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# Bone healing after Le Fort I osteotomy with SSRO, using uHA/PLLA plates and screws, in class II and III patients

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## ABSTRACT

**Purpose:** The purpose of this study was to compare bone healing after Le Fort I osteotomy with sagittal split ramus osteotomy (SSRO) in class II and class III patients.

**Patients and methods:** The subjects consisted of 46 Japanese class II and III patients. Le Fort I osteotomy was performed in combination with SSRO. They were divided into two groups (23 class II cases and 23 class III cases). Four absorbable plates (uncalcined and unsintered hydroxyapatite and poly-L-lactic acid — uHA/PLLA) and screws were used to fix the maxillary segment in all patients, in the same manner. Postoperative computed tomography (CT) was analyzed for all patients at 1 week and 1 year postoperatively. The anterior and lateral areas between the maxillary segments were measured using two-dimensional frontal and lateral views from the three-dimensional images reconstructed over a constant CT value.

**Results:** There were no significant differences in the area of bone defect healing between classes II and III at 1 year postoperatively, although there were significant differences between the two groups at 1 week postoperatively ( $p < 0.05$ ). Furthermore, there were no significant differences in the areas of bone defect between 1 week and 1 year postoperatively, in both groups.

**Conclusion:** Using measurements based on CT value threshold within 1 year after Le Fort I osteotomy, this study suggests that the areas of bony defect in the region of the anterior and lateral walls of the maxilla do not always decrease in both classes II and III.

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## 1. Introduction

Rigid fixation with titanium plates has for some time been used to fix maxillary segments in Le Fort I osteotomy. However, recently developed bioresorbable plates are increasingly being used in place of the titanium plates in orthognathic surgery. Some studies on stability after Le Fort I osteotomy have suggested that the use of absorbable plates is reliable in terms of stability following Le Fort I osteotomy (Norholt et al., 2004; Landes et al., 2007; Landes et al., 2014; Landes and Ballon, 2006a, 2006b; Dhol et al., 2008; Cheung et al., 2008; Ueki et al., 2012). However, there are differences in material properties among the available products. Therefore, surgeons should not assume that all absorbable plates have the same properties.

Generally, absorbable plates are weaker than titanium plates, and their strength gradually decreases over time. Therefore, it is important to understand the balance between the increase in healed bone strength and the decrease in strength of the absorbed plate. The materials used for resorbable plates are poly-glycol-acid (PGA), poly-lactic-acid (PLA) and polydioxanone-sulfate (PDS), which is a copolymer of PGA and PLA (Suuronen et al., 2000). Although PGA has an initial strength similar to stainless steel, it loses its mechanical properties within 6 weeks and is absorbed within 1 year because it is a hydrophilic material (Böstman, 1991). PLA has a longer absorption period of 4–5 years, because PLA is a hydrophobic polymer. PLA is sub-classified into L-lactic acid and D-lactic acid (Bergsma et al., 1995). Recently, P(L/DL) LA — an L-lactic acid and D-lactic acid copolymer of PLA — has been used clinically. It has a mechanical stability of 3–4 months and its absorption period is 2–3 years (Landes et al., 2003). In a plate made from composites of uncalcined and unsintered hydroxyapatite (u-HA) particles and poly-L-lactic acid (PLLA) (Super Fixsorb-MX®; Teijin,

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Osaka, Japan), the morphological changes during biodegradation and bone replacement have been shown to occur over a period of 4.5 years, with molecular weight and bending strength decreasing to 50 kDa and 200 MPa, respectively, after 6 months (Shikinami and Okuno, 1999, 2001; Shikinami et al., 2005). Bone healing after osteotomy within the early period is very important in order to maintain skeletal stability over the long term.

Our previous study indicated that bone healing was not always complete within 1 year after Le Fort I osteotomy in class III patients. However, there has been no report regarding bone healing after surgery in class II patients.

Our hypothesis was that there is a difference in bone healing in the region of the anterior and lateral wall of the maxilla between classes II and III patients. This is due to the difference in force distribution in the area generated by occlusion.

The purpose of this study was to compare bone healing after Le Fort I osteotomy in class II and III patients.

## 2. Material and methods

The subjects were 46 Japanese female patients with jaw deformities diagnosed as skeletal classes II and III. At the time of orthognathic surgery, the patients ranged in age from 16 to 42 years, with a mean age of 25.5 years (standard deviation, 8.6 years). This was a retrospective factorial cohort study, and informed consent was obtained from the patients.

