UNIVERSIDADE FEREDAL DE UBERLÂNDIA

Cristiano Elias Figueiredo

A precisão da cirurgia ortognática com placas de titânio personalizadas – revisão sistemática

"The precision of orthognathic surgery with customized titanium plates – A systematic review"

Dissertação apresentada à Faculdade de Odontologia da Universidade de Uberlândia, para obtenção do Título de Mestre em Odontologia na Área de Clínica Odontológica Integrada
Orientador: Prof. Dr. Darceny Zanetta Barbosa

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Banca Examinadora
Prof. Dr. Darceny Zanetta Barbosa
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ATA DE DEFESA - PÓS-GRADUAÇÃO

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Iniciando os trabalhos o(a) presidente da mesa, Dr(a). Darceny Zanetta Barbosa, apresentou a Comissão Examinadora e o candidato(a), agradeceu a presença do público, e concedeu ao Discente a palavra para a exposição do seu trabalho. A duração da apresentação do Discente e o tempo de arguição e resposta foram conforme as normas do Programa.

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Nada mais havendo a tratar foram encerrados os trabalhos. Foi lavrada a presente ata que após lida e achada conforme foi assinada pela Banca Examinadora.

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SUMÁRIO

RESUMO

O objetivo deste trabalho foi realizar uma revisão sistemática para avaliar a precisão da cirurgia ortognática com placas de titânio customizadas em relação ao planejamento virtual. Trata-se de uma revisão sistemática com protocolo registrado na base de dado PROSPERO, que seguiu o guideline PRISMA e recomendaçãoes Cochrane. Seis bases de dados (Embase, LILACS, PubMed, SciELO, Scopus, Web of Science) foram utilizadas como fonte primária de pesquisa. E duas bases (OpenThesis e OpenGrey) para capturar parte da literatura cinzenta. Foi realizado registro do protocolo de pesquisa junto ao PROSPERO (CRD42019133769). Foram incluídos estudos clínicos descritivos que realizaram cirurgia ortognática com o uso de placas de titânio customizadas, sem restrição de ano, idioma e status de publicação. O risco de viés dos estudos selecionados foi avaliado pela ferramenta "The Joanna Briggs Institute Critical Appraisal tools for use in JBI Systematic Reviews Checklist for Case Series". Dos 11.916 estudos identificados inicialmente, somente sete preencheram os critérios de elegibilidade e foram incluídos nessa revisão. Os estudos são séries de casos publicados entre 2015 e 2019. A maioria dos estudos (57%) apresentou risco de viés baixo, enquanto apenas um estudo apresentou alto risco de viés. A amostra total incluiu 74 pacientes, com 63 cirurgias bimaxilares, e 11 cirurgias unimaxilares. Conclui-se que todos os estudos mostraram precisão aceitável dentro de parâmetros clínicos previamente estabelecidos. Embora todos os artigos elegíveis para esta revisão sistemática tenham comparado a precisão da cirurgia ortognática em relação ao planejamento virtual, a grande variabilidade das metodologias de avaliação impossibilitou o cálculo de uma medida de precisão combinada. Apesar disso, todos estudos sugeriram que a utilização de placas de titânio customizadas em cirurgia ortognática obteve alta precisão em relação ao planejamento virtual.

PALAVRAS-CHAVE: Cirurgia Ortognática, CAD-CAM, Placas ósseas, Impressão 3D

ABSTRACT

The objective of this work was to do a systematic review to access the precision of orthognathic surgery with customized titanium plates in relation to the outcome of virtual planning. This is a systematic review with a protocol registered in the PROSPERO database, which followed the PRISMA guideline and Cochrane recommendations. Six databases and two gray literature repositories were used as sources of research articles. The research protocol was registered in PROSPERO (CRD42019133769). Descriptive clinical studies that performed orthognathic surgery using custom titanium plates were included. The risk of bias of the selected studies was assessed by "The Joanna Briggs Institute Critical Appraisal tools for use in Systematic Reviews Checklist for Case Series". Of the 11,916 studies initially identified, 7 met the eligibility criteria and were included in this review. The studies were case series published between 2015 and 2019. Most of the studies (57%) had a low risk of bias, while only one had a high risk of bias. The total sample included 74 patients with 63 bimaxillary surgeries and 11 unimaxillary surgeries. It can be concluded thar all studies showed acceptable precision within previously established clinical parameters. Although the eligible articles assessed the precision of the orthognathic surgery with respect to virtual planning, the wide variability of evaluation methodologies made it impossible to calculate a combined precision measure. Nevertheless, all studies have suggested that the use of custom titanium plates in orthognathic surgery had high precision compared to the outcome of virtual planning.

KEYWORDS: Orthognathic Surgery, CAD-CAM, Bone Plates, 3D Printing

1 - INTRODUÇÃO E REFERNCIAL TEÓRICO

As primeiras descrições de procedimentos cirúrgicos para tratar deformidades dento-faciais datam de 1849, de autoria do norte-americano Simon Hullihen (HULLIHEN, 1849). O autor relatou o tratamento de uma deformidade mandibular, causada por contração cicatricial ocasionada por queimaduras durante a infância, com osteotomia na região anterior de mandíbula, usando fio de aço para fixação intraóssea. O primeiro relato de osteotomia maxilar que hoje é nomeada Le Fort I é de autoria de David Williams Cheever, para remoção de um grande pólipo nasofaríngeo (CHEEVER, 1870). Após estas publicações, vários trabalhos surgiram na intenção de aprimorar o tratamento e apresentar novas técnicas que pudessem tratar as discrepâncias maxilo-mandibulares. Foi onde se iniciou a busca por resultados mais previsíveis, estáveis, funcionais e estéticos. Neste sentido podemos destacar o ortodontista Edward Angle, que desempenhou papel fundamental na ortodontia em conjunto com a cirurgia ortognática, seja na adequação ortodôntica, ou mesmo no desenvolvimento de dispositivos oclusais de esplintagem para fixação e estabilização das osteotomias (ANGLE, 1898). Seus contemporâneos Vilary Blair e Max Ballin, contribuíram para grandes avanços no campo cirúrgico, como a osteotomia do corpo mandibular (BLAIR, 1906). A evolução desta ciência seguiu com cirurgiões dos Estados Unidos e Europa, que desenvolveram novos desenhos de osteotomias e técnicas inovadoras. Obwegeser e Dal Pont revolucionaram a cirurgia ortognática ao apresentaram a osteotomia sagital do ramo mandibular (DAL PONT, 1959, 1961; OBWEGESER, 1964), que foi aprimorada por Hunsuck, ao promover a osteotomia horizontal incompleta na face medial do ramo mandibular (HUNSUCK, 1968). Posteriormente, Wolford e colaboradores apresentaram uma modificação importante neste desenho (WOLFORD; BENNETT; RAFFERTY, 1987). A osteotomia moderna tipo Le Fort I foi desenvolvida por Obwegeser (OBWEGESER, 1965, 1969) onde a maxila foi totalmente mobilizada, com disjunção pterigomaxilar entre as tuberosidades maxilares e as placas pterigoides (NAINI, 2016). Este desenho foi modificado por Bennet e Wolford, que criaram a osteotomia Le Fort I com degrau, para evitar o fenômeno de “rampagem” da maxila (BENNETT; WOLFORD, 1985). Obwegeser foi o responsável pela primeira cirurgia ortognática bimaxilar do mundo, em 1970 (OBWEGESER, 1970).

