

UNIVERSIDADE DE CAXIAS DO SUL
ÁREA DO CONHECIMENTO DE CIÊNCIAS DA VIDA

MARIA EDUARDA PEREIRA GOULART

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**“QUAL A ACURÁCIA DA GUIA CIRÚRGICA NO PLANEJAMENTO DE
CIRURGIAS ORTOGNÁTICAS?”: UMA REVISÃO SISTEMÁTICA.**

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obtenção do título de Bacharel em
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Orientador: Prof. Dr. Thiago de Oliveira
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Coorientador: Prof. Me. Fernando Deon

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*“Que todos os nossos esforços estejam sempre focados no desafio à impossibilidade.
Todas as grandes conquistas humanas vieram daquilo que parecia impossível.”*

Charles Chaplin

RESUMO

O tratamento resolutivo de alterações esqueléticas faciais apresenta como alternativa a realização de cirurgias ortognáticas associadas com o tratamento ortodôntico, com o intuito de alcançar a oclusão dentária ideal, estética e harmonia facial. A transferência do planejamento pré-operatório no ato cirúrgico é realizada por meio de uma guia cirúrgica, que orienta o correto posicionamento dos ossos gnáticos de acordo com a oclusão previamente planejada. O presente estudo tem como objetivo avaliar por meio de uma revisão sistemática (RS) da literatura qual a acurácia da guia cirúrgica no planejamento de cirurgias ortognáticas. Para isso, foram selecionados artigos oriundos da base de dados Pubmed, para tal pesquisa, as palavras chaves utilizadas foram: *Orthognathic Surgery. Guide (splint). Rapid Prototyping (3D printing, CAD/CAM, accuracy)*. A partir da elaboração de um fluxograma, por meio de um protocolo PRISMA, os artigos foram avaliados, pelo título e resumo e, a partir disso, os mesmos foram lidos na íntegra, considerando os critérios de inclusão e exclusão previamente definidos. Como critérios de inclusão mais consideráveis pode-se ressaltar que os pacientes deveriam ser submetidos a Tomografia Computadorizada, apresentarem deformidades esqueléticas maxilofaciais, além de utilizarem estudos que foram realizados em pacientes vivos ou em cadáveres humanos. Destacou-se como critérios de exclusão à utilização da guia cirúrgica para outros procedimentos odontológicos, estudos que não citaram o uso da guia; pacientes diagnosticados com lesões malignas, ou com malformações congênitas e os mesmos não deveriam ter sido submetidos à cirurgia ortognática prévia. Desta forma, foram selecionados 7 artigos para análise de seus resultados, os quais analisaram a precisão dos movimentos pré-operatórios comparando aos resultados pós-cirúrgicos, os quais relataram valores de erros inferiores a 2 mm, nos quais o erro máximo apresentado pelos estudos foi bem controlado até 1,73mm e o erro médio foi inferior a 1mm, o que é considerado dentro de uma margem clinicamente aceitável. Entretanto, a real veracidade da acurácia da guia cirúrgica não pôde ser estimada, pelo fato de que nenhum dos estudos apresentados realizou o teste estatístico ideal, representado pela Curva ROC, para avaliar tal resultado. Além disso, por apresentarem informações de dados estatísticos heterogêneas e insatisfatórias, não foi possível estabelecer um padrão de análise entre as pesquisas, dificultando a realização da metanálise da RS. Já com relação ao risco de viés dos estudos selecionados não preencheram todos os critérios de qualidade determinados pelo QUADAS-2, que é avaliado em quatro domínios: seleção da amostra, teste de índice (acurácia da guia, diferença entre planejamento, distorção da guia e curva ROC), padrão de referência, fluxo e tempo. A capacidade de reprodução do posicionamento maxilo-mandibular tridimensionalmente pode ser considerada adequada e com resultados semelhantes aos oferecidos pelo planejamento convencional. Ainda que todas as técnicas alcançaram resultados precisos, é importante destacar que o método virtual apresentou valores de erro inferiores aos das demais técnicas, indicando uma maior precisão de transferência de planejamento.

Palavras-chave: Cirurgia Ortognática. Guia. (*splint*). Prototipagem rápida (Impressão 3D.CAD/CAM. Acurácia).

ABSTRACT

The resolutive treatment of facial skeletal alterations presents, as an alternative, orthognathic surgeries associated with orthodontic treatment, aiming at achieving the ideal dental occlusion, aesthetics and facial harmony. The transfer of preoperative planning during surgery is performed by means of a surgical guide, which orient the correct positioning of the gnatic bones according to the previously planned occlusion. This study aims to evaluate through a systematic review (SR) the accuracy of the surgical guide in the planning of orthognathic surgeries. For this, articles from the Pubmed database were selected and the keywords used were: Orthognathic Surgery. Guide (splint). Rapid Prototyping (3D printing, CAD / CAM, accuracy). From the elaboration of a flowchart, through a PRISMA protocol, the articles were evaluated by title and abstract and, from this, were read in full, considering the previously defined inclusion and exclusion criteria. As the most important inclusion criteria, should be emphasized that patients should undergo computed tomography, present maxillofacial skeletal deformities and use studies that were performed in living patients or human cadavers. Exclusion criteria were the use of the surgical guide for other dental procedures, studies that did not mention the use of the guide; Patients diagnosed with malignant lesions or congenital malformations should not have undergone previous orthognathic surgery. In this manner, 7 articles were selected for analysis of their results that analyzed the accuracy of preoperative movements in relation to postoperative results, which reported error values below 2 mm, in which the maximum error presented by the studies was well controlled up to 1.73 mm and the average error was lower. 1 mm, which is considered to be within a clinically acceptable range. However, the real accuracy of the surgical guide's accuracy could not be estimated, since none of the studies presented performed the ideal statistical test, represented by the ROC curve, to evaluate such result. In addition, because they presented information from heterogeneous and unsatisfactory statistical data, it was not possible to establish a pattern of analysis between the studies, making difficult to perform SR meta-analysis. Regarding the risk of bias in the selected studies, did not meet all the quality criteria determined by QUADAS-2, evaluated in four domains: sample selection, index test (guide accuracy, difference between planning, guide, distortion and ROC curve), reference standard, flow and timing. The reproductive capacity of the three-dimensional maxillomandibular positioning can be considered adequate and with results similar to those offered by conventional planning. Although all techniques achieved precision results, is important to highlight that the virtual method presented lower error values than the other techniques, indicating a higher planning transfer precision.