Lateral cephalometric measurements were analyzed pre- and postoperatively, according to previous reports (Iguchi et al., 2017; Ueki et al., 2017). All 46 patients underwent sagittal split ramus osteotomy (SSRO) and Le Fort I osteotomy. Mandibular advancement and maxillary impaction were performed for 23 class II cases (mean age 25.3 years and standard deviation 8.4 years; mean body weight 49.2 kg and standard deviation 6.8 kg), and mandibular setback and maxillary advancement or impaction for 23 class III cases (mean age 25.7 years and standard deviation 8.9 years; mean body weight 51.3 kg and standard deviation 10.1 kg). Two L-type absorbable plates (with screws) at the site of the piriform rim and two L-type absorbable plates (with screws) at the site of the zygomatic buttress (uncalcined and unsintered hydroxyapatite and poly-L-lactic acid (uHA/PLLA): Super Fixsorb-MX<sup>®</sup>, Teijin, Osaka, Japan) were used for all patients, in the same manner. Bone grafts or bone alternative materials were not applied at the osteotomy gap region. Postoperative intermaxillary fixation was not performed, but traction by elastic was performed in all cases.

A high-speed, advantage-type, CT generator (Aquilion One; Toshiba Medical Systems Corp, Tochigi, Japan) was used, similar to the method reported previously (Iguchi et al., 2017). The CT threshold value (in Hounsfield units, HU) for the measurable maxillary bone was standardized as 150 (when the condition was FC21) for both pre- and postoperative images of all patients. The 3D image was reconstructed using 3D visualization and measurement software (Med View version 5.5; LEXI Co, Tokyo, Japan). A 1-year follow up by CT scan was performed for all patients.

The frontal and lateral (right and left) two-dimensional views perpendicular to the FH (Frankfurt) plane were reconstructed to measure the bone defect area between the superior and inferior segments of the maxilla after Le Fort I osteotomy on the right and left sides. A total of 92 sides (46 right and 46 left) were measured. The defective area was measured on the frontal and lateral views using two-dimensional images, which were constructed from the 3DCT images using imaging software (Image J<sup>®</sup>, National Institutes of Health, ML, USA), as in a previous report (Ueki et al., 2011). On the frontal projection view, the bone defect area between the plate on the paranasal area and the plate on the zygomatic buttress was determined as the frontal bone defect area. On the lateral

projection view, the bone defect area between the plate on the zygomatic buttress and the posterior wall of the maxilla was determined as the lateral bone defect area. Then, an outline of the bone defect area was drawn and measured using the same imaging software (Figs. 1 and 2).

Fifteen patients were selected randomly and CT images measured again 10 days later (paired t-test;  $p > 0.05$ ). All CT images were measured by one author (K.U.) after two radiologists in same hospital had checked the images.

### 2.1. Statistical analysis

A t-test was used to compare the data between class II and class III, using the SPSS software program (SPSS Japan Inc., Tokyo, Japan). Differences were considered significant at  $p < 0.05$ .

## 3. Results

Subjects were all female, and there was no significant difference between class II and III in terms of age or body weight. Therefore, this cohort study was considered to be valid.

Postoperative complications such as plate breakage and infection were not observed in class II and III patients after 1 week or 1 year. Wound healing was good in all cases. Postoperative relapse of the maxillary position and occlusion was not observed in any cases.

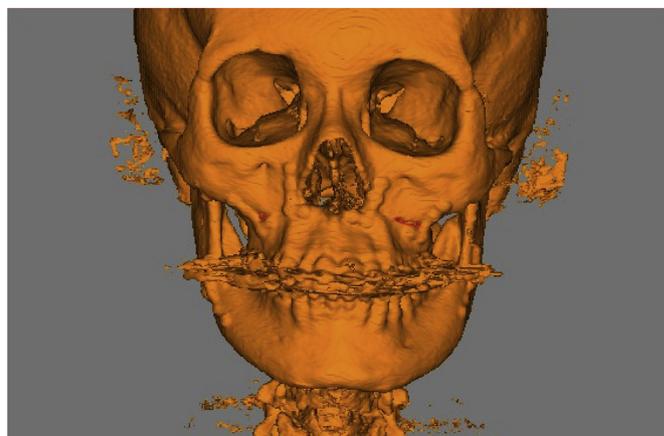


Fig. 1. Measurement of the area of bone defect on a 3DCT image — frontal view. Red area shows bone defect.