Mais uma grande revolução na cirurgia ortognática foi a introdução de fixação rígida com placas e parafusos de titânio, em substituição aos fios de aço. O primeiro relato de fixação rígida em cirurgia ortognática foi do cirurgião alemão Bernd Spiessl em 1974, que usou parafusos do tipo *lag screw* para fixar uma osteotomia sagital do ramo mandibular, defendendo para isso a redução da recidiva esquelética (SPIESSL, 1974). Hans Luhr contribuiu no desenvolvimento de placas com parafusos desde a década de 1960. Ele foi seguido pelo francês Michelet e colaboradores, que em 1971 descreveram o uso de placas e parafusos para osteotomia mandibular (MICHELET et al., 1971).

Nas primeiras décadas da Cirurgia Ortognática moderna, ainda no século XIX, não havia planejamento cirúrgico com embasamento anatômico. Os cirurgiões planejavam as osteotomias, mas reposicionavam os segmentos ósseos sem referências importantes. Esta condição foi melhorada significativamente com o trabalho de Angle, que apresentou o planejamento em modelos de gesso, com a cirurgia de modelos (ANGLE, 1903). Esta técnica abriu caminho para grandes avanços nos resultados cirúrgicos, melhorando a precisão cirúrgica em relação ao planejamento. O trabalho de Angle também representou uma evolução no que concerne à busca pela oclusão ideal, preocupação que não existia até então. A técnica de planejamento evoluiu ao longo do século XX, entretanto, ainda estava sujeita a alguns desvios e alterações no resultado final (SCHNEIDER et al., 2005). Ellis realizou estudos importantes sobre a precisão deste tipo planejamento com modelos de gesso, sugerindo mudanças para aumentar a precisão cirúrgica em comparação ao planejamento (ELLIS, 1990).

Outro grande marco na cirurgia ortognática, que representou uma mudança de paradigmas, foi a introdução do planejamento cirúrgico virtual no fim da década de 1990. Okumura e colaboradores foram os primeiros a apresentar o uso da tomografia computadorizada e modelos escaneados no auxílio ao planejamento e reposicionamento cirúrgico (OKUMURA et al., 1999). Esta ciência foi aprimorada com os estudos de Jaime Gateno e James Xia (GATENO et al., 2003, 2007; GATENO; TEICHGRAEBER; XIA, 2003; XIA et al., 2007; XIA; GATENO; TEICHGRAEBER, 2005), e Gwen Swennen (SWENNEN et al., 2007). Estes trabalhos foram considerados os primeiros passos na era do planejamento virtual em cirurgia ortognática. Eles introduziram métodos validados clinicamente de planejamento cirúrgico em ambiente virtual 3D, e impressão 3D de guias interoclusais para transferência do planejamento para a realidade. Depois destes estudos, outros foram publicados para aplicar e validar a precisão do planejamento cirúrgico virtual com guias interoclusais, de forma multicêntrica, mostrando que esta nova tecnologia é superior à cirurgia de modelos em termos de precisão (BELL, 2010; FARRELL; FRANCO; TUCKER, 2014; GELESKO et al., 2012; HSU et al., 2013; WANG et al., 2019).

Seguindo na direção da evolução com ajuda da tecnologia, surgiram novos tipos de guias cirúrgicos. Uma vez que é possível planejar a posição exata das osteotomias em ambiente virtual, tornou-se simples criar dispositivos para orientar os cortes através da impressão 3D. Estes guias replicam exatamente a osteotomia que foi planejada virtualmente, de forma que é possível proteger estruturas nobres, diminuir tempo cirúrgico, e obter linhas de corte mais precisas. Adicionalmente, surgiram dispositivos que auxiliam no reposicionamento ósseo, que são criados virtualmente e impressos tridimensionalmente. Em alguns tipos, não há necessidade de *splint* interoclusal ou bloqueio maxilo-mandibular transoperatório, o que pode diminuir o tempo operatório, proporcionando uma melhor recuperação para o paciente (POLLEY; FIGUEROA, 2013; ZINSER et al., 2012, 2013a, 2013b).

Na busca de aumentar o controle do cirurgião no transoperatório e melhorar os resultados pós-operatórios, surgiu a navegação guiada por computador. Trata-se de um artifício de imagem oriunda de dois tipos: eletromagnética ou ótica. Esta imagem transoperatória orienta o cirurgião maxilofacial com relação à posição das osteotomias, instalação de placas e parafusos, posição dos segmentos ósseos e estruturas nobres que devem ser protegidas. Isso pode trazer inúmeras vantagens para cirurgião maxilofacial e paciente (BOBEK, 2014; MAZZONI et al., 2010).

Mais recentemente grandes avanços surgiram nos sistemas de fixação das osteotomias. Após o desenvolvimento das placas de titânio que substituíram os fios de aço, surgem novas tecnologias que auxiliam o cirurgião maxilofacial na obtenção de melhores resultados. As placas pré-dobradas reduzem o tempo cirúrgico e melhoram a precisão da fixação. Trata-se de um sistema onde um modelo anatômico é obtido por impressão 3D após o planejamento virtual e na conformação final do reposicionamento ósseo. Placas de titânio convencionais são então dobradas e adaptadas neste biomodelo, de forma que podem ser instaladas posteriormente na cirurgia, sem necessidade de novas dobras, reduzindo o tempo cirúrgico. Entretanto, o tempo de planejamento por parte do cirurgião maxilofacial é aumentado, e ocorre stress nas regiões de dobra das placas (XUE et al., 2018).

Outra inovação nos sistemas de fixação são as placas customizadas, ou implantes específicos do paciente. Como o próprio nome já diz, são placas personalizadas para cada paciente em cada cirurgia. São obtidas através de impressão 3D em titânio, após o planejamento cirúrgico virtual e desenho das placas em ambiente computadorizado. Adicionalmente, são usados guias de osteotomia para aumentar a precisão dos cortes e posicionamento das placas customizadas. Os primeiros estudos sobre o assunto apontam para uma série de vantagens, como a grande precisão das osteotomias promovidas pelos guias, instalação de parafusos em zonas de osso mais espesso, maior resistência das placas, redução de tempo cirúrgico, maior controle das movimentações ósseas, ausência de bloqueio maxilo-mandibular transoperatório (HEUFELDER et al., 2017; KIM et al., 2019; LI et al., 2017; MAZZONI et al., 2015; RAMOS; PINTO; BASTING, 2017; STOKBRO et al., 2019). Algumas desvantagens são o maior custo operacional, maior tempo de planejamento e produção dos guias e placas (HEUFELDER et al., 2017; LI et al., 2017). As placas customizadas representam uma das tecnologias mais recentes em cirurgia ortognática, que necessita de uma série de estudos para comprovar sua eficácia clínica. Alguns autores defendem seu uso e apresentam resultados positivos em relação à precisão cirúrgica promovida por elas (BRUNSO et al., 2016, 2017; HEUFELDER et al., 2017; KIM et al., 2019; KRAEIMA; JANSMA; SCHEPERS, 2016; LI et al., 2017; MAZZONI et al., 2015). Entretanto, não existem revisões sistemáticas ou estudos clínicos randomizados que respondem se a precisão promovida pelas placas customizadas é igual ou superior aos tratamentos já bem estabelecidos.

Neste sentido, este trabalho é uma revisão sistemática que busca responder se as placas de titânio customizadas em cirurgia ortognática promovem uma boa precisão em relação ao planejamento cirúrgico virtual.

2 - CAPÍTULO 1 – ARTIGO

Journal of Cranio-Maxillo-Facial Surgery

The precision of orthognathic surgery with customized titanium plates – A systematic review

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Abstract:	This is a systematic review on the precision of orthognathic surgery with customized titanium plates in relation to the outcome of virtual planning. Six databases and two gray literature repositories were used as sources of research articles. The research protocol was registered in PROSPERO. Descriptive clinical studies that performed orthognathic surgery using custom titanium plates were included. The risk of bias of the selected studies was assessed by “The JBI Critical Appraisal tools for use in Systematic Reviews Checklist for Case Series”. Seven studies met the eligibility criteria and were included in this review. The studies were case series published between 2015 and 2019. Most of the studies (57%) had a low risk of bias, while only one had a high risk of bias. The total sample included 74 patients with 63 bimaxillary surgeries and 11 unimaxillary surgeries. All studies showed acceptable precision within previously established clinical parameters. Although the eligible articles assessed the precision of the orthognathic surgery with respect to virtual planning, the wide variability of evaluation methodologies made it impossible to calculate a combined precision measure. Nevertheless, all studies have suggested that the use of custom titanium plates in orthognathic surgery had high precision compared to the outcome of virtual planning.

