mm</p> <p>Open treatment subcondylar fracture: 4mm</p> <p>Open treatment neck fracture: 0mm</p> <p>Open treatment head fracture: 1.3mm</p>
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						Mandibular function impairment questionnaire (MFIQ)		
2010	Danda et al	-	32	<p>Closed reduction (Rigid MMF followed by elastic maxillomandibular fixation)</p> <p>n=16</p> <p>Open reduction and internal fixation</p> <p>n=16</p>	Neck or subcondylar	<p>Range of motion</p> <p>Closed: MMO- 40mm</p> <p>P- 6.9mm</p> <p>L- 7mm</p> <p>Open: MMO- 42.1mm</p> <p>P- 7.3mm</p> <p>L- 8mm</p> <p>Pain</p> <p>Malocclusion</p> <p>Radiography</p>	<p>Closed Treatment:</p> <p>21.5 months</p> <p>Open Treatment:</p> <p>22.3 months</p>	<p>Closed Treatment:</p> <ul style="list-style-type: none"> Malocclusion: 25% Pain: 37.5% <p>Open Treatment:</p> <ul style="list-style-type: none"> Malocclusion: 6.25% Pain: 12.5% Temporary facial nerve weakness: 12.5%
2010	Singh et al	30.6	40	<p>Closed Reduction (MMF with elastics)</p> <p>n=22</p> <p>Open Reduction followed by elastic maxillomandibular fixation</p> <p>n=18</p>	Subcondylar	<p>Range of motion</p> <p>Closed: MMO- 33.54mm</p> <p>P- 4.13mm</p> <p>L- 9.86mm</p> <p>Open: MMO- 39.6mm</p> <p>P- 5.94mm</p> <p>L- 12.55mm</p> <p>Deviation or deflection</p> <p>Pain (VAS)</p>	6 months	<p>Closed treatment:</p> <ul style="list-style-type: none"> Deflection: 54% -1.18mm Occlusal disturbances: 9% Pain: 45.45% <p>Open treatment:</p> <ul style="list-style-type: none"> Deflection: 22% - 0.38mm Occlusal disturbances: 5% Pain: 11%

						Occlusal disturbances Motor nerve function Sensory perception Panoramic and Towne's Radiographs		
2013	Kotrashetti et al	-	22	Closed reduction (Arch bars followed by MMF using elastics and then replacing wires to achieve rigid MMF) n=12 Open reduction and internal fixation n=10	Subcondylar	Motion range Occlusion Pain Deviation Facial nerve function TMJ clicking sounds Ear sensitivity Scar Orthopantomogram (OPG), Lateral cephalogram, and Posteroanterior Closed: Posterior ramal heights: 65.33mm Distance of the condyle from the midline: 51.33 Surgical: Posterior ramal heights: 70.5mm	6 months	Closed Treatment: <ul style="list-style-type: none"> • Pain: 33% • Occlusal disturbances: 8.3% • Restriction in movements: 33% • Oral opening limitation (<40mm): 41.7% • Deviation: 16.67% Open treatment: <ul style="list-style-type: none"> • Oral opening limitation (<40mm): 10% • Facial nerve weakness: 10%

						Distance of the condyle from the midline: 53		
2015	Rastogi et al	-	50	<p>Closed management (Rigid MMF using Erich arch bar followed by guiding elastics)</p> <p>n=25</p> <p>Open Reduction and Internal Fixation followed by elastic maxillomandibular fixation</p> <p>n=25</p>	Subcondylar or condylar neck	<p>Range of motion</p> <p>Malocclusion by means of photographs</p> <p>Deviation or deflection</p> <p>Pain (VAS)</p> <p>Posteroanterior and orthopantomogram radiographs</p> <p>Shortening of ascending ramus</p>	6 months	<p>Closed treatment:</p> <ul style="list-style-type: none"> Deviation: 70% <p>Open treatment:</p> <ul style="list-style-type: none"> None
2015	Shiju et al	-	50	<p>Closed management (Rigid MMF using Erich arch bar followed by guiding elastics)</p> <p>n=25</p> <p>Open Reduction and Internal Fixation followed by elastic maxillomandibular fixation</p> <p>n=25</p>	Subcondylar or condylar neck	<p>Range of motion</p> <p>Malocclusion by means of photographs</p> <p>Pain (VAS)</p> <p>Deviation on mouth opening</p> <p>Shortening of ascending ramus</p> <p>Posteroanterior and orthopantomogram radiographs</p>	6 months	<p>Closed treatment:</p> <ul style="list-style-type: none"> Deviation: 70% <p>Open treatment:</p> <ul style="list-style-type: none"> Parotid fistula: 4%

Abbreviations: MMF, maxillomandibular fixation; MMO, maximum mouth opening; P, protrusive movement; L, lateral excursion movement; VAS, visual analogue scale.

	Worsaae et al, 1994 ³⁶	Eckelt et al, 2006 ²⁹	Landes et al, 2008 ³⁵	Schneider et al, 2008 ³⁸	Danda et al, 2010 ³²	Singh et al, 2010 ³¹	Kotrashetti et al, 2013 ³⁴	Rastogi et al, 2015 ²⁵	Shiju et al, 2015 ³⁰
Random sequence generation	-	+	-	+	+	+	+	?	+
Allocation concealment	-	+	-	+	+	+	-	?	+
Blinding of participants and personnel	?	?	?	?	?	?	?	?	?
Blinding of outcome assesment	+	?	?	?	+	+	?	?	?
Incomplete outcome data	+	+	+	+	+	+	+	+	+
Selective reporting	+	+	+	+	+	+	+	-	-
Other bias	?	+	+	+	+	+	+	+	+

Figure 2. Risk of bias summary: each risk of bias item was presented in each included study

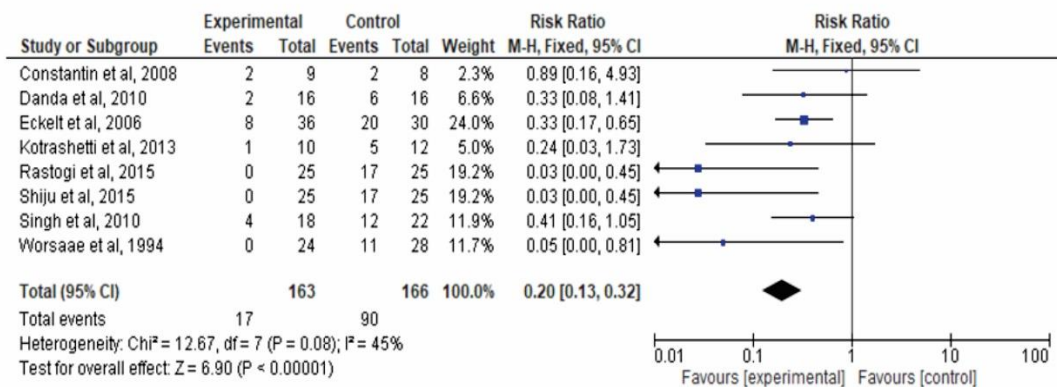


Figure 3. Complications association with both treatments. Forest plot for risk ratio. CI, Confidence interval.

CAPÍTULOS

3.2 Capítulo 2

Analysis of patterns, etiology and treatment strategies for mandibular condyle fractures: epidemiological and multicenter study, 9 years follow-up

Artigo será submetido para publicação no periódico Dental Traumatology

Title: Analysis of patterns, etiology and treatment strategies for mandibular condyle fractures: epidemiological and multicenter study, 9 years follow-up

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Running title: Analysis epidemiological of the mandibular condyle fractures

Keywords: Wounds and injuries, Mandibular Condyle, Epidemiology.

Analysis of patterns, etiology and treatment strategies for mandibular condyle fractures: epidemiological and multicenter study, 9 years follow-up

Aim: To evaluate retrospectively the epidemiologic characteristics of the prevalence, type and treatment modalities of condylar fractures of the mandible in two different centers.

Patients and methods: Data of all patients who underwent surgical and nonsurgical management for condyle mandibular fracture between 2009 and 2018 were collected. The study was conducted to assess the etiology of trauma, age group, gender, treatment method, anatomic distribution of injury and complications by reviewing patients' records.

Results: There were 139 patients with 171 mandibular condylar fractures. 85 percent of the patients were males with an overall male:female ratio of 5.6:1. The highest occurrence of trauma was in the 21-30 years (27.33%) age group. The etiology most frequently observed was motorcycle traffic accidents in 68 patients and the subcondylar region was the most common location with 109 (63.75%) fractures. There was statistically significant difference between the treatments ($p < 0,001$). In the nonsurgical treatment group, the prevalence of complications was observed compared to the surgical group ($p < 0.001$). The predominant complications were: mouth opening limitation, mandibular deviation, malocclusion, temporomandibular disorder, paresthesia and facial paralysis.

Conclusion: The results of the study show that males suffer from fractures of the condyle mandible at a rate of 5.6 times that women. In general, most fractures occur in the age group between 21 and 30 years and the main etiological factor was a traffic accident. A predominant region was the subcondylar. In addition, there was a statistically significant difference between the treatments and the presence of complications.

Keywords: Wounds and injuries. Mandibular Condyle. Epidemiology.

Introduction

Maxillofacial fractures are one of the most frequent traumas treated in a maxillofacial surgery department, representing a serious public health and economic problem ^{1,2}. The condyle is the primary site of fracture for the mandibular bone in terms of prevalence ^{3,4} and this fact is attributed to the mandibular ramus with high stiffness and mandibular condyle head with low stiffness ⁵. The epidemiology varies widely in different countries. These differences can be explained by varying economic and social conditions and local patterns of behavior ⁶.

The most common cause of the mandibular condyle fracture is road traffic accident (RTA). Moreover, studies show that interpersonal violence, assault, sporting accidents, falls from heights, and industrial accidents have a direct relation with this facial trauma ^{7,8}.

Various classification systems have been developed and published, essentially since the development of treatment protocols for these injuries ⁹. Thus, according to the affected anatomic region can be classified as condyle head, condyle neck or subcondylar ¹⁰. The classification is important to determine the form of therapeutic approach used and to standardize the clinical and radiographic findings ¹¹.

The management of mandibular condylar fractures is perhaps the most controversial topic in maxillofacial trauma ¹². The choice of treatment depends on fracture characteristics and imaging of the fracture ¹³. Factors considered are type and level of fracture, size and position of the condylar part, and degree of displacement. Additionally, the dental state, (mal)occlusion and mandibular dysfunction, presence of foreign bodies and presence of concomitant mandibular or facial fractures play a role in clinical

decisions. Finally, experience of the surgeon and the willingness of the patient to undergo operation can determine the choice between surgical or nonsurgical treatment ¹³⁻¹⁵.

Considering the high prevalence of condylar fractures and the importance of treatment in the restoration of function, this study aimed to evaluate retrospectively the epidemiologic characteristics of the prevalence, type and treatment modalities of condylar fractures of the mandible in two different centers. The tested hypothesis was that sociodemographic factors influence the features of the fractures.

Materials and Methods

Data were collected retrospectively regarding patients who were seen at the Department of Oral and Maxillofacial Surgery of two centers (Dental School of Federal University of Uberlândia and Trauma Emergency Hospital of Campina Grande Dom Luís Gonzaga Fernandes / Brazil), from August 2009 to December 2018.

This study was based on the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE Checklist) ¹⁶ and respected the principles of the Declaration of Helsinki (1.990.227). The sample size calculated considered 90% chance for detecting outcomes and level of significance at 5% was $n=98$ ¹⁷.

Information was obtained from clinical notes and dental records of each patient using a standardized data collection form. The inclusion criteria were patients who presented the diagnosis of condyle fracture, treated by open reduction internal fixation or conservative treatment. Volunteers who presented only mandibular fracture without involvement of the condylar region, those who did not perform treatment or dental records that had incomplete data were excluded from the epidemiological survey.

The variables investigated were age, gender, cause of the fracture, fracture classification, others affected mandibular sites, type of treatment and postoperative complications.

The following categories of injury cause were considered: falls, road traffic accidents, assaults, sport injuries, work injuries, and other causes ¹. Moreover, the fractures were classified according to their location in condylar head, condylar neck, or subcondylar ¹⁰.

The treatment modalities analyzed included surgical or nonsurgical treatment. Conservative therapy was divided into rigid maxillomandibular fixation, maxillomandibular fixation associated with elastic therapy, elastic therapy, physiotherapy and follow-up.

Complications were also divided into categories: absent, mouth opening limitation, ankylosis, condylar degeneration, unilateral mandibular deviation, occlusal disorders, temporomandibular disorders, malocclusion, pain and other complications.

Statistical analysis

Statistical analysis was performed using Excel (2016; Microsoft, Redmond, WA) and SigmaPlot software version 12.0 (Systat Software, Inc. Chicago, EUA). The chi-square test was used to assess the association between categorical variables such as treatment type and presence of complication, with p value set at $p < 0.05$.

