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Review

# Accuracy of orthognathic surgery with customized titanium plates – Systematic review

C.E. Figueiredo [a], L.R. Paranhos [b,*], R.P. da Silva [a], Á.M. Herval [b], C. Blumenberg [c], D. Zanetta-Barbosa [a]

[a] Department of Oral and Maxillofacial Surgery, School of Dentistry, Federal University of Uberlândia, Uberlândia, Brazil
[b] Department of Preventive and Community Dentistry, School of Dentistry, Federal University of Uberlândia, Uberlândia, Brazil
[c] Centre for Epidemiological Research, International Centre for Equity in Health, Federal University of Pelotas, Pelotas, Brazil

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ABSTRACT

This systematic review aimed to evaluate the accuracy of customized titanium plates in orthognathic surgery compared to standard outcome in virtual surgical planning. PRISMA and JBI guidelines were followed. Research protocol was registered in PROSPERO. Six databases and two gray literature repositories were used as sources of research articles. Descriptive clinical studies, that performed orthognathic surgery using custom titanium plates, were included. Risk of bias 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, seven met the eligibility criteria and were included. The studies were published between 2015 and 2019. Most of the studies (57%) had a low risk of bias, while one had a high risk of bias. Total sample included 74 patients with 63 bimaxillary surgeries and 11 unimaxillary surgeries. All studies showed acceptable accuracy within previously established clinical parameters. Although the eligible articles assessed the accuracy of the orthognathic surgery with respect to virtual planning, the wide variability of evaluation methodologies made it impossible to calculate a combined accuracy measure. It was not possible to perform a meta-analysis, so a pragmatic recommendation on the use of these plates is not possible.



## 1. Introduction

The search for accuracy surgical planning and controlled outcomes in orthognathic surgery has been a constant challenge since its inception in the 19th century [1,2]. Several surgical techniques have been explored to achieve planned results prior to surgery [3–8]. One of the most used in the past was a handmade interocclusal splint made after plaster model surgery. Recently, 3D virtual surgical planning has gained ground due to better control and responses of bone movements [2,9–11]. 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 [10,12–14].

State of the art planning and performing of orthognathic surgery is closely linked to computer assistance. Several techniques are used to increase surgical accuracy in relation to virtual planning, including surgical guided navigation [3], CAD-CAM repositioning guides [4], and more recently, customized titanium plates (CTP) [2,7,9,15–21]. CTP are made specific for each surgery, and are based on surgical guide-oriented osteotomies, capable of repositioning bone segments without an occlusal splint [2,15–17]. Some advantages are correct and accurate osteotomy and easy bone repositioning [15,17], reduced surgical time, and there is no need to perform intermaxillary fixation or intraoperative measures [9,16]. Some disadvantages are that longer time is spent on the whole process and the higher final cost [16]. There are studies that have tested customized plates by assessing the accuracy of the surgical outcome compared to the virtual planning and presented good results [2,9,15–19]. Also, a systematic review on the computer-assisted techniques has been published, but not specific on CTP, and, with a small sample of selected studies on the subject [22].

This systematic review aims to answer the question: Do patients submitted to orthognathic surgery with customized titanium plates present surgical outcomes of the repositioned bone segments similar to the virtual orthognathic surgical planning?

* Corresponding author at: School of Dentistry, Federal University of Uberlândia, Pará avenue, 1720, 2G Block, Umuarama, 38400902 Uberlândia/MG, Brazil.
*E-mail address:* paranhos.lrp@gmail.com (L.R. Paranhos).

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## 2. Methodology

### 2.1. Protocol and registration

This systematic review was performed according to the list of Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) recommendations [23] and the JBI guidelines [24]. The systematic review protocol was registered in the PROSPERO database under CRD42019133769.

### 2.2. Study design and eligibility criteria

The present study aims to answer the PEO question: "Do patients submitted to orthognathic surgery (population) with customized titanium plates (exposure) present surgical outcomes of the repositioned bone segments similar to the virtual orthognathic surgical planning (outcome)?"

In this study, VSP will represent the method to verify the accuracy, as the standard values to be matched.

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. The study population was composed of all publication on OGS using CTP until 31 March 2019. There was no restriction of year, language, or publication status.