The precision of orthognathic surgery with customized titanium plates – A systematic review

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The precision of orthognathic surgery with customized titanium plates – A systematic review

ABSTRACT

This is a systematic review on the precision of orthognathic surgery with customized titanium plates in relation to the outcome of virtual planning. Six databases and two gray literature repositories were used as sources of research articles. The research protocol was registered in PROSPERO. Descriptive clinical studies that performed orthognathic surgery using custom titanium plates were included. The risk of bias of the selected studies was assessed by “The JBI Critical Appraisal tools for use in Systematic Reviews Checklist for Case Series”. Seven studies met the eligibility criteria and were included in this review. The studies were case series published between 2015 and 2019. Most of the studies (57%) had a low risk of bias, while only one had a high risk of bias. The total sample included 74 patients with 63 bimaxillary surgeries and 11 unimaxillary surgeries. All studies showed acceptable precision within previously established clinical parameters. Although the eligible articles assessed the precision of the orthognathic surgery with respect to virtual planning, the wide variability of evaluation methodologies made it impossible to calculate a combined precision measure. Nevertheless, all studies have suggested that the use of custom titanium plates in orthognathic surgery had high precision compared to the outcome of virtual planning.

Keywords: Orthognathic Surgery; CAD-CAM; Bone Plates; 3D Printing.

INTRODUCTION

The search for precision surgical planning and controlled outcomes in orthognathic surgery has been a constant challenge since its inception in the 19th century (Kretschmer et al., 2009; Brunso et al., 2016). Several surgical techniques have been explored to achieve planned results prior to surgery (Mazzoni et al., 2010; Bai et al., 2012; Zinser et al., 2012, 2013; Kokuryo et al., 2014; Gander et al., 2015). The traditional technique, based on the use of an interocclusal splint, is to perform a model surgery based on two-dimensional (2D) cephalogram surgical planning and handmade interocclusal splints for bone repositioning during surgery. The disadvantage of this method is that it does not promote good three-dimensional (3D) control of planning and movement and can lead to condylar mispositioning and osteotomy errors (Heufelder et al., 2017). Recently, 3D virtual surgical planning has gained ground due to better control and responses of bone movements (Hernández-Alfaro and Guijarro-Martínez, 2013; Lin and Lo, 2015; Brunso et al., 2016, 2017). Interocclusal splint printing through computer-aided design (CAD) and computer-aided manufacturing (CAM) for bone repositioning is already widely used and has shown good results (Xia et al., 2007; Hernández-Alfaro and Guijarro-Martínez, 2013; Sun et al., 2013; Kwon et al., 2014).

State of the art planning and performing of orthognathic surgery is closely linked to computer assistance. Several techniques are used to increase surgical precision in relation to virtual planning, including surgical guided navigation (Mazzoni et al., 2010), CAD-CAM repositioning guides (Zinser et al., 2012), and more recently, customized titanium plates (Philippe, 2013a, 2013b; Gander et al., 2015; Mazzoni et al., 2015; Brunso et al., 2016, 2017; Kraeima et al., 2016; Heufelder et al., 2017; Li et al., 2017; Kim et al., 2019). Customized titanium plates are based on surgical guide-oriented osteotomies, capable of repositioning bone segments without an occlusal splint (Mazzoni et al., 2015; Brunso et al., 2016; Heufelder et al., 2017; Li et al., 2017). Treatment with these plates has some advantages, such as shorter surgical time, greater vertical control and the absence of an occlusal splint or intermaxillary block during surgery (Brunso et al., 2016). There are studies that have tested customized plates by assessing the precision of the surgical outcome compared to the virtual planning (Mazzoni et al., 2015; Brunso et al., 2016, 2017; Kraeima et al., 2016; Heufelder et al., 2017; Li et al., 2017; Kim et al., 2019); however, there are no systematic reviews on the subject.

The present study aims to assess the precision of orthognathic surgery (OGS) using customized titanium plates compared to virtual surgical planning (VSP) through a systematic review of the literature. Since the literature does not yet consistently include a proper control group, in this study VSP will represent the control group to be matched.

METHODOLOGY

Protocol and registration

This systematic review was performed according to the list of Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) recommendations (Moher et al., 2009) and the Cochrane guidelines (Higgins et al., 2019). The systematic review protocol was registered in the PROSPERO database under nº [*Blinding*].

Study design and eligibility criteria

This systematic review aimed to answer the following question guided by the PICO strategy: “Do patients submitted to orthognathic surgery (Population) with customized titanium plates (Intervention) present surgical outcomes (Outcome) similar to the virtual orthognathic surgical planning (Comparative)?"

The inclusion criteria were clinical descriptive studies that performed orthognathic surgery using customized titanium plates and compared the cone-beam computed tomography (CT/CBCT) outcomes with those expected from the VSP. There was no restriction of year, language, or publication status.

The exclusion criteria were as follows: 1) studies not related to the objective; 2) studies that did not use customized titanium plates; 3) studies with no CT/CBCT analysis after the surgery; 4) in vitro studies; and 5) case reports, review articles, letters to the editor/editorials, personal opinions, books/book chapters, textbooks, conference abstracts.

Sources of information and search

The Embase, Latin-American and Caribbean Health Sciences Literature (LILACS), PubMed (including MedLine), SciELO, Scopus, and Web of Science databases were used as primary study sources. OpenThesis and OpenGrey were used to partially capture articles considered "gray literature". A manual search was also performed through a systematized analysis of the references of the eligible articles. All steps were performed to minimize selection and publication biases.

The MeSH (Medical Subject Headings), DeCS (Health Sciences Descriptors), and Emtree (Embase Subject Headings) resources were used to select the search descriptors. The Boolean operators "AND" and "OR" were used to enhance the research strategy through several combinations (Table 1). The bibliographic search was performed in March 2019. The results obtained were exported to the EndNote Web™ software (Thomson Reuters, Toronto, Canada), in which duplicates were removed. The remaining results were exported to Microsoft Word™ 2016 (Microsoft™ Ltd, Washington, USA), where the remaining duplicates were manually removed.

Study selection

The selection of studies was performed in three phases. Before the first phase, as a calibration exercise, the reviewers discussed the eligibility criteria and applied them to a sample of 20% of the studies retrieved to determine interexaminer agreement. After achieving a proper level of agreement (Kappa ≥ 0.81), two eligibility reviewers [Blinding] started the first phase, performing a methodical analysis of the titles of the studies independently. The reviewers were not blind to the names of the authors and journals. Titles not related to the topic were eliminated in this phase. In the second phase, the reviewers [Blinding] independently read the abstracts to initially apply the exclusion criteria mentioned above.

In the third phase, preliminarily eligible studies had their full texts obtained and evaluated to verify whether they fulfilled the eligibility criteria. When both reviewers disagreed, a third reviewer [Blinding] was consulted to make a final decision. The studies were rejected in this phase for not fulfilling the inclusion criteria or for fulfilling the exclusion criteria.

Process of data collection and extraction

After the selection, the studies were analyzed, and two reviewers [*Blinding*] extracted the study data for the following information: identification of the study (author, year, location), sample characteristics (number of patients and distribution by sex, average age, problem that led to surgery), characteristics of the planning and surgery (type of surgery, time of postoperative CT, software, screw system, design of plates, type of titanium alloy) and specific results (differences between planning and outcome).