Keywords: *Orthognathic Surgery. Guide (splint). Rapid Prototyping (3D printing. CAD/CAM. accuracy).*

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LISTA DE ABREVIATURAS E SIGLAS

<i>CAD/CAM</i>	<i>Computer Aided Design / Computer Aided Manufacturing</i>
CO	Cirurgia Ortognática
<i>ROC Curve</i>	<i>Receiver Operator Characteristic Curve</i>
<i>DICOM</i>	<i>Digital Imaging and Communications in Medicine</i>
GC	Guia Cirúrgica
<i>PRISMA</i>	<i>Preferred Reporting Items for Systematic Reviews</i>
<i>QUADAS-2</i>	<i>Quality Assessment of Diagnostic Studies-2</i>
RS	Revisão Sistemática
TC	Tomografia Computadorizada
TCFC	Tomografia Computadorizada de Feixe Cônico
TCFL	Tomografia Computadorizada de Feixe em Leque

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1. INTRODUÇÃO

Deformidades dentofaciais, assimetrias faciais, maloclusões severas, que não são possíveis de serem tratadas somente por ortodontia, além de outros problemas como apneia obstrutiva do sono podem ser resolvidas por meio da cirurgia ortognática (CO) sendo este o tratamento resolutivo¹. Essas alterações esqueléticas faciais existem em decorrência de distúrbio de desenvolvimento da relação maxilomandibular, pelo excesso ou insuficiência de crescimento ósseo. O tratamento consiste em uma intervenção cirúrgica com o intuito de atingir a oclusão dentária ideal para cada paciente (buscando o mais próximo à classe I), estética, harmonia, equilíbrio facial e baixa taxa de complicações pós-operatórias^{2, 3, 4, 5}.

Para o planejamento de cirurgias ortognáticas é necessário unir o diagnóstico clínico e imaginológico. Por meio do planejamento, é possível simular os movimentos ideais para o correto reposicionamento dos ossos gnáticos da face⁵. O principal instrumento utilizado para a transferência do plano cirúrgico pré-operatório no ato cirúrgico é pela construção de uma guia cirúrgica que tem como objetivo orientar o correto posicionamento dos maxilares na oclusão idealizada⁴.

A cirurgia pode ser reproduzida pelo método convencional, cuja fabricação da guia ocorre pelo uso de arcos faciais, aquisição de modelos de gesso que são montados em articuladores semi-ajustáveis, assim como pela análise de imagens bidimensionais, dentre elas a cefalometria e radiografias panorâmicas e fotografias extra e intra orais^{5,6}. Esse método apresenta abordagens bidimensionais, limitando quanto a avaliação tridimensional do movimento e a inviabilidade de visualização das estruturas circundantes e adjacentes, o que impossibilita a observação do cirurgião sobre as mudanças que ocorrem no esqueleto durante a cirurgia de modelo, estando associada a uma desvantagem da técnica^{6,7,8}. Pelo fato desse método envolver diversas etapas manuais, pode induzir ao desenvolvimento de erros, desde o processo de obtenção dos modelos de gesso e sua transferência para montagem no articulador até a confecção da guia cirúrgica propriamente dita⁹, assim como alterações nas fases de diagnóstico, avaliação inadequada do tipo de deformidade craniofacial que o paciente apresenta e movimentação maxilomandibular inadequada,⁶ podem acarretar em imprecisões na posição final, comprometendo o resultado pós-operatório esteticamente e funcionalmente¹⁰.

Com o intuito de tentar superar as dificuldades encontradas no tipo de planejamento descrito anteriormente, foi desenvolvida a técnica digital, por meio de softwares como

CAD/CAM (Computer-Aided Design/Computer-Aided Manufacturing), que permitiu ao cirurgião, importar dados da Tomografia Computadorizada mustislice ou tomografia computadorizada de feixe cônico (TCFC) em arquivos *DICOM (Digital Imaging and Communications in Medicine)* para um computador gerando uma representação tridimensional do esqueleto, onde, virtualmente, o cirurgião planeja as osteotomias necessárias, e por meio desses dados da Tomografia, a guia cirúrgica pode ser confeccionada por meio da fresagem por uma impressora de prototipagem rápida, gerando um modelo tridimensional (3D)^{11,12}. Essa técnica surgiu para facilitar o diagnóstico, planejamento, procedimento cirúrgico e o acompanhamento pós-cirúrgico, que apresenta superioridade em relação à quantidade de vantagens, pelo fato de permitir um planejamento 3D, a produção virtual de um crânio composto e da dentição, além da fabricação das guias cirúrgicas digitalmente, resultando em economia de tempo, além de permitir ao paciente uma visualização prévia do resultado pós-operatório e facilitar a comunicação entre o cirurgião, ortodontista e o paciente^{13, 14, 15}. Por meio dos dados da Tomografia Computadorizada (TC) a partir do qual as imagens dentárias são geradas, estão sujeitas a interferências pela presença de artefatos resultantes de implantes dentários, restaurações de amálgama frequentemente presente nos dentes dos pacientes⁷. O alto custo associado à aquisição de softwares, *scanners* e impressoras pode ser um ainda um fator limitador para os cirurgiões-dentistas adquirirem esses equipamentos em seus consultórios¹⁶.

