Stability and surgical complications in segmental Le Fort I osteotomy: A systematic review

*Article in* International Journal of Oral and Maxillofacial Surgery · June 2017

DOI: 10.1016/j.ijom.2017.05.011

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Stability and surgical complications in segmental Le Fort I osteotomy: a systematic review


Abstract. This systematic review was conducted to evaluate the stability and surgical complications of segmental Le Fort I osteotomy. The search was divided into a main search (PubMed, Embase, and Cochrane Library), grey literature search (Google Scholar), and manual search. Twenty-three studies were included: 14 evaluating stability as the outcome and nine evaluating surgical complications. The level of agreement between the authors was considered excellent ($k = 0.893$ for study selection and $k = 0.853$ for study eligibility). The segmental Le Fort I osteotomy provides stable outcomes in the sagittal plane, is less stable dentally than skeletally in the transverse plane, and provides little stability in the posterior segment after downward movement. The most frequent complications are oral fistula (six studies) and damage to the adjacent teeth (five studies), but the most prevalent complication is postoperative infection (32.62%). Four studies evaluating stability as the outcome showed a medium potential risk of bias, whereas all studies addressing surgical complications showed a high potential risk of bias. The segmental Le Fort I osteotomy should not be excluded from the technical armamentarium in orthognathic surgery. On the contrary, the literature consulted suggests it to be a useful tool for the three-dimensional surgical correction of maxillary malposition.

The treatment of dentofacial deformity often calls for a combined orthodontic and surgical approach to obtain satisfactory functional and aesthetic results with long-term stability. Many anomalies affect the width of the maxillary arch as well as the curve of Spee. In this context, the preeminent technique for surgical correction is the segmental Le Fort I osteotomy, which provides coordination of the premaxilla with the posterior segments while simultaneously enabling an improvement in the transverse dimension.

The segmental Le Fort I osteotomy is recommended for the single-stage correction of transverse maxillary deficiencies up to 6–7 mm, the correction of anterior open bite when there is a difference in the occlusal planes between the posterior and

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Key words: orthognathic surgery; segmental Le Fort I osteotomy; stability; complication; systematic review

Accepted for publication 17 May 2017
Available online 7 June 2017

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anterior segments of the maxilla not amenable to orthodontic correction, and the correction of severe proclination of the anterior teeth. According to Proffit et al., 30% of patients with a dentofacial deformity who seek treatment present a transverse maxillary deficiency component. Nevertheless, surgeons may hesitate to use the segmental Le Fort I osteotomy because the safety and stability of this technique remain unclear.

Concern about stability is based on the net that maxillary expansion is considered the least stable surgical procedure, and that many factors contribute to post-surgical instability, such as masticatory muscle activity, incorrect orthodontics, intraoperative complications, inadequate maxilla mobilization, the type and amount of surgical movement, inappropriate or no bone grafting, soft tissue tension, and segmental stabilization.1,8

Doubts about safety, in turn, are based on the increased risk of intraoperative and postoperative complications1,2, due to the adverse sequelae that can occur in the anatomical structures adjacent to the segmental osteotomies, such as tooth damage, oral fistula, non-union, and partial or total segment loss.7

Research into the long-term stability and surgical complications of this technique could help patients, orthodontists, and surgeons estimate the benefit of an elective operation versus its imminent risks, as well as prevent the occurrence of complications and facilitate their management.9 Within this context, systematic reviews are particularly relevant, as they are able to summarize and organize data from interventional studies – thus improving effect estimates – and analyze the risk of bias in the published literature.11,12

This systematic review was conducted to evaluate the stability and surgical complications related to the segmental Le Fort I osteotomy. The two specific questions for which answers were sought were the following: (1) Can this surgical procedure provide and maintain stability in the post-operative period? (2) What are the main complications and their causal factors?

Methods

A systematic search of the PubMed, Embase, and Cochrane Library databases was performed, using the PICO strategy (population: dentofacial deformity or orthognathic surgery; intervention: segmental Le Fort I osteotomy or segmentated Le Fort I osteotomy; comparison: multi-segmented Le Fort I osteotomy and/or Le Fort I osteotomy; outcome: stability and/or complications). No restrictions were placed on language or year of publication, and Boolean operators (”OR” and ”AND”) were used for the combinations of thesaurus terms related to dentofacial deformity, segmental Le Fort I osteotomy, stability, and surgical complications.

Search strategy

Main search

The PubMed search strategy employed the following medical subject heading (MeSH) entry terms: ["Dentofacial Deformities" OR "Deformities, Dentofacial" OR "Deformity, Dentofacial" OR "Dentofacial Deformity" OR "Dentofacial Abnormalities" OR "Abnormalities, Dentofacial" OR "Abnormality, Dentofacial" OR "Dentofacial Dysplasia" OR "Dentofacial Dysplasias" OR "Dysplasia, Dentofacial" OR "Dysplasias, Dentofacial" OR "Orthognathic Surgery" OR "Orthognathic Surgeries" OR "Surgery, Orthognathic" OR "Surgery, Orthognathic procedures" OR "Orthognathic Surgeries" OR "Orthognathic Surgery"") AND ["Rhinomaxillofacial Orthognathic Surgery" OR "Rhinomaxillofacial Orthognathic Surgeries" OR "Orthognathic Surgeries, Maxillofacial" OR "Orthognathic Surgery, Maxillofacial" OR "Surgery, Maxillofacial Orthognathic" OR "Surgery, Maxillofacial Orthognathic procedures" OR "Orthognathic Surgical Procedures" OR "Orthognathic Surgical Procedure" OR "Procedures, Orthognathic Surgical"") AND ["Maxillary Osteotomy" OR "Maxillary Osteotomies" OR "Osteotomies, Maxillary" OR "Osteotomy, Maxillary" OR "Osteotomy, Le Fort" OR "Le Fort Osteotomy" OR "LeFort Osteotomy"") AND ["Recurrence" OR "Recurrent" OR "Recurrence, Recurrent" OR "Recurrences" OR "Recurrent" OR "Recurrence, Recurrent" OR "Recurrences"") OR ["Intraoperative Complications" OR "Complication, Perioperative" OR "Complications, Perioperative" OR "Perioperative Complication" OR "Perioperative Complications" OR "Complication, Intraoperative" OR "Complications, Intraoperative" OR "Intraoperative Complication" OR "Injuries, Surgical" OR "Injury, Surgical" OR "Surgical Injury" OR "Surgical Injuries" OR "Postoperative Complications" OR "Complication, Postoperative" OR "Complications, Postoperative" OR "Postoperative Complication"")].