The exclusion criteria were as follows:

- studies not related to the objective;
- studies that did not use customized titanium plates;
- studies with no CT/CBCT analysis after the surgery;
- in vitro studies;
- review articles, letters to the editor/editorials, personal opinions, books/book chapters, textbooks, conference abstracts.

### 2.3. Sources of information and search

A computerized systematic search was conducted on 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". Furthermore, the reference lists of the selected articles were hand-searched for any additional references that might have been missed in the electronic searches. 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.

### 2.4. 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 $\geq 0.81$), two eligibility reviewers (CEF and RPS) 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 (CEF and RPS) 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. The studies were rejected in this phase for not fulfilling the inclusion criteria or for fulfilling the exclusion criteria.

Any disagreement between the reviewers was solved through discussions, and if both reviewers still disagreed, a third (LRP) was consulted to make a final decision.

### 2.5. Process of data collection and extraction

After the selection, the studies were analysed, and two reviewers (CEF and AMH) 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, cutting guide material, plate design and manufacturing method, 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 in which information was extracted jointly from an eligible study.

### 2.6. 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 [25] for case series. Two authors (AMH and DZB) systematically assessed each domain and independently estimated the potential risk of bias for each study, as recommended by the PRISMA statement [23].

The potential risk of bias for each study was categorized according to the percentage of positive answers to the ten 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.

### 2.7. Summary results

The main outcome evaluated was the surgical accuracy, defined as the difference between the postoperative CT (outcome) and the virtual planning (comparative). The more accurate the postoperative outcome, the lower the accuracy value. This difference was shown in two ways: the mean difference of bone area and/or position of dental landmarks (in millimetres) or the percentage difference in the bone area within 1 or 2 mm.

## 3. Results

### 3.1. 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, 9897 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

**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 "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') | 936 |
| 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 | |

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 analyse images after surgery [26,27], and one was not considered, as it did not use prefabricated customized miniplates but prebent miniplates [28].

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

### *3.2. Characteristics of eligible studies*

All seven eligible articles were clinical descriptive studies, prospective [2,9,15–17] or retrospective [18,19], case series or cases reports (more than 2 cases). The studies were published between 2015 and 2019 and were performed in upper-middle- and high-income countries: Italy [15], The Netherlands [19], Spain [2,9], Germany [16], China [17] and South Korea [18]. 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 [2,9,15–18] or a direct oral scan of the dentition [19] were made before the VSP, and at least one CT scan was performed after the surgery. Two studies made CBCT scans [15,18], and five studies made helicoidal CT scans [2,9,16,17,19] to create virtual planning. All studies evaluated the accuracy of orthognathic surgery compared to the virtual planning by postoperative CT analysis. To compare the CTs, all studies used the 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 analysed the differences between surgically moved bone surfaces [2,9,15] or only the dentition differences [19]. 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 [16]. Two studies used dental and bone landmarks to evaluate dental and bone accuracy [17,18]. 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 [18]. The other study used incisor points, first molar mesiobuccal cusps, pogonions, bilateral gonions, bilateral condyle poles and coronoids

