Segmental maxillary osteotomy in cleft lip and palate patients: a stepwise planning in the orthodontic presurgical preparation with Invisalign

Abstract

Aim To show the potential of Invisalign in multi-segmental Le Fort I preparation with the aid of an occlusogram-like method.

Study Design Retrospective clinical series.

Methods Nine patients treated with Invisalign before segmental osteotomy of the maxilla (study sample) were matched for diagnosis, surgical procedure, and complexity of orthodontic preparation with nine patients treated with fixed appliances (control sample). A superimposition technique was adapted to complement the Invisalign software to carry out an appropriate ClinCheck in segmental pre-surgical treatments. The correct pre-surgical positions of the maxillary teeth were guided with the use of virtual added curves that followed the lower arch. The number of impressions needed in both groups to reach adequate pre-surgical coordination of the segmented arches was compared.

Results Invisalign patients needed one or no refinement phase to reach an acceptable pre-surgical occlusion. The average total treatment time was not statistically different from the fixed appliance group.

Statistics Student's t-test, setting p-value at 0.05 was carried out to compare differences.

Conclusions With the aid of the proposed superimposition method, during the digital simulation of presurgical movements, clear aligner therapy appears to be an effective treatment even in patients with skeletal discrepancies and craniofacial anomalies involving the need for segmental Le Fort I osteotomies. More sophisticated software will certainly be implemented in the future.

Introduction

Orthodontic treatment of cleft lip and palate (CLP) patients is a challenging and often lifelong treatment. The most common problem is related to maxillary hypoplasia, both transversal and sagittal. The orthodontist and paediatric dentist should keep the burden of total care as low as possible, given the high rate of recurrence [Meazzini et al., 2015]. Usually, treatment is started in the mixed dentition. Palatal expansion is the most common first orthodontic approach. The addition of a face mask is reserved to patients affected by functional issues, such as hypopacusia due to otitis media [Rosso et al., 2022] (Fig. 1). Unfortunately, early protraction has an elevated recurrence rate (Fig. 2). Some relatively new approach such as the Altramec [Meazzini et al., 2019] or the use of skeletal plates [Faco et al., 2019] reduce the need for final surgery, but not all patients accept treatment during adolescence. During growth Class III progressively worsens (Fig. 3), requiring orthognathic surgery. One of the most common surgical procedures for the correction of maxillary skeletal deformities is the Le Fort I osteotomy, and it has been widely used in orthognathic surgery since 1921 [Buchanan end Hyman, 2013]. Patients with CLP frequently ask for maxillary surgical correction at the completion of growth in the three planes of space. Some authors report that 13 to 28.6 % of CLP patients require a multi-segment Le Fort I osteotomy [Meazzini et al., 2015; Good et al., 1927]. When vertical or transversal discrepancies exist, it is possible to divide the maxilla in multiple segments, more commonly in 3 or 2 parts [Kretschmer et al., 2010]. In patients with CLP, given the frequent absence of the permanent lateral incisor [Tortora et al., 2008], the surgical advancement of the lesser segment is often performed during maxillary osteotomy [Posnick and Tompson, 1992; Broome et al., 2010; Susarla et al., 2020]. Orthodontic pre-surgical preparation is essential to obtain a stable occlusion during surgery and guarantee a more stable post-surgical result by eliminating dental compensations in all planes of space. Conventional fixed appliances facilitate optimal dental pre-surgical positioning. Traditional fixed appliances can also be used for intermaxillary fixation and stabilisation of the dental arches after surgery. However, one of the main shortcomings of fixed appliance treatment is that it is often not well accepted by adult patients. Clear aligners are often deemed not ideal for complex orthodontic pre-operative preparation, although patients are reported to be more at ease in terms of aesthetic self-perception, social interactions and self-consciousness of the appliance as compared to those treated with fixed appliances [Jeremiah et al., 2011; Meazzini et al., 2020; Meazzini et al., 2020; Posnick et al., 2019]. Segmental Le Fort I osteotomies require a specific orthodontic preparation [Arnett et al., 2022]. Preparation with clear aligners in complex orthognathic surgery is not generally used, since the Invisalign software (Align Technology, Inc., San José, California) does not allow prediction when multi-segment maxillary surgery is planned. The aim of this study was to describe in detail an easy superimposition technique which allows to forecast the correct segmental arch.
shapes, in comparison with traditional fixed appliance treatment. Surely, in the future, more sophisticated software will allow to put cuts in the maxillary bone and manipulate the segments in order to predict the orthodontic preparation needed in such complex cases, but for the time being this approach might be of aid to both cleft surgeons and orthodontists.