For Embase, the PICO search strategy was employed, with the following Emtree terms and their synonyms: "dentofacial deformity", "orthognathic surgery", "maxilla osteotomy", "relapse", "recurrence risk", "postoperative complication", and "perioperative complication". The specific search query was the following: ["dentofacial deformity/exp OR dentofacial deformities/exp OR dentofacial deformity OR dentofacial malformation/exp OR orthognathic surgery/exp OR orthognathic surgery OR orthognathic surgical procedures""] AND ["maxilla osteotomy/exp OR Le Fort operation OR Le Fort osteotomy OR maxilla osteotomy OR maxillary osteotomy OR osteotomy, Le Fort OR osteotomy, maxilla""] AND ["relapse/exp OR relapse OR recrudescence OR recrudescence risk OR recrudescence risk OR recrudescence risk OR recrudescence risk OR recrudescence risk OR recrudescence risk OR recrudescence risk OR recrudescence risk""] AND ["non-union, maxilla""] AND ["peroperative complication/exp OR peroperative complication OR peroperative complication OR peroperative complication OR peroperative complication OR peroperative complication""].

The Cochrane Library search strategy was based on MeSH terms: ["Dentofacial Deformities" OR "Orthognathic Surgery"") AND ["Maxillary Osteotomy" OR "Osteotomy, Le Fort"") AND ["Recurrence" OR "Recurrence, Recurrent" OR "Intraoperative Complications" OR "Postoperative Complications""]]

Grey literature

This search strategy was designed to retrieve studies published in journals not indexed by the major databases or identified with key words not included in MeSH or in the Emtree thesaurus. For this purpose, the Google Scholar database was searched using two queries: (1) Systematic 1, using MeSH terms as for the Cochrane Library Search; (2) Systematic 2, using the
PICO strategy key words: [“Dentofacial Deformities” OR “Orthognathic Surgery”) AND (“Segmental Le Fort I Osteotomy” OR “Segmented Le Fort I Osteotomy”) AND (“Stability” OR “Intraoperative Complications” OR “Postoperative Complications”)].

Manual search
The reference lists of all articles retrieved through the main search and grey literature strategy were hand-searched for additional relevant papers.

Study selection
The systematic database searches were performed by one author (OLHJ), while studies were selected independently by two authors (OLHJ and APSG). After an analysis of titles and abstracts, studies were assessed against the study eligibility criteria and those that fulfilled these were selected for full-text reading. The inclusion criteria were: (1) intervention study; (2) includes analysis of stability and/or complications after maxillary osteotomy. The exclusion criteria were: (1) case report; (2) review of the literature; (3) patient sample integrated completely with patients with cleft lip and palate or other craniofacial syndromes.

Studies that did not meet all of these prerequisites were excluded. In the case of disagreement between the authors, the study was selected for full-text reading. The eligibility of the selected articles was then assessed.

The kappa statistic (κ) was used to evaluate the level of agreement between OLHJ and APSG.

Study eligibility
The same two authors assessed the selected studies for eligibility independently. To facilitate and maintain consistency in the analysis of articles after full-text reading, a standardized form was created and used to check studies against the following inclusion criteria: (1) the research topic is segmental maxillary osteotomy; (2) the article reports data on stability and/or complications after maxillary osteotomy; (3) the article reports data on the segmental Le Fort I osteotomy, not only anterior or posterior segmental osteotomy of the maxilla; (4) the article reports an original study.

At this stage, any disagreement between the two independent investigators regarding the eligibility of the study was discussed with a third author (RGM).

Studies that did not meet the eligibility criteria were excluded from further analysis and the reason for exclusion was recorded.

The kappa statistic (κ) was used to evaluate the level of agreement between authors.

Data extraction
The same two authors (OLHJ and APSG) independently extracted demographic data, methodological data, and data on stability outcomes and/or complications for analysis. In the event of disagreement, the article was discussed with a third author (RGM); if doubts persisted, the corresponding author of the study in question was contacted via e-mail.

Analysis of surgical stability
The stability of the surgical procedure was assessed using the mean and standard deviation (SD) of dental and/or skeletal recurrence in the anterior and posterior segments of the maxilla, between the immediate postoperative period (mean surgical changes – T1) and the moment of the last follow-up (mean stability changes – T2). Results were expressed in millimetres (mm). Surgical movement in the sagittal, vertical, and transverse planes was taken into account.

Analysis of surgical complications
The following complications were assessed: intraoperative bleeding, postoperative bleeding, blood transfusion, segmental necrosis, tooth damage, periodontal damage, soft tissue damage, nerve damage, oral fistula, bad split, infection, non-union, and relapse. The prevalence of each complication was assessed in relation to the sample reported by the authors.

Analysis of methodological quality
The assessment of methodological quality was performed using the same risk of bias scale for small intervention studies employed in a previous study by Haas Jr et al. The criteria take into account sample selection, comparison of intervention effects, blinding of outcome assessors, validation of measures, statistical analysis, definition of inclusion and exclusion criteria, and postoperative follow-up.

Studies were classified as having a low risk of bias if all items were present, as having a medium risk of bias if one or two items were missing, and as having a high risk of bias if three or more items were missing.