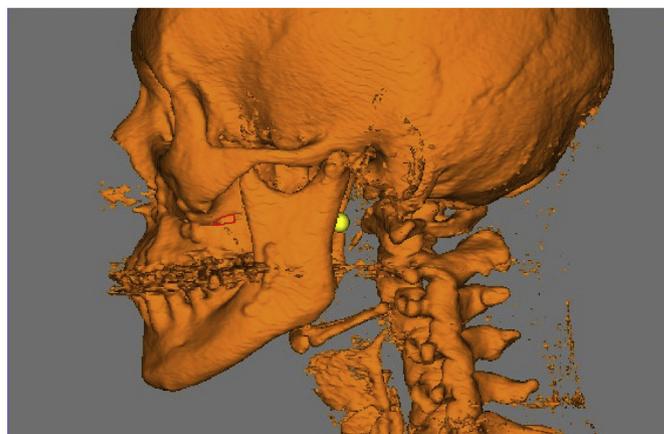


Fig. 2. Measurement of the area of bone defect on a 3DCT image — lateral view (left). Red area shows bone defect.

There were significant preoperative differences between classes II and III regarding SNB ( $p < 0.0001$ ), mandibular plane angle ( $p = 0.0003$ ), and overbite ( $p < 0.0001$ ). There were significant postoperative differences between classes II and III regarding SNB ( $p = 0.0020$ ) and mandibular plane angle ( $p = 0.0474$ ). These data proved that the comparison between the groups was statistically valid (Table 1).

Average amount of maxillary movement in the class III cases was  $1.2 \pm 1.3$  mm anteriorly, with impaction  $2.6 \pm 2.1$  mm at the right molar and  $2.4 \pm 1.9$  mm at the left molar. Average setback amount in the class III cases was  $5.9 \pm 2.6$  mm on the right side and  $5.0 \pm 2.7$  mm on the left side. In the class II cases, average amount of maxillary movement was based on impaction only, with the amount of impaction  $4.5 \pm 1.9$  mm at the right molar and  $3.5 \pm 1.5$  mm at the left molar. Average advancement in the class II cases was  $4.7 \pm 2.1$  mm on the right side and  $4.5 \pm 1.4$  mm on the left side. There was no significant difference regarding the amount of movement of the maxilla between classes II and III.

After 1 week, the area of bone defects for class II was significantly larger than for class III on the right side of the frontal view ( $p = 0.0463$ ), the right side of the lateral view ( $p = 0.0081$ ), and the

left side of the lateral view ( $p = 0.0098$ ). After 1 year, the area of bone defects for class II was still significantly larger than for class III on the right side of the frontal view ( $p = 0.0217$ ) and on the right side of the lateral view ( $p = 0.0088$ ). There were no significant differences between classes II and III at 1 week and 1 year postoperatively for all areas of bone defects (Table 2).

Furthermore, in the class III cases, the proportion of cases in which the area of bone defect was reduced was 8/23 (34.8%) on the right side and 8/23 (34.8%) on the left side of the frontal view, and 6/23 (26.1%) on the right side and 10/23 (43.5%) on the left side of the lateral view. On the other hand, for class II, the proportion of cases in which the area of bone defect was reduced was 10/23 (43.5%) on the right side and 8/23 (34.8%) on the left side of the frontal view, and 6/23 (26.1%) on the right side and 8/23 (34.8%) on the left side of the lateral view. There was no significant difference between classes II and III in the distribution of cases in which the area of bone defect had reduced at 1 year postoperatively (Fig. 3).

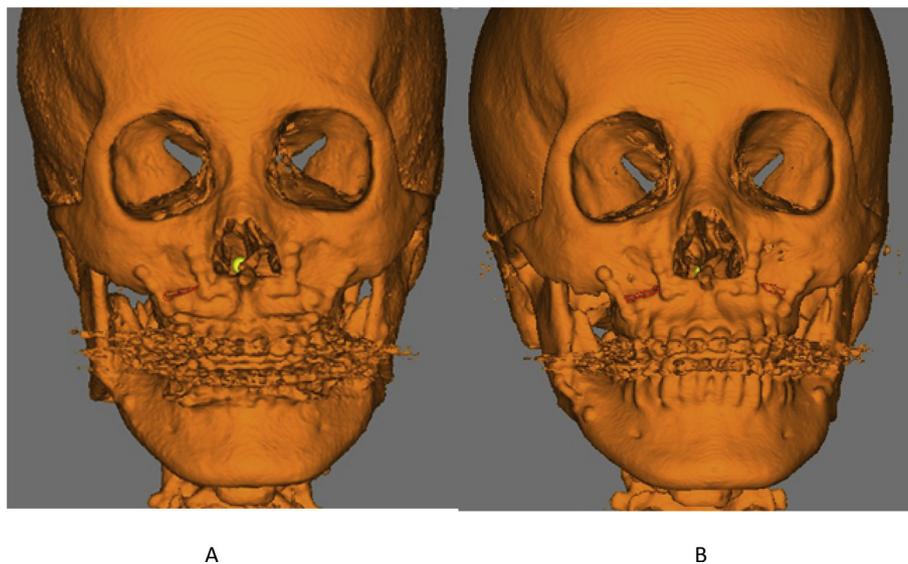
The study examined which factors, including maxillary impaction, advancement amount, cephalometric measurements etc., influenced the rate of reduction in area of bone healing. However, no significant factor could be found.

