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Comparison of Autologous and Heterologous Bone Graft Stability Effects for Filling Maxillary Bone Gap After Le Fort I Osteotomy

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A – research concept and design; **B** – collection and/or assembly of data; **C** – data analysis and interpretation; **D** – writing the article; **E** – critical revision of the article; **F** – final approval of article; **G** – other

Abstract

Background. The amount of postoperative maxillary relapse of two different bone graft materials after Le Fort I osteotomy were compared in this study.
Objectives. The aim of this study is to compare postoperative maxillary relapse rates using heterologous and autologous graft materials after Le Fort I osteotomy.
Material and Methods. A total of 80 patients who had developmental malocclusion were analyzed retrospectively in this study. Twenty nine (36.2%) and 51 (63.8%) patients underwent Le Fort I osteotomy, and Le Fort I and bilateral sagittal split ramus osteotomy (two-jaw surgery), respectively. Forty two (52.5%) maxillary bone gaps were filled with heterologous bone grafts (group A) and 38 (47.5%) were filled with autologous bone grafts (group B) after Le Fort I osteotomy. The cephalometric graphics and measurements were taken before (T1), 1 week after (T2), and 1 year after (T3) the surgery. The results were documented and determined by the Dolphin imaging 10.5 (Dolphin Imaging, Chatsworth, Calif.) computer program for skeletal relapse. Whether or not the relationship between group A's and B's maxillary relapse rates was evaluated in the postoperative period.
Results. It was observed that both graft materials have positive effects on maxillary relapse rate in the postoperative period. When the groups are compared to each other, the relapse rates were similar between group A (8.3%) and group B (10.8%) ($p > 0.05$).
Conclusions. Heterologous bone graft material (Osteoplant®-Flex) is thought to be a good alternative to autologous grafts in decreasing the relapse rates and reducing the morbidity of the donor area of the patients who underwent Le Fort I osteotomy (**Adv Clin Exp Med 2015, 24, 2, 341–348**).

Key words: bone graft, Le Fort, malocclusion.

Orthognathic surgery is performed in order to ensure a proper anatomic and functional relationship between jaw and dental structures. The most commonly orthognathic surgical procedures are Le Fort I osteotomy and bilateral sagittal split ramus osteotomy (BSSRO) [1].

Despite advances in surgical techniques, since the first orthognathic surgical intervention performed by Hullinen, skeletal relapse continues to be the most significant and the most difficult complication up to now [1, 2]. The relapse risk increases in patients who undergo a large amount of bone movement with only rigid fixation due to less contact of the bone margins after orthognathic operations [3, 4]. Therefore, autogenous, homogeneous (allograft) and heterogeneous bone grafts (xenograft), and alloplastic implants can be used for filling the bone gaps after orthognathic surgery [5].

Xenografts are bone grafts that are taken from a donor of another species. This natural material, similar to those of the human bone, shows great osteoconductive properties [6]. There are a few studies on equine-derived bone substitutes [7, 8] for filling the bone gap. The material used in the present study was an equine-derived bone substitute material commercially available (Osteoplant-Flex, Bioteck Srl, Arcugnano, Vicenza, Italy), which was deantigenated through a low-temperature (max 37°C) enzymatic process that should not alter its mineral component.

Stabilization is another important factor during orthognathic surgery to prevent relapses. Recently, titanium plates and screws are used for this purpose in orthognathic surgical procedures as a standard technique [9, 10].

Orthognathic surgery aims for aesthetic and functional unity and long-term stability. Therefore one of the important points is selecting a reliable graft material for filling the bone gap formed after Le Fort I osteotomy. The equine-derived bone graft material's (Osteoplant-Flex) and the autologous graft's postoperative relapse rates are compared in this study.