Results
A flowchart of this systematic review, describing the steps from the search strategy to final article inclusion, is provided in Fig. 1.

Search strategy
Main search
The search of the major databases was performed on August 5, 2016. A total of 599 articles were retrieved (PubMed, n = 366; Embase, n = 220, Cochrane Library, n = 13). After eliminating duplicate records, 351 articles remained for the study selection stage.

Grey literature
The Google Scholar database was searched on August 15, 2016. Systematic 1 yielded 12 potentially eligible studies, while Systematic 2 retrieved seven records. These articles were selected for full-text reading and assessment of eligibility.

Manual search
After the selection of eligible papers identified by the main search and grey literature search, a manual search of the reference lists of these studies was conducted. This search yielded five additional articles that were ultimately included in the systematic review.

Study selection
The titles and abstracts of the 351 articles retrieved by the main search were read independently by the two investigators (OLHJ and APSG). Of these studies, 90 were selected. The inter-rater agreement coefficient was κ = 0.893 (95% confidence interval 0.789–0.997).

Study eligibility
The same two authors independently evaluated the full texts of 109 articles (90 selected from the main search strategy and 19 from the grey literature). Of these, 12 studies identified by the major database search and six studies identified in the Google Scholar search met the criteria for inclusion in the systematic review.
The remaining 91 articles (78 from the main search and 13 from the grey literature search) were excluded for the following reasons: 57 studies did not report their samples for segmental maxillary osteotomy, 23 studies did not report an analysis of stability and/or complications after segmental maxillary osteotomy, and 11 studies analyzed only anterior or posterior segmental maxillary osteotomy, without Le Fort I osteotomy. As all retrieved studies were original, none was excluded on the basis of this criterion. The level of inter-rater agreement was \( k = 0.853 \) (95% confidence interval 0.661–1).

Data extraction

After the study inclusion process, 23 articles were selected for data extraction and synthesis: 12 studies identified by the main search, six studies from the grey literature, and five studies through the manual search. Data refer to Table 1. The primary studies were essentially retrospective (only three used a prospective design) and were published in the last 25 years (1991–2016). During this period, Kretschmer et al. published two retrospective studies with surgical stability as an outcome.
<table>
<thead>
<tr>
<th>Author, year, and country of origin</th>
<th>Type of study</th>
<th>Samplea</th>
<th>Age (years) Mean ± SD (range)</th>
<th>Sex</th>
<th>Segmental maxillary osteotomy, number of segments</th>
<th>Mono or bimaxillary surgeryb</th>
<th>Non-rigid or rigid fixationc</th>
<th>Bone graft</th>
<th>Stability and/or complication analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phillips et al., 199215 USA</td>
<td>Clinical trial Prospective</td>
<td>N(n) = 39</td>
<td>26 ± 9 (14–56)</td>
<td>M (11)</td>
<td>Two (26)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>Stability: transverse</td>
</tr>
<tr>
<td>Chow et al., 19958 Hong Kong</td>
<td>Case series</td>
<td>N(n) = 18</td>
<td>24 ± 5</td>
<td>M (10)</td>
<td>Three (13)</td>
<td>M (0)/B (18)</td>
<td>N (0)/R (18)</td>
<td>0</td>
<td>Stability: vertical and sagittal</td>
</tr>
<tr>
<td>Hoppenreijs et al., 199716 Netherlands</td>
<td>Clinical trial Multicentre</td>
<td>N = 267</td>
<td>23.6 (14.3–45.5)</td>
<td>M (57)</td>
<td>Four (12)</td>
<td>M (67)/B (25)</td>
<td>N (65)/R (27)</td>
<td>NA</td>
<td>Stability: vertical and sagittal</td>
</tr>
<tr>
<td>Perez et al., 199725 USA</td>
<td>Clinical trial Retrospective</td>
<td>N = 28</td>
<td>NA</td>
<td>M (11)</td>
<td>Multiple (18)</td>
<td>M (9)/B (19)</td>
<td>N (0)/R (28)</td>
<td>16</td>
<td>Stability: vertical</td>
</tr>
<tr>
<td>Hoppenreijs et al., 199818 Netherlands</td>
<td>Clinical trial Retrospective</td>
<td>N = 130</td>
<td>23 (14–45)</td>
<td>M (28)</td>
<td>Two (23)</td>
<td>M (14)/B (9)</td>
<td>N (17)/R (6)</td>
<td>16</td>
<td>Stability: transverse</td>
</tr>
<tr>
<td>Arpornmaeklong et al., 200317 Australia</td>
<td>Clinical trial Retrospective</td>
<td>N = 26</td>
<td>22.3 (13–38)</td>
<td>M (8)</td>
<td>Three (17)</td>
<td>M (16)/B (1)</td>
<td>N (12)/R (5)</td>
<td>9</td>
<td>Stability: vertical and sagittal</td>
</tr>
<tr>
<td>Marchetti et al., 20094 Italy</td>
<td>Clinical trial Retrospective</td>
<td>N = 20</td>
<td>27.7 years</td>
<td>M (3)</td>
<td>Three (60)</td>
<td>M (0)/B (60)</td>
<td>N (0)/R (60)</td>
<td>28</td>
<td>Stability: vertical and sagittal</td>
</tr>
<tr>
<td>Kretschmer et al., 201010 Germany</td>
<td>Clinical trial Retrospective</td>
<td>N = 120</td>
<td>27.1 ± 9 (16–61)</td>
<td>M (30)</td>
<td>Three (3)</td>
<td>M (0)/B (3)</td>
<td>N (0)/R (3)</td>
<td>0</td>
<td>Stability: transverse</td>
</tr>
<tr>
<td>Kretschmer et al., 201119,d Germany</td>
<td>Clinical trial Multicentre</td>
<td>N(n) = 87</td>
<td>24.6 ± 91</td>
<td>M (33)</td>
<td>Three1 (28)</td>
<td>M (0)/B (87)</td>
<td>N (0)/R (87)</td>
<td>91</td>
<td>Stability: transverse</td>
</tr>
<tr>
<td>Moure et al., 201224 France</td>
<td>Case series Retrospective</td>
<td>N(n) = 30</td>
<td>20.4 (16–34)</td>
<td>M (17)</td>
<td>Two (3)</td>
<td>M (0)/B (3)</td>
<td>N (0)/R (3)</td>
<td>0</td>
<td>Stability: vertical and sagittal</td>
</tr>
<tr>
<td>Silva et al., 20133 Sweden</td>
<td>Case series Retrospective</td>
<td>N(n) = 33</td>
<td>23 years</td>
<td>M (11)</td>
<td>Three (5)</td>
<td>M (0)/B (33)</td>
<td>N (0)/R (33)</td>
<td>NA</td>
<td>Stability: vertical and sagittal</td>
</tr>
<tr>
<td>Brandtner et al., 201528 Austria</td>
<td>Case series Retrospective</td>
<td>N(n) = 47</td>
<td>NA</td>
<td>M (35)</td>
<td>Two (47)</td>
<td>NA</td>
<td>N (0)/R (47)</td>
<td>NA</td>
<td>Stability: transverse, vertical and sagittal</td>
</tr>
<tr>
<td>Yao et al., 201532 USA</td>
<td>Clinical trial Prospective</td>
<td>N = 13</td>
<td>28.4 (17.1–45.3)</td>
<td>M (5)</td>
<td>Two (NA)</td>
<td>NA</td>
<td>N (0)/R (9)</td>
<td>NA</td>
<td>Stability: transverse</td>
</tr>
<tr>
<td>de Mol van Otterloo et al., 199131 Netherlands</td>
<td>Case series Retrospective</td>
<td>N = 410</td>
<td>NA</td>
<td>M (5)</td>
<td>Three (NA)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>Complications: intraoperative and postoperative</td>
</tr>
<tr>
<td>Wolford et al., 200234 USA</td>
<td>Clinical trial Retrospective</td>
<td>N(n) = 311</td>
<td>28.5 (12–62)</td>
<td>M (87)</td>
<td>Two (10)</td>
<td>M (36)/B (46)</td>
<td>NA</td>
<td>3</td>
<td>Complications: postoperative</td>
</tr>
<tr>
<td>Kahnberg et al., 200530 Sweden</td>
<td>Case series Retrospective</td>
<td>N(n) = 82</td>
<td>24.5 ± 7</td>
<td>M (43)</td>
<td>Three (33)</td>
<td>M (36)/B (46)</td>
<td>NA</td>
<td>7</td>
<td>Complications: postoperative</td>
</tr>
</tbody>
</table>