No entanto, a acurácia do planejamento e sua reprodutibilidade cirúrgica devido ao uso da guia cirúrgica ainda não foi estimada, visto que a comparação entre os dados pré-operatórios com os resultados pós-operatórios, não permite informar e analisar a quantificação acurada da guia cirúrgica⁵. Portanto, o objetivo desta revisão sistemática é analisar qual a acurácia da guia cirúrgica no planejamento de cirurgias ortognáticas.

2. CAPÍTULO 1

What is the accuracy of the surgical guide in the planning of orthognathic surgeries? A systematic review.

Maria Pereira Eduarda Pereira Goulart, Thaís Cargnino Biegelmeier, Thiago de Oliveira Gamba

Keywords: Orthognathic surgery, Guide, Splint, Rapid prototyping, CAD/CAM, Accuracy, 3D Printing, QUADAS-2.

ABSTRACT:

Objective: To evaluate the accuracy of the surgical guide in the orthognathic surgeries planning.

Source: PubMed

Data: Studies that included patients with dentofacial deformity including anteroposterior, vertical and asymmetry problems who were undergoing an orthognathic surgery procedure were included; QUADAS-2 was used to determine the risk of bias by analysing the quality of the studies.

Study Selection: A PRISMA (flowchart) was created to show the studies selection, keywords, nomination processes, inclusion and exclusion criteria. Meta-analysis was not performed, because there was no agreement between statistical tests for accuracy analysis. Finally, seven articles were selected for qualitative synthesis.

Conclusion: All studies evaluated described high precision of the surgical guide, where the lowest error values presented were represented by the CAD/CAM technique. However the results obtained provided insufficient and heterogeneous information between the selected studies, preventing the development of a meta-analysis, which require further studies that use appropriate statistical tests, such as the ROC curve test, to define the real accuracy of the guide.

Clinical Significance: The different planning methods used to perform orthognathic surgeries presented similar results, indicating high accuracy, but the real accuracy was not analysed.

1. Introduction

Facial skeletal deformities and malocclusions have been corrected by orthognathic surgery (OS). The inadequate relationship between maxilla and mandible can be the result of excess and / or deficiency in either maxilla or mandible development or even in both jaws. Facial skeletal deformities may result in dental occlusion disorders, phonation, breathing and articular and aesthetic problems [1]. However, OS has functional and aesthetic goals of achieving class I dental occlusion, facial symmetry and proportion [2].

This surgical procedure can be simulated by the conventional method. Physical examination is first performed, which asymmetries, facial proportions and facial profile type are evaluated. Patient is classified in straight, concave or convex profile type [3]. Imaging exams as panoramic and cephalometric radiography (CR) are also required, which prediction tracings are made. Once the OS involves the jaws, it is also necessary to use plaster dental models, which are attached on a dental articulator. The surgical simulation is completed by moving the bone tracings to the desired position [3].

However, with this conventional method, it is impossible to simulate surgery in 3-dimensions. Moreover, plaster dental model does not show the surrounding bony structures. Therefore, it is impossible to visualize the skeletal changes that occur during model surgery, which is essential in the treatment of complex craniomaxillofacial deformities [3]. Other dimensional errors can occur during the steps of this conventional method, which can occur during the obtention of plaster models and/or during the mounting models in the articulator. In addition, errors may be observed on physical examination or on cephalometric analysis which may also induce technique failures [4].

On the other hand, virtual planning in OS has overcome the limitations of the conventional method. Computed tomography (CT) images in a DICOM file (*Digital Imaging and Communication in Medicine*) has been used in addition of jaw scanning, which can be done by an intraoral scanner or by the plaster cast models obtained from a prosthetic laboratory. The CT is acquired with the skull orientation in the natural head position, and the physical examination associated with clinical photographs are done [5].

Cephalometric analysis is performed using 3D planning, which consists of marking soft tissue stitches and measuring in the frontal and lateral planes (upper and lower lip thickness, maxillary plane inclination, relationship between the dental and facial midline, and mental protuberance positioning) [5]. This predictive tracing can be performed directly in the 3D

software. The virtual surgery simulation uses three-dimensional images, which can simulate osteotomies, jaw replacement, intercuspidal control, and postoperative results showed on a computer screen [5] and stored in the software [4].

The virtual surgery is reproduced in a surgical splint, which is a digitally simulated guide. It can be printed by a 3D printer or a dental milling machine which is usually made from a resinous material [4]. The surgical splint confection is based on the use of rapid prototyping. Imaging exams such as CT scan, which offers high-resolution three-dimensional images, permits a detailed visualization of bone structures and adjacent tissues, providing a better diagnosis, surgical planning and allowing patients to preview the final treatment outcome [6].

However, CT images has possible disadvantages, as imaging artefacts, once brackets and metal restorations may interfere in the visualization of important anatomical landmarks [7]. On the other hand, the virtual method does not require many laboratory steps, as required in the conventional one, and there is no need for the use of a facial arch, since it uses three-dimensional images, which allow the visualization of adjacent structures and their influence on occlusion. Because of this, the virtual planning technique is expected to be more accurate than the conventional one [4] and the use of surgical splint is expected to provide faster surgeries. This systematic literature review aims to investigate the real accuracy of the surgical guide in the planning of orthognathic surgeries that have been performed worldwide.