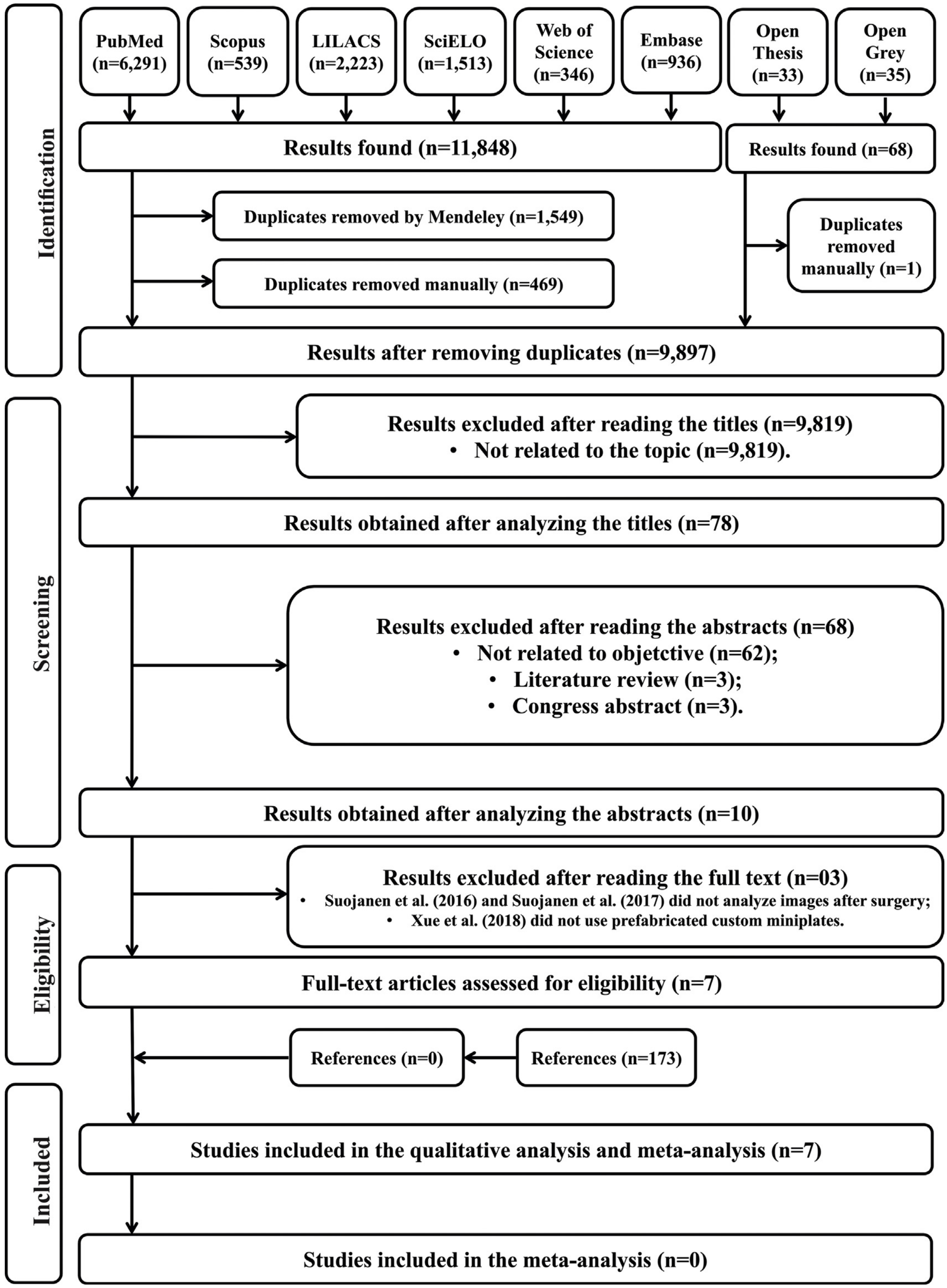


**Fig. 1.** Flow chart – search, identification, inclusion, and exclusion of articles.

[17]. Only one article [16] analysed the superimposition accuracy, 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.

Two studies used a 2.0 screw system [15,17], two used a 1.5 screw system [16,19], and the other three [2,9,18] did not mention which type of screw was used. More details about the characteristics of the studies are shown in Table 2.

### 3.3. Risk of individual bias of the studies

Four eligible studies presented low risk of bias [2,16–18], two studies presented moderate risk [9,15] and only one study presented high risk of bias [19]. Table 3 shows detailed information on the questions considered to assess the risk of bias of the studies.