Material and Methods

In our study, a total of 80 patients who underwent orthognathic surgery due to developmental malocclusion, including 55 (68.8%) women and 25 (31.2%) men were analyzed retrospectively. Cleft lip and palate, congenital syndromes, traumatic deformities and patients who were treated by distractor with malocclusions were excluded from the study. The average age of patients was 22.1 ± 4.1 (15–36) and the average postoperative hospitalization was 5.5 ± 2.2 days. Nineteen (23.8%) patients were diagnosed as class II, and 61 (76.2%) patients as class III malocclusion according to the "Angle" classification system. The mean duration of orthodontic treatment prior to surgery was 14.2 months. Le Fort I osteotomy was performed in 29 patients (36.2%) and two-jaw surgery was performed in 51 patients (63.8%). Of the 80 patients who underwent only Le Fort I osteotomy or the two-jaw procedure (including Le Fort I osteotomy), 63 (78.7%) of them underwent maxillary advancement (MA) and 17 (21.3%) of them underwent maxillary elongation (ME) and/or MA.

Patients whose bone gaps were greater than 4 mm after MA and all ME were grafted. Forty-two patient's (52.5%) maxillary bone gaps after Le Fort I osteotomy were filled with xenogeneic spongiotic bone material (Osteoplant-Flex) (group A) (Fig. 1) and 38 (47.5%) were filled with autologous cancellous bone graft (group B) (Fig. 2) which were taken from the patient's own iliac crest. The rigid fixation was achieved with 4 pieces of 2.0 mm titanium plates (2 plates on each side) and screws in all patients. In 8 (10%) of the patients, correctable operative complications such as hematoma, decreased hemoglobin level, foreign body reaction leading to titanium, localized infection, edema, and malocclusion were encountered and treated. Maxillomandibular fixation time was 4 weeks for all cases in the postoperative period.

Lateral cephalometric graphics were taken 1.5 months before, 1 week after, and 1 year after the operation with a Planmeca Promax Digital Panoramic X-ray unit (Planmeca Inc., Helsinki, Finland) and these graphics were used and determined using the Dolphin imaging 10.5 (Dolphin Imaging and

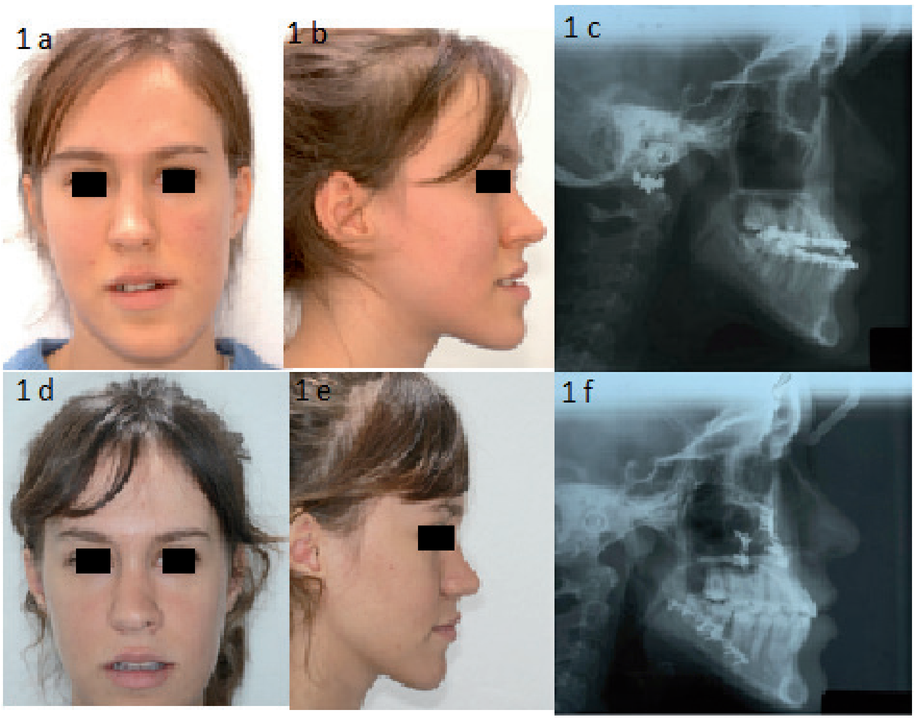

Fig.1. 19-year-old female patient who has developmental malocclusion, treated with two-jaw surgery (including Le Fort I osteotomy) and bone gap filled with Osteoplant-Flex. 1a – preoperative anterior view; 1b – preoperative lateral view; 1c – preoperative lateral cephalogram; 1d – one year postoperative anterior view; 1e – one year postoperative lateral view; 1f – one year postoperative lateral cephalogram