Results

There were 139 patients with mandibular condylar fractures with a total of 171 fractures. Most of the patients were males (85%) with an overall male:female ratio 5.6:1. The highest occurrence of trauma was in the 21-30 years range (27.33%) followed by the 31-40 years range (25.17%) (Figure 1).

The most frequent etiology of fracture (Figure 2) was motorcycle traffic accidents (49%), followed by falls (13.66%), fight (13%), bicycle accidents (6.47%), car accidents (5.03%), sports accidents (3.6%), and others (5.03%).

Table 1 compares the types of condylar fractures associated with the treatment modalities (surgical and nonsurgical). There is prevalence of subcondylar fractures with indication for surgical treatment. Moreover, the statistically significant difference between the kind of treatments is observed ($p < 0.001$).

Table 2 shows the different types of complications associated with treatment modalities. In the nonsurgical treatment group, the prevalence of complications was observed compared to the surgical group. This difference was statistically significant ($p < 0.001$). The predominant complications were: mouth opening limitation (28.4%), mandibular deviation (14.9%), malocclusion (13.5%), temporomandibular disorder (12.17%), pain (10.9%), paresthesia (6.75%), and facial paralysis (4.05%).

The most common mandibular fracture that occurred in association with mandibular condyle was symphysis fractures (37 cases – 63.8%). Other regions affected were body (15 cases – 25.7%), angle (3 cases – 5.2%), ramus (2 cases – 3.5%) and coronoid (1 case – 1.8%) (Figure 3).

Discussion

The hypothesis tested in this study was rejected. The patients reviewed were from institutions located in the northeast and southeast of Brazil. Although the two regions have cultural and sociodemographic differences, fractures of the condylar process presented similar epidemiological characteristics, thus representing a public health problem and reflecting a worldwide epidemiological characteristic ^{13, 18}.

In the present study, the gender male was the more affected (85%) compared with female gender (15%). The male:female ratio was 5.6:1. The very disproportionate rates between males and females is reported in several papers ^{19, 20} and explained by the increase violence rates, negligence in traffic and exposition of men to risk activities ^{21, 22}. Another factor observed, was the predominance of fracture between 21-30 years of age group (Figure 1). The reason that might be in this period of life, people are more engaged in high-speed transportation, fights, sporting, violent activities and industry ^{23, 24}. The lower prevalence in the very young and elderly age groups is due to family care, surveillance of children and characteristics of the elderly in developing activities with less impact. In these age groups trauma is usually simple fractures related to household accidents such as slipping, falling from stairs and child play ²⁵.

The aetiology of maxillofacial trauma is an important epidemiological factor that directly affects the clinical presentation and treatment modalities of the facial fractures ²⁶. The results showed a higher prevalence of associated fractures motorcycle traffic accidents (49%), followed by falls (13.66%), fight (13%), bicycle accidents (6.47%), car accidents (5.03%), sports accidents (3.6%), and others (5.03%) (Figure 2). The higher risks of traffic accident sustained by motorcycle drivers are due to a set of factors, among which risky driving behaviors in traffic can be highlighted, which is largely made up of young people. The lack of investment in road infrastructure capable of protecting the most

vulnerable road users, contributes to increase of the index. Indeed, the Brazilian Association of Manufacturers of motorcycles, scooters and bicycles, emphasizes that the advancement of consumption of this type of vehicle in the regions was due to the versatility of its use, supplying diverse needs of the regions and also contributing to the data presented ²⁷. For motorcyclists and cyclists, the helmet is the main safety measure that protects them in case of accidents ²⁸. Another relevant factor associated with RTAs is the recklessness related to alcohol consumption and non-compliance with traffic laws influencing the increase of this index ²⁹. Therefore, there is a need to reinforce legislation aimed to prevent motor vehicle accident and the total enforcement of existing laws to reduce traffic accidents in the country ²⁶.

In this study, 63.75% of the fractures were localized in subcondylar region, 15.2% neck condylar and 21.05% head condylar (Table 1). The force applied to the mandible is distributed, affects the weakest point in the mandibular arch, and causes extreme bending and tensile failure at that point. Subcondylar fractures are tension failures in response to bending of the mandibular neck. Because the mandible distributes the force of impact, frequently fractures occur only in subcondylar region ³⁰.

The classification systems allow for more effective clinical communication and support for decision making when formulating treatment plans ³¹. It is a consensus that in adult patients the treatment of choice depends on the anatomical site of the fracture and the grade of displacement, but the specific treatment method is still a matter of debate ³². In general, nondisplaced fractures in which natural occlusion is maintained can be successfully treated with a soft diet for several weeks to allow bony healing, without need fixation. Associated with diet, jaw exercises, or physiotherapy, are useful in maintaining or improving jaw movement. Another treatment modality also considered nonsurgical is

the fixation maxillomandibular consisting in the immobilized fracture segments after manual reduction to achieve premorbid occlusion. This procedure is often accomplished with arch bars and elastic bands, though interdental wiring for more rigid fixation can also be used ^{33, 34}. On the other hand, the surgical treatment allows anatomic reduction and immediate functional movement, and various approaches have been described as preauricular, submandibular and retromandibular ^{35, 36}.

When analyzing the forms of treatment associated with fracture levels, statistically significant difference was observed between the therapies of choice ($p < 0.05$). Over half (57.9%) of the fracture were treated surgically. The prevalence in choosing this form of treatment may be associated with fracture characteristics. In this epidemiological study, 47.95% of the fractures were located at the base of the condyle (Table 2). Correct anatomical position of the fragments have been achieved significantly more accurately in the open reduction internal fixation group in contrast to the closed treatment group ³⁷. Other indications for surgical treatment include displacement of the condyle to the middle cranial fossa, condylar displacement of more than 45° from the longitudinal axis in lateral or frontal projection, impossibility of obtaining adequate occlusion by conservative treatment and impairment by condylar fragment of mandibular mobility ³⁸. It is important to mention that 15.8% of the patients who had subcondylar fractures were treated conservatively. This type of treatment has been performed in cases where the patient has a stable occlusion after the trauma, presence of bilateral fracture, in children or patients seek treatment belatedly.

The post-operative complications in the management of mandibular condylar fractures showed that conservative treatment group had more complications (Table 2) compared to the surgical group. These data showed statistically significant differences (p

< 0.001). While open reduction internal fixation has ability to restore the most ideal anatomical position, the conservative treatment results in functional adaptation to the altered anatomy. During this period of adaptation can have triggering comorbidities ⁴⁰.

The most common complaint after treatment was mouth opening limitation (28.4%) (Table 2). Two factors may be associated with this complication: first, a short period of assessment of mandibular mobility (up to 45 days) and the period of immobilization of the injured joint. Early mobilization of the mandible has been associated with better outcomes regarding mandibular movement ³⁹.

Another complication resulting from condylar fracture, in both treatments, was mandibular deviation (14.9%) (Table 2). However, the conservative group was most affected. Factors affecting midline deviation during maximum interincisal opening include damage to the temporomandibular joint, shortening of the ramus height, and loss of lateral pterygoid muscle function. Deflection and lateral shift of the mandible are often signs of compensatory movements of the contralateral joint due to shortening of the ramus height on the affected side. Since there is no repositioning of the condylar head in nonsurgical treatment, a greater lateral deviation is expected in the group ^{7, 11, 40}.

The malocclusion also was reported (13.5%) (Table 2). The incidence of occlusal disturbance is attributed to the reduction in ramus height or to condyle dislocation from the fossa. In the long term, incomplete anatomical restoration with a remaining reduced ramus height in nonsurgical treatment can cause facial asymmetry and inclination of the occlusal plane, as well as functional occlusal problems, such as premature contact ¹¹. The presence of this morbidity also is related to a decrease in quality of life ⁴¹.

Mandibular condylar fractures in addition to increasing the risk in the restricting mouth opening, may influence in triggering pain, disc displacement or other

temporomandibular disorders ¹⁴. 12.7% of the patients related the dysfunction (Table 2). A systematic review showed a prevalence of myofascial pain of 6–12.9%, intra-articular joint disorders of 8.9–15.8%, and arthralgia diagnoses of 2.6% ⁴². This indicates that the findings of this study are similar to those in the general population with regard to prevalence rates ⁴³.

The facial nerve damage and paresthesia of the mental nerve were observed in the surgical treatment with percentage 10.8% (Table 2). The temporozygomatic division of the facial nerve has an intimate anatomic relationship to the condylar process. When approaching the condylar region from a retromandibular approach or preauricular approach, visualization of the facial nerve-condyle relationship is limited, and moderately strong retraction is frequently required to obtain an adequate visual field and working space for osteosynthesis. Although the temporozygomatic (upper) division of the facial nerve should not be encountered during the submandibular approaches, the nerve is retracted laterally and easily stretched when attempting to achieve an ample working space and optical field. The surgeon must appreciate that blind and aggressive lateral or superior retraction of overlying soft tissue in this region can easily result in stretch injury. Understanding this close relationship should help reduce the incidence of facial nerve injury during surgical treatment of the condylar region ⁴⁴.

In this epidemiological study, other mandibular regions were also affected. A total 58 mandibular fractures were associated with the condylar fractures (Figure 3). Symphysis were the most common site of injuries. These findings suggest that the fracture pattern of the mandible (different locations) depends on the effect of an external force and that the magnitude and direction of the force influences the location of mandibular

fractures ⁴⁵. Applying a greater external force to the symphysis region of the mandible produces a fracture condylar by indirect impact ³⁰.

Limitations to this study are associated with clinical and radiographic evaluation immediately after the treatment of choice. Longitudinal studies analyzing motion mandibular, in long term, are required. However, the results do provide important information necessary for the development and evaluation of preventative measures aimed at reducing the frequency of condylar injuries, mainly due to road traffic accidents in Brazil, where the incidence is increasing annually.

Conclusions

In conclusion, the results of the study show that males suffer from fractures of the condyle mandible at a rate of 5.6 times that women. In general, most fractures occur in the age group between 21 and 30 years and the main etiological factor was a traffic accident. A predominant region was the subcondylar. In addition, there was a statistically significant difference between the treatments and the presence of complications.

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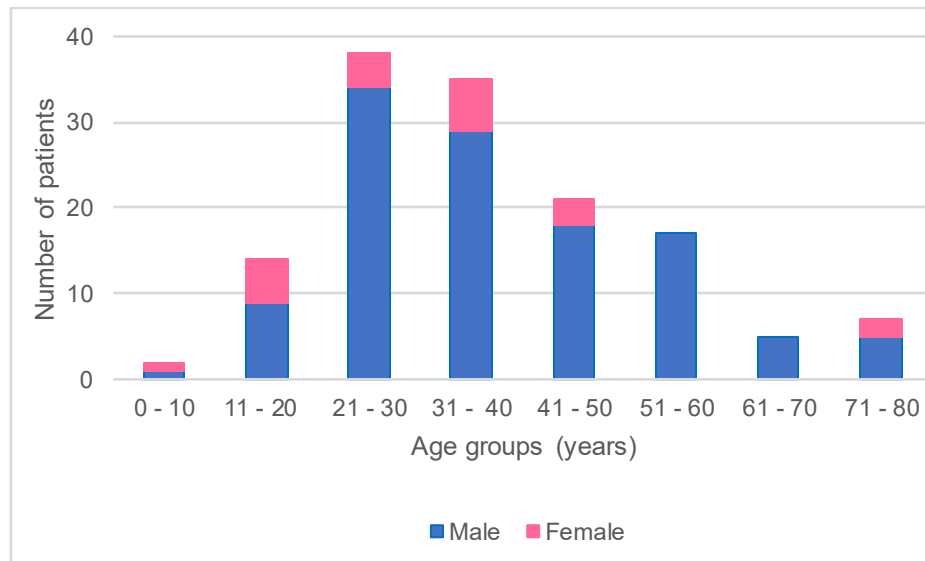


Figure 1. Distribution by age groups and gender

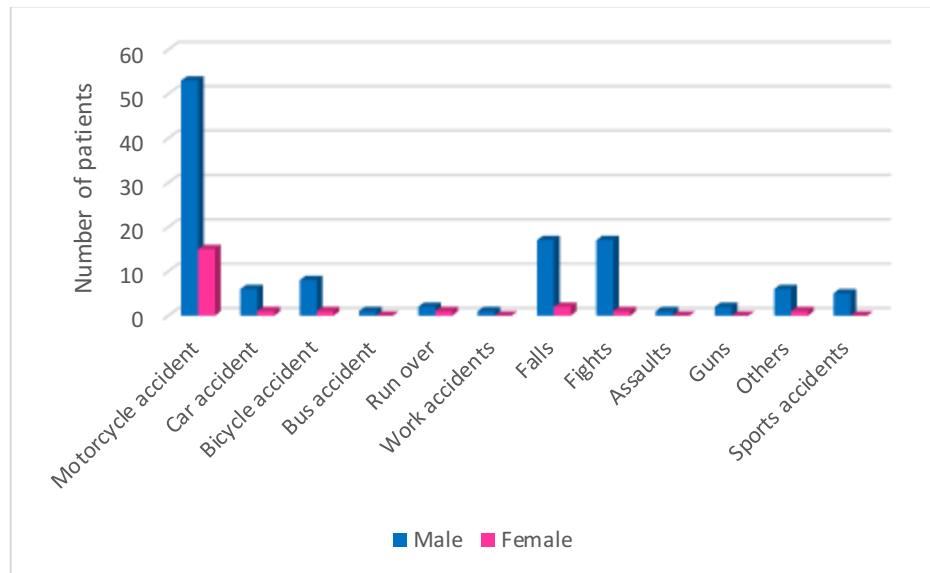


Figure 2. Distribution of etiologies in the study population

Table 1. Comparison between fracture type and treatment modality (n=171)

	Head	Neck	Subcondylar
Nonsurgical	33 (19.3%) A	12 (7%) A	27 (15.8%) A
Surgical	3 (1.75%) B	14 (8.2%) B	82 (47.95%) B

Different letters represent statistically significant differences ($p < 0.05$, Chi-Square Test); upper-case letters compare treatments (lines).