**Table 2**
Summary of the main characteristics of the eligible studies.

| Author, year | Country | Sample (*n*) | Average age (SD) | Problem | Surgery | Times of CT postoperative | VSP software | Plate design Software | Cutting guides material | Plate design and manufacturing method | Titanium alloy |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Mazzoni et al. [15] | Italy | 10 (5♀ 5♂) | + | 1 Class II<br>9 Class III<br>(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. [2] | Spain | 6 (5♀ 1♂) | 34.3 (9,9) | 4 OSA<br>1 Class II<br>1 Class III+ asymmetry | 5 Double Jaw<br>1 Single Jaw<br>(2 chins) | 1 month | SimPlant Pro OMS (Materialise, Leuven, Belgium) | PowerShape (Delcam, Birmingham, UK) | Resin | 2 plates 2 by 2 system<br>1 simple plate at SRO (DMLS) | Grade 5 Titanium |
| Kraeima et al. [19] | 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. [17] | China | 10 (5♀ 5♂) | 22 | 2 Class II<br>8 Class III<br>(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<br>1 simple plate ate SRO (DMLS) | Ti6AIV4 |
| Heufelder et al. [16] | Germany | 22 (+♀ +♂) | 25,9 | 2 Class I<br>18 Class III<br>(11 asymmetry)<br>2 Class II<br>(1 asymmetry) | 22 Double Jaw<br>(PSI only in Maxilla) | + | ProPlan CMF (Materialise, Leuven, Belgium) | + | Titanium | 1 plate 4 by 4 system (DMLS) | + |
| Brunso et al. [9] | Spain | 10 (1♀ 9♂) | 40.3(9.2) | 8 OSA<br>2 Class II | 10 Double Jaw<br>(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 system (DMLS) | Grade II Commercially Pure Titanium |
| Kim et al. [18] | South Korea | 13 (7♀ 6♂) | 22.9 (3.3) | 10 Class III<br>3 Class I<br>All asymmetric | 13 Double Jaw<br>(4 chins) | 3 days<br>4 months<br>1 year | FaceGide (Mega-Gen Co., Daegu, Korea) | FaceGide (Mega-Gen Co., Daegu, Korea) | Resin | 4 plates 4 by 4 system<br>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.

| Authors | Q1 | Q2 | Q3 | Q4 | Q5 | Q6 | Q7 | Q8 | Q9 | Q10 | % Yes | Risk |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Brunso et al. [2] | √ | √ | √ | √ | -- | √ | √ | √ | NA | -- | 77,78 | Low |
| Brunso et al. [9] | √ | √ | √ | -- | -- | √ | √ | √ | NA | -- | 66,67 | Moderate |
| Heufelder et al. [16] | √ | √ | √ | √ | √ | √ | √ | √ | NA | √ | 88,89 | Low |
| Kim et al. [18] | √ | √ | √ | -- | √ | √ | √ | √ | NA | √ | 88,89 | Low |
| Kraeima et al. [19] | -- | √ | √ | -- | -- | √ | √ | -- | NA | -- | 44,44 | High |
| Li et al. [17] | √ | √ | √ | -- | √ | √ | √ | √ | NA | √ | 88,89 | Low |
| Mazzoni et al. [15] | -- | √ | √ | -- | -- | √ | √ | √ | 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.

Question 9 was considered "Not Applicable" for all studies, as the outcome assessed in our study (customized titanium plate accuracy) is not influenced by geographic region or population.

### 3.4. Specific results of the eligible studies

Accuracy, defined as the difference values between postoperative CT and virtual planning outcomes, for each patient and the mean values are shown in Table 4. Three studies showed the percentage of bone surface within an acceptable error for under- or overcorrection [2,9,15]. Two studies considered errors lower than 1 mm acceptable [2,9]. They reached 71.2% [9] and 68.1% of the postoperative bone surface within 1 mm for the maxilla [2], and 75.3% for the mandible [2]. Another study considered errors smaller than 2 mm as acceptable, reaching 92.7% for the maxilla [15]. Six studies measured the accuracy 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 accuracy by the different studies [2,15–19].

Other specific measurements were found in some articles. As primary outcomes, Li et al. [17] measured the differences in the mediolateral, anteroposterior and superoinferior axes for both dental arches, the mandibular body and each proximal segment (small table inside 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) [17]. Heufelder et al. [16] 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) [16]. Due to the heterogeneity of the methods and results of the selected studies, it was not possible to perform a meta-analysis.

## 4. Discussion

This systematic review aimed to evaluate the accuracy promoted by CTP in OGS compared to the outcome expected after VSP. The hypothesis was that OGS with CTP would promote a high accuracy to the VSP.