2. Materials and methods

This systematic review (SR) was reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist.

2.1 Problem specification

This SR was developed through selection of studies that presented results capable of informing and proving the following question: What is the accuracy of the surgical guide in the planning of orthognathic surgeries?

2.2 Information sources and search

The selection of scientific articles was conducted in PUBMED database (Medline) from August 2018 to October 2019. The EndNote Basic® software (Thompson Reuters, New York, NY) was used, and duplicated hits were removed. Appropriate truncation and word combinations

were selected with the support of a health sciences librarian and were adapted for the database. The keywords applied in the research were: Orthognathic Surgery, Guide (splint), Rapyd Prototype (3D printing, CAD/CAM, Accuracy).

2.3 Eligibility Criteria

Inclusion criteria: Studies in which the primary aim was to evaluate the accuracy of the surgical guide for orthognathic surgeries planning using assessments in CBCT in humans (in vivo and cadavers) were considered. Studies that have patients diagnosed with maxillofacial skeletal deformities as sample were selected. Studies published in English only. No date and year filters were used to select the articles.

Exclusion Criteria: Articles characterized as narrative reviews, systematic reviews, expert opinions, letters, case reports, book chapters, and conference abstracts. Studies regarding the use of surgical guide for other dental procedures such as dental implants and endodontic treatment. In vitro studies were excluded, as well as the studies that evaluated the presence of patients diagnosed with malignant lesions, trauma to facial bones, congenital malformations affecting facial development, patients diagnosed with obstructive sleep apnea and temporomandibular joint disorder and finally studies that did not mention the use of the surgical guide as a tool for orthognathic surgical planning.

2.4 Publication retrieval

A two-phase selection of the articles was conducted. In phase 1, two authors (MEG and TCB) independently reviewed the titles and abstracts of all references. Any articles that did not appear to meet the inclusion criteria were excluded of this SR. In phase 2, full texts were independently reviewed by the same authors. They selected the articles that met the previously determined inclusion and exclusion criteria. Any disagreement was resolved by means of discussion. When mutual agreement between the reviewers was not accomplished, a third author (TOG) became involved to make a final decision. The articles selected should mention all the inclusion criteria described previously.

Population: Patients with dentofacial deformity including anteroposterior, vertical and asymmetry problems who underwent an orthognathic surgery.

Study design: The selected studies were experimental, prospective observational, prospective randomized trial, and pilot study.

Methods: Studies that assessed the accuracy of the surgical guide to be applied in orthognathic surgery in human patients or even in cadavers. All studies comparing values between pre and post orthognathic surgery planning.

Index test: Articles that presented the possibility of clinical application in patients undergoing orthognathic surgery and protocols can be reproduced in patients with indication for this surgery due to skeletal alterations.

Reference standard: Accuracy values between the measures or angles obtained from the initial planning and the results of the orthognathic surgery were analysed in each article.

Result: Statistical tests were assessed in each article to calculate the accuracy and / or the difference between the planning and final position, after orthognathic surgery, which were: Bland-Altman tests, Wilcoxon rank sum test, Wilcoxon test of paired samples, unpaired Student's t-test, two-tailed test, Fisher's exact test, Procrustes record, and Euclidean distance between two sets of coordinate unpaired paired methods parametric and absolute differences between the reference points.

Language: English

2.5 Quality assessment and data synthesis

Regarding the quality assessment of the selected articles, three authors of the present study (MEG, TCB and TOG) used QUADAS 2 tool (Quality Assessment of Diagnostic Accuracy Studies-2) and assessed the risk of bias of the articles according to the following criteria: (low, high or unclear) in four domains: (I) sample selection, (II) index test, (III) Reference standard and (IV) flow and timing. The domains I, II, and III was re-assessed to investigate their applicability. For such analysis a QUADAS 2 protocol (Table 3) was adapted according to the problem specification [8].

A final evaluation was made to assess the quality of the studies, prognostic questions were created and adapted according to the guidelines of systematic reviews. Any disagreements in the analysis of the answers were determined with consensus among the three evaluators. The two reviewers (MEG, TCB) extracted and tabulated the characteristics of each study; subsequently a third reviewer (TOG) confirmed the veracity of the data.

2.6 Risk of bias in individual studies

The analysis of the quality of the articles was evaluated by QUADAS 2. Two authors of the present study (MEG, TCB), independently of this tool, classified the selected articles

according to the answers, yes, no or unclear. Possible disagreements were defined by a third evaluator (TOG), also author of the study.

2.7 Summary Measures

The primary outcome of the selection of articles was to obtain the accuracy of the SG in the planning of OS or the comparison between the final surgical outcome in relation to the initial planning. In addition, any measure aimed at comparing the accuracy of the initial planning with the final one was analysed. As well as all its variables and values of the statistical tests shown in the studies were evaluated. In addition, possible distortion values of the surgical guides were investigated.

2.8 Risk of Bias Across Studies

Through the planning of CT in humans (in vivo or cadavers), the result of the surgery compared to the initial planning was analysed. The heterogeneity of the different methodologies of the different studies was compared with respect to their measurement evaluated, software used, statistics and risk of bias.