Table 2. Complications associated with different treatment modalities (n=74)

Complications	Surgical			Nonsurgical		
	Head	Neck	Subcondylar	Head	Neck	Subcondylar
Degeneration	-	-	1	-	-	-
Hearing Loss	-	-	-	1	-	-
Malocclusion	-	-	1	6	1	2
Mandibular Deviation	-	1	3	4	-	3
Mouth opening limitation	-	-	8	6	-	7
Pain	-	-	4	2	-	2
Paresthesia	-	-	5	-	-	-
Facial paralysis	-	-	3	-	-	-
Occlusal Disorders	-	-	-	4	-	-
Temporomandibular Disorders	-	-	4	2	-	3
Tinnitus	-	-	-	-	-	1
Total in each region	-	1	29	25	1	18
Overall	30			44*		

* Represents statistically significant difference between groups ($p < 0.05$), chi-square test.

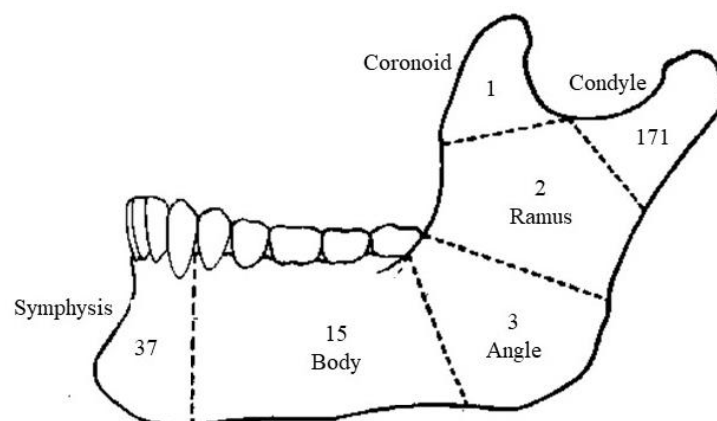


Figure 3. Anatomical distribution of fractures associated with region condylar

CAPÍTULOS

3.3 Capítulo 3

Are temporomandibular disorders an outcome after treatment of condylar fractures?

Artigo será submetido para publicação no periódico International Journal of Oral and Maxillofacial Surgery

Title: Are temporomandibular disorders an outcome after treatment of condylar fractures?

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Are temporomandibular disorders an outcome after treatment of condylar fractures?

Abstract

Purpose: to assess the effect of open reduction internal fixation (ORIF) or maxillomandibular fixation (MMF) on function jaw and components of temporomandibular joint.

Patients and methods: Adult patients with condylar fractures treated from September 2013 to August 2019 in the Oral and Maxillofacial Surgery Service at the Federal University of Uberlândia (Brazil) were included. The study used of clinical and tomographic parameters. The following variables were analyzed: mouth opening, excursions of the mandible and pain. The RDC/TMD questionnaire was applied for diagnose temporomandibular disorders.

Results: 25 patients with 30 fractures condylar were analyzed. The mandibular movements were satisfactory for both treatments (ORIF and MMF). 44% showed symptomatology. This symptom was statistically significant for MMF group. 36% were diagnosed disc displacement with reduction and 20% with degenerative disorder.

Conclusion: The both methods produced satisfactory mobility mandibular. However, the MMF group reported frequently the presence of symptoms that were statistically significant. Regarding TMDs, were observed disc displacement with reduction and degenerative joint diseases for both treatments.

Keywords: Mandibular Condyle. Open Fracture Reduction. Maxillomandibular Fixations. Temporomandibular Joint Disorders.

Introduction

Temporomandibular disorders (TMDs) are a group of clinical problems involving the masticatory musculature, the temporomandibular joint (TMJ), surrounding bony and soft tissue components, and combinations of these structures ¹. It is complex disorder with overlapping comorbidities of physical signs and symptoms, as well as changes in behaviors, emotional status, and social interactions as manifestations of general central nervous system dysregulation ^{2,3}. Direct or indirect trauma, in the articular region, has been associated with triggering of TMDs ⁴.

Condyle fractures are considered to be one of the most common fractures of the mandible ^{5,6}. The decision to treat adult condylar fractures through open reduction internal fixation (ORIF) or maxillomandibular fixation (MMF) techniques is one of the greatest debates within maxillofacial trauma. This controversy stems from the complexity of biomechanical principles of the posttraumatic temporomandibular joint ⁷. In addition, although fracture management can restore function, the forms of treatment have also been associated with risk of the development of temporomandibular disorders.

The use of the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) in this field of maxillofacial surgery is new. The taxonomy of RDC/TMD represent a well-described, reproducible and evidence-based system for the assessment of TMD complaints and jaw dysfunction ⁸. This tool is a useful method to classify and quantify both the physical (subjective and objective evaluation) and the psychosocial components of TMDs ^{9,10}. Clinical evaluation, together with various imaging modalities, may help to elucidate a stage of changes in the TMJ's components, contributing diagnosis and treatment planning ¹¹.

Therefore, the purpose this study was to assess the effect of open reduction internal fixation (ORIF) or maxillomandibular fixation (MMF) on function jaw and components of temporomandibular joint. The hypothesis null to be tested was that both treatment show changes mandibular and articular similar.

Material and Methods

The medical records of all patients with mandibular condyle fracture from September 2013 to August 2019 in the Oral and Maxillofacial Surgery Service at the Federal University of Uberlândia (Brazil), were retrospectively reviewed for selection. Patients were eligible if they gave written informed consent, had received either open treatment or closed treatment for mandibular condylar process fractures (with or without concomitant mandibular fractures) and preoperative and postoperative radiographic documentation. Patients aged < 18 years and who had other fractured regions without condyle involvement, presence panfacial fracture, total dental absence and those who did not finish the treatment were excluded. The study was performed in accordance with the Helsinki declaration and approved by the Ethics Committee of the Federal University of Uberlândia (2.319.377). Moreover, it was reporting according to The Strengthening the Reporting of Observational Studies in Epidemiology Statement (STROBE Check-list) ¹².

Physical examination

The functional examination of the masticatory system was made using the protocol of the RDC/TMD axis I questionnaire ⁹. This assessment was performed by one

of the authors calibrated. The active and passive mouth opening, presence of deviation of the mandible at maximal mouth opening (MMO), protrusion and laterotrusion were measured (including the possible intensity and site of pain). MMO of less than 30 mm was considered restricted. The masseter muscle, temporal muscle, lateral pterygoid muscle, posterior mandibular region, submandibular and the temporomandibular joint were palpated bilaterally. In total, 12 sites were palpated on both sides: 10 extraoral, 2 intraoral muscle sites. Finally, static and dynamic pain tests were done, and directly after each test, patients were asked if they experienced any sensitivity or pain in the investigated area.

Tomography Evaluation

The fracture type evaluation with computed tomography (CT) was categorized according to the classification of Neff et al ¹³ as following: condylar head, neck or basis fracture. For the postoperative tomography outcome analysis, the RDC/TMD guideline for image analysis also was considered. During evaluation, the presence of sclerosis, flattening of the margins condylar, erosion of the cortical plate, subcortical cyst formation, osteophytes and calcified loose bodies in the soft tissues were investigated (Fig. 1). Then, it was possible to classify degenerative joint disorders as: no osteoarthritis; indeterminate for osteoarthritis or presence of osteoarthritis ¹⁴.

Statistical analysis

The patient population was described using median and percentages. Normality was determined using the Shapiro-Wilk test. The t-test (continuous data) and Mann–

Whitney U-test (ordinal data) were used to compare the results from the clinical measurements between ORIF and MMF treatment groups to determine whether there was a significant difference of the treatment modalities. SigmaPlot software version 12.0 (Systat Software, Inc. Chicago, EUA) was used for the data analysis. The significance level was set at $p < 0.05$.

Results

Twenty-five patients (21 men and 4 women) were eligible for inclusion in this study. Mean age was 33 years (range, 21-61yr). Five of 25 patients presented bilateral fractures, making a total of 30 condyle process fractures. The follow-up time varied between 5 months to 6 years. In all, 14 fractures were classified as condylar basis fractures, 10 as condylar neck fractures, and 6 as condylar head fractures (Table 1). ORIF was performed in 18 patients (72%), while 7 patients (28%) received MMF.

As shown in Fig. 2, maximum mouth opening ranged from 23 to 81 mm in the open treatment group and from 36 to 52 mm in the closed treatment group, with no significant difference between the groups ($p = 0.190$).

Maximum right side excursion ranged from 1 to 16 mm in the open treatment and from 3 to 12 mm in the closed treatment, with no significant difference between the groups ($p = 0.771$) (Fig. 3). The maximum left side excursion ranged from 2 to 11 mm in the surgical treatment and from 4 to 13 mm in the conservative treatment. These data also showed no statistically significant differences ($p = 0.526$) (Fig. 4).

The values for protrusion movement ranged from 2 to 10 mm in the open treatment and from 4 to 10 mm in the closed treatment, with no significant difference between the groups ($p=0.284$) (Fig. 5).

When analyzing the presence of symptoms, 56% were free of pain (Table 2). The results of the visual analog scale (0 to 10) assessment were 1.44 (range, 0 to 5; SD, 2.2) in the open treatment group and 5.71 (range, 0 to 10; SD, 4.53) in the closed treatment. Comparison of the arithmetic means revealed significant difference ($p<0.05$).

With regard to the Axis I assessment, disc displacement with reduction was present in nine (36%) patients. Of these, five received open treatment and four received closed treatment. Osteoarthritis was found in three (16.6%) patients, of whom were in the open group and two in the closed group (28.6%); one patient (4%) was diagnosed with myofascial pain. According to the RDC/TMD, 12 (48%) patients did not receive a diagnosis of temporomandibular disorders (Fig. 6).

In addition to functional evaluation, the tomography finding also revealed results associated joint degeneration. Of the total of 25 patients, 19 underwent computed tomography. In the open treatment, 6 were diagnosed with absence osteoarthritis, 5 indeterminate for osteoarthritis and 3 presence osteoarthritis. On the other hand, in the closed treatment, 1 showed absence osteoarthritis, 2 indeterminate for osteoarthritis and 2 diagnosed with osteoarthritis.

Discussion

In the present study, the null hypothesis was rejected. The success rate, considering the absence of complications, was 66.67% in ORIF and 42.86% in MMF.

The design study is relevant because we can identify key outcomes in the clinical practice. A total of 25 patients with 30 fractures were analyzed. According to the affected region, 46.67% located basis condylar, 33.33% neck and 20% head (Table 1). Strategies for the treatment of condylar fractures are still controversial due to the temporomandibular joint dysfunction anatomy and complications such as mandibular deviation, malocclusion, ankylosis, internal derangement of the joint being able to take severe impairment to the stomatognathic system. This issue deserves special attention, not only due to the frequent occurrence of condylar fractures but also due the serious sequelae that may result if not adequately treated ¹⁵.

The results related to motion mandibular are consistent with those reported in the literature ¹⁶ indicating that there are no statistically significant differences between open (surgical) and closed (nonsurgical) treatment of condylar process fractures ($p > 0.05$) (Fig. 2). It is worth noting that, only 1 patient (4%) failed to achieve a mouth opening > 30 mm (1 patient was in the open treatment group). The interincisal distance during mouth opening is produced by a combination of rotation and translation within the TMJ, and identical degrees of mouth opening can be achieved with widely different amounts of condylar rotation and translation. To put it simply, greater rotation than normal might be a compensation for limited translation in the hypomobile TMJ ^{17,18}. Therefore, using only the maximum mouth opening to clinically evaluate condylar movements may mistakenly suggest normal function when, in fact, condylar movements are abnormal ¹⁶. Concerning the variable excursive movements, no significant differences also were observed between the two treatments (Figs 3, 4 and 5). This have been associated as well with compensation for by the contralateral joint which can balance abnormalities in coordination of movement ^{19,20}.