Materials and Methods
This case-series study was approved by the internal review board of our institution, and it follows the principles of the declaration of Helsinki. Informed consent was obtained from all the participants included in the study (Hospital Internal Ethical Committee (HSPC/0022678/2019). All patients were subjected to a maxillary segmental osteotomy by the same surgeon and were treated orthodontically by the same orthodontist. Since the purpose of this study was not to compare the whole treatment but to evaluate the adequacy of aligners in pre surgical treatment, the groups were selected in terms of occlusion and orthodontic needs in preparation for surgery. Stability of surgical result was not considered in this study.

Study Sample
Out of fifteen patients treated with Invisalign aligners in preparation for segmental maxillary surgery we selected nine UCLP (unilateral cleft lip and palate) patients, aged 19 to 27 years (average 22.2 ± 2.9) (Table 1). All patients underwent a 2-piece Le Fort 1 osteotomy.

Control Sample
Nine UCLP patients treated with fixed appliances by the same orthodontist, in preparation for 2-piece maxillary surgery, were retrospectively collected from our center. We were unable to find a sample that could be adequately matched for sex and age. An attempt, extremely simplified, was made to match patients for complexity of pre-orthodontic preparation: extraction or non-extraction treatment plan, sagittal decompensation (needed/not needed) or lateral decompensation (needed/not needed), to prepare for the correction of compensations in mandibular asymmetries. Although matching was only by large simple categories, it was carried out by the same orthodontist to compare treatments which might at least be more similar in terms of complexity (Table 1). All 18 UCLP patients underwent a 2-piece Le Fort 1 osteotomy, but in terms of orthodontic preparation 14 patients were treated with non-extraction treatment and sagittal decompensation (7 in each sample); two patients with non-extraction treatment, sagittal and lateral decompensation (one...
in each sample, and two patients with extraction treatment and sagittal decompensation (one in each sample).

**Orthodontic pre-surgical treatment**

**Traditional fixed appliances technique**

Orthodontic wires were periodically changed and bent until the orthodontist considered the occlusions potentially ready for surgery. Impressions were taken and plaster casts obtained. Segmental arch coordination was evaluated by manipulating the patient’s casts, which were cut at the osteotomy sites. Dental arches were deemed correctly prepared for surgery when a “good stability” of the segmented pre-surgical models was found through a qualitative evaluation of the contacts by the same orthodontist and the same surgeon, together. Once preparation was approved, surgical hooks were positioned, and the patient underwent surgery. In patients where an adequate coordination was not yet achieved, the needed orthodontic movements were carried out and further impressions were taken until coordination was considered satisfactory.

**Invisalign technique**

Impressions were taken for each patient and a personal virtual file of the arches was elaborated with ClinCheck® software (Align Technology, Inc., San José, California) (Fig. 4). ClinCheck® software allows to manipulate the final location of each tooth. Since this software does not allow simulation of maxillary segmental osteotomies, to coordinate the segments of the maxillary arch to the mandibular arch, a simple 3 step method similar to an occlusogram [She Tsang et al., 2021] that includes the following actions was developed:

- **1st step**: Align the mandibular teeth in the correct final position eliminating compensations where needed. (Fig. 5 a, b)
- **2nd step**: Draw virtual curves following the final aligned image of the lower arch both in the horizontal and vertical planes. (Fig. 5 c - e)
- **3rd step**: Superimpose these curves on the maxillary arch segments to guide the corresponding dental movements to be carried out during the Clin Check (Fig. 5 f - j) obtaining the final presurgical occlusion (Fig. 6).