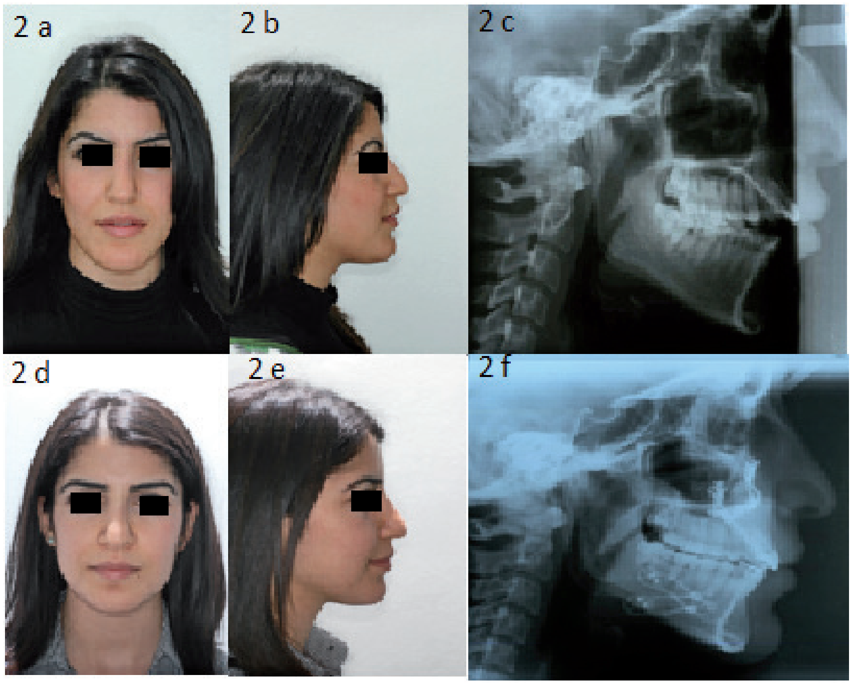

Fig. 2. 24-year-old female patient who has developmental malocclusion, treated with two-jaw surgery and bone gap filled with autologous bone graft. 2a – preoperative anterior view; 2b – preoperative lateral view; 2c – preoperative lateral cephalogram; 2d – one year postoperative anterior view; 2e – one year postoperative lateral view; 2f – one year postoperative lateral cephalogram

Management Solutions, Chatsworth, Calif., USA) computer program in order to evaluate skeletal relapse ratios. The cephalometric measurements used in this study were SNA angle, maxillary depth angle, McNamara (mm), and maxillary height angle. Teeth or soft tissue points and planes were ignored.

Statistical Analysis

Statistical analysis was performed using SPSS software (version 16.0, SPSS Inc., Chicago, IL, USA). All numerical data is expressed as mean values ± SD or as proportions. For each continuous variable, normality was checked using Kolmogorov Smirnov and Shapiro-Wilk tests and by histograms. Pre-post measurement data was analyzed using a Wilcoxon test for data not distributed normally. Correlations between all numerical variables were tested using Spearman's correlation test. Spearman's correlation coefficients were interpreted as either excellent relationship $r \geq 0.91$; good $0.90 \leq r \geq 0.71$; fair $0.70 \leq r \geq 0.51$; weak $0.50 \leq r \geq 0.31$; little or none $r \leq 0.3$ (ref). Values of $p < 0.05$ were considered statistically significant.

Results

The data obtained from the cephalometric analysis of the patients is given in Table 1 and 2. Regardless of the direction of surgical movement,

Table 1. The mean and standard deviation values of calculated cephalometric points and angles before surgery, one week after and one year after surgery in group A

Group A	n (patients)	T1–T2 (mean ± SD)	T2–T3 (mean ± SD)	p
SNA°	42	4.7 ± 4.0	–1.7 ± 2.1	0.0001
A – N⊥Fh (McNamara)	42	4.8 ± 4.6	–0.4 ± 0.6	0.0001
Maxillary depth angle	42	5.7 ± 5.1	–1.4 ± 3.5	0.0001
Maxillary height angle	42	–0.2 ± 4.4	–0.1 ± 2.7	0.718