To ensure consistency among the reviewers, a calibration exercise was performed with both reviewers [*Blinding*], in which information was extracted jointly from an eligible study. Any disagreement between the reviewers was solved through discussions, and if both reviewers still disagreed, a third [*Blinding*] was consulted to make a final decision.

Risk of individual bias of the studies

The risk of bias of the studies was assessed by The Joanna Briggs Institute Critical Appraisal Tools for use in Joanna Briggs Institute (JBI) Systematic Reviews(Joanna Briggs Institute, 2017) for case series. Two authors [*Blinding*] systematically assessed each domain and independently estimated the potential risk of bias for each study, as recommended by the PRISMA statement (Moher et al., 2009). Any disagreement between the reviewers was solved through discussions; if the disagreement persisted after discussion, a third reviewer [Blinding] was consulted to make the final decision.

The potential risk of bias for each study was categorized according to the percentage of positive answers to the questions in the assessment tool. The risk of bias was considered *high* when the study obtained 49% or fewer "yes" answers, *moderate* when the study obtained 50% to 69% of "yes" answers, and *low* when the study reached 70% or more "yes" answers.

Summary results

The difference between the postoperative CT (outcome) and the virtual planning (comparative) was the main outcome evaluated. This difference was shown in two ways: the mean bone area and/or position of dental landmarks (in millimeters) or the percentage difference in the bone area within 1 or 2 mm.

RESULTS

Study selection

During the first phase of study selection, 11.916 results were found distributed across in eight electronic databases, including the gray literature. After removing duplicates, 9.897 articles remained for title analysis. Seventy-eight of those were considered for abstract evaluation, and the remaining 10 articles were considered for full-text reading. The references of the 10 potentially eligible studies were carefully evaluated (173 titles), and no additional article was selected. After reading the full text of the 10 studies, three did not fulfil the inclusion criteria and were not considered. Two out of the three studies were eliminated because they did not analyze images after surgery (Suojanen et al., 2016, 2017), and one was not considered, as it did not use prefabricated custom miniplates but prebent miniplates (Xue et al., 2018).

Thus, seven studies were selected and considered in this systematic review. Figure 1 presents a flowchart describing the article search, identification, inclusion, and exclusion processes.

Characteristics of eligible studies

All seven studies are clinical case series, five prospective (Mazzoni et al., 2015; Brunso et al., 2016, 2017; Heufelder et al., 2017; Li et al., 2017) and two retrospectives (Kraeima et al., 2016; Kim et al., 2019). The studies were published between 2015 and 2019 and were performed in upper-middle- and high-income countries: Italy (Mazzoni et al., 2015), The Netherlands (Kraeima et al., 2016), Spain (Brunso et al., 2016, Brunso et al. 2017), Germany (Heufelder et al., 2017), China (Li et al., 2017) and South Korea (Kim et al., 2019). The total sample included 74 patients who underwent orthognathic surgery with customized bone plates for fixation. The mean age of the patients ranged from 22.0 to 40.3 years.

Bimaxillary surgeries were performed in 63 cases, and single jaw surgeries were performed in 11 cases, with 9 genioplasties among all of them. All studies mentioned following adequate ethical principles. A CT and an arch model scan (Mazzoni et al., 2015; Brunso et al., 2016; Brunso et al., 2017; Heufelder et al., 2017; Li et al., 2017; Kim et al., 2019), or a direct oral scan of the dentition (Kraeima et al., 2016), were made before the VSP, and at least one CT scan was performed after the surgery. Two studies made CBCT scans (Mazzoni et al., 2015; Kim et al., 2019), and five studies made helicoidal CT scans (Brunso et al., 2016; Brunso et al., 2017; Kraeima et al., 2016; Heufelder et al., 2017; Li et al., 2017) to create virtual planning. All studies evaluated the precision of orthognathic surgery compared to the virtual planning by postoperative CT analysis. To compare the CTs, all studies used VSP software to merge images and measure differences.

Four studies superimposed pre- and postoperative bone structures not related to surgical movements, such as orbital rims, skull base, or zygomatic buttress, and analyzed the differences between surgically moved bone surfaces (Mazzoni et al., 2015; Brunso et al., 2016; Brunso et al., 2017) or only the dentition differences (Kraeima et al., 2016). One study used dental landmarks (incisor points, mesiobuccal cuspids of the first molars, tips of the canines) for positioning and evaluating the differences in dental arches and bone surface after and before surgery (Heufelder et al., 2017). Two studies used dental and bone landmarks to evaluate dental and bone precision (Li et al., 2017;

Kim et al., 2019). One of these used the point between the upper central incisors, the cusp of the upper canines cusp, the mesiobuccal cusp of the upper first molars, the anterior nasal spine (ANS), the posterior nasal spine (PNS) and the A point (Kim et al., 2019). The other study used incisor points, first molar mesiobucal cusps, pogonions, bilateral gonions, bilateral condyle poles and coronoids (Li et al., 2017). Only one article (Heufelder et al., 2017) analyzed the superimposition precision, which had good results. This was performed by selecting four landmarks in each zygoma and measuring the differences in the positions pre- and postoperatively, allowing an acceptable error of 0.3 mm. Additionally, the authors calculated the difference between the virtual plan and the postoperative configuration by subtracting the planned and surgical movements. One study evaluated the stability of the surgery after 4 months and one year with a new CT and found stable results (Kim et al., 2019).

Two studies used a 2.0 screw system (Mazzoni et al., 2015; Li et al., 2017), two used a 1.5 screw system (Kraeima et al., 2016; Heufelder et al., 2017), and the other three (Brunso et al., 2016; Brunso et al., 2017; Kim et al., 2019) did not mention which type of screw was used. More details about the characteristics of the studies are shown in Table 2.

Risk of individual bias of the studies

Four eligible studies presented low risk of bias (Brunso et al., 2016; Heufelder et al., 2017; Li et al., 2017; Kim et al., 2019), two studies presented moderate risk (Mazzoni et al., 2015; Brunso et al., 2017) and only one study presented high risk of bias (Kraeima et al., 2016). Table 3 shows detailed information on the questions considered to assess the risk of bias of the studies. Question 9 was considered 'Not

Applicable' for all studies, as the outcome assessed in our study (customized titanium plate precision) is not influenced by geographic region or population.

Specific results of the eligible studies

Two out of the seven studies reported information about the stability of the fixation. Kim and colleagues described an unstable maxilla after fixation in 23% of the patients and used conventional miniplates for reinforcement (Kim et al., 2019). This was the only study performing stability analyses, which found a difference between the three-day CT and the one-year CT of 0.37 mm (SD = 0.29) (Kim et al., 2019). Another study described that the fixation was not perfectly stable, especially for large movements, and considered that some early adaptive changes could occur (Brunso et al., 2016).

Three studies showed the percentage of bone surface within an acceptable error for under- or overcorrection (Mazzoni et al., 2015; Brunso et al., 2016; Brunso et al., 2017). Two studies considered errors lower than 1 mm acceptable (Brunso et al., 2016; Brunso et al., 2017). They reached 71,2% (Brunso et al., 2017) and 68.1% of the postoperative bone surface within 1 mm for the upper maxilla (Brunso et al., 2016), and 75.3% for the mandible (Brunso et al., 2016). Another study considered errors smaller than 2 mm as acceptable, reaching 92.7% for the upper maxilla (Mazzoni et al., 2015). Six studies measured the precision by comparing the difference between the virtual planning and the postoperative results; however, there was a high variability between the methods and measures used to assess precision by the different studies (Mazzoni et al., 2015; Brunso et al., 2016; Kraeima et al., 2016; Heufelder et al., 2017; Li et al., 2017; Kim et al., 2019).