The table contains demographic data for the studies included, with columns for author, year, and country of origin, type of study, sample size, age (mean ± SD), sex, segmental maxillary osteotomy, number of segments, mono or bimaxillary surgery, non-rigid or rigid fixation, bone graft, and stability and/or complication analysis.
<table>
<thead>
<tr>
<th>Author, year, and country of origin</th>
<th>Type of study</th>
<th>Sample&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Age (years) Mean ± SD (range)</th>
<th>Sex</th>
<th>Segmental maxillary osteotomy, number of segments</th>
<th>Mono or bimaxillary surgery&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Non-rigid or rigid fixation&lt;sup&gt;c&lt;/sup&gt;</th>
<th>Bone graft</th>
<th>Stability and/or complication analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chow et al., 2007&lt;sup&gt;29&lt;/sup&gt; Hong Kong</td>
<td>Case series Retrospective</td>
<td>$N = 1294 \ n = 760$</td>
<td>24.1 (16–54) Total sample</td>
<td>M (492) F (802)</td>
<td>Two (210) Three (34)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>Complications: postoperative</td>
</tr>
<tr>
<td>Landes et al., 2008&lt;sup&gt;23&lt;/sup&gt; Germany</td>
<td>Clinical trial Prospective/retrospective</td>
<td>$N = 136 \ n = 51$</td>
<td>(16–46) Total sample</td>
<td>M (76) F (60)</td>
<td>Four (516) Two (33) Three (18)</td>
<td>M (25)/B (8) M (6)/B (12)</td>
<td>N (0)/R (33) N (0)/R (18)</td>
<td>NA</td>
<td>Complications: intraoperative</td>
</tr>
<tr>
<td>Kretschmer et al., 2010&lt;sup&gt;22&lt;/sup&gt; Germany</td>
<td>Case series Retrospective</td>
<td>$N(n) = 225$</td>
<td>26 (16–54) Total sample</td>
<td>M (91) F (134)</td>
<td>Two (59) Three (163) Four (2) Five (1)</td>
<td>M (0)/B (225) M (0)/B (225)</td>
<td>N (0)/R (225)</td>
<td>49</td>
<td>Complications: intra and postoperative</td>
</tr>
<tr>
<td>Ho et al., 2011&lt;sup&gt;21&lt;/sup&gt; UK</td>
<td>Case series Retrospective</td>
<td>$N(n) = 85$</td>
<td>23.3 (13.9–50.7) Total sample</td>
<td>M (28) F (57)</td>
<td>Two (13) Three (70) Four (2)</td>
<td>M (16)/B (69)</td>
<td>N (0)/R (85)</td>
<td>21</td>
<td>Complications: intra and postoperative</td>
</tr>
<tr>
<td>Robl et al., 2014&lt;sup&gt;26&lt;/sup&gt; USA</td>
<td>Case series Retrospective</td>
<td>$N = 1000 \ n = 342$</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>Complications: intra and postoperative</td>
</tr>
<tr>
<td>Posnick et al., 2016&lt;sup&gt;2&lt;/sup&gt; USA</td>
<td>Clinical trial</td>
<td>$N = 262$</td>
<td>25 (13–63) Total sample</td>
<td>M (128) F (134)</td>
<td>Two (78) Three (90)</td>
<td>M (0)/B (262)</td>
<td>N (44)/R (218)</td>
<td>44</td>
<td>Complications: intra and postoperative</td>
</tr>
</tbody>
</table>

F, female; M, male; NA, no data provided by the authors; OS, occlusal splint kept in the postoperative period; WOS, occlusal splint removed in the postoperative period.

