Available online at www.sciencedirect.com
ScienceDirect
British Journal of Oral and Maxillofacial Surgery 54 (2017) 757–761
BRITISH Journal of Oral and Maxillofacial Surgery
www.bjoms.com

Biomechanical evaluation of different fixation systems after Le Fort I osteotomy in polyurethane models of unilateral clefts

Alparslan Esen [a,*], Kubilay Isik [a], Haci Saglam [b], Yusuf Bugra Ozdemir [c], Dogan Dolanmaz [c]

[a] *Necmettin Erbakan Universtiy, Faculty of Dentistry, Department of Oral and Maxillofacial Surgery, Konya/Turkey*
[b] *Selcuk Universtiy, Faculty of Technology, Department of Mechanical Engineering, Konya/Turkey*
[c] *Selcuk Universtiy, Faculty of Dentistry, Department of Oral and Maxillofacial Surgery, Konya/Turkey*

Accepted 19 April 2016
Available online 12 May 2016

Abstract

We compared the stability of three different titanium plate-and-screw fixation systems after Le Fort I osteotomy in polyurethane models of unilateral clefts. Thirty-six models were divided into 3 groups. In the first group, we adapted standard Plates 1 mm thick with 2.0 mm screws and placed them bilaterally on the zygomatic buttress and the piriform rim. In the second group, we did the same and added Plates 0.6 mm thick with 1.6 mm screws between the standard 2 mm miniplates on both sides. In the last group, we placed Plates 1.4 mm thick with 2.0 mm screws bilaterally on the maxillary zygomatic buttress and piriform rim. Each group was tested in the inferosuperior (IS) and anteroposterior (AP) directions with a servo-hydraulic testing unit. In the IS direction, displacement values were not significantly different up to 80 N, but between 80 and 210 N, those in the 2 × 1.4 mm group were better. In the AP direction, displacement values were not significantly different up to 40 N, but between 40 and 180 N, they were better in the standard with 1.6 × 0.6 mm group and the 2 × 1.4 mm group. When normal biting forces (90 - 260 N) in the postoperative period are considered, the greatest resistance to occlusal loads was seen in the 2 × 1.4 mm group. In the others, the biomechanical properties were better in the AP direction.
© 2016 The British Association of Oral and Maxillofacial Surgeons. Published by Elsevier Ltd. All rights reserved.

Keywords: Cleft palate; Le fort osteotomy; Orthognathic surgery; Skeletal stability

Introduction

The craniofacial morphology of patients with cleft lip and palate (CLP) is different from that of those without clefts. The profile of adults who have had repair of an isolated cleft palate is characterised by general retrusion relative to the cranial base that involves the nasal bone, maxilla, and mandible.[1]

Maxillary deficiencies in patients with and without clefts are usually corrected by Le Fort I osteotomy. However, in those with clefts, previous scar tissue or pharyngoplasty, the severity of the deformity, and the presence of pharyngeal flaps or grafts, can lead to skeletal instability and relapse after operation.[2,3] As instability and relapse can also depend on mobilisation, orthodontics, and the operating surgeon, the technique used for fixation is vital.[4] Different miniplates have been used, but to our knowledge, their effectiveness alone has not been reported, and we know of few biomechanical studies on fixation after Le Fort I osteotomy in patients with clefts.[5]

* Corresponding author at: Necmettin Erbakan Universitesi, Dis Hekimligi Fakultesi, Ankara Cd. No:74/A, Konya/Turkiye. Tel.: +90 332 220 00 25; fax: +90 332 220 00 45.
E-mail address: dtaesen@hotmail.com (A. Esen).

http://dx.doi.org/10.1016/j.bjoms.2016.04.019
0266-4356/© 2016 The British Association of Oral and Maxillofacial Surgeons. Published by Elsevier Ltd. All rights reserved.

Fig. 1. Standard titanium L-shaped miniplates 1 mm thick and 2.0 mm diameter screws adapted and placed bilaterally (2 × 1 mm group).