Other specific measurements were found in some articles. As primary outcomes, Li et al. (Li et al., 2017) measured the differences in the mediolateral, anteroposterior and superoinferior axes for both dental arches, the mandibular body and each proximal segment (Table 4). In turn, as secondary outcomes, they reported mean differences in the maxillary dental arch midline (0.32 mm), the mandibular dental arch midline (0.74 mm), the chin midline (0.70 mm), the left gonial angle (-0.20 mm) and the right gonial angle (0.21 mm) (Li et al., 2017). Heulferder et al. (Heufelder et al., 2017) reported the absolute mean difference in the three axes: X (0.30 mm), Y (0.33 mm) and Z (0.72 mm). They also provided signed values representing maximum under (-2.02 mm)- and overcorrection (1.74 mm) (Heufelder et al., 2017). The differences between postoperative and virtual planning outcomes are shown in Table 4.

DISCUSSION

This review aimed to evaluate the precision promoted by customized titanium plates in orthognathic surgery compared to the outcome expected after virtual planning. Despite the different forms of data evaluation and presentation, the selected studies described a high precision comparing virtual planning with the period after orthognathic surgery.

Regarding the methodologies, it should be noted that there were differences in the methods used to acquire the preoperative images for virtual planning. CBCT (Mazzoni et al., 2015; Kim et al., 2019) and the helicoidal method (CT) were used (Brunso et al., 2016; Brunso et al., 2017; Kraeima et al., 2016; Heufelder et al., 2017; Li et al., 2017). For surgical planning, the main method used was creating plaster models followed by scanning (Mazzoni et al., 2015; Brunso et al., 2016; Brunso et al., 2017;

Heufelder et al., 2017; Li et al., 2017; Kim et al., 2019), and only one study used an intraoral scanner (Kraeima et al., 2016), eliminating the molding and fabrication phases of plaster models.

These methods generated DICOM and STL files, respectively, which were imported into the surgical planning software; thus, it was possible to perform virtual surgical planning. Other software was used to design the cutting guides and titanium plates. These guides were printed on resin with a 3D Rapid Prototyping machine (Mazzoni et al., 2015; Kraeima et al., 2016; Brunso et al., 2017; Kim et al., 2019) or were manufactured in titanium (Brunso et al., 2016; Heufelder et al., 2017; Li et al., 2017). The cutting guides were introduced into the surgical field and stabilized in the correct position using the best anatomical fit in the anterior maxilla walls or mandibular body and then fixed by screws. Two studies further used bone-surface guides and one arm on the cusp of the teeth, indicating that this was to improve stability (Brunso et al., 2016; Kim et al., 2019). The screw holes of the cutting guides were also used to stabilize the titanium plates.

Customized titanium plates have been designed to fixate bone segments in their new position correctly and safely. For the positioning of cutting guides, customized plates and bone segments, one study also used a surgical navigation system to verify the correct position (Mazzoni et al., 2015). The plates were made of titanium by machining (Kraeima et al., 2016; Kim et al., 2019) or layer-by-layer sintering (Mazzoni et al., 2015; Brunso et al., 2016; Brunso et al., 2017; Heufelder et al., 2017; Li et al., 2017). Layer-by-layer sintering is generally cheaper and faster than machining, allows better architecture and better meets biomechanical requirements. On the other hand, it may result in lower rigidity and a higher risk of contamination (Brunso et al., 2016; Brunso et al., 2017). To assess surgical precision, postoperative CT was performed, and the virtual planning outcome was superimposed with postoperative tomography for precision measurements.

However, there is no consensus on the form of postoperative evaluation. Four studies performed bone surface analysis by overlapping skull cephalometric points that were not involved in surgical movement (Mazzoni et al., 2015; Brunso et al., 2016; Brunso et al., 2017; Kraeima et al., 2016). One study overlapped dental arch surfaces through the molar and canine cusps and the incisor points (Heufelder et al., 2017). Another used the cephalometric maxillary points (ANS and PNS) and the same dental points previously mentioned (Kim et al., 2019). One study used both the bone surface and dental arches (Li et al., 2017). The great methodological heterogeneity of the precision estimation methods made it impossible for the results to be grouped and meta- analyzed, and this may undermine the level of evidence of this review. Nevertheless, the results of all articles included in this study were positive regarding the use of customized plates.

Good average surgical precision was achieved in the analysis of the maxillary dental arches (ranging from -0.1 mm (Li et al., 2017) to 2.2 mm (Kraeima et al., 2016)), of the maxillary bone surface (ranging from 0.2 mm (Mazzoni et al., 2015) to 1.1 mm (Brunso et al., 2016)) or of the mandible bone surface (from -0.1 mm (Li et al., 2017) to 0.6 mm (Brunso et al., 2016)). The authors of these studies consider these differences to be clinically acceptable, which corroborates previous studies that defined differences of up to 2.0 mm as acceptable (Proffit et al., 1987; Donatsky et al., 1997; Ong et al., 2001; Marchetti et al., 2007; Proffit et al., 2007; Xia et al., 2007).

The results are similar in terms of postoperative accuracy. Kretschmer et al. (Kretschmer et al., 2009) evaluated 239 patients operated with a traditional intermediate guide and nasal pin and found a precision of 0.5 mm. Kwon et al. (Kwon et al., 2014) evaluated 42 patients and found a surgical precision of 1.2 mm with traditional guides and of 1.0 mm with 3D printed guides. Kokutyo et al. (Kokuryo et al., 2014) tested a three-dimensional repositioning system with occlusal splints in 26 patients and found, compared with traditional occlusal splints, average differences of 0.3 mm and 1.4 mm, respectively. However, these authors (Kretschmer et al., 2009; Kokuryo et al., 2014; Kwon et al., 2014) performed only 2D postoperative analysis with cephalograms. This type of analysis may be subject to discrepancies of up to 0.6 mm (Donatsky et al., 1997). Other studies have evaluated surgical precision three-dimensionally (Mazzoni et al., 2010; Hernández-Alfaro and Guijarro-Martínez, 2013; Sun et al., 2013; Stokbro and Thygesen, 2018a). Hernandez et al. (Hernández-Alfaro and Guijarro-Martínez, 2013) tested a CAD-CAM interocclusal splint and found a mean deviation of 0.5 mm in dry skulls (in vitro) and 0.7 mm in 6 patients (in vivo). Sun et al. (Sun et al., 2013) found a precision of 0.5 mm with a CAD-CAM interocclusal splint in 15 patients. Mazzoni et al. (Mazzoni et al., 2010) tested splintless repositioning with surgical guided navigation in 15 patients with a precision of 1.1 mm. Stokbro (Stokbro and Thygesen, 2018a) evaluated 20 patients with inferior maxillary repositioning with a 3D occlusal splint and found a mean difference of 0.2 mm. These data found in the literature show that the results with customized titanium plates may be clinically acceptable compared to other types of bone repositioning devices.

The stability of the titanium plates was acceptable both immediately and long term. After 1 year of surgery, Kim et al. (Kim et al., 2019) observed a deviation of only

-0.4 mm. Nevertheless, 23% of the cases in this study presented unstable maxilla after fixation, requiring additional use of traditional plates to complete fixation (Kim et al., 2019). Proffit et al. (Proffit et al., 2007) considered differences of up to 2.0 mm to be clinically acceptable, even after 1 year of surgery. Two studies (Brunso et al., 2016; Brunso et al., 2017) reported that customized titanium plates do not provide perfect stability by themselves, especially in cases of large movements, such as major advances. This can be influenced by the thickness and mechanical arrangement of the plates in the fixed bone, as well as the type and magnitude of movements. This instability can also be seen with traditional plates, where large advances or lower jaw movements can generate instability and relapses (Bailey et al., 2004; Proffit et al., 2007). The authors did not specify which type of mandibular movement was associated with unstable jaws, but it is important to note that this may contribute to greater instability (Proffit et al., 2007). Furthermore, Brunso et al. (Brunso et al., 2016) used only one plate on each side of the maxilla and made advances greater than 10.0 mm in 82% of their sample, which may have led to greater instability. In cases of large movements that generate greater instability, 2 plates on each side of the jaw should be used to promote greater fixation rigidity.