Regarding the methodologies, it should be noted that there were differences in the methods used to acquire the preoperative images for virtual planning. Two used CBCT [15,18] presenting results of mean difference of 0.24 mm [15] and 1.01 [18] for bone surface, and 0.67 [18] for dental landmarks. Five studies used helicoidal method (CT) [2,9,16,17,19]. They showed a mean difference of 1.09 and 0.61[2], 0.39 [16], and 0.69 [17] for bone surface, and for dental landmarks mean difference of 1.3 [19], 0.57 and 0.82 [17]. CBCT presents better image for small details such as dental landmarks, and CT images are superior for larger structures, such as cortical bone [29]. Also, the image depends on the model of the tomography device. For dental arches' images, the main method used was by creating plaster models followed by scanning [2,9,15–18], and only one study used an intraoral scanner [19], presenting the worst mean accuracy of maxilla dentition (1.3 mm). This could be explained by the vulnerability to inaccuracies presented by full-arch intra-oral scans [30].

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 [9,15,18,19] or were manufactured in titanium [2,16,17]. 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 [2,18]. 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 [15]. The plates were made of titanium by machining [18,19] or layer-by-layer sintering [2,9,15–17]. 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 if compared to machining [2,9]. To assess surgical accuracy, postoperative CT was performed, and the virtual planning outcome was superimposed with postoperative tomography for accuracy 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 [2,9,15,19]. One study overlapped dental arch surfaces through the molar and canine cusps and the incisor points [16]. Another used the cephalometric maxillary points (ANS and PNS) and the same dental points previously mentioned [18]. One study used both the bone surface and dental arches [17]. The great methodological heterogeneity of the accuracy estimation methods made it impossible for the results to be grouped and meta-analysed, 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.

The best mean value for surgical accuracy achieved in the analysis of the maxillary dental was 0.45 mm [16], and the worst was 1.3 mm [19]. On the maxillary bone surface, the best mean

**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. [15] | *Mean: 0,24 (2,3)*<br>Min/Max<br>−3.4/+3.2<br>−2.0/+1.2<br>−0.6/+0.7<br>−0.08/0<br>0/+2.4<br>−0.07/0.02<br>−1.6/+1.2<br>−1.6/0<br>−1.0/+6.0<br>−0.8/+1.4 | + | + | + | Cutting guides and customized titanium plates allow accurate reproduction of preoperative virtual planning. It allows direct operative transfer of virtual surgical plans to the theatre; it is easy to use, relatively inexpensive, and clinical efficient; and it shortens the surgical duration |
| Brunso et al. [2] | *Mean: 1,09 (0,78)*<br>1,29(0,76)<br>1,42(0,8)<br>1,61(1,13)<br>1,01(0,66)<br>0,14(0,57) | *Mean: 0,61 (0,69)*<br>0,95(0,74)<br>0,62(0,45)<br>0,54(1,04)<br>0,94(0,39)<br>0,34(0,86)<br>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. [19] | + | + | *Mean: 1,3 (1,4)*<br>2,2(2,0)<br>0,7(1,0)<br>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. [17] | | *Mean: 0,69(0,77)*<br>Body<br>MD:0 (0.52)<br>AP: 0.15 (0.79)<br>SI: −0.26 (0.83)<br>Left Ramus<br>MD: −0.10 (1.03)<br>AP: 0.23 (0.82)<br>SI: −0.10 (0.79)<br>Right Ramus<br>MD: −0,18 (0,7)<br>AP: 0,05 (0,54)<br>SI: −0,28 (0,94) | *Mean:0,57(0,47)*<br>MD: −0,18 (0,35)<br>AP: −0,54(0,53)<br>SI: 0,33(0,53) | *Mean: 0,82(0,65)*<br>MD:−0,33 (0,53)<br>AP: −0,67 (0,50)<br>SI: 0,38 (0,92) | 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 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 |
| Heufelder et al. [16] | *Mean: 0,39*<br>(Minimum 0,0<br>Maximum 2,2) | + | *Mean: 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. [9] | *Accuracy within ± 1 mm (%)*<br>*Mean: 68,1%*<br><br>81<br>64<br>53<br>59<br>84<br>71<br>75<br>65<br>65<br>64 | + | + | + | The PSI the procedure considerably and reduce surgical times. Allows to increase the accuracy 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 allow the use of conventional osteosynthesis systems |