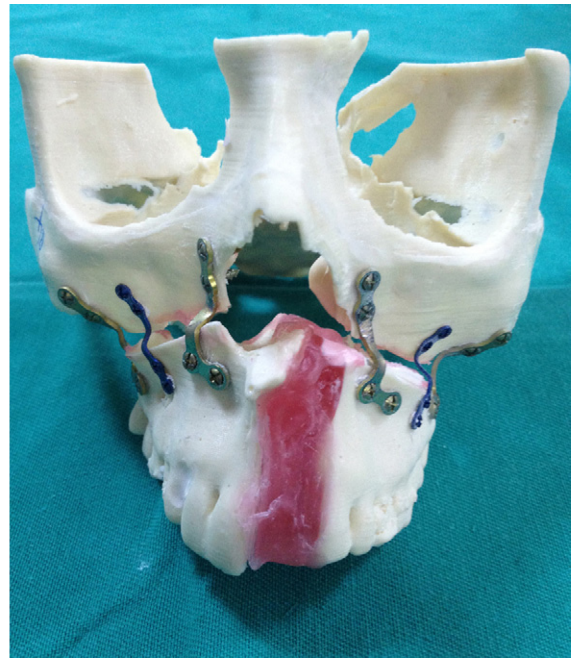

Fig. 2. Microplates 0.6 mm thick with screws 1.6 mm in diameter added between the standard L-shaped miniplates on both sides (1.6 × 0.6 mm group).

We therefore compared the stability of three different titanium plate-and-screw fixation systems after Le Fort I osteotomy in polyurethane models of unilateral clefts.

Material and methods

We used slices from a 3-dimensional computed tomogram of a patient with a unilateral cleft to make 36 polyurethane skulls. Before conventional Le Fort I osteotomy, we filled the clefts with wax to advance the maxillary segments in a single piece and to simulate alveolar bone grafts. We made a palatal splint to cover the maxillary teeth.

All the cuts were standardised with reference to certain anatomical landmarks such as the medial and distal orbital wall, the zygomatic buttress, and the teeth. After positioning the excised maxilla uniformly using reference lines along the lateral wall of the maxilla, we advanced it 7 mm and fixed it to the skull with a utility wax strip. We also used the wax strip to leave a 3 mm gap between the maxillary segment and the base of the skull to prevent bony contact and to allow us to measure the strength of the plates.

We divided the 36 models into 3 groups. In the first group (A), we adapted standard 4-hole, L-shaped titanium miniplates 1 mm thick from a standard 2 mm miniplating system and placed them bilaterally on the zygomatic buttress and piriform rim (Fig. 1). In the second group (B), in addition to the standard titanium plates, we placed a 1.6 mm microplating system with 4-hole titanium microplates 0.6 mm thick between the L-shaped miniplates on both sides (Fig. 2). In the last group (C), we used a 2 mm miniplating system with L-shaped titanium plates 1.4 mm thick and placed them bilaterally on the zygomatic buttress and piriform rim (Fig. 3) (all systems Trimed Titanium Implant System, Trimed Ucmed Medical Ltd, Ankara, Turkey). We applied load forces in the inferosuperior (IS) and anteroposterior (AP) directions.

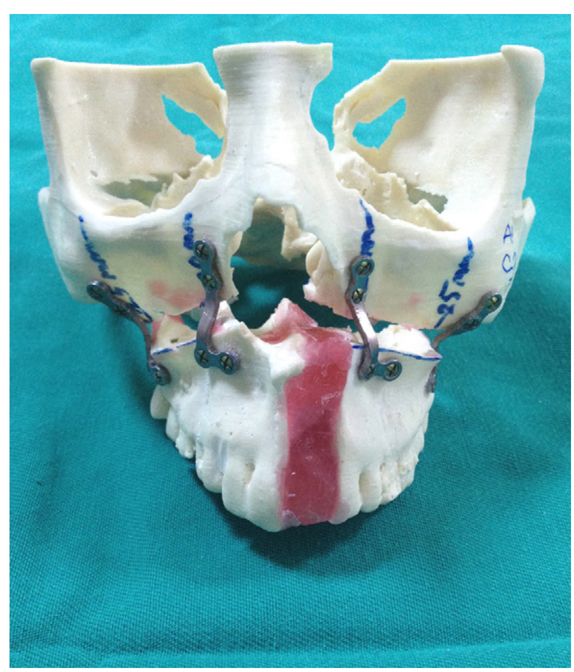

Fig. 3. L-shaped titanium Plates 1.4 mm thick with 2.0 mm diameter screws placed bilaterally on the zygomatic buttress and the piriform rim (2 × 1.4 mm group).