3. Results

3.1 Study selection

After the references initially identified by the abstracts and titles, 53 references remained after phase 1 of the selection process. After phase 2 of the selection process, the final included sample was 7 studies. Details about the selection process can be found in Figure 1. Due to the disagreement of statistical tests for accuracy analysis, no meta-analysis was performed. Finally, seven articles were included for qualitative synthesis.

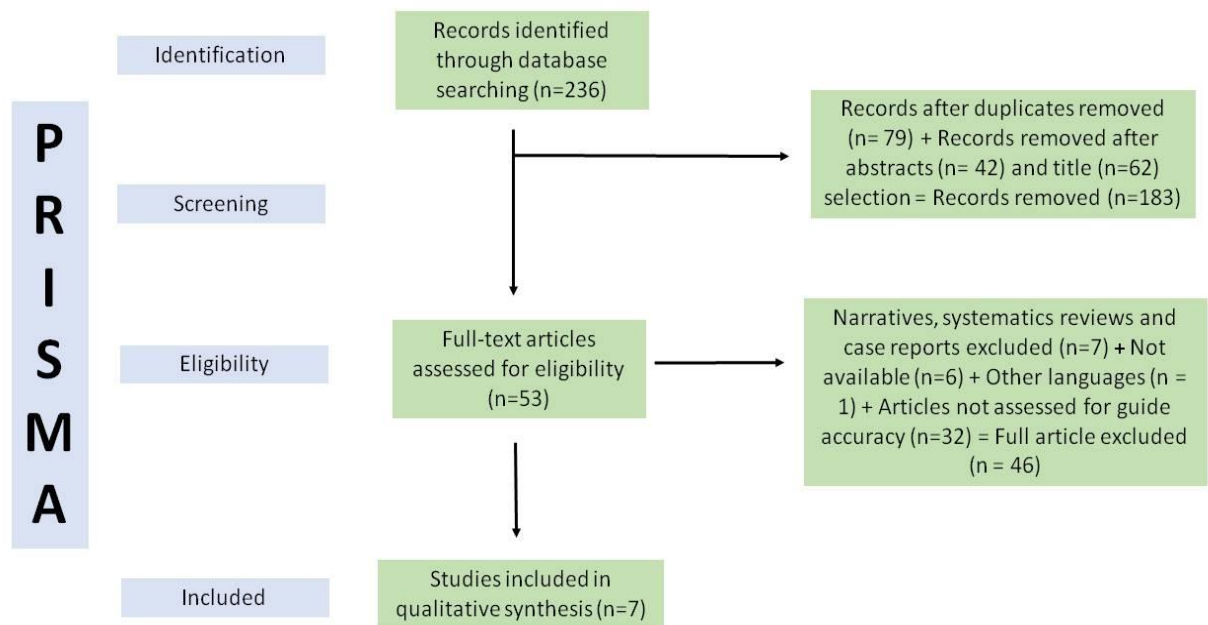


Figura 1. Flow diagram according to the PRISMA Statement presenting study selection process with number publications retrieved included and excluded for systematic review about the accuracy of surgical guide.

3.2 Study characteristics

Seven studies were selected, four in Europe (two in Germany, one in Belgium and one in Switzerland) [7,9,10,11], one in North America (Canada) [12] and two in Asia (China) [13,14]. The articles were published in English, between 2013 to 2018.

Regarding the types of studies, one experimental study, four observational prospectives, one randomized prospective and one pilot study were selected. Three studies evaluated the accuracy of splints or occlusal wafers generated by CAD / CAM for orthognathic surgery, one study developed and validated a new CAD / CAM model, another compared versatility and accuracy of CAD / CAM products, analysing surgical operations, intraoperative navigation and intermaxillary occlusal operations. In addition, a study compared the accuracy of the defined angles by conventional and virtual surgical planning, through analysis of the accuracy, surgical time and the costs of virtual planning. Finally, one study printed surgical guides based on orthognathic surgery 3D planning and did a validation of accurate estimates in a large-scale comparative study of conventional analogous configuration in terms of absolute errors.

On the other hand, in the analysis of the sample size, studies with 10 human cadaver heads and 6, 10, 20, 21, 23 and 28 patients were observed. The analysis regarding surgical procedures in each article were: Le Fort I osteotomy, maxillary segmentation, bimaxillary surgery, Le Fort I high osteotomy, Le Fort I low – with an additional genioplasty; Bimaxillary orthognathic

surgery; Le Fort I; maxillary and mandibular combined osteotomy; maxillary advancement; impaction previously; impaction later; disimpaction previously; bilateral sagittal osteotomy surgery; bimaxillary surgery (and Le Fort I). A summary of the descriptive characteristics of the included articles is provided in Table 1.