For this reason, the measurement of mandibular motion associated with tools that analyze comorbidities such as TMD and pain are essential. In the present study, the temporomandibular disorders were evident in the patients evaluated in the long term (5 months to 6 years).

The data showed that 56% of the patients were pain-free, which is comparable to earlier findings ²¹. This may suggest that sensations of pain can diminish or even disappear over time, which could be of great importance when counseling new patients ²². It is important to note, the patient's perception of pain was statistically significant in the MMF group (5.71 ± 4.53) compared ORIF group (1.44 ± 2.2) (Table 2). It is presumed that a new neuromuscular and occlusal balance is created and a compensatory mechanism results in proper physiologic balance, leading to discomfort in the post-MMF phase. Besides, the presence of pain is probably associated with muscle spasms and ulcers in the oral mucosa resulting from MMF ^{23, 24}. The prolonged immobilization of the temporomandibular joint leads to symptomatology, ankylosis and bone resorption ²⁴. In order to decrease this damage, the mean duration of treatment with MMF is 3–4 weeks, followed by the use of guiding elastics for 2 weeks ¹⁶.

The purpose of treatments for condylar fractures is to restore the pre-traumatic condylar position and recapture the disc without the need for additional surgery. However, the results showed that the disc was not always recaptured. In other words, in 36% of patients (5 ORIF group and 4 MMF group) was observed disc displacement with reduction (Figure 6). The key factors to the failure appeared to be the state of either the joint capsule or the disc. They can be disrupted by trauma ²⁵ or surgical procedures. In the condylar fracture dislocated, disc displacement is more often expected ²⁶. In order to achieve access to the dislocated condylar process, the capsule can be detached during

surgery. With the detached joint capsule, activity of the lateral pterygoid muscle will pull the disc anteromedially during open reduction condylar, as the superior head of the muscle attaches directly to the capsule and disc anteromedially. This might preclude spontaneous discal repositioning simply by fracture reduction²⁷.

In addition disc displacement with reduction, other outcome observed was the presence of osteoarthritis (20%) (Figure 6). The etiology of the degenerative joint disease involves dysfunctional articular remodeling due to decreased adaptive capacity of the articulating structures. The adaptive capacity depends on the patient's general condition. Aging, systemic illness, and hormonal factors may define the adaptive capacity of the TMJ²⁸. In examining the treatment protocols, TMJ rapidly display changes as an effect of immobilization. A consequence of immobilization is decreased thickness of the cartilage and alterations of the glycosaminoglycan content, changes consistent with those seen in osteoarthrosis and osteoarthritis. This degenerative disorder could, therefore, be a consequence of intermaxillary fixation, but in experimental studies, where jaw immobilization has been released, destructive changes have been reported to be reversible²⁹.

We acknowledge the limitations of the retrospective, nonrandomized nature of our study. Studies with sample size and power test larger are necessary. Although there are numerous publications in the matter of condyle fracture, it is important to develop prospective studies assessing the onset of TMD using questionnaires validated as RDC/TMD or DC/TMD.

Conclusion

The present results are consistent with those reported in the literature as both methods produced satisfactory mobility mandibular. However, the MMF group reported frequently the presence of symptoms that were statistically significant. Regarding TMDs, was observed disc displacement with reduction and degenerative joint diseases for both treatments.

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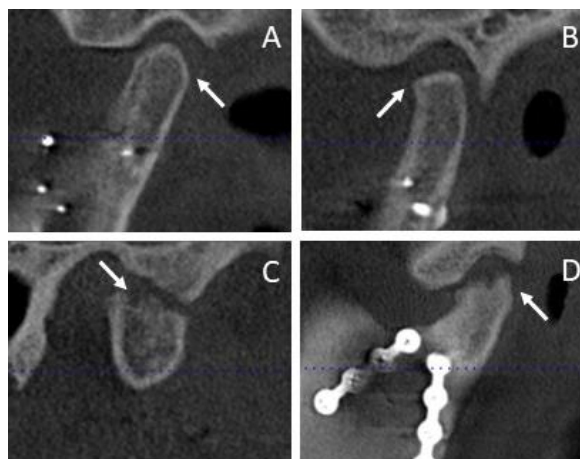


Fig. 1 Sagittal CT views of condyles. Representing examples of osseous changes observed, and corresponding osteoarthritis (OA) diagnoses. **A.** No osteoarthritic condyles, rounded condylar head, and well-defined cortical margin. **B.** Indeterminate for OA, flattened superior margin, and well-defined cortical margin. **C.** OA: surface erosion. **D.** OA: surface erosion and sclerosis.

Table 1. Distribution of the fracture site according to the treatment of choice (n = 30)

	Head	Neck	Basis
Closed treatment (MMF)	6 (20%)	1 (3.33%)	2 (6.67%)
Open treatment (ORIF)	-	9 (30%)	12 (40%)

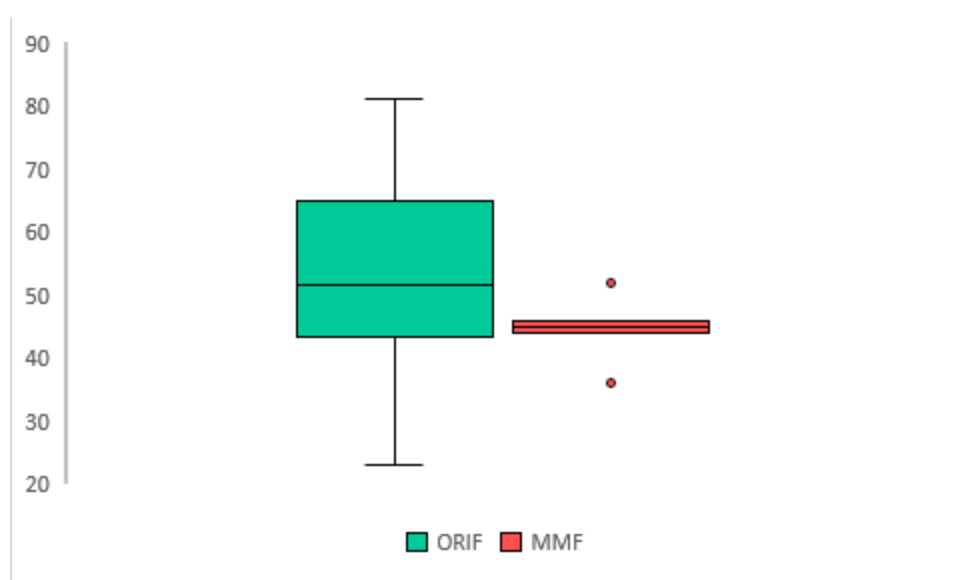


Fig. 2 Maximum mouth opening (measured in mm) for the open treatment and closed treatment groups

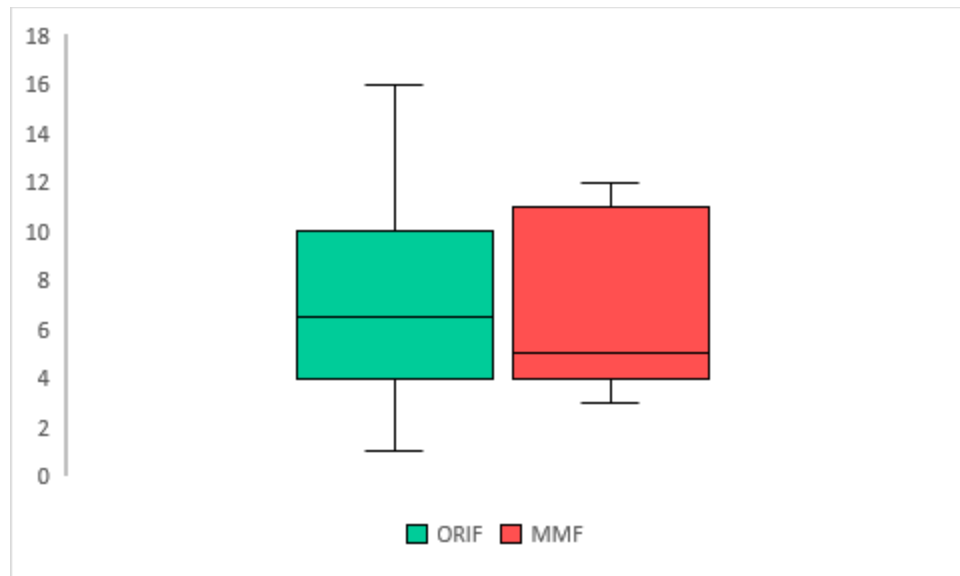


Fig. 3 Maximum right lateral excursion of the mandible (measured in mm) for the open treatment and closed treatment groups

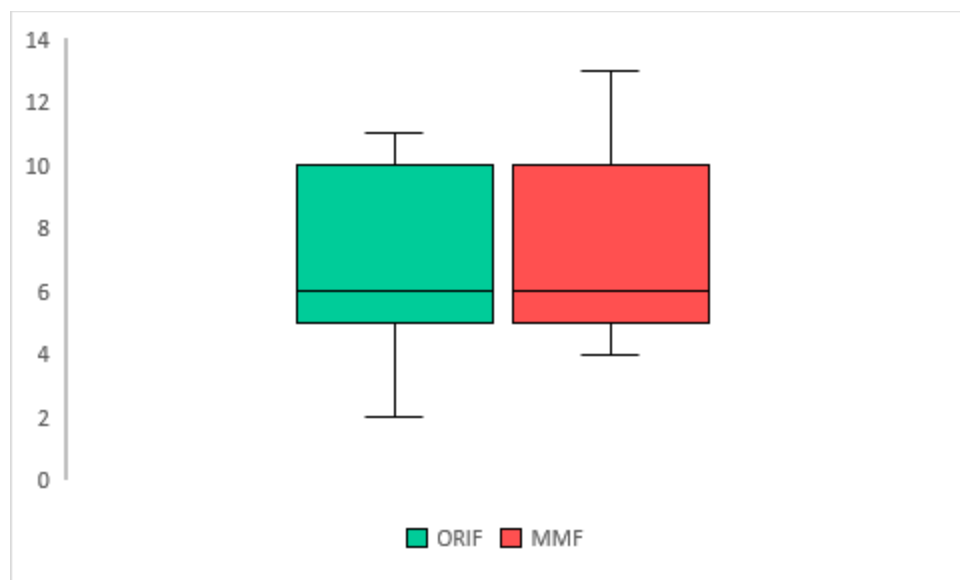


Fig. 4 Maximum left lateral excursion of the mandible (measured in mm) for the open treatment and closed treatment groups

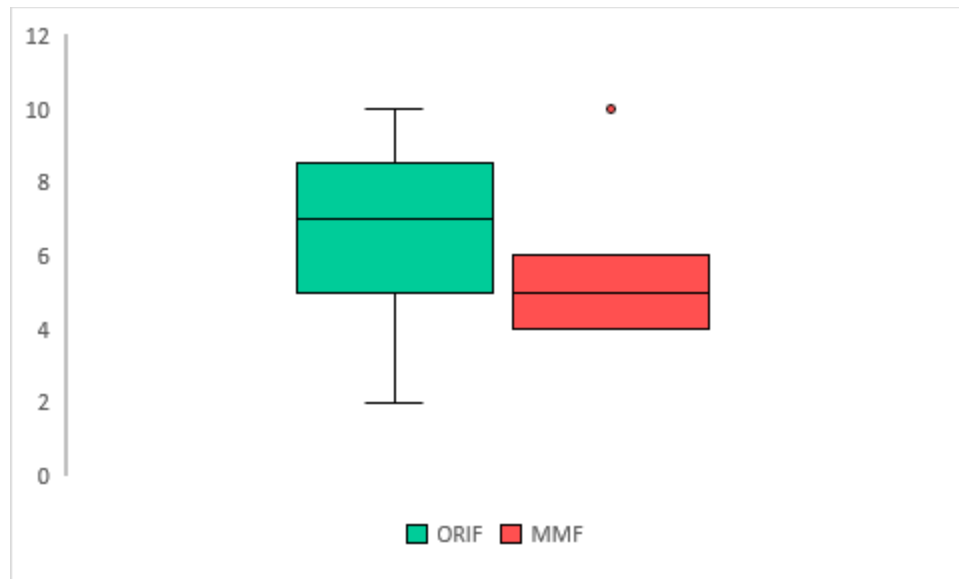


Fig. 5 Protrusion excursion of the mandible (measured in mm) for the open treatment and closed treatment groups