<sup>a</sup>Total sample ($N$), segmental Le Fort I osteotomy sample ($n$).

<sup>b</sup>Monomaxillary surgical procedure (M), bimaxillary surgical procedure (B).

<sup>c</sup>Non-rigid fixation (N), rigid fixation (R).

<sup>d</sup>1 = unilateral palatal osteotomy with or without bone graft; 2 = bilateral palatal osteotomy; 3 = unilateral palatal osteotomy with resorbable plate stabilization.
<table>
<thead>
<tr>
<th>Author and year</th>
<th>Method of analysis</th>
<th>Follow-up (months)</th>
<th>Sagittal Mean (SD), mm</th>
<th>Vertical Mean (SD), mm</th>
<th>Transverse Mean (SD), mm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Anterior maxilla</td>
<td>Posterior maxilla</td>
<td></td>
</tr>
<tr>
<td>Phillips et al., 1992</td>
<td>Dental casts</td>
<td>7.5</td>
<td>Two</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Hoppenreijs et al., 1998</td>
<td>Dental casts</td>
<td>69</td>
<td>Three</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Marchetti et al., 2009</td>
<td>Dental casts</td>
<td>24</td>
<td>Two</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Kretschmer et al., 2011</td>
<td>Dental casts</td>
<td>12–15</td>
<td>Three</td>
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<tr>
<td>Yao et al., 2015</td>
<td>CBCT</td>
<td>8.1</td>
<td>Two or three</td>
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<td>Dental casts</td>
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<tr>
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<td>CR</td>
<td>12</td>
<td>Two or four</td>
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<tr>
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<td>CR</td>
<td>69</td>
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<td>12–15</td>
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<td>Two</td>
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<td>Blæhr et al., 2014</td>
<td>CR</td>
<td>2</td>
<td>Three (OS)</td>
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<td></td>
<td></td>
<td>Three (WOS)</td>
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</table>

CBCT, cone beam computed tomography; CR, cephalometric radiographs; D, stability analysis by dental measurement; NA, data not provided by the authors; OS, occlusal splint kept in the postoperative period; PA, postero-anterior; S, stability analysis by skeletal measurement; SD, standard deviation; WOS, occlusal splint removed in the postoperative period.

\[ T1 = \text{mean surgical changes}; T2 = \text{mean stability changes}. \]

* Sagittal: (−) retrusion/(no sign) protrusion. Vertical: (−) intrusion/(no sign) extrusion. Transverse: (−) constriction/(no sign) expansion.
models in three studies \(^4,15,18\), cephalometric radiographs and plaster models in two \(^14,20\), and cone beam computed tomography (CBCT) in one \(^9\).

In patients undergoing two-segment osteotomy, anterior expansion of the maxilla (measured by dental changes) ranged from 1.8 ± 1.4 mm \(^15\) to 2.5 ± 1.9 mm \(^4\) (T1), whereas recurrence during the follow-up period (T2) ranged from −0.2 ± 1.5 mm \(^15\) to −0.9 ± 1.1 mm \(^15\). In patients undergoing three-segment osteotomy, expansion ranged from 0.2 ± 0.9 mm \(^15\) to 1.3 ± 1.7 mm \(^18\) (T1), while movement at follow-up (T2) ranged from 0.1 ± 1.2 mm \(^15\) to −0.9 ± 1.3 mm \(^19\).

In patients undergoing two-segment osteotomy, the dental change due to posterior expansion ranged from 2.7 mm \(^18\) to 5.7 ± 3.0 mm \(^15\) (T1), while recurrence (T2) ranged from −1.1 ± 2.0 mm \(^8\) to −2.7 ± 1.4 mm \(^15\). In patients who underwent three-segment osteotomy, posterior expansion ranged from −1.2 ± 3.0 mm \(^18\) to 5.2 ± 3.1 mm \(^15\) (T1), and recurrence (T2) ranged from −0.4 ± 0.7 mm \(^18\) to −2.3 ± 1.5 mm \(^15\). The skeletal change in the posterior region in patients undergoing three-segment osteotomy was assessed in a single study, which reported surgical changes of 2.1 ± 1.5 to 2.2 ± 1.4 mm (T1) and recurrence (T2) ranging from −0.4 ± 1.0 mm to −0.2 ± 0.6 mm \(^8\) (Fig. 2).

Analysis of maxillary expansion in patients undergoing four-segment osteotomy revealed a posterior dental change of −0.8 ± 1.2 mm, which exceeded the expected surgical movement of 0.0 ± 2.00 mm \(^18\).

**Sagittal and vertical stability**

Nine studies \((n = 318)\) analyzed surgical stability in the vertical plane as an outcome measure \(^8,16,17,20,24,25,28,27,28\), while eight \((n = 300)\) assessed stability in the sagittal plane \(^8,16,17,20,24,25,28\). Seven studies used lateral cephalograms for analysis of these outcomes \(^8,16,17,20,24,25,27\), one used both plaster models and cephalograms \(^28\), and one used clinical examination and plaster models \(^9\).

Dental stability in the sagittal plane varied widely in the incisors (T1: −3.3 ± 4.7 mm \(^16\) (retrusion) to 4.3 ± 2.1 mm \(^17\) (protrusion); T2: −1.3 mm \(^28\) (retrusion) to 2.0 mm ± 1.3 mm \(^28\) (protrusion)) and little in the molars (T1: 2.2 ± 2.6 mm \(^20\) (protrusion) to 2.4 ± 2.4 mm \(^8\) (protrusion); T2: 0.4 ± 1.1 mm \(^20\) (protrusion) to 1.5 ± 1.3 mm \(^8\) (protrusion)).