**Table 1**  
Cephalometric analysis results. SD indicates standard deviation.

		SNA (degree)		SNB (degree)		Mandibular plane angle (degree)		Gonial angle (degree)		Overbite (mm)		Overjet (mm)	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Class III	Pre-operation	82.0	3.1	82.8	3.8	32.3	6.3	130.3	7.4	-3.1	3.6	-1.6	2.7
	Post-operation	82.4	5.1	80.7	4.1	31.8	8.9	128.0	8.6	2.6	1.3	1.6	1.5
Class II	Pre-operation	81.4	3.5	74.9	2.8	38.6	4.5	127.7	6.5	5.5	4.3	-2.6	3.4
	Post-operation	81.1	5.1	76.3	4.9	37.0	8.3	128.9	7.1	3.0	1.4	1.1	1.0

**Table 2**  
Area of bone defect results. SD indicates standard deviation.

		Frontal view (mm <sup>2</sup> )				Lateral view (mm <sup>2</sup> )			
		Right		Left		Right		Left	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD
Class III	After 1 week	5.6	6.4	9.2	10.9	7.2	7.6	9.5	7.2
	After 1 year	4.2	5.4	7.2	6.4	6.0	8.4	10.5	9.8
Class II	After 1 week	13.9	18.4	10.4	11.8	16.8	14.7	18.5	14.3
	After 1 year	10.4	11.3	8.9	10.4	19.9	22.8	19.6	20.4



**Fig. 3.** Frontal view of a 3DCT image: (A) after 1 week; (B) after 1 year. The bone defect was still present on the right side after 1 year.

#### 4. Discussion

The ideal fixation system for stabilization of an osteotomy or bone fracture is one likely to provide adequate strength initially, to permit bone healing when the bone is in use, and then to decrease in strength, thereby increasing physiological force transference to the bone. Biodegradable polymers can achieve this, but not metal materials (Turvey et al., 2011). In short, bone fixation material is not needed after bone healing is complete or if enough strength at the osteotomy site can be obtained by other means.

There are several studies on stability after Le Fort I osteotomy using absorbable plate systems (Norholt et al., 2004; Landes and Ballon, 2006a, 2006b; Dhol et al., 2008; Cheung et al., 2008; Ueki et al., 2012).

In a study comparing resorbable PLLA/PGA plates (LactoSorb<sup>®</sup>, W Lorenz Surgical, Jacksonville, Florida) and titanium mini-plates following Le Fort I osteotomy, Norholt et al. (2004) reported that there were no statistically significant changes in the position of the maxilla from 6 weeks to 12 months postoperatively. However, from immediately to 6 weeks postoperatively there were significant changes at the three points in the anterior site of the maxilla in the LactoSorb<sup>®</sup> group. Landes and Ballon (2006a) concluded that resorbable osteofixation was proven to be as reliable as titanium, but there were notable variations in distributions between the groups in the study, which used poly-L-lactide-co-DL-lactide (PLLDL) plates (MacroSorb<sup>®</sup>, MacroPore, San Diego, CA; or PolyMax, Synthes, Oberdorf, Switzerland) and titanium plates. Furthermore, they noticed that resorbable materials permitted clinically faster occlusion and condylar settling than standard titanium osteosynthesis, because bone segments showed slight clinical mobility up to 6 weeks postoperatively. Dhol et al. (2008) concluded that the use of resorbable copolymer fixation (LactoSorb<sup>®</sup>) for Le Fort I impaction only is a viable alternative to titanium fixation. Cheung et al. (2008) reported that maxillae with bioresorbable fixation (PLLDL; 2.0 compact plating system<sup>®</sup>, Inion Ltd., Tampere, Finland) were significantly more mobile during the second postoperative week, and patients with bioresorbable plate fixation showed significantly more upward displacement in the anterior maxilla following impaction and posterior maxilla following downgrafting from the 2nd to 6th postoperative week. Our previous studies (Ueki et al., 2006, 2012) also suggested that the PLLA (Fixsorb<sup>®</sup>; Takiron, Osaka, Japan) group showed greater displacement at the anterior site of the maxilla in the early postoperative period after Le Fort I osteotomy than the uHA/PLLA and titanium plate groups. Choi et al. (2011) suggested that, in the case of a short anterior facial height, PLLDL resorbable plates (Inion CPS, Inion Ltd., Tampere, Finland) do not provide enough vertical stability in the maxillary position due to the muscle forces.