Table 2. Assessment of pain intensity

	ORIF (n=18) (Mean - SD)	MMF (n=7) (Mean - SD)	P value
Pain (Visual analog scale)	1.44 ± 2.2	5.71 ± 4.53	p= 0.023

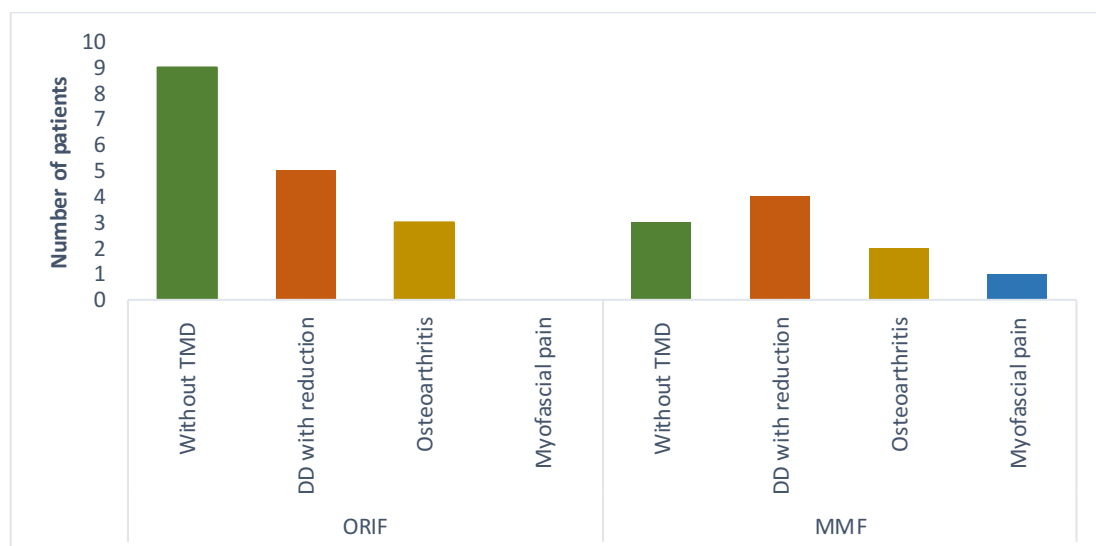


Fig. 6 Distribution of temporomandibular disorders according to the treatment group. DD: disc displacement

CONCLUSÕES

4. Conclusões

Dentro das limitações desse estudo, pode-se concluir que:

- A proporção de fraturas condilares entre homens e mulheres é de 5,6:1, afetando principalmente adultos jovens (21 – 30 anos).
- O principal fator etiológico são os acidentes de trânsito, e os motociclistas é o grupo mais acometido. Sequencialmente, quedas, brigas e acidentes esportivos também foram observados.
- A redução aberta e fixação interna assim como a fixação maxilomandibular apresentaram longevidade e previsibilidade.
- Os fatores determinantes para análise da taxa de sucesso longitudinalmente são: mobilidade mandibular e presença de comorbidades após as condutas terapêuticas.
- Ambos os tratamentos apresentaram resultados satisfatórios para a mobilidade mandibular.
- As principais complicações observadas e com predominância no tratamento conservador foram: má-oclusão, dor e desvio mandibular.

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ANEXOS

6. ANEXOS

6.1 PROSPERO – International Prospective register of systematic reviews

PROSPERO International prospective register of systematic reviews

Review title and timescale

- 1 Review title
Give the working title of the review. This must be in English. Ideally it should state succinctly the interventions or exposures being reviewed and the associated health or social problem being addressed in the review.
Complicações associadas with surgical or non-surgical treatment of mandibular condylar fractures: a systematic review
- 2 Original language title
For reviews in languages other than English, this field should be used to enter the title in the language of the review. This will be displayed together with the English language title.
Complicações associadas aos tratamentos cirúrgico ou não-cirúrgico das fraturas mandibulares condilares: revisão sistemática
- 3 Anticipated or actual start date
Give the date when the systematic review commenced, or is expected to commence.
27/09/2016
- 4 Anticipated completion date
Give the date by which the review is expected to be completed.
30/12/2017
- 5 Stage of review at time of this submission
Indicate the stage of progress of the review by ticking the relevant boxes. Reviews that have progressed beyond the point of completing data extraction at the time of initial registration are not eligible for inclusion in PROSPERO. This field should be updated when any amendments are made to a published record.

The review has not yet started ☒

Review stage	Started	Completed
Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	Yes
Formal screening of search results against eligibility criteria	No	Yes
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	Yes

Provide any other relevant information about the stage of the review here.

Review team details

- 6 Named contact
The named contact acts as the guarantor for the accuracy of the information presented in the register record.
Luana Cardoso Cabral
- 7 Named contact email
Enter the electronic mail address of the named contact.
luanacardoso29@yahoo.com.br
- 8 Named contact address
Enter the full postal address for the named contact.
Avenue Pará, 1720 – Block 4L, anexo A.
- 9 Named contact phone number
Enter the telephone number for the named contact, including international dialing code.
5534 3225-8105
- 10 Organisational affiliation of the review

Full title of the organisational affiliations for this review, and website address if available. This field may be completed as 'None' if the review is not affiliated to any organisation.
Dentistry School, Federal University of Uberlandia.

Website address:

- 11 Review team members and their organisational affiliations
Give the title, first name and last name of all members of the team working directly on the review. Give the organisational affiliations of each member of the review team.

Title	First name	Last name	Affiliation
Dr	Luana	Cardoso Cabral	Federal University of Uberlandia
Professor	Alfredo	Júlio Fernandes Neto	Federal University of Uberlandia
Professor	Paulo	Cézar Simamoto Júnior	Federal University of Uberlandia

- 12 Funding sources/sponsors
Give details of the individuals, organizations, groups or other legal entities who take responsibility for initiating, managing, sponsoring and/or financing the review. Any unique identification numbers assigned to the review by the individuals or bodies listed should be included.
Not applicable.

- 13 Conflicts of interest
List any conditions that could lead to actual or perceived undue influence on judgements concerning the main topic investigated in the review.
Are there any actual or potential conflicts of interest?
None known

- 14 Collaborators
Give the name, affiliation and role of any individuals or organisations who are working on the review but who are not listed as review team members.

Title	First name	Last name	Organisation details
Ms	Giovanna Morais	Alves	Federal University of Uberlandia

Review methods

- 15 Review question(s)
State the question(s) to be addressed / review objectives. Please complete a separate box for each question.
What complications are associated with treatment modalities for condylar mandibular fractures?
- 16 Searches
Give details of the sources to be searched, and any restrictions (e.g. language or publication period). The full search strategy is not required, but may be supplied as a link or attachment.
We will search the following electronic bibliographic databases: MEDLINE, EMBASE, LILACS, Scopus and Web of Science. The search strategy will include only terms relating to complications of condylar fractures. A partial search of the gray literature will also be performed using Google Scholar.
- 17 URL to search strategy
If you have one, give the link to your search strategy here. Alternatively you can e-mail this to PROSPERO and we will store and link to it.

I give permission for this file to be made publicly available
Yes
- 18 Condition or domain being studied
Give a short description of the disease, condition or healthcare domain being studied. This could include health and wellbeing outcomes.
Mandibular injuries are the most common facial traumas involving the condyle region with a prevalence of 26% to

- 57%. This high index is related to a zone of fragility associated with this region.
- 19 Participants/population
Give summary criteria for the participants or populations being studied by the review. The preferred format includes details of both inclusion and exclusion criteria.
Patients diagnosed with condylar fractures and treated surgically or non-surgically.
 - 20 Intervention(s), exposure(s)
Give full and clear descriptions of the nature of the interventions or the exposures to be reviewed
The treatment modalities described in the literature still remain controversial, due to the anatomical complexity of the region and the complications associated with the treatments. The surgical treatment consists of a direct surgical approach to the fracture site, allowing for the repositioning and fixation of the fractured segments. The rigid internal fixation technique promotes a stable three-dimensional reconstruction, primary bone repair, a reduction in treatment time, and the elimination of the need to perform rigid maxilomandibular blocking after surgery.
 - 21 Comparator(s)/control
Where relevant, give details of the alternatives against which the main subject/topic of the review will be compared (e.g. another intervention or a non-exposed control group).
The non-surgical treatment consists of rigid maxilomandibular fixation over a period of time. In some cases of high condylar fracture, the conservative protocol involves intense physiotherapy using elastics (referred to as elastic therapy).
 - 22 Types of study to be included
Give details of the study designs to be included in the review. If there are no restrictions on the types of study design eligible for inclusion, this should be stated.
We will include randomised trials and observational studies to assess the complications associated with the treatments.
 - 23 Context
Give summary details of the setting and other relevant characteristics which help define the inclusion or exclusion criteria.
 - 24 Primary outcome(s)
Give the most important outcomes.
To evaluate the complications associated with surgical or conservative treatments. To categorize these complications according to the presence of temporomandibular dysfunction, occlusal alterations, ankylosis, condylar deformities and mandibular deviation.

Give information on timing and effect measures, as appropriate.
 - 25 Secondary outcomes
List any additional outcomes that will be addressed. If there are no secondary outcomes enter None.
None.

Give information on timing and effect measures, as appropriate.
 - 26 Data extraction (selection and coding)
Give the procedure for selecting studies for the review and extracting data, including the number of researchers involved and how discrepancies will be resolved. List the data to be extracted.
 - 27 Risk of bias (quality) assessment
State whether and how risk of bias will be assessed, how the quality of individual studies will be assessed, and whether and how this will influence the planned synthesis.
Two review authors will independently assess the risk of bias in included studies. Disagreements between the authors will be resolved by discussion with the involvement of a third author when necessary. The standard scales used will be the STROBE statement for the assessment of observational studies and the Cochrane risk of bias tool for the assessment of randomised trial studies.
 - 28 Strategy for data synthesis
Give the planned general approach to be used, for example whether the data to be used will be aggregate or at the

level of individual participants, and whether a quantitative or narrative (descriptive) synthesis is planned. Where appropriate a brief outline of analytic approach should be given.

We will provide a narrative synthesis of the findings from the included studies, structured around the type of intervention and the type of complication. We will provide summaries of the intervention effects for each study by calculating the risk ratios (for dichotomous outcomes) or the standardised mean differences (for continuous outcomes). We anticipate that there will be limited scope for meta-analysis because of the range of different outcomes measured across the small number of existing trials. However, where studies have used the same type of interventions and comparators, with the same outcome measures, we will pool the results using a random-effects meta-analysis, with standardised mean differences for continuous outcomes and risk ratios for binary outcomes, and will calculate 95% confidence intervals and two-sided P values for each outcome.

- 29 Analysis of subgroups or subsets
Give any planned exploration of subgroups or subsets within the review. 'None planned' is a valid response if no subgroup analyses are planned.
If the necessary data are available, subgroup analyses will be carried out separately for the following cases: Type of complication: presence of temporomandibular dysfunction, occlusal alterations, ankylosis, condylar deformities and mandibular deviation. Condylar fracture classification: high, medium or low.

Review general information

- 30 Type and method of review
Select the type of review and the review method from the drop down list.
Systematic review
- 31 Language
Select the language(s) in which the review is being written and will be made available, from the drop down list. Use the control key to select more than one language.
English

Will a summary/abstract be made available in English?
Yes
- 32 Country
Select the country in which the review is being carried out from the drop down list. For multi-national collaborations select all the countries involved. Use the control key to select more than one country.
Brazil
- 33 Other registration details
Give the name of any organisation where the systematic review title or protocol is registered together with any unique identification number assigned. If extracted data will be stored and made available through a repository such as the Systematic Review Data Repository (SRDR), details and a link should be included here.
- 34 Reference and/or URL for published protocol
Give the citation for the published protocol, if there is one.
Give the link to the published protocol, if there is one. This may be to an external site or to a protocol deposited with CRD in pdf format.

I give permission for this file to be made publicly available
Yes
- 35 Dissemination plans
Give brief details of plans for communicating essential messages from the review to the appropriate audiences.
Do you intend to publish the review on completion?
Yes
- 36 Keywords
Give words or phrases that best describe the review. (One word per box, create a new box for each term)
- 37 Details of any existing review of the same topic by the same authors

Give details of earlier versions of the systematic review if an update of an existing review is being registered, including full bibliographic reference if possible.

In addition to producing a report for the funders of this review, which will be made available free of charge on their website, a paper will be submitted to the leading journal in this field.

- 38 Current review status
Review status should be updated when the review is completed and when it is published.
Ongoing
- 39 Any additional information
Provide any further information the review team consider relevant to the registration of the review.
- 40 Details of final report/publication(s)
This field should be left empty until details of the completed review are available.
Give the full citation for the final report or publication of the systematic review.
Give the URL where available.