**Table 4** (*Continued*)

| 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 |
|---|---|---|---|---|---|
| Kim et al. [18] | *Mean: 1,01(0,3)*<br><br>Incisor Root: 0,82 (0,694)<br>Right Superior Canine Root: 0,819 (0,904)<br>Left superior canine root: 0,817 (1,196)<br>Superior first right molar: 1,196 (1,303)<br>Superior first left molar: 1,022 (1,161)<br>Anterior nasal spine: 0,883 (1,793)<br>posterior nasal spine: 1,661 (1,489)<br>A point: 0,860 (1,071) | + | *Mean: 0,67 (0,58)*<br><br>Mean cusp points<br>Incisor point: 0.26<br>Right superior canine cusp: 0.47<br>Left superior canine cusp: 1.11<br>Superior first right molar cusp: 0.02<br>Superior first left molar cusp: 1.6<br>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; MD: mediolateral; AP: anteroposterior; SI: superoinferior.

accuracy was 0.24 mm [15] and the worst was 1,09 mm [9]. Only two studies evaluated the accuracy on mandible bone surface; the best result was 0.61 mm [2] and the worst was 0.69 mm [17]. For the mandible dentition, only one study evaluated the accuracy, presenting a mean accuracy of 0.82 mm [17]. The studies consider these differences to be clinically acceptable, which corroborates previous studies that defined mean differences of up to 2.0 mm as acceptable [13,31–35]. However, doubts should be raised about clinically acceptable differences. For example, a maxillary dental midline with a 2 mm deviation is not accepted by most surgeons.

The results are similar in terms of postoperative accuracy to previous studies with different types of bone repositioning devices. Kretschmer et al. [1] evaluated 239 patients operated with a traditional intermediate guide and nasal pin and found an accuracy of 0.5 mm. Kwon et al. [14] evaluated 42 patients and found a surgical accuracy of 1.2 mm with traditional guides and of 1.0 mm with 3D printed guides. Kokutyo et al. [6] 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 [1,6,14] performed only 2D postoperative analysis with cephalograms. This type of analysis may be subject to discrepancies of up to 0.6 mm [34]. Other studies have evaluated surgical accuracy three-dimensionally [3,10,12,36]. Hernandez et al. [10] 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. [12] found an accuracy of 0.5 mm with a CAD-CAM interocclusal splint in 15 patients. Mazzoni et al. [3] tested splintless repositioning with surgical guided navigation in 15 patients with an accuracy of 1.1 mm. Stokbro et al. [36] 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. However, as it is a new technique that adds more technology and coasts, superior results from customized plates would be expected.

The authors of the studies point to a number of advantages. 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 [15,17]. Moreover, the choice of screw hole locations allows the determination of the thickest bone region to achieve greater screw locking and plate stability [17]. These screw holes are easily positioned away from the dental roots [15,18]. Surgical time is reduced since there is no need to bend plates, perform intermaxillary fixation or intraoperative measures to check bone repositioning [2,9,15,16]. This technique positions the upper jaw independent of the mandible or condylar position [2,9,16–19]. 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 [2], since it does not use interocclusal splints or intermaxillary fixation [2,9,17]. Regarding the rigidity of customized plates, the authors note that they are highly rigid, enabling correct repositioning of bone segments and withstanding functional loads [2,9,17]. It has been proven in vitro that customized plates have greater rigidity when compared to prefabricated plates [37,38].

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) [16,17]. Accuracy 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 accuracy errors [18].

Due to the heterogeneity of the accuracy 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 accuracy measurements. Stokbro et al. [39] suggested a methodology for evaluating postoperative results compared with planning and found favourable 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 randomised 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 minimize 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 observed results hereby presented.

## 5. Conclusion

We cannot affirm that patients submitted to orthognathic surgery with customized titanium plates present accurate surgical outcomes compared to the virtual orthognathic surgical planning. All individual studies selected for this systematic review have suggested the great potential of using customized titanium plates in orthognathic surgery. 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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### Disclosure of interest

The authors declare that they have no competing interest.

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