The authors (Mazzoni et al., 2015; Brunso et al., 2016; Brunso et al., 2017; Kraeima et al., 2016; Heufelder et al., 2017; Li et al., 2017; Kim et al., 2019) of the studies point to a number of advantages to using cutting and fixing guides with custom plates. The cutting guides are easy to position and rarely have poor adaptation to the bone surface. This allows correct and accurate osteotomy and facilitates bone repositioning (Mazzoni et al., 2015; Li et al., 2017). Moreover, the choice of screw hole locations allows the determination of the thickest bone region to achieve greater screw locking and plate stability (Li et al., 2017). These screw holes are easily positioned away from the dental roots (Mazzoni et al., 2015; Kim et al., 2019). When the guides are fixed with screws, the use of the same screw holes to fixate the plates facilitates their installation and the consequent bone repositioning (Mazzoni et al., 2015; Heufelder et al., 2017). Another advantage is the reduction in surgical time since there is no need to bend plates, perform intermaxillary fixation or intraoperative measures to check bone repositioning (Mazzoni et al., 2015; Brunso et al., 2016; Brunso et al., 2017; Heufelder et al., 2017). This technique positions the upper jaw independent of the mandible or condylar position (Brunso et al., 2016; Brunso et al., 2017; Kraeima et al., 2016; Heufelder et al., 2017; Li et al., 2017; Kim et al., 2019). Furthermore, it preserves the condyles correctly in the articular fossa, promotes good control of vertical movements, and is advantageous in cases of large asymmetries or unstable postoperative occlusion resulting from either dental absences or a surgery-first technique (Brunso et al., 2016), since it does not use interocclusal splints or intermaxillary fixation (Brunso et al., 2016; Brunso et al., 2017; Li et al., 2017). Regarding the rigidity of customized plates, the authors note that they are highly rigid, enabling correct repositioning of bone segments and withstanding functional loads (Brunso et al., 2016, 2017; Li et al., 2017). It has been proven in vitro that customized plates have greater rigidity when compared to prefabricated plates (Ramos et al., 2017; Stokbro et al., 2019).

The limitations of the technique involve a longer time spent in the surgical planning and design of the guides and plates, the higher operating cost, and the difficulty of changing the planning intraoperatively (as customized plates are highly rigid and it is very difficult to bend them) (Heufelder et al., 2017; Li et al., 2017).

Precision errors can occur in all treatment steps, such as model scanning, insertion and integration of DICOM and STL files, determination of coordinates in the 3D environment, and making guides and plates. Minor errors in each of these steps accumulate and can lead to precision errors (Kim et al., 2019). We agree with the authors of the seven studies that the differences found are clinically irrelevant.

Due to the heterogeneity of the precision assessment methods and the varied presentation of the data, it was not possible to perform a reliable meta-analysis that could answer the proposed question quantitatively. Thus, a remaining open issue is the need for a standardization of measurement methods and precision measurements. Stokbro (Stokbro and Thygesen, 2018b) suggested a methodology for evaluating postoperative results compared with planning and found favorable results with differences of 0.1 mm. Although there are different forms of assessment among the selected studies, a surgeon must combine the best methods from each study to achieve a standard and reliable assessment.

This review is not exempt of limitations. The small sample size, the absence of a control group in the included studies, and the lack of randomized control group clinical studies diminish the strength of its scientific evidence. We attribute this to the fact that customized plates in orthognathic surgery have only started to be used very recently. Even so, the inclusion and exclusion criteria made it possible to select studies with good methodological quality, which showed promising results. Moreover, the extensive search in different databases, without restriction on the year and language of publication, and the use of “gray literature”, considerably minimizes the risk of study selection bias. Finally, the absence of systematic reviews on the subject increases the importance and timeliness of this review. Clinical studies are encouraged to reinforce the results we found.

CONCLUSION

All individual studies selected for this systematic review have suggested the great potential of using customized titanium plates in orthognathic surgery to adhere to virtual planning. However, due to differences between the included studies, it was not possible to perform a meta-analysis, so a pragmatic recommendation on the use of these plates is not possible. Further standardized studies are needed to increase the strength of evidence and confirm the accuracy of using custom titanium plates with respect to virtual planning.

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TABLE 1. STRATEGIES FOR DATABASE SEARCH.

Database	Search Strategy (March 2019)	Results
PubMed **http://www.ncbi.nlm.nih.gov/pubmed**	((“Three-Dimensional Printing” OR “3D Printing” OR “Stereolithography” OR “Bone Plate” OR “Computer-Aided Design” OR “Computer-Assisted Manufacturing” OR “Computer-Aided Manufacturing” OR “Splint-Less Orthognathic Surgery” OR “Custom Plate” OR “Customized Bone Plate” OR “Custom Osteosynthesis Plate” OR “Customized Titanium Plates” OR “Custom-Machined Miniplates” OR “Custom-Made Prefabricated Titanium Miniplates” OR “Custom-Made Miniplates” OR “Patient Specific Implants” OR “Patient Specific Osteosynthesis”) AND (“Orthognathic Surgery” OR “Le Fort Osteotomy” OR “Sagittal Split Ramus Osteotomy” OR “Mandibular Advancement” OR “Mandibular Osteotomy” OR “Maxillary Osteotomy” OR “Jaw Surgery”))	6291
Scopus **http://www.scopus.com/**	((("Three-Dimensional Printing" OR "Customized Titanium Plates" OR "Bone Plate" OR "Computer Assisted Manufacturing" OR "Splint-Less Orthognathic Surgery") AND ("Orthognathic Surgery" OR "Le Fort Osteotomy " OR "Sagittal Split Ramus Osteotomy")))	383
	(((“3D Printing” OR “Stereolithography” OR “Computer-Aided Design” OR “Titanium” OR “Customized Bone Plate” OR “Custom-Machined Miniplates” OR “Patient Specific Implants”) AND (“Mandibular Advancement” OR “Mandibular Osteotomy” OR “Maxillary Osteotomy”)))	156
LILACS **http://lilacs.bvsalud.org/**	(“Printing, Three-Dimensional” OR “Stereolithography” OR “Bone Plate” OR “Computer-Aided Design” OR “Computer-Assisted Manufacturing” OR “Titanium” OR “Manufacturing, Computer-Aided” OR “Orthognathic Surgery”)	2233
SciELO **http://www.scielo.org/**	("Three-Dimensional Printing" OR "Stereolithography" OR "Bone Plate" OR "Computer-Aided Design" OR "Computer-Assisted Manufacturing" OR "Titanium" OR "Computer-Aided Manufacturing" OR "Orthognathic Surgery")	1513
Web of Science **http://apps.webofknowledge.com/**	(((“Printing, Three-Dimensional” OR “3D Printing” OR “Stereolithography” OR “Bone Plate” OR “Computer-Aided Design” OR “Computer-Assisted Manufacturing” OR “Titanium” OR “Manufacturing, Computer-Aided” OR “Splint-Less Orthognathic Surgery” OR “Custom Plate” OR “Customized Bone Plate” OR “Custom Osteosynthesis Plate” OR “Customized Titanium Plates” OR “Custom-Machined Miniplates” OR “Custom-Made Prefabricated Titanium Miniplates” OR “Custom-Made Miniplates” OR “Patient Specific Implants” OR “Patient Specific Osteosynthesis”) AND (“Orthognathic Surgery” OR “Osteotomy, Le Fort” OR “Osteotomy, Sagittal Split Ramus” OR “Mandibular Advancement” OR “Mandibular Osteotomy” OR “Maxillary Osteotomy” OR “Jaw Surgery”)))	346
Embase **https://www.embase.com**	('printing, three-dimensional'/exp OR 'printing, three-dimensional' OR '3d printing'/exp OR '3d printing' OR 'stereolithography'/exp OR 'stereolithography' OR 'bone plate'/exp OR 'bone plate' OR 'computer-aided design'/exp OR 'computer-aided design' OR 'computer-assisted manufacturing' OR 'titanium'/exp OR 'titanium' OR 'manufacturing, computer-aided' OR 'splint-less orthognathic surgery' OR 'custom plate' OR 'customized bone plate' OR 'custom osteosynthesis plate' OR 'customized titanium plates' OR 'custom-machined miniplates' OR 'custom-made prefabricated titanium miniplates' OR 'custom-made miniplates' OR 'patient specific implants' OR 'patient specific osteosynthesis') AND ('orthognathic surgery'/exp OR	936