Regarding skeletal stability, results tended towards greater surgical movement (T1) (anterior segment: 2.6 ± 2.4 mm \(^2\) to 4.5 ± 3.4 mm \(^15\), posterior segment: 2.0 mm \(^25\) to 4.2 ± 1.4 mm \(^2\)) and less recurrence (T2) (anterior segment: −1.0 ± 0.8 mm \(^2\) to 0.1 ± 1.3 mm \(^2\), posterior segment: −0.7 mm \(^25\) to −0.3 ± 2.0 mm \(^2\)) than in the assessment of dental stability.

In the vertical plane, the anterior segment was most commonly extruded, and the trend towards recurrence was equivalent to the magnitude of surgical movement, regardless of whether the analysis was dental (T1: 5.4 ± 2.2 mm; T2: −1.5 ± 1.6 mm \(^2\)) or skeletal (T1: 4.2 ± 1.6 mm; T2: −1.1 ± 1.1 mm \(^2\)). Regarding the posterior segment, only one study reported surgical extrusion (2.8 ± 3.3 mm \(^25\); despite bone grafting.
this was followed by severe recurrence (−2.1 ± 3.1 mm), unlike in the majority of studies1,8,16,17,20,24, in which surgical intrusion was achieved and associated with stability in the follow-up period (Fig. 3).

Analysis of surgical complications

Data refer to Table 3. Surgical complications were assessed as outcomes in nine studies, involving 2078 patients (80.1% of the systematic review sample)2,4,14,21–23,26,29–31, with follow-up ranging from 3 months2 to 40.8 months14). Of these patients, 177 (8.5%) experienced a total of 187 surgical complications. Overall, the most prevalent was infection of an operated segment, accounting for 61 cases (32.6%) from three studies2,4,14,21,23. However, oral fistula (36 cases (19.3%) in six studies2,4,14,21,26,29,31) and damage to the adjacent teeth (15 cases (8.0%) in five studies2,4,14,21,26,29,31) were the most commonly reported complications among the articles included. No cases of postoperative bleeding or nerve damage were reported (Fig. 4). Ho et al.21 reported the highest prevalence of patients with complications (27.1%, 23 patients in 85 interventions), while Kretschmer et al.22 reported the lowest rate (1.2%, five patients in 54 interventions).

Analysis of methodological quality

Data refer to Table 4. The risk of bias in the included articles was classified as medium for four studies16–18,20 and high for 19 studies2,4,8,14,15,19,21–32. The articles classified as having a medium risk of bias reported surgical stability and did not present sample randomization or blind assessment as methodological criteria.

In fact, none of the included studies reported blind assessment. The study by Robl et al.26 had the highest risk of bias – all criteria for methodological quality were ignored.

Discussion

The surgical correction of dentofacial deformities of the maxilla through segmental Le Fort I osteotomy is opposed by some clinical and academic communities on the basis that it is assumed to provide unsatisfactory postoperative stability2,3,7,8 and to carry a high risk of complications2,3,9. This systematic review of the literature, using a search strategy that prioritized sensitivity over specificity, was conducted to debunk these myths with the highest available level of evidence. This was done for two reasons: first, there is no standardized cataloguing of articles on this topic in the major databases, as neither “segmental Le Fort I osteotomy” nor “surgical stability” are MeSH or Emtree terms, and the authors of these studies use a wide range of key words to describe them. Second; studies reporting on outcomes of Le Fort I osteotomy may also include data analysis of a segmental osteotomy subgroup. To mitigate these effects; the main search strategy combined MeSH or Emtree thesaurus terms such as “maxillary osteotomy”; “ostectomy; Le Fort I”; and “recurrence”; while the search of the grey literature was systematically divided into two protocols: Systematic 1 and Systematic 2. These measures were successful; as demonstrated by the sensitivity of the main search strategy and Systematic 1 search strategy; which covered not only studies with segmental Le Fort I osteotomy as a primary outcome2–4,8,19–22; but also studies with segmental osteotomy subgroups within larger samples23–26,29,31. Conversely; the Systematic 2 search of the grey literature; based on the PICO strategy; was more specific than sensitive; retrieving only articles with segmental Le Fort I osteotomy as a primary outcome27,28,30,31.

Of the 109 articles retrieved through these search strategies and selected for full-text reading, only 18 (12 identified with the main search strategy2–4,8,19–22; and six from the grey literature27–32) were ultimately included in the review. As two authors worked independently on study selection and analysis of eligibility, unsatisfactory inter-rater agreement was a possibility. In this context, the use of standardized inclusion and exclusion criteria is extremely important. The criteria led to an excellent level of agreement according to the Landis and Koch classification25 (κ = 0.893 for study selection, κ = 0.853 for eligibility) and ensured the reproducibility of this systematic review.

Setting a sensitive search strategy, rigorous study selection and analysis of eligibility, the outcome data could be extracted from the 23 studies included in the final sample for synthesis and review2–4,8,14–32. It was found that several academic institutions and research groups have conducted intervention studies of segmental Le Fort I osteotomy with sur-

Fig. 2. Transverse stability in two- and three-piece segmental Le Fort I osteotomy. *Recurrence not distinguished for two- and three-piece segmental Le Fort I osteotomy.
Table 3. Analysis of the studies reporting surgical complications as the outcome.