The drawing of the curves and the superimpositions are both executed virtually. The curves follow the lower vestibular cusps and are used to guide the upper arch alignment. This superimposition is allowed by means of “always-on-top” free software (OnTopReplica®, 2021 GitHub, Inc.). Our suggested protocol is completely versatile and can be followed with any other always-on-top software that allows superimposition of any image on the computer screen. It can even be carried out with acetate paper on the screen. The criteria used for each patient by the same orthodontist and the same surgeon to assess the adequacy of the presurgical preparation were the absence of...
occlusal interferences and good occlusal stability, correct space between the segments. Again, criteria for assessment of occlusal presurgical stability were only qualitative. No quantitative calculation of contact points was carried out. To assess the suitability of the pre-surgical orthodontic treatment with Invisalign we calculated the number of refinements needed before surgery and compared it with the number of pre-surgical impressions needed prior to surgery in the fixed appliance control group. Given that the two groups of patients were matched, not only for the type of surgery and malocclusion, but also for the complexity of the pre-surgical orthodontic preparation (Tab. 1), the number of appointments needed, and total treatment time were also compared, as an additional information to understand whether decompensation with aligners, while more aesthetic, might require a longer time. A Student’s t-test, setting the p-value at 0.05 was carried out to compare differences.

Brief outline of the surgical procedure

The procedure started with the injection of a diluted solution of epinephrine and local anaesthetic in the maxilla mucosal tissue. Facial height measurements were calculated from the medial canthus to one incisor bracket to assess the changes in facial height after surgery. Sagittal osteotomy of the maxilla was performed in the cleft area unilaterally (2 segments). It requires sufficient space for the execution of the osteotomy and the roots of the teeth next to the osteotomy have to be slightly divergent. All patients of the two groups were treated by the same surgeon. A final splint was used to guide the position of the maxillary segments and the intermaxillary fixation. Rigid wire fixation was used for the first week, inter-maxillary elastics for the subsequent four weeks and only guidance elastics for the following eight weeks. The occlusal splint was fixed to the maxillary arch with ligatures wires and kept in place for at least one month, and then replaced with continuous arch wires in all patients. Patients of the sample group were debonded three months after surgery and continued with aligners for post-surgical orthodontic finishing. Rigid stabilisation was performed with four plates and screws.

Results

Four of the Invisalign patients needed one refinement phase after the first Clin Check in order to undergo surgery (average impressions needed 1.4±0.4). All other patients were considered ready by the team at the end of the first phase. In the fixed appliance group, an average of 1.8 ± 0.6 impressions (range 1–3) were taken during pre-surgical treatment to obtain ideal arch coordination (p>0.05 n.s.). Treatment time was similar in the two groups. The Invisalign sample was treated for an average of 18.4 ± 3 months (range 11–23) pre-surgically, with an average of 5.1±0.8 appointments. Fixed appliance patients needed an average of 16.3±4 months (range 9–22 months) (p > 0.05 n.s.), with an average of 10.2±1.6 appointments (p<0.05). The figures refer to a UCLP patient of the sample group treated with a two-piece Le Fort I osteotomy (Fig. 8).