SD – standard deviation; SNA° – angle between the sella-nasion plane and nasion – A point plane; A – deepest point between anterior nasal spine and upper incisival alveolus; N – nasion point; FH – Frankfort horizontal line; A – N⊥Fh (McNamara) – measured in mm from the line drawn perpendicular N to FH (if the A point, in front of the McNamara was measured positive and behind the McNamara was measured negative); maxillary depth angle – angle between N–A and FH. Maxillary height angle – angle between N-CF and A; CF – intersection point with pterygoid vertical plane and FH. PTV – a perpendicular line drawn from the distal part of the pterygopalatine fossa to FH; T1–T2 – amount of changed points and angles between preoperatively and 1 week postoperatively; T2–T3 – amount of changed points and angles between 1 week and 1 year postoperatively; p – Wilcoxon test.

Table 2. The mean and standard deviation values of calculated cephalometric points and angles before surgery, one week after and one year after surgery in group B

Group B	n (patients)	T1–T2 (mean ± SD)	T2–T3 (mean ± SD)	p
SNA°	38	3.3 ± 3.5	–0.8 ± 1.5	0.0001
A–N⊥Fh (McNamara)	38	4.1 ± 4.1	–0.4 ± 0.6	0.0001
Maxillary depth angle	38	4.6 ± 4.4	–1.5 ± 3.2	0.0001
Maxillary height angle	38	0.2 ± 4.1	0.2 ± 2.2	0.849

SD – standard deviation; SNA° – angle between sella-nasion plane and nasion – A point plane; A – deepest point between anterior nasal spine and upper incisival alveolus; N – nasion point; FH – Frankfort horizontal line; A – N⊥Fh (McNamara): measured in mm from the line drawn perpendicular N to FH (if the A point, in front of the McNamara was measured positive and behind the McNamara was measured negative); maxillary depth angle: angle between N–A and FH. Maxillary height angle: angle between N–CF and A. CF – intersection point with Pterygoid vertical plane and FH. PTV – a perpendicular line drawn from the distal part of the pterygopalatine fossa to FH; T1–T2: amount of changed points and angles between preoperatively and 1 week postoperatively; T2–T3 – amount of changed points and angles between 1 week and 1 year postoperatively

only the size of the maxilla was used in the analyses. When the change amount differences (T_1–T_2 and T_2–T_3) of angles and points were calculated, movements in the same direction with the direction of movement was assessed as positive and movements in the direction opposite to the movement direction was assessed as negative.

In both groups, there were statistically significant differences in all the points and angles calculated between the preoperative period and the first week after the operation. Except SNA angle in group B, all angles and points after surgery (one week and one year) were found to be related to the amount of relapse in the correlation test (T1–T2/ /T2–T3) in Table 3.

The results according to the type of operation and type of bone graft are listed in table 4.

The postoperative relapse ratios of graft materials are listed in Table 5.

Results were statistically as well as clinically significant in changes of at least 2 mm or 2 degrees.

Table 3. Correlation table

		Group A	Group B
	n (patients)	T1–T2/T2–T3 (r)	T1–T2/T2–T3 (r)
SNA°	42	–0.461**	–0.306
A – N⊥Fh (McNamara)	42	–0.379*	–0.519**
Maxillary depth angle	42	–0.679**	–0.554**
Maxillary height angle	42	–0.664**	–0.373*

** $p < 0.01$ * $p < 0.05$; r – coefficient of correlation.
T1–T2/T2–T3 – the correlation between early and late change amounts.

Table 4. Average amount of displacement, amount of relapses and relapse ratio after one year according to the graft materials used and type of operation

Type of operation	(n) patients group A/group B	Average amount of displacement (mm) group A/group B	Amount of relapse (mm) group A/group B	Relapse ratio (%) group A/group B
MA	33/30	5.8/4.4	0.4/0.3	6.9/6.8
ME	9/8	3.8/3.0	0.4/0.5	10.5/16.6

Group A – Osteoplant-Flex group; group B – autologous graft group; MA – maxillary advancement; ME – maxillary elongation; mm – millimeters.