TABLE 1 Descriptive characteristics of the included articles

Author/ Year of publication	Country	Type of study	Aim	Sample	Surgical procedure
Schouman et al. 2015	Switzerland (Geneva)	Experimental study	To evaluate the accuracy of CAD/CAM splints in orthognathic surgery by comparing planned surgery and post-operative 3D images.	10 human cadaver heads	Le Fort I osteotomy and maxillary segmentation.
Li et al. 2013	China (Shanghai)	Prospective observational study	To develop and validate a new CAD/CAM template for orthognathic surgery.	6 patients	Bimaxillary Surgery (without maxillary segmentation).
Zinser et al. 2013	Germany (Cologne)	Prospective observational study	To compare the usefulness and precision of innovative computer-aided designed and computer-aided manufactured (CAD/CAM) surgical splints, intraoperative navigation, and 'conventional' intermaxillary occlusal splints for surgical transfer of virtual orthognathic planning.	Total of 28 patients 8 patients - Approach A (CAD/CAM splints) 10 patients - Approach B (navigation); 10 patients - Approach (intermaxilla ry occlusal splints).	All patients were undergoing bimaxillary surgery: high Le Fort I osteotomy - 6 patients; low Le Fort I - 22 patients; 4 patients - received an additional genioplasty.
Schneider et al. 2018	Germany	Prospective randomized trial	To assess the accuracy of determined angles, when comparing conventional and virtual surgical planning, and to assess the accuracy of splints, the time required for surgery and the costs of the virtual versus conventional planning in bimaxillary orthognathic surgery.	21 patients: 9 using virtual planning; 12 conventional planning.	Bimaxillary orthognathic surgery: Le Fort I osteotomy of the maxilla and bilateral sagittal split osteotomy of the mandible.
Shqaidef et al. 2014	China (Hong Kong)	Pilot study	To assess the accuracy of rapid prototype final orthognathic occlusal wafers produced by CAD/CAM software, and to compare them with conventional acrylic wafers produced by plaster model.	10 patients	Information Not Available

Bouchard and Landry. 2013	Canada (Québec)	Prospective study	To assess the precision of surgical splints produced by model surgery and by an external reference guide to position the maxilla correctly during orthognathic surgery.	23 patients: 19 females and 4 males	7 patients = Le Fort I; 16 patients = combined maxillary and mandibular osteotomy; 20 patients = advanced the maxilla; 9 patients = anteriorly impacted; 13 patients = posteriorly impacted; 11 patients = anteriorly disimpacted.
Shaheen et al. 2017	Belgium (Leuven)	Prospective observational study	To show how to design and printing final digital occlusal splints based on 3D planning in orthognathic surgery, and to validate the accuracy of final digital splints in a larger scale study by comparing the printed splints to the conventional analogue ones in terms of absolute errors.	20 patients	14 bilateral sagittal split osteotomy surgery; 6 bimaxillary surgery (and Le Fort I).

In addition, Table 2 describes the articles, CT, scanners, type of guide, time of surgery and the accuracy results, that were:

- 1- The error related to the guide was less than 2 mm, confirming an acceptable accuracy of the digital guides.
- 2- The mean absolute maxillary position error was less than 1 mm, providing clinically acceptable accuracy in maxillary repositioning and the maximum error was well controlled at 1.7 mm. The absolute errors between the planned and actual maxillary positions were 0.7 mm axially, 0.6 mm horizontally and 0.8 mm vertically.
- 3- Precision for maxillary planning transfer: <0.23mm for CAD / CAM guides; <0.61mm for waferless navigation; <1.1 mm for classic intermaxillary occlusal guides.
- 4- In 58.3% of the cases, the conventional guides presented inaccuracy problems (27.7-84.4%) and in the planned virtual guides 0% presented this lack of precision.
- 5- Error in prototyped guide is up to 1.73 mm, but if this results from the rapid prototyping process present in the virtual digital Splint needs further investigation.
- 6- The average difference between planned and executed movement in any direction was 0.1 mm.
- 7- The maximum error was 0.88 mm and the average error was 0.4 mm (which is smaller than the clinically relevant error margin of 0.5 mm).

TABLE 2 Particular characteristics of the included articles

Article	Tomography	Software	Scanner	Splint	Time of surgical operation	Results (accuracy)	Additional information
Schouman et al. 2015	FBCT: slice thickness: 1mm; Pixel: 512	SimPlant OMS Standalone 14.0 MATLAB 7.11 R Development Core Team	Siemens Sensation 64 Dental 3D Scanner D-200	Final occlusal splint.	Information Not Available	The error related to the splint was less than 2mm, confirming an acceptable accuracy of digital splints.	Factors that could have impact on the overall accuracy: osteosyntheses (it can influence in the final position of the maxilla), images of metal artefacts related to the high material density, errors related to the virtual mandibular autorotation, timing of post-operative imaging.
Li et al. 2013	FBCT: axial slice thickness: 1,25mm	SurgiCase CMF 5.0 Unigraphics NX 7.5 (Siemens PLM Software) Statistical Package for the Social Sciences	GE Medical System Lightspeed	Osteotomy splint (intermediate). Repositioning splint (occlusal/final).	Operatory average time: 160 minutes (virtual surgical planning - CAD/CAM).	The mean absolute error of the maxillary position was less than 1 mm and the maximum error was well-controlled within 1.7mm. Absolute errors between the planned and actual maxillary positions were 0.7mm axially, 0.6mm horizontally, and 0.8mm vertically.	Information Not Available
Zinser et al. 2013	CBCT (GALILEOS Comfort, Sirona) CT: slice thickness: 1-1,25mm	I-plan Brainlab SimPlant Crystal Materialize	Information Not Available	CAD/CAM (3 splints: definition of landmarks on the skull, intraoperative transformation of the virtual position of the maxilla	Classic intermaxillary occlusal splints = 4,3 hours; CAD/CAM splints = increased in 20 minutes; Navigation's	Precision for the maxillary planning transfer: <0,23mm for CAD/CAM splints; <0,61mm for waferless navigation; <1,1 mm for classic intermaxillary occlusal splints.	Information Not Available