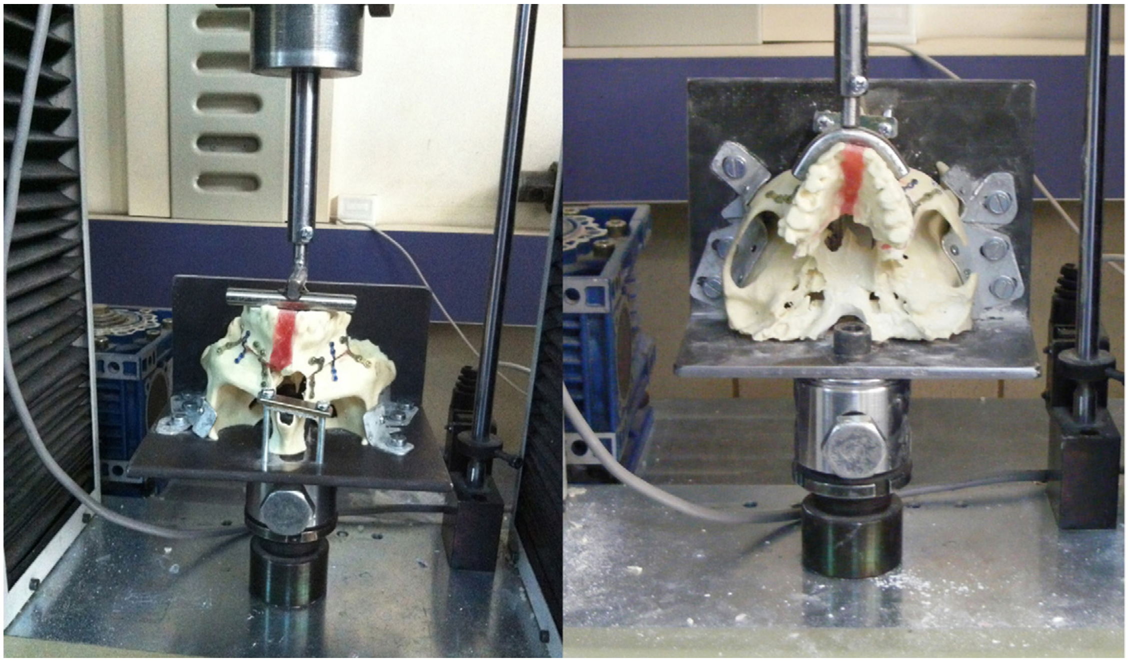

Fig. 4. The polyurethane models mounted on a fixation apparatus with fixing screws and plaques in the inferosuperior and anteroposterior directions.

The occlusal surfaces of the premolars-molars were flattened with a bur in the IS group to establish smooth contact. To apply the load force in the AP direction, we made a horseshoe-shaped arm that encompassed both segments of the maxilla then mounted each prepared model on a servo-hydraulic testing unit (TST 2500 mxe, ELISTA Electronic Informatics System Design Ltd, Istanbul, Turkey) (Fig. 4). The unit was equipped with a 2500 kg load cell (maximum load capacity 5000 kg) set to produce linear displacement at a rate of 5 mm/minute. Initially, a 10 N preload was applied to each specimen, and at the beginning of the test the load was recalibrated to zero. Each model was then subjected to a continuous vertical linear load until fracture. During the test, data on the load and vertical displacement were digitally recorded, and load-displacement graphs were drawn with the help of dedicated software (tst 2500 mxe, ELISTA Electronic Informatics System Design Ltd, Istanbul, Turkey). The samples were subjected to experimental loads until deformation occurred, and the displacement caused by bending of the fixation materials was recorded. Each group was compared using 2-way analysis of variance and regression tree analysis, which was done with the help of CHAID (Chi-Square Automatic Interaction Detector).