Table 5. Average amount of displacement, amount of relapse and relapse ratio according to graft materials used

Type of graft material	n (patients)	Average amount of displacement (mm)	Amount of relapse (mm)	Relapse ratio (%)
Group A	42	4.8	0.4	8.3
Group B	38	3.7	0.4	10.8

mm – millimeters; measurements of displacements were calculated in the cephalometric graphics according to "A" point.

Discussion

In spite of the advancements in operative techniques in the last three decades, research to decrease complications and relapses is ongoing in the orthognathic field. The relapse risk increases in patients who undergo large amounts of MA with only rigid fixation due to less contact of bone margins after orthognathic surgery [3, 4]. If the MA is greater than 4 mm, a bone gap will occur in the lateral wall of the maxillary sinus, but it is still not well established what size gaps should be grafted [11]. Often, buccal soft tissue prevents bone fusion and stabilization by herniating into the maxillary gap.

The reconstructive options in the osseous reconstruction of the maxillofacial skeleton include autogenous, allogeneic, and xenogeneic bone grafts and synthetic materials such as hydroxyapatite (HA), other ceramics and polymers. Apart from HA, there are 3 other types of ceramics: tricalcium phosphate, bioglasses, and calcium sulphate. Osteoactive agents such as bone morphogenetic protein (BMP), transforming growth factor β (TGF-β), platelet derived growth factor (PDGF), short amino acid chain peptides (P-15 and OSA-117MV), stem cells and hybrid grafts also have the ability to create new bone [12].

The main reasons for using bone grafts are to act as a barrier against the soft tissues, providing a contact area to accelerate bone healing, and forming a physical barrier against opposing forces [13]. The gold standard of bone grafting is autologous. Superior osteogenic capacity and no immunological reactions are the advantages of autologous bone grafts. On the other hand, there are a few disadvantages of autologous bone graft usage. These are: (1) prevention of another additive operative procedure in the donor area; (2) prolonged operation time; (3) increased pain in the postoperative period; (4) restriction of movement in the lower trunk and extremity; (5) prolonged hospital stay; and (6) resorption of the graft which may lead to osseous instability [14, 15].

Osteoplant-Flex is a demineralized, deantigenized, equine-derived, biocompatible, spongiotic bone material [8]. The preservation of the collagen component (type I bone collagen) allows the grafted material to respond physiologically to the action of the cell elements involved in the regeneration process, thereby facilitating bone regeneration. As it is enzyme deantigenized, it fully undergoes remodeling and is replaced by the patient's endogenous tissue. Deantigenicity is considered to prevent immunogenic reactions in the body. It also undergoes partial demineralization, making it flexible and easily adaptable to curved surfaces and profiles. Therefore, the healing of bone can be achieved in whole bone gap margins. Average remodeling time takes 4–6 months and varies due to individual factors. This feature of the material may contribute to stability in the early postoperative period.

In this study, the cause of usage of Osteoplant-Flex was to eliminate the risk of additional surgery such as pain, bleeding, infection, additional scarring in the donor area, restricted movement, elongated operative time and hospital stays. However, immunogenic reactions and higher cost are the disadvantages of this material. Even so, we saw no immunological reactions when using Osteoplant-Flex. Kramer and his colleagues reported that, of 1000 patients with Le Fort I osteotomy, the incidence of complications was 6.4% [16]. In the present study, the incidence of complications according to the operative technique was 10% (n = 8). But we did not see any complications associated with the described graft.

Relapse is usually 3D, with vertical, horizontal and sagittal components that may occur concurrently after orthognathic surgery. For statistical reasons, relapse has been divided arbitrarily into horizontal and vertical components, depending on the procedure. In cases in which the maxillary movement was in more than one direction, the direction that the maxilla moved the most was evaluated. MA is not a stable approach as it has upward and backward movement of the maxilla [3]. Recent studies show that MA with rigid fixation and graft gives better results in terms of stability [17, 18]. Louis [3], Hoffmann [19], Waite [18], Apornmaeklong [20], and Landes and Ballon [21] published that relapse rates after MA without the use of grafts varies between 10% and 26%. In addition, Egbert [17] and Waite [18] studied that this ratio using bone graft appears to be 6–7% in their studies. Mehra [22] also showed that this relapse rate was 9% in the use of porous block hydroxyapatite (PBHA) as a graft material. These studies show that the relapse rates are lower in graft-used operations than in operations without grafts.