Discussion

Multiple piece Le Fort I osteotomies need an orthodontic pre-
operative preparation phase to adequately coordinate the maxillary arch segments to the mandibular arch. The orthodontic treatment consists in eliminating all dental compensations. In a 3-piece Le Fort I, anterior teeth extrusion should be avoided as well as lateral expansion, given that those movement will be reached with surgery with less risk of relapse. In cleft patients 2-piece Le Fort I osteotomies may be indicated, and the lesser segment may be advanced during maxillary osteotomy so that the canine is positioned in the lateral space. Pre-surgical preparation in these patients foresees a palatal movement of the canine and a reshaping of the hemi-arch so that the premolar may be positioned, during surgery in the canine space [Posnick et al., 2016] (Fig. 7). No transverse orthodontic expansion should be carried out pre-surgically. Furthermore, the two segments should not be orthodontically aligner in the vertical plane as the lesser segment is often vertical hypoplastic and will be corrected surgically. Some patients will need more than one impression during the pre-operative phase to achieve adequately coordinated arches. When segmental maxillary surgery is planned, plaster casts need to be cut to simulate the surgical osteotomy. If a surgical patient asks to be treated with clear aligners, a standard virtual simulation may be performed only for symmetrical maxillary or mandibular sagittal movements using the ClinCheck software. Invisalign software does not allow virtual cutting of the arches. This retrospective clinical series suggests that the Invisalign software may be used in patients who need segmental Le Fort I osteotomy applying the simple 3-step method recommended. The use of this additional work up, has shown that it is possible to obtain a satisfactory pre-surgical coordination with aligners. There are few articles dealing with the treatment with clear aligners before orthognathic surgery. A study of Kankam et al. [2019] aimed to assess post-operative outcome in patients treated with Invisalign and conventional fixed appliances; however, they only report on post-operative edema and fail to investigate other outcomes such as arch coordination, patient satisfaction or treatment time. Although the accuracy of dental movements obtained with Invisalign technique is reported to be only 60 % to 80 % [Galan-Lopez et al., 2019; Izhar et al., 2019] compared to fixed appliances, it appears sufficient to plan and achieve a pre-surgical preparation that allows sufficient occlusal pre-surgical stability [Cong et al., 2022; Mazyar, 2022]. The accuracy in terms of occlusion in a pre-surgical preparation is very different from the accuracy in terms of multiple occlusal contacts expected at the completion of an orthodontic treatment [Kobayashi and Tadaharu, 1993]. Despite the fact that stability was assessed qualitatively might seem a major limitation, the definition of a stable presurgical occlusion is subjectively judged by the surgical orthodontic team, aiming for a firm position of each segment. In our center, it was carried out by the same orthodontist and surgeon, both for the sample and control groups, thus allowing
for a more reliable comparison. The fact that time of treatment was very similar might suggest that matching for severity was adequate. The matching of the samples was by no means perfect, and patients’ compliance is an added variable in the Invisalign group which might always bias treatment time. Comparison of treatment time was carried out only because we initially feared that such a complex preparation in three planes of space using clear aligners might be too long to make it acceptable in terms of burden of care, which does not seem to be the case. On the other hand, the difference in terms of appointments might suggest that Invisalign could be an interesting option for patients who need to travel long distances to reach the center. Two impressions were always taken before surgery, the first one after the 1st set of aligners to check the occlusion and the second one, three weeks after the passive orthodontic bonding to make sure no unwanted dental movements had occurred and to construct the surgical splint. This procedure is an obvious disadvantage of the approach. In multi-segment Le Fort I osteotomies fixed appliances are preferred by our surgeon in the fixation of the skeletal segments and bases both during surgery and through the post-operative healing period. A fundamental drawback, which we have already mentioned, but we must emphasise, of pre-surgical preparation with Invisalign, is the need to position passive fixed appliances immediately before surgery and keep them until complete bone healing (at least 2–3 months). At our center, although they represent an alternative to dental post-surgical fixation, no screws for skeletal anchorage are provided by the hospital. This method does not need any computer ability or learning curve. Experience on surgical cases and the ability of performing a simple occlusogram for the orthodontist is enough. It is also possible to carry out the same steps by using acetate paper superimposed on the computer screen. Of course, this method will certainly be substituted in the future by more sophisticated software, which, nevertheless, will be based the same rationale.

Conclusion

With the aid of the simple superimposition method proposed during the digital simulation of presurgical movements, it seems that clear aligner therapy may be an acceptable treatment method, even in patients with skeletal discrepancies and craniofacial anomalies involving the need for complex multisegmented Le Fort I osteotomies.

Availability of data and materials The data underlying this article will be shared on reasonable request to the corresponding author.

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