These studies all suggest that vertical change at the anterior site of the maxilla occurs in the early period after surgery in cases using absorbable plates. Turvey et al. (2011) reported that 40/685 cases where orthognathic surgery had been performed with the PLLD plate system failed in the review, and suggested that minor mobility with the use of the PLLDL system in the maxilla was expected, and was much more frequent than with the use of a more rigid titanium system. In particular, use of the PLLA/PGA, PLLDL, and PLLA plate systems showed a tendency for early change at the anterior site of the maxilla after Le Fort I osteotomy. This period of facial height change, which occurred within 2–6 weeks, was much shorter than the period of mechanical strength reduction reported by manufacturers. Therefore, plate breakage might occur in the early stage after surgery. However, these PLLA/PGA, PLLDL, and PLLA plates are radiolucent, making it difficult to recognize plate breakage. We have experienced cases where breakage of all four PLLA plates has occurred within 1 week after Le Fort I osteotomy.

When absorbable plates are used in Le Fort I osteotomy, clinicians should consider the balance between increase in bone healing strength and decrease in absorbable plate strength. It has been reported that the effect of the number of plates on fixation stability is also important. Using finite element analysis, Erkmen et al. (2009) reported that a four-plate fixation following Le Fort I advancement surgery exerted less stress on the maxillary bones and fixation materials than a two-plate fixation. Uckan et al. (2009) suggested that, with a two-plate fixation, there was a great risk of plate fracture and screw deformation under incisor bite forces greater than 44 N. Wu et al. (2014) stated that fixation using two resorbable plates was not stable, a zygomaticomaxillary pillars fixation was more stable than other fixations, and the stability of fracture fixation was influenced by molar occlusion. In our study, four uHA/PLLA plates were used to fix the maxillary segment at the bilateral zygomaticomaxillary and nasal pillars. Therefore, plate breakage was not found.

Our previous study showed that there were no significant differences in the area of bone defect among the plate types (Ueki et al., 2011). This suggested that differences in absorbable plate materials did not influence bone healing of the maxillary anterior and lateral walls. In the present study, there were no significant differences in the area of bone defect healing between classes II and III at 1 year postoperatively, although there were significant differences between the two groups at 1 week postoperatively. This suggested that preoperative skeletal class and occlusion did not affect bone healing at the maxillary anterior and lateral wall after Le Fort I surgery. Surprisingly, the increase in area showed over 150 HU was not statistically significant at 1 year postoperatively in both class II and class III. This might be due to the large variation in bone quality after surgery.

Regarding the amount of maxillary advancement and impaction, there were no significant differences, although the rotation amount was not measured. In this study, a correlation between the amount of maxillary movement and the area of bony defect in the region of the anterior and lateral walls could not be established.

Lettry et al. (2003) reported that CT values for mandibular cortical bones in 10 cadavers ranged from 976 HU to 1478 HU, with a mean of 1183.9 HU (SD 112.1). In our earlier studies, CT values for the anterior and lateral walls of the maxillary bone exceeded 1200 HU (Ueki et al., 2011, 2013). However, a different CT system was used in the present study, with the CT value recognized as representing bone in these areas changing to 150 HU. In our earlier studies, areas of bone defect as revealed using a different type of CT scan system decreased significantly at 1 year after Le Fort I osteotomy (Ueki et al., 2011, 2013). Differences in CT scan systems may therefore influence results. Although immature bone tissue may not have been detected as bone tissue in this study, the chosen CT value was considered acceptable in that the detection of only hard bone tissue — needed to maintain skeletal strength and stability — was necessary for this study. Although, CT value does not always reflect bone quality and strength, these data can provide important information for selecting fixation materials.

This study suggested that bone formation in the anterior and lateral regions of the maxilla are not complete even at 1 year after surgery. Therefore, when absorbable plates are to be applied in Le Fort I osteotomy, attention should be paid to the material property, fixation site, and plate number.

#### 5. Conclusion

Measurements based on a CT value threshold and taken within 1 year of Le Fort I osteotomy suggest that areas of bony defect in the region of the anterior and lateral walls of the maxilla do not always decrease in both classes II and III.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jcms.2019.06.006>.

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