Results

The displacement values for the 3 groups differed significantly ($P < .05$) in both the IS and AP directions (Table 1). In the IS direction, the displacement values for the 3 groups were not significantly different up to 80 N, but between 80 and 210 N, those in the 2×1.4 mm group were better. The displacement values for the 3 groups also differed significantly after 210 N ($p = 0.026$) (rankings of the best biomechanical response after 210 N were the 2×1.4 mm group, the 2×1 mm group, and the 1.6×0.6 mm group). The screws did not loosen and the plates did not fracture in the 2×1 mm group and the 1.6×0.6 mm group after permanent deformation of the model, but the plates bent. In the other group the screws did not loosen and the plates did not bend.

Table 1
Displacement values for the 3 groups.

Groups	Mean (SD)	Range (mm)	p value
Inferosuperior (IS) direction:			
A	1.65 (1.01)	0.09 -3.86	
B	1.96 (1.22)	0.09 - 4.93	0.026
C	1.19 (0.68)	0.06 - 2.58	
Anteroposterior (AP) direction:			
A	2.60 (1.58)	0.11- 6.02	
B	1.78 (1.06)	0.08 - 4.52	0.008
C	1.98 (1.36)	0.08 - 5.98	

In the AP direction, the displacement values for the 3 groups were not significantly different up to 40 N, but between 40 and 180 N, they were better in the standard with 1.6×0.6 mm group and the 2×1.4 mm group. The displacement values for the 3 groups differed significantly after 180 N ($p = 0.008$) (rankings of the best biomechanical response after 180 N were the 1.6×0.6 mm, the 2×1.4 mm, and the 2×1 mm groups). The skulls fractured in all groups but no plates or screws failed.

Discussion

Maxillary deficiencies are conventionally managed with Le Fort I osteotomies, and bimaxillary procedures may also be

Table 2
Reported rates of horizontal and vertical relapse.

First author, reference, and year	Horizontal (%)	Vertical (%)
Heliövaara [1] 2002	8	17
Ayliffe [6] 1995	5	21
Chua et al[8] 2010	37	65
Cheung [9] 2006	15	10
Hirano [10] 2001	24	70
Daimaruya [11] 2010	25	50
Posnick [12] 1994	23	19

required to ensure masticatory function and aesthetics.[6,7] Maxillary advancements are often successful in patients with maxillary hypoplasia,[4] but a high rate of relapse has been reported in patients with CLP or severe hypoplasia.[2–4] The direction of movement is usually anterior and inferior,[8] so relapse occurs in the horizontal and vertical directions. Clinical studies have shown that rates of vertical relapse are higher than those of horizontal relapse (Table 2).[1,6,8–12]

Fixation is vital for the stability of maxillofacial osteotomies or fragments. We used models of unilateral clefts obtained from a real patient to emulate clinical conditions, and as patients with CLP or severe hypoplasia often have maxillary advancement of between 5 and 10 mm,[3,8,9] we did a 7 mm advancement. Studies[1,8–12] have also shown that increases in the mean vertical height ranged from 1 to 4.5 mm. We therefore left a 3 mm gap between the maxillary segment and base of the skull to prevent bony contact and to allow us to measure the strength of the plate. The load forces were applied in the IS and AP directions by an Instron® machine (Instron, High Wycombe, UK). The purpose of loading in the AP direction was to simulate relapse forces, while the purpose in the IS direction was to simulate biting forces.