<table>
<thead>
<tr>
<th>Author and year</th>
<th>Follow-up (months)</th>
<th>Segmental osteotomy, number of segments</th>
<th>Surgical change</th>
<th>Bleeding</th>
<th>Segmental necrosis</th>
<th>Tooth damage</th>
<th>Periodontal damage</th>
<th>Soft tissue damage</th>
<th>Nerve damage</th>
<th>Oral fistula</th>
<th>Bad split</th>
<th>Infection</th>
<th>Non-union</th>
<th>Relapse</th>
<th>Total</th>
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<td>12</td>
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<td>1</td>
<td>3</td>
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<tr>
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<td>40.8</td>
<td>Three</td>
<td>8.2 mm</td>
<td>5–14</td>
<td>18</td>
<td>8</td>
<td>9*</td>
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<td>30</td>
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<td>6</td>
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<td>NA</td>
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<td></td>
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<td></td>
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<td>Robl et al., 2014</td>
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<td>7</td>
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<td>Two to five</td>
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<td>n = 4</td>
<td>2.14%</td>
<td>n = 4</td>
<td>2.14%</td>
<td>n = 15</td>
<td>8.02%</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>n = 15</td>
<td>(8.02%)</td>
<td>n = 24</td>
<td>(12.83%)</td>
<td>n = 19</td>
<td>(10.16%)</td>
<td>n = 36</td>
<td>(19.25%)</td>
<td>n = 2</td>
<td>(1.07%)</td>
<td>n = 3</td>
<td>n = 17</td>
<td>n = 187</td>
</tr>
</tbody>
</table>

AP, segmental maxillary osteotomy with additional procedures; NA, data not provided by authors; NAP, segmental maxillary osteotomy without additional procedures.

* Number of patients with complications (N), number of complications (n).

1 Infection only in the cases with graft.
gical stability and complications as the outcome measures over the last 25 years. Of these, Kretschmer et al. and Hoppenreijs et al. appear to have devoted the most time to demystifying this topic and have produced the most relevant scientific evidence, in controlled trials that accounted for three of the four studies with a medium risk of bias.

After data extraction and analysis, the selected studies that included an outcome measure of stability were organized by stratifying surgical movement outcomes in the sagittal, vertical, and transverse planes. Taking into account that maxillary expansion is the most unstable surgical procedure, it is believed that transverse stability outcomes were the most relevant for this systematic review. Through analysis of these outcomes, it was possible to infer that instability is greater in terms of dental movement than in skeletal structures, which implies that preoperative and postoperative orthodontic treatment may be the main determinant of recurrence after maxillary expansion; this is compounded by the fact that the main objective of such combined orthodontic-surgical treatment is to correct crossbite. One of the main reasons for this greater dental instability is demonstrated in the study by Brandtner et al., who showed, over a follow-up period of 8 to 10 years, that the area of greatest preoperative orthodontic expansion is also the region of greatest recurrence after removal of the orthodontic appliance.

Some surgical techniques may be able to improve orthodontic stability in the transverse plane. The results of the six included studies that evaluated this outcome suggest that the two-segment osteotomy provides greater dental stability in the anterior region of the maxilla than three-segment surgery and that both techniques are associated with a similar pattern of recurrence in the posterior region, with the

Fig. 4. (A) Prevalence of the surgical complications reported in the systematic review (n = 187 surgical complications). (B) The complications most often reported: number of studies out of the nine included that reported the surgical complications.
### Table 4. Quality assessment of included studies.

<table>
<thead>
<tr>
<th>Study</th>
<th>Randomization or consecutive patients in a prospective study</th>
<th>Comparison between treatments\textsuperscript{a}</th>
<th>Blind assessment</th>
<th>Validation of measurements</th>
<th>Statistical analysis</th>
<th>Defined inclusion and exclusion criteria</th>
<th>Report of follow-up (at least 12 months)</th>
<th>Risk of bias</th>
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<td>Yes</td>
<td>Medium</td>
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<td>Yes\textsuperscript{b}</td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td>Yes</td>
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<tr>
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<td>No\textsuperscript{b}</td>
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<td>No\textsuperscript{b}</td>
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<td>No\textsuperscript{b}</td>
<td>No</td>
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<td>Yes</td>
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<td>Posnick et al., 2016\textsuperscript{7}</td>
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\textsuperscript{a} Comparison between different treatments modalities (control group vs. test group – controlled study).
\textsuperscript{b} Comparison between different surgical techniques (test group vs. test group – comparative study).
\textsuperscript{c} Risk of bias: high, 0–4 ‘yes’ responses; medium, 5–6 ‘yes’ responses; low, 7 ‘yes’ responses.

msLeF, multi-segmental Le Fort I osteotomy; OS, occlusal splint kept in the postoperative period; SARPE, surgically assisted rapid palatal expansion; WOS, occlusal splint removed in the postoperative period.
two-segment technique providing the advantage of larger surgical movement (5.7 mm², 4.1 mm²)⁶,¹⁵,¹⁸,¹⁹,²⁸,³². Another important issue is the need for rigid fixation, which appears to be the primary determinant of skeletal stability.¹⁰,¹² This is illustrated by the fact that the worst recurrence outcomes, considering the ratio of magnitude of surgical movement to instability, were reported by Hoppenreis et al. in a study in which the majority of cases were not treated with rigid fixation; consequently, the sum of dental and skeletal instability probably increased the recurrence rate.

The summary analysis of dental stability outcomes in the sagittal plane was hindered by orthodontic movement in the follow-up period. However, there was a trend towards clockwise rotation of the anterior segment of the maxilla, and this surgical movement remained extremely stable from a skeletal standpoint⁸,¹⁷,²⁰,²⁴. The pattern of surgical movement found in these studies is typical of correction of incisor proclination. Having determined through this systematic review of the literature that this pattern provides skeletal stability, it is believed that the segmental Le Fort I osteotomy is the most indicated surgical technique for the correction of maxillary deformity when using the 'surgery first' protocol¹²³–¹²⁶, especially in patients with a class III malocclusion.