				and final occlusion and establishing condylar concentricity); Navigation (waferless) Classic Intermaxillary occlusal splints - 1 splint (Final occlusal splint).	method = increased in 50 minutes.		
Schneider et al. 2018	CBCT	Dolphin 3D imaging; CAD	Information Not Available	Three splints: including centric, intermediate, and target splint.	162 minutes in virtual planning; 202 minutes in conventional planning, reduction the time in 31%.	In 58,3% of the cases, the conventional splints 27,7 -84,4% and in virtual planned splints 0% had this lack of accuracy.	Information Not Available
Shqaidef et al. 2014	Information not available about the kind of tomography	CAD/CAM software VRMesh ; - LightYear (3D systems) - MATLAB; - DiView (Dimensional Imaging)	NextEngine desktop 3-dimensional	Final occlusal splint.	Information Not Available	Error in the rapid prototyped wafer of up to 1,73mm. However, if these results from the rapid prototyping process are present in the virtual digital wafer, it needs further investigation.	Information Not Available
Bouchard and Landry. 2013	Information not available about the kind of tomography	Information Not Available	Information Not Available	Intermediate and; final occlusal splint;	Information Not Available	The mean difference between planned and executed movement for any given direction was 0.1 mm.	Based on these results, it appears that an external reference point combined with surgical splints is a reliable intraoperative method to position the maxilla

							properly after a Le Fort I osteotomy
Shaheen et al. 2017	CBCT (128- slice multi- slice spiral, slice thickness 0,75mm)	PROPLA N version 2.1 -Amira -3-matic (version Medical 10)	Activity 885- SmartOp tics	Intermediat e and final occlusal splint.	Informati on Not Available	The error maximum was 0.88 mm and the mean error was 0.4 mm (is lower than the clinically relevant error margin of 0,5mm).	Information Not Available

3.3 Additional informations

Some factors are important to report and can be directly related to the accuracy of the different studies selected. The main factor is that accuracy indicates the proximity of a measurement value with the standard reference. However, in fact, the selected studies presented precision rather than accuracy. Moreover, the presence of metal artefacts from restorations or plates may alter the measurement variation during the registration and fusion process. As well, possible errors resulting from the movement of maxillary and mandible rotation in planning may alter or hinder the true accuracy value. Finally, a centric relationship pattern is essential to decrease the chance of error during the acquisition of Cone-Beam Computed Tomography (CBCT) images and in the planning of orthognathic surgeries.

3.4 Risk of bias within studies

In the risk of bias analysis of the studies, no study met all the methodological quality criteria according to QUADAS-2 (Table 3). For each study, item 1 of the QUADAS criteria -2 (Domain 1- Sample selection) was classified as “no”, since all patients selected in the sample had indication for orthognathic surgery, except for two studies that the sample selection was not clear. Regarding domain 2 (Index Test), which require the assessment of the accuracy found in each study, it was observed that the accuracy of the studies was not correctly found, since no study correlated possible guide distortion and no study correlated possible guide distortion and no study used the most appropriate statistical test for accuracy analysis, which is the ROC curve (Receiver Operator Characteristic).

On the other hand, five studies compared the difference between orthognathic surgery planning and the outcome, which represent a low risk of bias. Only one study was not clear and the other did not evaluate this criterio. When assessed in relation to the reference standard, as a domain of risk of bias, a high risk of bias was evidenced in all studies, since the accuracy analysis was done in five studies comparing the postoperative outcome to the surgical planning.

It does not correspond the best way to assess the accuracy result. It is recommended the use of ROC curve. Finally, in the analysis of the domain of flow and time bias risk, a low risk of bias was observed in all studies, since there were appropriate intervals between the comparative patterns of planning prior to the result.

TABLE 3. Risco de viés de acordo com QUADAS-2 para domínios: seleção da amostra, teste de índice, padrão de referência, fluxo e tempo avaliados.

STUDY	DOMAINS						
	Sample Selection	Index Test				Reference Standard	Flow and Timing
		Guide accuracy	Differences between Planning	Guide distortion	Curva ROC		
Schouman et al. 2015							
Li et al. 2013							
Zinser et al. 2013							
Schneider et al. 2018							
Shqaidef et al. 2014							
Bouchard and Landry 2013							
Shaheen et al. 2017							
 Low risk  High risk  Unclear risk							

4. Discussion

Different dental professionals around the world have been introducing rapid prototyping as a possible method for OS. This procedure recommends the use of a virtual planning for the preparation of guides or splints that can help the oral surgeons to manage the correct position of the maxilla and / or mandible during the patient's surgery. This systematic review aims to find through a selection of articles using exclusion and inclusion criteria studies that identify the true accuracy of surgical guides and virtual planning in relation to the final postoperative outcome [3, 9].

After analysis of the PRISMA protocol, seven articles from the Europe, North America and Asia were selected. Europe and North America has countries that virtual technologies are commonly used, and the digital systems are constantly upgraded. However, two of the selected studies are from China, which is a country that has invested in new technologies in order to compete with developed countries. When developing countries invest in technologies, as tools that can improve the results of OS, it allows dental surgeons to acquire a new option for orthognathic surgery treatment planning [13, 14].

The study sample size includes 118 cases evaluated (Table 1). In the article published by ZINSER et al. (2013), 8 patients were submitted to a virtual planning, 10 patients were submitted to the navigation technique and 8 patients were submitted to the conventional method using occlusal intermaxillary guides [7]. As shown by SCHNEIDER et al. (2018), virtual surgical planning was used in 9 patients, while conventional method was used in 12 patients [9]. Regarding the distribution between male and female, according to BOUCHARD and LANDRY (2013), in their study, 19 patients were female and 4 were male [12]. Studies with cadavers or even with only patient's images are equivalent in relation to the sample size, and they have an average of 16.85 years [12].