	'orthognathic surgery' OR 'osteotomy, le fort'/exp OR 'osteotomy, le fort' OR 'osteotomy, sagittal split ramus'/exp OR 'osteotomy, sagittal split ramus' OR 'mandibular advancement'/exp OR 'mandibular advancement' OR 'mandibular osteotomy'/exp OR 'mandibular osteotomy' OR 'maxillary osteotomy'/exp OR 'maxillary osteotomy' OR 'jaw surgery'/exp OR 'jaw surgery')	
OpenGrey http://www.opengrey.eu/	("Customized Titanium Plates" OR "Customized Bone Plate" OR "Computer-Assisted Manufacturing" OR "Patient Specific Implants")	35
OpenThesis http://www.openthesis.org/	(Customized Titanium Plates OR Customized Bone Plate OR Computer-Assisted Manufacturing OR Patient Specific Implants)	33
TOTAL		11926

TABLE 2 - SUMMARY OF THE MAIN CHARACTERISTICS OF THE ELIGIBLE STUDIES.

Author, year	Country	Sample (n)	Average age (SD)	Problem	Surgery	Times of CT post-operative	VSP Software	Plate design Software	Cutting Guides Material	Plates	Titanium alloy
Mazzoni et al. 2015	Italy	10 (5♀ 5♂)	+	1 Class II 9 Class III (2 asymmetry)	10 Single Jaw	1 month	Surgicase CMF 5.0 (Materialise, Leuven, Belgium)	Rhino 4.0 (Robert McNeel & Associates, Seattle, WA).	Resin	2 plates 4 by 4 system (DMLS)	EOS Titanium Ti64 (Electro-Optical Systems)
Brunso et al. 2016	Spain	6 (5♀ 1♂)	34.3 (9,9)	4 OSA 1 Class II 1 Class III+ asymmetry	5 Double Jaw 1 Single Jaw (2 chins)	1 month	SimPlant Pro OMS (Materialise, Leuven, Belgium)	PowerShape (Delcam, Birmingham, UK)	Resin	2 plates 2 by 2 system 1 simple plate at SRO (DMLS)	Grade 5 Titanium
Kraeima et al. 2016	The Netherlands	3 (2♀ 1♂)	40	+	3 Double Jaw	2 weeks	Simplant O&O (Dentsply Implants NV, Kessel-Lo, Belgium)	Createch Medical SL	Resin	4 plates 4 by 4 system (CNC-MM)	Medical-grade Titanium
Li et al. 2017	China	10 (5♀ 5♂)	22	2 Class II 8 Class III (6 asymmetry)	10 Double Jaw	3 days	ProPlan 2.0 (Materialise NV, Leuven, Belgium)	Geomagic Studio (Research Triangle Park, NC, USA)	Titanium	2 plates 4 by 4 system 1 simple plate ate SRO (DMLS)	Ti6AIV4
Heufelder et al. 2017	Germany	22 (+♀ +♂)	25,9	2 Class I 18 Class III (11 asymmetry) 2 Class II (1 asymmetry)	22 Double Jaw (PSI only in Maxilla)	+	ProPlan CMF (Materialise, Leuven, Belgium)	+	Titanium	1 plate 4 by 4 system (DMLS)	+
Brunso et al. 2017	Spain	10 (1♀ 9♂)	40.3(9.2)	8 OSA 2 Class II	10 Double Jaw (3 chins) – CTP only in Maxilla	1 month	Mimics 18.0 (Materialise NV, Belgium)	3-matic (Materialise NV, Belgium)	Titanium	1 plate 4 by 4 sytem (DMLS)	Grade II Commercially Pure Titanium

Kim et al. 2019	South Korea	13 (7♀ 6♂)	22.9 (3.3)	10 Class III 3 Class I All assymetric	13 Double Jaw (4 chins)	3 days 4 months 1 year	FaceGide (Mega-Gen Co., Daegu, Korea)	FaceGide (Mega-Gen Co., Daegu, Korea)	Resin	4 plates 4 by 4 system 1 simple plate at SRO (CNC-MM)	+

+Not mentioned by the author; ♀ Women; ♂ Men; OSA Obstructive Sleep Apnoea, SRO Sagittal Ramus Osteotomy, CTP Customized Titanium Plate, DMLS direct metal laser sintering, CNC-MM Computer Numerical Control Milling Machine

Table 3 – Risk of bias assessed by the Joanna Briggs Institute Critical Appraisal Tools for use in JBI Systematic Reviews for Case Series (Moola et al. 2017)

Authors	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	% Yes	Risk
Brunso et al. 2016	√	√	√	√	--	√	√	√	NA	--	77,78	Low
Brunso et al. 2017	√	√	√	--	--	√	√	√	NA	--	66,67	Moderate
Heufelder et al. 2017	√	√	√	√	√	√	√	√	NA	√	88,89	Low
Kim et al. 2019	√	√	√	--	√	√	√	√	NA	√	88,89	Low
Kraeima et al. 2016	--	√	√	--	--	√	√	--	NA	--	44,44	High
Li et al. 2017	√	√	√	--	√	√	√	√	NA	√	88,89	Low
Mazzoni et al. 2015	--	√	√	--	--	√	√	√	NA	--	55,56	Moderate

Q1. Were there clear criteria for inclusion in the case series? Q2. Was the condition measured in a standard, reliable way for all participants included in the case series? Q3. Were valid methods used for identification of the condition for all participants included in the case series? Q4. Did the case series have consecutive inclusion of participants? Q5. Did the case series have complete inclusion of participants? Q6. Was there clear reporting of the demographics of the participants in the study? Q7. Was there clear reporting of clinical information of the participants? Q8. Were the outcomes or follow up results of cases clearly reported? Q9. Was there clear reporting of the presenting site(s)/clinic(s) demographic information? Q10. Was statistical analysis appropriate? √ - Yes;
-- - No; NA – Not Applicable; U - Unclear

TABLE 4 –SUMMARY OF THE MAIN RESULTS OF THE ELIGIBLE STUDIES.