Vertical stability outcomes in the literature were consistent with less dental and skeletal recurrence in the anterior segment (when downward surgical movement was achieved)⁸,²⁰,²⁵ than in the posterior segment, in which substantial skeletal recurrence occurred even when investigators employed techniques designed to minimize this phenomenon⁷,¹²², such as bone grafting, rigid internal fixation, and bimaxillary surgery⁸. One possible explanation, corroborated by clinical experience, is that anterior extrusion of the maxilla rarely causes loss of bone contact and that stabilization of grafted bone is easier. In addition, vertical movement in this segment may be the result of clockwise rotation and not a linear displacement, unlike in the posterior region, in which there is less contact between segments due to the hollow structure and thin bone walls of this area. Overall, the segmental Le Fort I osteotomy was associated with a vertical recurrence pattern similar to that of the non-segmental procedure¹⁶,²⁰,²⁵, with surgical movement being most unstable when downward displacement was achieved.⁷,²⁵,¹²²

Surgical complications were also analyzed in this systematic review. Nine studies that evaluated this outcome in a sample of 2078 patients were summarized. Overall, only 177 patients (8.5%) experienced some form of complication. Given the retrospective design of the included studies, this might be considered an underestimation. However, it is believed that the prevalence of complications is actually overestimated because of the convenience sampling strategies, in which only studies reporting surgical complications were included. To estimate the actual rate of complications, not only should the aforementioned 2078 subjects be taken into account, but also those in the stability sample in whom complications were not reported (n = 516)⁴,⁸,¹⁵, ²⁰,²₄,²₅,₂₈,₂₉,³⁰ and the patients in the 23 studies in which neither stability nor complications were analyzed and which were therefore excluded from the review⁹,¹⁰,⁸⁹–¹⁰⁹. Hence, the risk of surgical complications after segmental Le Fort I osteotomy is in fact much lower than 8.5%.

Another finding that is likely to have been overestimated is the prevalence of postoperative infection (32.6%)¹⁴,²¹,²⁹, as the sample of Chow et al.²⁹ accounted for 47 of the 61 cases (77.0%) of infection reported in all included studies. Although this rate appears high, 47 infections in 760 patients represents a prevalence of 6.2%, similar to that reported for sagittal split ramus osteotomy in the same study²⁹. Therefore, the segmental Le Fort I osteotomy should not be avoided for the misguided belief that it is particularly prone to infectious complications.

Despite the overall safety of this procedure, segmentation of the maxilla evidently makes complications more likely than in simple Le Fort I osteotomy, although the difference is not statistically significant on direct comparison². Circumstances such as difficulty performing an osteotomy between the teeth and in areas adjacent to soft tissues mean that the most common complications of segmental maxillary osteotomy, such as oral fistulae¹²,¹⁶,²₁,⁻²₆,⁻₂₉,⁻₃₁, dental injury¹₂,⁻₂₁,⁻₂₆,⁻₃₀,⁻₃₁, do not occur with non-segmental techniques. Operator experience and certain advanced technologies, such as piezoelectric surgery, can reduce the risk of complications by minimizing soft tissue damage and enhancing the precision of the osteotomy, which limits the risk of trauma to the adjacent structures and, consequently, reduces blood loss, as well as facilitating bone healing compared to traditional osteotomy with burs and saws.¹²⁸

The methodological quality of the articles included in this review was compared to a set of criteria used by the present research group in a previous systematic review¹³. Using this standard, only randomized clinical trials with outcome assessor blinding could be classified as having a low risk of bias. None of the included studies used such a rigorous design. Only four articles were considered to have a medium risk of bias, all included surgical stability as an outcome measure, and none reported sample randomization or blind assessment. The included studies that had surgical complications as an outcome measure²,¹²³–¹²₅,₂₉–₃₁ were less methodologically robust than those that assessed surgical stability, and this was an expected finding, as studies of prevalence often use a retrospective, non-comparative design, with no validation of analyses and no sample follow-up. Thus, a meta-analysis could not be performed, as the sample was heterogeneous both clinically and methodologically (as no randomized controlled trials were included). Nevertheless, this systematic review was able to analyze the outcomes reported in the 23 included studies²,⁴,⁻¹₄,⁻₃₂ and provides improved effect estimates for surgical stability and complications of segmental Le Fort I osteotomy.

The effect estimates found at the highest level of evidence suggest that the segmental Le Fort I osteotomy provides extremely stable outcomes in the sagittal plane, is less stable from a dental standpoint than skeletally in the transverse plane, and provides little stability in the posterior segment after downward movement. The most common complications are oral fistulae and damage to the adjacent teeth, both of which can be minimized by employing techniques such as piezoelectric surgery. Therefore, according to the results of this systematic review, this procedure should not be considered particularly unsafe or unstable in the field of orthognathic surgery, and it is particularly indicated in patients requiring three-dimensional correction of maxillary deformities, especially in 'surgery first' protocols in the context of anomalous incisal projection and/or maxillary atresia. Indeed, clockwise rotation of the anterior segment of the maxilla used for the correction of incisal projection has been proved to be stable. In addition, since skeletal expansion is more stable than dental expansion, it can be assumed that proceeding with surgery without the conventional dental deceleration of a ‘surgery late’ protocol is correct from a technical standpoint.
According to the studies reviewed herein, some measures can be taken to ensure the intervention is as predictable as possible. At the orthodontic stage, dental expansion should be kept to a minimum, and retention should be maintained after removal of the orthodontic appliances. From a surgical standpoint, the osteotomy should be limited to two or three segments, with additional segmentalization only in extreme cases; inferior mobilization of the posterior segment should be avoided whenever possible, even when bone grafting is performed; dental overcorrection should be discouraged; rigid fixation is mandatory; and piezoelectric technology should be used if available.

**Funding**
Brazilian Ministry of Education, Coordination for the Improvement of Higher Education Personnel (Coordenação de Aperfeiçoamento de Pessoal de Nível Superior, CAPES), Programa de Doutorado no Exterior (PDSE), grant number 99999.006660/2015-00 awarded to Orion Luiz Haas Junior.

**Competing interests**
No conflict of interest.

**Ethical approval**
Not applicable.

**Patient consent**
Not applicable.

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