The accuracy of the surgical planning compared with the postoperative results found in the present sample had error values of less than 2mm, which are clinically acceptable. SCHOUMAN et al. (2015), affirm that movements less than 2mm are undetectable to the naked eye or even cannot be identified by patients [11]. The accuracy, which suggests the proximity of a measurement value to a standard reference, was not assessed by the selected studies. It was evaluated the precision. We believe that it occurred because the authors did not use the correct statistical test, such as ROC curve. It can be solved whether the word 'accuracy' be changed for the word 'precision' or applying a different methodology using the ROC curve statistical test to analyse the proposed results [11].

Three of the seven selected studies assessed the surgical time required to perform guided surgery with different types of planning. According to ZINSER et al. (2013), orthognathic surgery performed by the virtual method had a longer duration compared to the conventional one, which presented an average of 4.3 hours of surgery, increasing by 20 minutes using CAD/CAM guides and 50 minutes using the navigation method [7]. On the other side, SCHNEIDER et al. (2013) reported a decrease of 31% of time in virtual planning (162 minutes) compared to conventional planning (202 minutes) [9]. LI et al. (2013) highlighted an average operating time of 160 minutes when planning surgery is virtually [13]. Independently of the time of surgical planning, it is important to emphasize that the use of guided surgeries can offer

less risk of intraoperative complications and consequently better postoperative outcomes. In addition, more the professional has experience with the virtual planning and 3D software, more the time of planning will be gradually decreased [13].

The knowledge in three-dimensional imaging exams, such as CT, is important to achieve better performances in orthognathic surgery planning. SCHOUMAN et al. (2015) and LI et al. (2013) mentioned the use of fan beam computed tomography (FBCT) in their studies [11,13]. ZINSER et al. (2013), SCHNEIDER et al. (2018) and SHAHEEN et al. (2017) reported cone beam computed tomography (CBCT) as the imaging exam of choice [7,9,10]. The other authors did not report the kind of computed tomography used in their studies. The authors of the present systematic review suggest the use of CBCT for the orthognathic surgery planning because the radiation dose used to acquire the volumes are lower than the radiation dose offer by FBCT, which reduces the chance of stochastic effect in patients [7, 9, 10].

The purpose of the surgical guides is to conduct the professional to achieve the previews position of the jaws planned before the OS. SCHOUMAN et al. (2015) used an intermediate type guide to perform the procedures, while LI et al. (2013) employed a final occlusal splint, also reported by SHQAIDEF et al. (2014) and SHAHEEN et al. (2017) [11, 13, 14, 10]. According to ZINSER et al. (2013), three surgical guides were applied using the CAD / CAM system, including a final occlusal guide, condyle establishment (center guide) and a reference point of the skull. In addition, surgical guide was not used in navigation surgery, and in the conventional method, only the final occlusal guide was used [7]. SCHNEIDER et al. (2018) described the use of centric, intermediate and final occlusal guide [9]. The present authors observed a wide range of techniques for virtual orthognathic surgery planning. However, independently of the technique, we believe that the centralization of the median sagittal plane of the patient is essential, mainly when patients present facial asymmetries. It can help to standard the results and obtain the accuracy between what was planned and what achieved after the OS [9].

The risk of bias based on QUADAS-2 (Table 3) investigated the methodological quality of the articles selected for this systematic review. According to the previously criteria of sample selection, none of the studies matched all domains. Only two studies were not clear in affirm the indications of orthognathic surgeries evaluated. Regarding accuracy assessment of the surgical guide, none of the studies determined whether any distortion in the surgical guide occurred and did not even used the appropriated statistical test (ROC curve), which allows to define the true accuracy.

Regarding the reference standard, all studies presented a high risk of bias because they compared preoperative planning with the results obtained. However, we believe that accuracy cannot be analysed in this way. Most of the selected studies (n = 5) compared the pre and postoperative values, obtaining low risk of bias for different planning types. Only one study did not present this comparison.

In relation of the time and flow of the surgery, all studies demonstrated low risk of bias, once there were appropriate intervals since the virtual planning to the surgery outcomes [14].

5. Conclusion

The selected articles provided insufficient and heterogeneous information, which explains the lack of meta-analysis in the present study. The authors believe that further investigations are needed, using appropriate statistical tests to obtain the accuracy of the surgical guide. The use of ROC curve allows a better methodological quality, which could permit to better answer the question proposed by this systematic review.

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3. CONSIDERAÇÕES FINAIS

Ao idealizar a cirurgia tridimensionalmente no que se refere à capacidade de reproduzir o reposicionamento maxilo-mandibular planejado, pode ser considerada igual e aceitável quando comparado ao planejamento convencional. A fabricação de guias cirúrgicas por meio da prototipagem rápida para utilização em cirurgias ortognáticas apresentam vantagens em relação à técnica clássica. No entanto, com os resultados adquiridos referentes a acurácia da guia são insuficientes para determinar se há alguma superioridade do planejamento digital em relação ao convencional. Há a necessidade da realização de mais estudos *in vitro* e *in vivo*, que analisem, individualmente, as diferentes etapas da confecção da guia para identificação e posterior aprimoramento de seu valor real de acurácia.

Portanto, diante dos estudos analisados, todos apresentaram elevada precisão em relação aos resultados pós-cirúrgicos, para ambos os tipos de planejamentos referente à CO, sendo mensurados valores de erro inferiores a 2mm de acordo com as movimentações planejadas, tornando essas mínimas alterações, como sendo clinicamente aceitáveis. Embora todas as técnicas obtiveram resultados altamente precisos, é válido ressaltar que os valores referentes às distorções ao método virtual representado pelo sistema *CAD/CAM*, mostraram-se ligeiramente inferiores às demais técnicas, indicando assim uma maior precisão de transferência de planejamento.

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