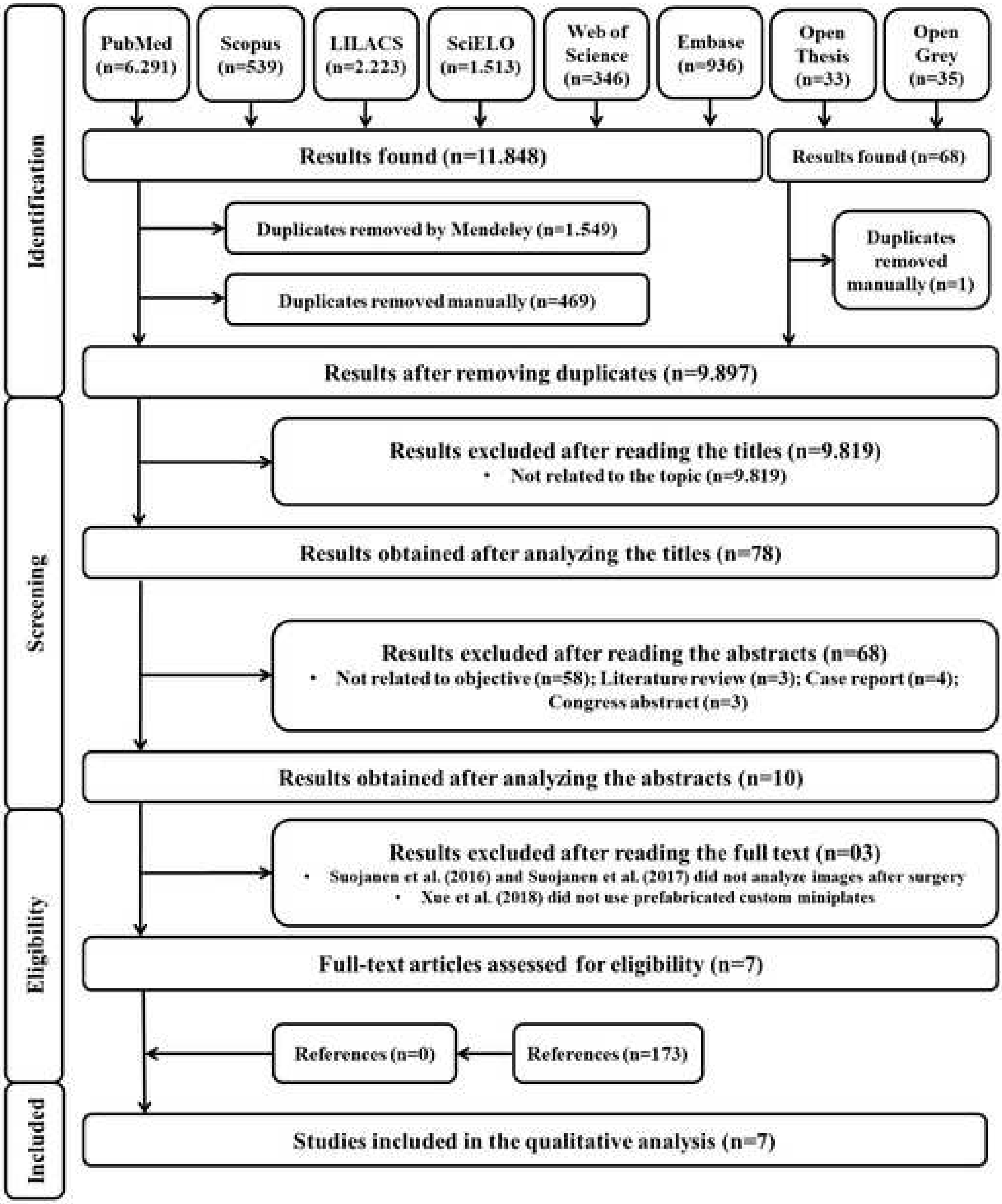
Author, year	Maxilla Surface Difference Outcome-Planned (mm)	Mandible Surface Difference Outcome-Planned (mm)	Maxilla dentition Difference Outcome-Planned (mm)	Mandible dentition Difference Outcome-Planned (mm)	Main Outcomes
Mazzoni et al. 2015	Min/Max -3.4/+3.2 -2.0/+1.2 -0.6/+0.7 -0.08/0 0/+2.4 -0.07/0.02 -1.6/+1.2 -1.6/0 -1.0/+6.0 -0.8/+1.4	+	+	+	Cutting guides and customized titanium plates allow accurate reproduction of preoperative virtual planning without. It. allows direct operative transfer of virtual surgical plans to the theater; it is easy to use, relatively inexpensive, and clinical efficient; and it shortens the surgical duration.
Brunso et al. 2016	1,29(0,76) 1,42(0,8) 1,61(1,13) 1,01(0,66) 0,14(0,57)	0,95(0,74) 0,62(0,45) 0,54(1,04) 0,94(0,39) 0,34(0,86) 0,3(0,71)	+	+	The cutting guides and customized titanium plates provided vertical control and correct condylar positioning with considerable surgical accuracy. The technique simplified surgery obviating the need for occlusal splints or intraoperative measurements and reduced operative time.
Kraeima et al. 2016	+	+	2,2(2,0) 0,7(1,0) 1,0(1,3)	+	Patient-specific CAD-CAM osteosynthesis plates are specifically indicated in patients who require a posterior maxillary downgraft. It is an advantage positioning of the maxilla independent of the condyle or mandible, and extraoral reference points are not needed. The technique accurately translates a 3-dimensional virtual treatment plan to an actual Le Fort I osteotomy.
Li et al. 2017	Mediolateral Anteroposterior	Body: 0 (0,52) 0,15 (0,79)	-0,18 (0,35) -0,54(0,53)	-0,33 (0,53) -0,67 (0,50)	The surgical guides and plates system are capable of accurately and effectively transferring the computerized surgical plan in the operating room, without the use of surgical splints. It allows

	Superoinferior	-0,26 (0,83) -0,10 (1,03) 0,23 (0,82) -0,10 (0,79)	0,33(0,53)	0,38 (0,92)	precisely duplicate the osteotomy and screw holes, also bone repositioning. The rigidity of the titanium plates ensures the correct position of the bony segments. Eliminates the potential problems associated with the traditional surgical splint.
		Left Ramus:			
		Right Ramus: -0,18 (0,7) 0,05 (0,54) -0,28 (0,94)			
Heufelder et al. 2017	Mean: 0,39 (Minimum 0,0 Maximum 2,2)	+	0,45	+	Waferless maxillary positioning in dento-facial deformities can be achieved with a very high degree of accuracy using CAD/CAM patient specific implants and surgical guides. This technique may change the current approach to maxillary positioning also in clinical routine, when training situations are taken into consideration.
Brunso et al. 2017	Precision within ±1mm (%) 81 64 53 59 84 71 75 65 65 64	+	+	+	The PSI the procedure considerably and reduce surgical times. Allows to increase the precision and the safety of the procedure. It would be especially indicated in large asymmetries with an important vertical component, cases fragmented, patients with regular occlusal stability postoperative and in severe anatomical alterations that do not they allow the use of conventional osteosynthesis systems.

Kim et al. 2019	Mean: 1,01(0,3) Incisor Root: 0,82 (0,694) Right Superior Canine Root: 0,819 (0,904) Left superior canine root: 0,817 (1,196) Superior first right molar: 1,196 (1,303) Superior first left molar: 1,022 (1,161) Anterior nasal spine: 0,883 (1,793) posterior nasal spine: 1,661 (1,489) A point: 0,860 (1,071)	+	Mean: 0,67 (0,58) Mean cusp points Incisor ponit: 0.26 Right superior canine cusp: 0.47 Left superior canine cusp: 1.11 Superior first right molar cusp: 0.02 Superior first left molar cusp: 1.6 Anterior nasal spine: 0.6	+	This type of PSI is believed to be more accurate than a bone-only supported guide because it is supported by both the bone surface and the cusp of the teeth. The repositioning of the maxilla was clinically accurate, and stable results were maintained one year after the operation. 3D evaluation, virtual simulation, and CAD-CAM technology can benefit both doctors and patients.

+ Not mentioned by the author

Figure 1. Flow Chart - search, identification, inclusion, and exclusion of articles



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