We showed the relapse rates after MA and ME operations to be 6.9% and 10.5% for group A, and 6.8% and 16.6% in group B, respectively (Table 4). Our relapse rates correlate with the literature. But in the present study, there is no comparison between grafted and non-grafted operations. We compared the effects of two types of graft on relapse rates. We found that the relapse rates of each (group A and B) were very similar in the same type of operation. The results show that postoperative stability in patients using the heterologous graft appear to be the same as those using autologous grafts. On the other hand, when we compare the relapse rates of each bone graft materials, we found that the autologous graft relapse rate was 10.8% and heterologous graft relapse rate was 6.8% in all groups (Table 5). According to this result, it can be thought that the heterologous graft is more advantageous than the autologous graft in preventing relapses. But this result is not statistically significant ($p > 0.05$). No matter how reliable the xenogeneic graft is, if there is not a contraindication or need, a defect of the body must be reconstructed with autologous tissue. The Osteoplant-Flex is useful, taking into account the damage/benefit ratio.

In addition, all the angles and points after surgery (one week and one year) were found to be related to the amount of relapse in the correlation test (Table 1 and 2). This result suggests that the measurements of the angles and points in this study are reliable.

One year after the operation, a 2 mm or less relapse is defined as clinically acceptable [23, 24]. In our study, there were no patients who had a relapse of 2 mm or more (Table 4). This result may suggest that our patients' maxillary movement is less than average or the stability which we applied is strong enough. In addition, we have not seen any relapses more than 2 mm even in the 25 patients who needed MA or ME more than 5 mm.

ME is an unstable movement of the maxilla and it is considered at highest risk for relapse, with horizontal extension of the maxilla as the second. Proffit [14], Baker [25], Major [26] and Gurstein [27] showed in their studies postoperative relapse rates between 0.4% and 48% in patients with ME with bone graft. Landes [21] confirmed a relapse rate of 14% without using bone grafts. In a study of Waite et al. [18], on 22 patients with sleep apnea syndrome, cases using bone grafts provided better stability than the reported cases that did not use it. In our study, relapse rates after ME with using a heterologous or autologous bone graft were 10.5% and 16.6% respectively (Table 4). These results confirm that graft usage reduces relapse rate as suggested in the literature.

After the downward movement of the maxilla to overcome the high risk of relapse, the use of rigid fixation methods, especially plaque placement to maxillozygomatic "buttress" and filling of the osteotomy gap with graft material is recommended [23, 28–30]. All operations in this study were done with a 2.0 mm titanium plate-screw system with the use of the graft, as suggested. All patients underwent same stabilization method to be able to evaluate more reliably the effects of the grafts on stability.

In the present study, 29 patients (36.2%) underwent only Le Fort I osteotomy and 51 patients (63.8%) underwent two-jaw surgery (Le Fort I and BSSRO). In both groups, we measured only maxillary relapse after the Le Fort I orthognathic procedure. By the way, the mandibular and soft tissue effects of orthognathic surgery were not calculated in our study.

To the best of our knowledge, we used equine-derived spongiotic bone material to fill the bone gap and to prevent postoperative relapse during Le Fort I osteotomy for the first time.

The authors have concluded that relapses appear to have the greatest impact on the success of orthognathic surgery. For preventing relapses, bone graft materials should be used for filling the maxillary gap and maintaining the stability during orthognathic surgery. Although the autologous graft is the gold standard, the advantages of Osteoplant-Flex are a decrease in postoperative relapse, an effect of stabilization equal to autologous grafts, lower complication rates, prevention of donor area morbidity, shortened operation time and hospital stay, and ease of use and to obtain. Heterologous bone graft material (Osteoplant-Flex) is thought to be a good alternative to autologous grafts in decreasing relapse rates and reducing the morbidity of the donor area in patients who underwent Le Fort I osteotomy.

Although this is the first comparative study of autologous bone graft and Osteoplant-Flex in the usage of the bone gap which is formed after Le Fort I osteotomy, we suggest a larger series of this comparison is needed.

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