6.2 Parecer Comitê de Ética em Seres Humanos – Estudo epidemiológico multicêntrico



PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: ANÁLISE EPIDEMIOLÓGICA DAS FRATURAS CONDILARES: ESTUDO MULTICÊNTRICO

Pesquisador: Paulo César Simamoto Júnior

Área Temática:

Versão: 2

CAAE: 36171919.1.0000.5152

Instituição Proponente: Universidade Federal de Uberlândia/ UFU/ MG

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 4.267.462

Apresentação do Projeto:

Trata-se de análise de respostas que os pesquisadores apresentaram às pendências apontadas no parecer consubstanciado número 4.233.998, de 24 de Agosto de 2020.

As injúrias mandibulares são o trauma facial mais comum com uma prevalência entre 26% a 57% envolvendo a região condilar. A etiologia está associada a fatores externos como acidentes automobilísticos, agressões físicas e atividades esportivas e fatores internos como a presença de tumores benignos, malignos ou osteomielite.

Tendo em vista a alta prevalência das fraturas condilares e a sua importância no restabelecimento da função e estética, o objetivo do estudo multicêntrico será avaliar retrospectivamente as características epidemiológicas como prevalência, tipo de fratura, modalidades de tratamento bem como a presença de complicações pós-operatórias.

Confirmar a hipótese que as fraturas condilares apresentam alta prevalência dentre os diversos tipos de fraturas mandibulares.

Objetivo da Pesquisa:

O objetivo do estudo multicêntrico será avaliar retrospectivamente as características

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Continuação do Parecer: 4.267.462

epidemiológicas como prevalência, tipo e modalidades de tratamento das fraturas condilares bem como a presença de complicações pós-operatórias associadas a conduta terapêutica.

Avaliação dos Riscos e Benefícios:

Os riscos previsíveis para a realização desta pesquisa envolvem a identificação dos participantes. Entretanto, cada ficha será identificada por um número, com a finalidade de diferenciá-lo e manter a integridade e identidade do mesmo, protegendo a confidencialidade. Os dados serão coletados pelos pesquisadores, que manterão a privacidade e o sigilo das informações, as quais serão armazenadas em arquivos na memória do computador para posterior análise. Assim, os riscos de divulgação da identidade dos voluntários serão minimizados.

Os pacientes da pesquisa serão beneficiados indiretamente pois a pesquisa promoverá a geração do conhecimento, a fim de compreender o papel do cirurgião-dentista frente as fraturas condilares.

Comentários e Considerações sobre a Pesquisa:

Pesquisa epidemiológica: fraturas condilares: estudo envolvendo o Ambulatório de Cirurgia e Traumatologia Buco-Maxilo-Facial da Universidade Federal de Uberlândia e o Hospital de Emergência e Trauma de Campina Grande Dom Luís Gonzaga Fernandes.

Considerações sobre os Termos de apresentação obrigatória:

São apresentados:

- 1- Resposta_pendencia_CEP.docx
- 2- TCLE.doc
- 3- PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1304283.pdf

Conclusões ou Pendências e Lista de Inadequações:

As pendências apontadas no parecer consubstanciado número 4.233.998, de 24 de Agosto de 2020, foram atendidas.

De acordo com as atribuições definidas na Resolução CNS 466/12, Resolução 510/16 e suas complementares, o CEP manifesta-se pela aprovação do protocolo de pesquisa proposto. O protocolo não apresenta problemas de ética nas condutas de pesquisa com seres humanos, nos limites da redação e da metodologia apresentadas.

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Data para entrega de Relatório Final ao CEP/UFU: Julho de 2021.

* Tolerância máxima de 06 meses para atraso na entrega do relatório final.

Considerações Finais a critério do CEP:

OBS.: O CEP/UFU LEMBRA QUE QUALQUER MUDANÇA NO PROTOCOLO DEVE SER INFORMADA IMEDIATAMENTE AO CEP PARA FINS DE ANÁLISE E APROVAÇÃO DA MESMA.

O CEP/UFU lembra que:

- a- segundo as Resoluções CNS 466/12 e 510/16, o pesquisador deverá manter os dados da pesquisa em arquivo, físico ou digital, sob sua guarda e responsabilidade, por um período mínimo de 5 (cinco) anos após o término da pesquisa;
- b- poderá, por escolha aleatória, visitar o pesquisador para conferência do relatório e documentação pertinente ao projeto.
- c- a aprovação do protocolo de pesquisa pelo CEP/UFU dá-se em decorrência do atendimento as Resoluções CNS 466/12, 510/16 e suas complementares, não implicando na qualidade científica do mesmo.

Orientações ao pesquisador :

- O participante da pesquisa tem a liberdade de recusar-se a participar ou de retirar seu consentimento em qualquer fase da pesquisa, sem penalização alguma e sem prejuízo ao seu cuidado (Res. CNS 466/12 e 510/16) e deve receber uma via original do Termo de Consentimento Livre e Esclarecido, na íntegra, por ele assinado.
- O pesquisador deve desenvolver a pesquisa conforme delineada no protocolo aprovado e descontinuar o estudo somente após análise das razões da descontinuidade pelo CEP que o aprovou (Res. CNS 466/12), aguardando seu parecer, exceto quando perceber risco ou dano não previsto ao participante ou quando constatar a superioridade de regime oferecido a um dos grupos da pesquisa que requeiram ação imediata.
- O CEP deve ser informado de todos os efeitos adversos ou fatos relevantes que alterem o curso normal do estudo (Res. CNS 466/12). É papel do pesquisador assegurar medidas imediatas adequadas frente a evento adverso grave ocorrido (mesmo que tenha sido em outro centro) e enviar notificação ao CEP e à Agência Nacional de Vigilância Sanitária – ANVISA – junto com seu

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Continuação do Parecer: 4.267.462

posicionamento.

- Eventuais modificações ou emendas ao protocolo devem ser apresentadas ao CEP de forma clara e sucinta, destacando a parte do protocolo a ser modificada e suas justificativas. Em caso de projetos do Grupo I ou II apresentados anteriormente à ANVISA, o pesquisador ou patrocinador deve enviá-las também à mesma, junto com o parecer aprobatório do CEP, para serem juntadas ao protocolo inicial (Res.251/97, item III.2.e).

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1304283.pdf	31/08/2020 14:26:37		Aceito
Outros	Resposta_pedencia_CEP.docx	31/08/2020 14:26:18	Luana Cardoso Cabral	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.doc	31/08/2020 14:25:51	Luana Cardoso Cabral	Aceito
Projeto Detalhado / Brochura Investigador	Projeto.docx	31/08/2020 14:25:38	Luana Cardoso Cabral	Aceito
Outros	Termo_pesquisador_atualizado.pdf	04/08/2020 13:41:13	Luana Cardoso Cabral	Aceito
Declaração de Pesquisadores	Termo_da_equipe_atualizado.pdf	04/08/2020 13:40:00	Luana Cardoso Cabral	Aceito
Folha de Rosto	Folha_de_rosto_atualizada.pdf	31/07/2020 10:06:35	Luana Cardoso Cabral	Aceito
Outros	Link_curriculo_lattes.docx	31/07/2020 09:55:07	Luana Cardoso Cabral	Aceito
Declaração de Instituição e Infraestrutura	Declaracao_Instituicao_Co_participante_PB.doc	31/07/2020 09:53:31	Luana Cardoso Cabral	Aceito
Declaração de Instituição e Infraestrutura	Declaracao_Instituicao_Co_participante_UFU.doc	31/07/2020 09:53:19	Luana Cardoso Cabral	Aceito
Outros	Instrumento_coleta_dados.pdf	13/07/2020 14:12:40	Luana Cardoso Cabral	Aceito

Situação do Parecer:

Aprovado

Necessita Avaliação da CONEP:

Situação do Parecer:

Aprovado

Necessita Avaliação da CONEP:

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Continuação do Parecer: 4.267.462

Não

UBERLÂNDIA, 09 de Setembro de 2020

Assinado por:
Karine Rezende de Oliveira
(Coordenador(a))

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6.3 Instrumento de coleta de dados – Estudo epidemiológico multicêntrico



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FACULDADE DE ODONTOLOGIA



Área de Oclusão, Prótese Fixa e Materiais Odontológicos

LEVANTAMENTO EPIDEMIOLÓGICO:

ANO DE ABERTURA: _____

GÊNERO: () M () F

IDADE: _____ ANOS

DATA DO ACIDENTE: _____

TIPO DE FRATURA CONDILAR	TIPO DE ENVOLVIMENTO CONDILAR
() ALTA () MÉDIA () BAIXA	() UNILATERAL DIREITA () UNILATERAL ESQUERDA () BILATERAL

FATOR ETIOLÓGICO ASSOCIADO	DADOS QUANTO AO ACIDENTE DE TRÂNSITO
() ACIDENTE DE TRÂNSITO () ACIDENTE ESPORTIVO () ACIDENTE DE TRABALHO () QUEDAS () BRIGAS INTERPESSOAIS () ASSALTO () ARMAS DE FOGO () OUTROS: _____	() CARRO () MOTO () BICICLETA () CAMINHÃO () ÔNIBUS () ATROPELAMENTO () OUTROS: _____



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Área de Oclusão, Prótese Fixa e Materiais Odontológicos

ENVOLVIMENTO DE MAIS REGIÕES FRATURADAS	TIPO DE TRATAMENTO UTILIZADO
<input type="checkbox"/> SÍNFISE MANDIBULAR <input type="checkbox"/> PARASÍNFISE MANDIBULAR <input type="checkbox"/> COMPLEXO ZIGOMÁTICO <input type="checkbox"/> ARCO ZIGOMÁTICO <input type="checkbox"/> MAXILA <input type="checkbox"/> NASO-ÓRBITO-ETMOIDAL (NOE) <input type="checkbox"/> MÚLTIPLAS <input type="checkbox"/> OUTROS:	<input type="checkbox"/> BLOQUEIO MAXILO-MANDIBULAR RÍGIDO <input type="checkbox"/> BLOQUEIO MAXILO-MANDIBULAR ASSOCIADO À ELASTICOTERAPIA <input type="checkbox"/> ELÁSTICOTERAPIA <input type="checkbox"/> CIRURGIA <input type="checkbox"/> ACOMPANHAMENTO <input type="checkbox"/> OUTROS

COMPLICAÇÕES PÓS-TRATAMENTO
<input type="checkbox"/> AUSENTE <input type="checkbox"/> LIMITAÇÃO DE ABERTURA DE BOCA <input type="checkbox"/> ANQUILOSE ARTICULAR <input type="checkbox"/> DEGENERAÇÃO CONDILAR <input type="checkbox"/> DESVIO MANDIBULAR UNILATERAL <input type="checkbox"/> ALTERAÇÕES OCLUSAIS <input type="checkbox"/> DISFUNÇÃO TEMPOMANDIBULAR <input type="checkbox"/> MÁ-OCCLUSÃO (Tipo) _____ Outros: _____

6.4 Parecer Comitê de Ética de Seres Humanos – Estudo retrospectivo



PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: AVALIAÇÃO MORFOFISIOLÓGICA DE INDIVÍDUOS AFETADOS COM FRATURAS CONDILARES: ESTUDO RETROSPECTIVO

Pesquisador: Alfredo Júlio Fernandes Neto

Área Temática:

Versão: 3

CAAE: 67814217.1.0000.5152

Instituição Proponente: FACULDADE DE ODONTOLOGIA

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 2.319.377

Apresentação do Projeto:

Conforme apresenta o protocolo:

Hipótese:

A hipótese é que ambos os tratamentos apresentam efeitos similares na biomecânica da articulação temporomandibular e na oclusão a longo prazo.

Desfecho Primário:

Avaliar a qualidade de vida e características morfológicas da articulação temporomandibular em indivíduos com fratura condilar após tratamento cirúrgico ou conservador.

Voluntários que finalizaram o tratamento da fratura condilar no Ambulatório de Cirurgia e Traumatologia da Universidade Federal de Uberlândia, no período de 2010 a 2017, serão avaliados retrospectivamente. A análise subjetiva da sintomatologia será realizada por meio da Escala Visual Analógica e a avaliação da qualidade de vida e impacto da saúde bucal no bem-estar será realizada por meio do questionário SF-36 Health Survey e Oral Health Impact Profile 14 (OHIP-14), respectivamente.

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A análise objetiva incluirá avaliação da relação oclusal (presença de má-oclusão), movimentos mandibulares e presença de disfunção temporomandibular por meio do questionário DiagnosticCriteria for Temporomandibular Disorders (DC/TMD).

Posteriormente os participantes serão submetidos a realização da tomografia computadorizada, para comparação dos achados articulares pré, imediatamente após o tratamento e longitudinalmente. Após a coleta, os dados obtidos serão avaliados estatisticamente, mensurando cada variável citada na metodologia.