Some retrospective clinical studies report the use of stronger fixation methods and autogenous bone grafts to prevent relapse and provide postoperative skeletal stability.[4,13] Burstein et al[4] used titanium plates 1.4 mm thick, iliac crest bone grafts, and bone morphogenetic protein in patients with severe maxillary hypoplasia, and reported that the plates were 1.6 times more rigid than standard 1.0 mm plates. They reported no evidence of relapse after a mean follow-up period of 6 months. Other clinical studies have shown that bone grafting of the lateral wall of the maxilla after Le Fort I osteotomy could reduce relapse.[1,6,13–15] Santos et al,[16] who did Le Fort I osteotomies for inferior positioning of the maxilla without grafts, used standard 2.0 mm miniplates and reported a high rates of relapse. They suggested that grafts are necessary to support the conventional system.

After orthognathic surgery, the occlusal force in the early postoperative period is considerably less than that of a healthy person. Choi et al[17] examined the changes in bite force after intraoral vertical ramus osteotomy with or without Le Fort I osteotomy. They showed that the postoperative mean bite force in 78 patients after orthognathic surgery was 97.6 N at 1 month, 206.9 N after 3 months, and 257 N after 6 months, and concluded that the surgical group had significantly lower bite forces and smaller areas of occlusal contact. Song et al[18] also investigated functional changes in patients after Le Fort osteotomy, and reported bite forces of 240 N between the molars after 6 months.

Differences among groups for IS displacement were not significant up to 80 N. Other studies suggest that when clinical conditions are considered, all methods of fixation have a similar resistance to the occlusal forces in a one-month postoperative healing period[17,18], but as the occlusal forces progressively increase after this period, rates of vertical relapse also increase. The significant resistance detected in the 2×1.4 group between loads of 80 and 210 N shows that strong fixation may help to reduce the numbers that relapse between 2 and 6 months postoperatively. Inferior repositioning of the maxilla usually leaves bony gaps in the lateral walls of the maxillary sinus into which buccal soft tissues can herniate, resulting in malunion and potentially reduced stability.[8]

The use of rigid fixation with bone grafts may minimise this problem. There was less displacement during AP loading between 40 and 180 N in the 1.6×0.6 mm and the 2×1.4 mm groups, which suggests that early stability should be carefully monitored when standard miniplates 1 mm thick are used. The better stability in the 1.6×0.6 mm group for loads of 180 N and more can be explained by the larger contact area, which was created by the extra plates and more fixation screws.

Sugiura et al. reported that load-bearing to the miniplates reached a peak 2 – 4 weeks after operation,[19] so their strength can also be an important factor in the success of the fixation. Additional or thicker plates can help to avoid micromovements through bending or distortion.

Although fixation with reinforced plates seems mechanically reasonable, the drifting or migration of screws may be another important cause of relapse, and could relate to the remodelling and resorption of bone around the screws. Sugiura et al[19] reported that high stresses applied to the bone during operation can loosen the screws, and if the critical threshold is exceeded, the bone that supports the fixation screws can start to resorb. It may therefore be necessary to avoid the stress that occurs when the screws are inserted.

The reinforced fixation systems were more resistant to the load forces than the conventional system. However, routine use of thicker plates may be limited because they are difficult to manipulate, and the use of additional plates increases cost. The biomechanical tests do not fully reproduce clinical situations, and the polyurethane models are different from natural bone. In humans, the forces applied to the maxilla are cyclical and multidirectional.

Our results primarily give a picture of early postoperative stability. Long-term stability depends on bony healing and the type of fixation. We therefore conclude that increasing the number or thickness of the plates, or both, can aid early stability after Le Fort I osteotomy in patients with clefts. Stronger plates can be particularly beneficial when the maxilla is repositioned anteriorly and inferiorly without a graft.

We did not simulate grafts in the osteotomy gap, and this was a limitation of the study. Also, it was not possible to simulate loosening of the screws that would be a result of bony remodelling. Randomised controlled trials are now needed to support our results.

Conflict of Interest

We have no conflict of interest.

Acknowledgements

This study was supported by Necmettin Erbakan University, Coordinatorship of Scientific Research Projects. The authors thank Assoc. Prof. Dr. Ismail Keskin from the Department of Animal Science, Faculty of Agriculture, Selcuk University for his help with statistical analysis.