Critério de Inclusão:

Para participação no estudo, os idosos deverão ter mais de 60 anos e apresentar um atestado médico.

Serão excluídos àqueles voluntários que não estiverem na faixa etária do estudo, bem como não apresentarem o atestado médico. Além disso, após a realização dos procedimentos experimentais serão excluídos da análise por protocolo os dados daqueles voluntários que não apresentarem um mínimo de 80% de presença nas aulas e que não comparecerem em alguma das avaliações.

Metodologia Proposta:

Inicialmente a equipe executora analisará os prontuários do Ambulatório de Cirurgia e Traumatologia Buco-Maxilo-Facial da Universidade Federal de Uberlândia e selecionará todos aqueles que constam que o indivíduo apresenta fratura mandibular, especificamente na região do côndilo. Após esse levantamento epidemiológico, todos os indivíduos que retornarem à consulta de controle posterior a finalização do tratamento serão convidados, a participar da pesquisa. Durante a abordagem inicial, os participantes serão submetidos ao exame clínico e aqueles que apresentarem os critérios de inclusão, irão constituir a amostra.

As etapas do estudo serão desenvolvidas no Ambulatório da Cirurgia e Traumatologia Buco-Maxilo-Facial da Universidade Federal de Uberlândia. Os procedimentos serão iniciados após aprovação do projeto pelo CEP/UFU, mediante assinatura do Termo de Consentimento Livre e Esclarecido. Os participantes recrutados serão indivíduos que se submeteram ao tratamento da

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fratura condilar no Ambulatório da Cirurgia e Traumatologia BucoMaxilo-Facial com idade entre 18 anos à 70 anos.

A avaliação funcional subjetiva incluirá duas partes: avaliação da sintomatologia e avaliação da qualidade de vida. A presença e a intensidade da dor serão avaliadas por meio da Escala Visual Analógica. Esse instrumento unidimensional trata-se de uma linha com extremidades numeradas de 0 a 10. O escore 0 corresponde a ausência de dor e o escore 10 a pior dor possível. O voluntário será orientado para classificar a dor presente naquele momento. Após a seleção dos voluntários, o questionário SF-36 Health Survey será utilizado para avaliação da qualidade de vida. Esse questionário é constituído por 36 itens, estratificados em oito domínios: capacidade funcional (10 itens), aspectos físicos (4 itens), dor (2 itens), estado geral de saúde (5 itens), vitalidade (4 itens), aspectos sociais (2 itens), aspectos emocionais (3 itens), saúde mental (5 itens) e uma questão de avaliação comparativa entre as condições de saúde atual e a do ano anterior. Os valores

alteram no intervalo de 0 a 100 e, quanto maior o escore, melhor é a qualidade de vida. Além disso, o Oral Health Impact Profile 14 (OHIP-14) será aplicado para mensurar a influência da saúde bucal no bem-estar dos indivíduos. O OHIP-14 possui dois itens de cada uma das dimensões incluídas no instrumento original de Slade (1997): limitação funcional (itens 1 e 2), dor física (itens 3 e 4), desconforto psicológico (itens 5 e 6), incapacidade física (itens 7 e 8), incapacidade psicológica (itens 9 e 10), incapacidade social (itens 11 e 12) e desvantagem social (itens 13 e 14). As questões serão pontuadas em uma escala tipo Likert (0 indica nunca; 1, raramente; 2, às vezes; 3, constantemente e 4, sempre).

Durante a avaliação funcional será avaliado as características oclusais os movimentos mandibulares e a presença de Disfunção Temporomandibular. Ao avaliar a relação oclusal, será considerado má-oclusão a presença de mordida aberta, mordida cruzada ou sobremordida. A avaliação dos movimentos mandibulares e presença de DTM será realizada por meio do questionário Diagnostic Criteria for Temporomandibular Disorders (DC/TMD). Esse critério é composto por duas partes, sendo a primeira um questionário relacionado à história do paciente, presença de dor e outros sinais e sintomas ligados à DTM.

A segunda parte consiste em exame clínico que inclui verificação da amplitude e desvios durante movimentos mandibulares, além de registrar a ocorrência de ruídos nas ATMs quando presentes e a realização da palpação muscular. Após aplicação do questionário DC/TMD será possível

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categorizar o tipo de DTM, por meio de algoritmos específicos, em: artroalgia, mialgia, dor miofascial, dor miofascial com referência, cefaleia atribuída a DTM, deslocamento de disco com redução, deslocamento de disco com redução e travamento intermitente, deslocamento de disco sem redução e com limitação de abertura, deslocamento de disco sem redução e sem limitação de abertura, doença degenerativa articular e subluxação.

A avaliação do tipo de fratura pré-operatória por meio da tomografia computadorizada será categorizada de acordo com a classificação de He(2009) como: fratura da cabeça do côndilo, pescoço do côndilo ou subcondilar.

A análise da tomografia imediatamente após a finalização do tratamento e a longo prazo será realizada por meio qualitativo e quantitativo. Para a análise qualitativa as características da região serão categorizadas da seguinte maneira: classe A, estrutura condilar normal sem sinais de alteração; B, leve alterações e remodelação consistindo de uma superfície condilar irregular; C, alterações moderadas e remodelação.

Tamanho da Amostra no Brasil: 25

Objetivo da Pesquisa:

O objetivo Primário desse estudo será avaliar as características clínicas, tomográficas e a qualidade de vida de indivíduos submetidos ao tratamento aberto ou fechado das fraturas condilares.

Objetivos Secundários:

- Avaliar os sinais e sintomas após a finalização do tratamento proposto (conservador ou cirúrgico);
- Avaliar a qualidade de vida após a terapia de escolha;
- Analisar as tomografias inicial, imediatamente após a finalização do tratamento de escolha e a longo prazo;
- Analisar e classificar o tipo de disfunção temporomandibular (Deslocamento de disco com redução e deslocamento de disco sem redução).

Avaliação dos Riscos e Benefícios:

Segundo os pesquisadores, os riscos consistem em dor muscular, cansaço temporário,

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possibilidade de alterações na frequência cardíaca e na pressão arterial. Existirá o risco de identificação do participante, contudo estratégias serão adotadas para que se evite ao máximo a ocorrência desse risco, tal como a utilização de códigos nas fichas de avaliação e na tabulação dos dados e o cegamento dos avaliadores em relação ao grupo em que os participantes estarão inseridos.

Os benefícios serão participar de aulas gratuitas de hidroginástica e musculação, sobre a supervisão de acadêmicos do curso de Educação Física da UFU com periodização individualizada. Além disso, a participação no estudo irá proporcionar ao idoso um estilo de vida mais saudável, sendo uma fonte para a promoção de saúde.

Comentários e Considerações sobre a Pesquisa:

O Protocolo apresenta uma pesquisa de relevância científica e está bem fundamentada.

Considerações sobre os Termos de apresentação obrigatória:

Os Termos Obrigatórios foram apresentados contemplando as orientações do CEP/UFU.

Recomendações:

Não há.

Conclusões ou Pendências e Lista de Inadequações:

As Pendências apontadas no Parecer 2.096.051 foram atendidas.

De acordo com as atribuições definidas na Resolução CNS 466/12, o CEP manifesta-se pela aprovação do protocolo de pesquisa proposto.

O protocolo não apresenta problemas de ética nas condutas de pesquisa com seres humanos, nos limites da redação e da metodologia apresentadas.

Considerações Finais a critério do CEP:

Data para entrega de Relatório Final ao CEP/UFU: julho/agosto de 2018.

OBS.: O CEP/UFU LEMBRA QUE QUALQUER MUDANÇA NO PROTOCOLO DEVE SER INFORMADA IMEDIATAMENTE AO CEP PARA FINS DE ANÁLISE E APROVAÇÃO DA MESMA.

O CEP/UFU lembra que:

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- a- segundo a Resolução 466/12, o pesquisador deverá arquivar por 5 anos o relatório da pesquisa e os Termos de Consentimento Livre e Esclarecido, assinados pelo Participante da pesquisa.
- b- poderá, por escolha aleatória, visitar o pesquisador para conferência do relatório e documentação pertinente ao projeto.
- c- a aprovação do protocolo de pesquisa pelo CEP/UFU dá-se em decorrência do atendimento a Resolução CNS 466/12, não implicando na qualidade científica do mesmo.

Orientações ao pesquisador :

- O Participante da pesquisa tem a liberdade de recusar-se a participar ou de retirar seu consentimento em qualquer fase da pesquisa, sem penalização alguma e sem prejuízo ao seu cuidado (Res. CNS 466/12) e deve receber uma via original do Termo de Consentimento Livre e Esclarecido, na íntegra, por ele assinado.
- O pesquisador deve desenvolver a pesquisa conforme delineada no protocolo aprovado e descontinuar o estudo somente após análise das razões da descontinuidade pelo CEP que o aprovou (Res. CNS 466/12),

aguardando seu parecer, exceto quando perceber risco ou dano não previsto ao participante da pesquisa ou quando constatar a superioridade de regime oferecido a um dos grupos da pesquisa que requeiram ação imediata.

- O CEP deve ser informado de todos os efeitos adversos ou fatos relevantes que alterem o curso normal do estudo (Res. CNS 466/12). É papel de o pesquisador assegurar medidas imediatas adequadas frente a evento adverso grave ocorrido (mesmo que tenha sido em outro centro) e enviar notificação ao CEP e à Agência Nacional de Vigilância Sanitária – ANVISA – junto com seu posicionamento.
- Eventuais modificações ou emendas ao protocolo devem ser apresentadas ao CEP de forma clara e sucinta, identificando a parte do protocolo a ser modificada e suas justificativas. Em caso de projetos do Grupo I ou II apresentados anteriormente à ANVISA, o pesquisador ou patrocinador deve enviá-las também à mesma, junto com o parecer aprobatório do CEP, para serem juntadas ao protocolo inicial (Res.251/97, item III.2.e).

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_892403.pdf	04/08/2017 10:44:54		Aceito

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Outros	Respostas_referentes_as_pendencias_2.docx	04/08/2017 10:43:52	Luana Cardoso Cabral	Aceito
Projeto Detalhado / Brochura Investigador	Projeto_retrospectivo_CEP.docx	04/08/2017 10:41:40	Luana Cardoso Cabral	Aceito
Outros	Respostas_referentes_as_pendencias.docx	22/06/2017 15:36:42	Luana Cardoso Cabral	Aceito
Outros	Anexos.docx	28/04/2017 10:10:48	Luana Cardoso Cabral	Aceito
Outros	Link_curriculo_lattes.docx	28/04/2017 10:10:24	Luana Cardoso Cabral	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_Estudo_retrospectivo.doc	13/04/2017 15:58:49	Luana Cardoso Cabral	Aceito
Declaração de Pesquisadores	Equipe_executora.pdf	13/04/2017 15:50:33	Luana Cardoso Cabral	Aceito
Declaração de Instituição e Infraestrutura	Declaracao_da_instituicao_co_participante.pdf	13/04/2017 15:50:06	Luana Cardoso Cabral	Aceito
Folha de Rosto	Folha_de_rosto_CEP.pdf	13/04/2017 15:49:24	Luana Cardoso Cabral	Aceito

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

UBERLÂNDIA, 06 de Outubro de 2017

Assinado por:
Sandra Terezinha de Farias Furtado
(Coordenador)

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6.5 Instrumento de coleta de dados – Estudo retrospectivo (Questionário RDC / TMD)

1. Você diria que a sua saúde em geral é excelente, muito boa, boa, razoável, ou precária?

☐ Excelente 1 ☐ Muito boa 2 ☐ Boa 3 ☐ Razoável 4 ☐ Precária 5

2. Você diria que a sua saúde oral em geral é excelente, muito boa, boa, razoável, ou precária?

☐ Excelente 1 ☐ Muito boa 2 ☐ Boa 3 ☐ Razoável 4 ☐ Precária 5

3. Você já teve dor na face, nos maxilares, têmpora, na frente do ouvido, ou no ouvido no mês passado?

☐ Não 0 ☐ Sim 1

[Em caso de Não ter tido dor no mês passado, PULE para a pergunta 14]

Se a sua resposta foi Sim:

4.a. Há quantos anos atrás a sua dor facial começou pela primeira vez? ____ anos

[Se há um ano atrás ou mais, PULE para a pergunta 5] [Se há menos de um anos atrás, marque 00]

4.b. Há quantos meses atrás a sua dor facial começou pela primeira vez? ____ meses

5. A sua dor facial é persistente, recorrente, ou foi um problema que ocorreu somente uma vez?

☐ Persistente 1 ☐ Recorrente 2 ☐ Uma vez 3

6. Você alguma vez já foi a um médico, dentista, quiroprático ou outro profissional de saúde devido a dor facial?

☐ Não 1 ☐ Sim, nos últimos seis meses 2 ☐ Sim, há mais de seis meses atrás 3

7. Como você classificaria a sua dor facial em uma escala de 0 a 10 no presente momento, isto é exatamente agora, onde 0 é “sem dor” e 10 é a “pior dor possível” ?

Sem dor 1 2 3 4 5 6 7 8 9 10 A pior dor possível

8. Nos últimos seis meses, qual foi a intensidade da sua pior dor, classificada pela escala de 0 a 10, onde 0 é “sem dor” e 10 é a “pior dor possível” ?

Sem dor 1 2 3 4 5 6 7 8 9 10 A pior dor possível

9. Nos últimos seis meses, em média, qual foi a intensidade da sua dor, classificada pela escala de 0 a 10, onde 0 é “sem dor” e 10 é a “pior dor possível” ? [Isto é, sua dor usual nas horas que você estava sentindo dor].

Sem dor 1 2 3 4 5 6 7 8 9 10 A pior dor possível

10. Aproximadamente quantos dias nos últimos 6 meses você esteve afastado de suas Atividades usuais (trabalho, escola, serviço doméstico) devido a dor facial ? ____ dias

11. Nos últimos 6 meses, o quanto esta dor facial interferiu com suas atividades diárias de acordo com uma escala de 0 a 10, onde 0 é “nenhuma interferência” e 10 é “incapaz de realizar qualquer atividade”?

Nenhuma interferência 1 2 3 4 5 6 7 8 9 10 Incapaz de realizar qualquer atividade

12. Nos últimos 6 meses, o quanto esta dor facial alterou a sua capacidade de participar de atividades recreativas, sociais e familiares onde 0 é “nenhuma alteração” e 10 é “alteração extrema”?

Nenhuma alteração 1 2 3 4 5 6 7 8 9 10 Alteração extrema

13. Nos últimos 6 meses, o quanto esta dor facial alterou a sua capacidade de trabalhar (incluindo serviço domésticos) onde 0 é “nenhuma alteração” e 10 é “alteração extrema” ?

Nenhuma alteração 1 2 3 4 5 6 7 8 9 10 Alteração extrema

14.a. Você alguma vez teve travamento articular de forma que não foi possível abrir a boca por todo o trajeto? () **Não 0** () **Sim 1**

[se nunca apresentou este tipo de problema, PULE para a pergunta 15]

Se a sua resposta foi Sim,

14.b. Esta limitação de abertura mandibular foi severa a ponto de interferir com a sua capacidade de mastigar? () **Não 0** () **Sim 1**

15.a. Os seus maxilares estalam quando você abre ou fecha a boca ou quando você mastiga?

() **Não 0** () **Sim 1**

15.b. Os seus maxilares crepitam quando você abre e fecha ou quando você mastiga?

() **Não 0** () **Sim 1**

15.c. Alguém lhe disse, ou você nota, se você range os seus dentes ou aperta os seus maxilares quando dorme a noite? () **Não 0** () **Sim 1**

15.d. Durante o dia, você range os seus dentes ou aperta os seus maxilares? () **Não 0** () **Sim 1**

15.e. Você sente dor ou rigidez nos seus maxilares quando acorda de manhã?

() **Não 0** () **Sim 1**

15.f. Você apresenta ruídos ou zumbidos nos seus ouvidos? () **Não 0** () **Sim 1**

15.g. Você sente a sua mordida desconfortável ou incomum? () **Não 0** () **Sim 1**

16.a. Você tem artrite reumatóide, lúpus, ou qualquer outra doença artrítica sistêmica?

() **Não 0** () **Sim 1**

16.b. Você conhece alguém na sua família que tenha qualquer uma destas doenças?

() **Não 0** () **Sim 1**

16.c. Você já apresentou ou apresenta inchaço ou dor em qualquer das articulações que não sejam as articulações perto dos seus ouvidos (ATM)? () **Não 0** () **Sim 1**

[em caso de Não ter tido inchaço ou dor nas articulações, PULE para a pergunta 17.a.]

Se a sua resposta foi Sim,

16.d. É uma dor persistente que você vem tendo por pelo menos um ano? () **Não 0** () **Sim 1**

17.a. Você teve alguma injúria recente contra sua face ou seus maxilares? () **Não 0** () **Sim 1**

[em caso de Não ter tido injúria, pule para a pergunta 18]

Se sua resposta foi Sim,

17.b. Você teve dor nos maxilares antes da injúria? () **Não 0** () **Sim 1**

18. Durante os últimos 6 meses você teve dor de cabeça ou enxaquecas? () **Não 0** () **Sim 1**

19. Que atividades o seu problema atual dos maxilares impedem ou limitam?

Atividade	Não (0)	Sim (1)
a) Mastigar		
b) Beber		
c) Exercitar-se		
d) Comer alimentos duros		
e) Sorrir/gargalhar		
f) Atividade sexual		
g) Limpar os dentes ou a face		
h) Bocejar		
i) Engolir		
j) Conversar		
l) Manter a sua aparência facial usual		

21. Como você classificaria os cuidados que tem tomado para com a sua saúde de uma forma geral?

() **Excelente 1** () **Muito bom 2** () **Bom 3** () **Satisfatório 4** () **Insatisfatório 5**

22. Como você classificaria os cuidados que tem tomado para com a sua saúde oral?

() **Excelente 1** () **Muito bom 2** () **Bom 3** () **Satisfatório 4** () **Insatisfatório 5**

23. Quando você nasceu? Dia ____ Mês ____ Ano ____

24. Sexo masculino ou feminino? () **Masculino ----- 1** () **Feminino ----- 2**

25. Qual dos grupos abaixo melhor representa a sua raça? () **Aleútas, Esquimó ou Índio Americano 1** () **Asiático ou Insulano Pacífico 2** () **Negro 3** () **Branco 4** () **Outro 5**

26. Alguns destes grupos representa a sua origem nacional ou ancestralidade?

- ☐ Porto Riquenho 1 ☐ Cubano 2 ☐ Mexicano 3 ☐ Mexicano Americano 4
☐ Chicano 5 ☐ Outro Latino Americano 6 ☐ Outro Espanhol 7 ☐ Nenhum acima 8

27. Qual o seu grau de escolaridade mais alto ou último ano de escola que você completou?

- ☐ Nunca frequentou a escola / jardim de infância 00 ☐ Escola Primária 1 2 3 4
☐ Escola Ginásial 5 6 7 8 ☐ Científico 9 10 11 12 ☐ Faculdade 13 14 15 16 17 18+

28a. Durante as últimas 2 semanas, você trabalhou no emprego ou negócio não incluindo trabalho em casa (inclui trabalho não remunerado em negócios/fazenda da família)?

- ☐ Não 0 ☐ Sim 1

[Se a sua resposta foi Sim, pule para a pergunta 29] Se a sua resposta foi Não:

28b. Embora você não tenha trabalhado nas duas últimas semanas, você tinha um emprego ou negócio? ☐ Não 0 ☐ Sim 1

[Se a sua resposta foi Sim, PULE para a pergunta 29] Se a sua resposta foi Não:

28c. Você estava procurando emprego ou de dispensa, durante aquelas duas semanas?

- ☐ Sim, procurando emprego 1 ☐ Sim, de dispensa 2
☐ Sim, ambos de dispensa e procurando emprego 3 ☐ Não 4

29. Qual o seu estado civil?

- ☐ Casado (a) – esposa (o) em casa 1 ☐ Casado (a) – esposa (o) fora de casa 2
☐ Viúvo (a) 3 ☐ Divorciado (a) 4 ☐ Separado (a) 5 ☐ Nunca casei 6

30. Qual a sua foi a sua renda doméstica durante os últimos 12 meses? R\$ _____

31. Qual o seu CEP? _____

Formulário de exame – RDC

1. Você tem dor no lado direito da sua face, lado esquerdo ou ambos os lados?

- ☐ nenhum 0 ☐ direito 1 ☐ esquerdo 2 ☐ ambos 3

2. Você poderia apontar as áreas aonde você sente dor?

Direito		Esquerdo	
Nenhuma	0	Nenhuma	0
Articulação	1	Articulação	1
Músculos	2	Músculos	2
Ambos	3	Ambos	3

Examinador apalpa a área apontada pelo paciente, caso não esteja claro se é dor muscular ou articular

3. Padrão de Abertura

() Reto	0
() Desvio lateral direito (não corrigido)	1
() Desvio lateral direito corrigido ("S")	2
() Desvio lateral esquerdo (não corrigido)	3
() Desvio lateral corrigido ("S")	4
() Outro Tipo:	5

4. Extensão de movimento vertical incisivos maxilares utilizados 11 e 21

- a. Abertura sem auxílio sem dor __ __ mm
- b. Abertura máxima sem auxílio __ __ mm
- c. Abertura máxima com auxílio __ __ mm
- d. Trespasse incisal vertical __ __ mm

Tabela abaixo: Para os itens "b" e "c" somente

Dor Muscular				Dor Articular			
Nenhuma	Direito	Esquerdo	Ambos	Nenhuma	Direito	Esquerdo	Ambos
0	1	2	3	0	1	2	3
0	1	2	3	0	1	2	3

5. Ruídos articulares (palpação)

- a. ABERTURA

	Direito	Esquerdo
Nenhum	0	0
Estalido	1	1
Crepitação Grosseira	2	2
Crepitação Fina	3	3

Medida do estalido na abertura

__ __ mm

__ __ mm

b. FECHAMENTO

	Direito	Esquerdo
Nenhum	0	0
Estalido	1	1
Crepitação Grosseira	2	2
Crepitação Fina	3	3

Medida do estalido no fechamento

__ __ mm

__ __ mm

c. ESTALIDO RECÍPROCO ELIMINADO DURANTE ABERTURA PROTRUSIVA

	Direito	Esquerdo
Sim	0	0
Não	1	1
NA	8	8

6. Excursões

a. Excursão lateral direita __ __ mm

b. Excursão lateral esquerda __ __ mm

c. Protrusão __ __ mm

Tabela abaixo: Para os itens “a”, “b” e “c”

Dor Muscular				Dor Articular			
Nenhuma	Direito	Esquerdo	Ambos	Nenhuma	Direito	Esquerdo	Ambos
0	1	2	3	0	1	2	3
0	1	2	3	0	1	2	3
0	1	2	3	0	1	2	3

d. Desvio de linha média __ __ mm

Direito	Esquerdo	NA
1	2	8

7. Ruídos articulares nas excursões

Ruídos direito

	Nenhum	Estalido	Crepitação Grosseira	Crepitação Final
Excursão Direita	0	1	2	3
Excursão Esquerda	0	1	2	3
Protrusão	0	1	2	3

Ruídos Esquerdo

	Nenhum	Estalido	Crepitação Grosseira	Crepitação Final
Excursão Direita	0	1	2	3
Excursão Esquerda	0	1	2	3
Protrusão	0	1	2	3

INSTRUÇÕES, ÍTENS 8-10

O examinador irá palpar (tocando) diferentes áreas da sua face, cabeça e pescoço. Nós gostaríamos que você indicasse se você não sente dor ou apenas sente pressão (0), ou dor (1-3). Por favor, classifique o quanto de dor você sente para cada uma das palpações de acordo com a escala abaixo. Circule o número que corresponde a quantidade de dor que você sente. Nós gostaríamos que você fizesse uma classificação separada para as palpações direita e esquerda.

0 = Sem dor / somente pressão 1 = dor leve 2 = dor moderada 3 = dor severa

8. Dor muscular extra-oral com palpação

	Direito	Esquerdo
a. Temporal (posterior) “parte de trás da têmpora”	0 1 2 3	0 1 2 3
b. Temporal (médio) “meio da têmpora”	0 1 2 3	0 1 2 3
c. Temporal (anterior) “parte anterior da têmpora”	0 1 2 3	0 1 2 3
d. Masseter (superior) “bochecha/abaixo do zigoma”	0 1 2 3	0 1 2 3
e. Masseter (médio) “bochecha/lado da face”	0 1 2 3	0 1 2 3
f. Masseter (inferior) “bochecha/linha da mandíbula”	0 1 2 3	0 1 2 3
g. Região mandibular posterior (estilo-hióide/região posterior do digástrico) “mandíbula/região da garganta”	0 1 2 3	0 1 2 3
h. Região submandibular (pterigóideo medial/supra-hióide/região anterior do digástrico) “abaixo do queixo”	0 1 2 3	0 1 2 3

9. Dor articular com palpação

	Direito	Esquerdo
a. Polo lateral “por fora”	0 1 2 3	0 1 2 3
b. Ligamento posterior “dentro do ouvido”	0 1 2 3	0 1 2 3

10. Dor muscular intra-oral com palpação

	Direito	Esquerdo
a. Área do pterigoide lateral “atrás dos molares superiores”	0 1 2 3	0 1 2 3
b. Tendão do temporal “tendão”	0 1 2 3	0 1 2 3