References

1. Heliövaara A, Ranta R, Hukki J, et al. Skeletal stability of Le Fort I osteotomy in patients with isolated cleft palate and bilateral cleft lip and palate. *Int J Oral Maxillofac Surg* 2002;**31**:358–63.
2. Hochban W, Ganss C, Austermann KH. Long-term results after maxillary advancement in patients with clefts. *Cleft Palate Craniofac J* 1993;**30**:237–43.
3. Saltaji H, Major MP, Alfakir H, et al. Maxillary advancement with conventional orthognathic surgery in patients with cleft lip and palate: is it a stable technique? *J Oral Maxillofac Surg* 2012;**70**:2859–66.
4. Burstein FD, Maurice SM, Granger M, et al. Maxillary advancement in patients with severe maxillary hypoplasia: role of adjuvant stabilization techniques and materials. *J Craniofac Surg* 2012;**23**:812–6.
5. Araujo MM, Waite PD, Lemons JE. Strength analysis of Le Fort I osteotomy fixation: titanium versus resorbable plates. *J Oral Maxillofac Surg* 2001;**59**:1034–40.
6. Ayliffe PR, Banks P, Martin IC. Stability of the Le Fort I osteotomy in patients with cleft lip and palate. *Int J Oral Maxillofac Surg* 1995;**24**:201–7.
7. Iannetti G, Cascone P, Saltarel A, et al. Le Fort I in cleft patients: 20 years' experience. *J Craniofac Surg* 2004;**15**:662–9.
8. Chua HD, Hägg MB, Cheung LK. Cleft maxillary distraction versus orthognathic surgery–which one is more stable in 5 years? *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2010;**109**: 803–14.
9. Cheung LK, Chua HD, Hägg MB. Cleft maxillary distraction versus orthognathic surgery: clinical morbidities and surgical relapse. *Plast Reconstr Surg* 2006;**118**:996–1009.
10. Hirano A, Suzuki H. Factors related to relapse after Le Fort I maxillary advancement osteotomy in patients with cleft lip and palate. *Cleft Palate Craniofac J* 2001;**38**:1–10.
11. Daimaruya T, Imai Y, Kochi S, et al. Midfacial changes through distraction osteogenesis using a rigid external distraction system with retention plates in cleft lip and palate patients. *J Oral Maxillofac Surg* 2010;**68**:1480–6.
12. Posnick JC, Dagys AP. Skeletal stability and relapse patterns after Le Fort I maxillary osteotomy fixed with miniplates: the unilateral cleft lip and palate deformity. *Plast Reconstr Surg* 1994;**94**:924–32.
13. Kerawala CJ, Stassen LF, Shaw IA. Influence of routine bone grafting on the stability of the non-cleft Le Fort 1 osteotomy. *Br J Oral Maxillofac Surg* 2001;**39**:434–8.
14. Major PW, Philippson GE, Glover KE, et al. Stability of maxilla downgrafting after rigid or wire fixation. *J Oral Maxillofac Surg* 1996;**54**:1287–91.
15. Waite PD, Tejera TJ, Anucul B. The stability of maxillary advancement using Le Fort I osteotomy with and without genial bone grafting. *Int J Oral Maxillofac Surg* 1996;**25**:264–7.
16. Santos SE, Moreira RW, de Moraes M, et al. Skeletal stability after inferior maxillary repositioning without interpositional graft. *Int J Oral Maxillofac Surg* 2012;**41**:477–81.
17. Choi YJ, Lim H, Chung CJ, et al. Two-year follow-up of changes in bite force and occlusal contact area after intraoral vertical ramus osteotomy with and without Le Fort I osteotomy. *Int J Oral Maxillofac Surg* 2014;**43**:742–7.
18. Song HC, Throckmorton GS, Ellis III E, et al. Functional and morphologic alterations after anterior or inferior repositioning of the maxilla. *J Oral Maxillofac Surg* 1997;**55**:41–50.
19. Sugiura T, Horiuchi K, Sugimura M, et al. Evaluation of threshold stress for bone resorption around screws based on in vivo strain measurement of miniplate. *J Musculoskelet Neuronal Interact* 2000;**1**: 165–70.