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**Key words:** 

Bone healing, Pterygoid plate, Le Fort I osteotomy, ultrasonic bone curette, 3-demensional

computed tomography (3DCT)

### **Abstract**

**Purpose.** The purpose of this study was to examine bone healing after Le Fort I osteotomy in Class III patients.

Patients and Methods. The study group consisted of 18 Japanese patients with mandibular prognathism with and without asymmetry, maxillary retrognathism or open bite. A total of 36 sides were examined. Le Fort I osteotomy was performed without a pterygoid osteotome, with an ultrasonic curette used to remove interference at the pterygomaxillary region. Titanium plates (Universal Mid-face fixation module, Stryker, Freiburg, German) were used for four patients, absorbable plates (poly-L-lactic acid (PLLA): NEOFIX®, Gunze, kyoto, Japan) were used for four patients and other absorbable plates (uncalcined and unsintered hydroxyapatite and poly-L-lactic acid (uHA/PLLA): super FIXSORB®MX, Takiron Co. Ltd, Osaka, Japan) were used for ten patients, in the same manner. Postoperative computed tomography (CT) was analyzed for all patients pre-operatively and 1 year post-operative. The anterior and lateral areas between the maxillary segments were measured with 3-dimensional (3D) CT. Bone healing at the pterygomaxillary region was also assessed.

**Results.** There were no significant differences in the area of bone defect healing among the plate types. The areas of bone defect after 1 year were significantly smaller than that immediately after surgery on the right side (p=0.0145) and left side (p=0.0010) in the frontal view and right side in the lateral view (p=0.0118). Bone healing at the pterygo-maxillary junction was found in all cases without artificial pterygoid plate fracture. 14 of 22 sides with artificial pterygoid plate fracture by an ultrasonic curette showed bone continuity between the pterygoid plate and posterior part of maxilla.

**Conclusion**. This study suggested that bony healing could occur in spaces between the segments of maxilla and pterygomaxillary regions as well as the region of the anterior and lateral walls in the maxilla, but it is not always complete within 1 year after Le Fort I osteotomy.

### Introduction

Le Fort I osteotomy is one of the standard procedures for the management of dentofacial deformities (*Bell* et al., 1980; *Bell* et al., 1988).

Factors that have been implicated for instability after Le Fort I osteotomies include presurgical orthodontics, inadequate mobilization, inappropriate or lack of grafting, increased masticatory forces, inadequate methods of fixation, type and amount of movement, soft tissue tension, and presence of cleft. Various fixation techniques have been used for maxillary stabilization including trans-osseous and suspension wires, intraoral skeletal fixation appliances, and bone plating (*Ueki* et al., 2007; *Marşan et al.*, 2009; *Mavili et al.*, 2009; *Kretschmer et al.*,2010). Post-operatively, the maxilla appears to be healed and in a stable position on clinical assessment.

With regard to animal studies, Bell et al. have reported primate studies that provide biologic insight into the bone healing and revascularization processes that accompany maxillary osteotomies (*Bell*, 1969; *Bell & Levy*, 1971; *Bell* et al., 1975). These studies have indicated that osseous union of osteotomized sites occurs as early as six weeks postoperative. However, there have been few histologic studies on human tissue to verify the type of repair that is initiated. A previous study by *Compton* et al. (1984) indicated that the area between the segments healed with mature compact bone, from the evaluation of punch biopsy at the osteotomy site of five patients after Le Fort I osteotomy. However, the period of biopsy was not constant, ranged from 17 to 30 months, and there was no detailed description of the site that was taken for biopsy. It was unclear whether all sites on the osteotomy line could induce new bone.

Although the evaluation of bone healing after Le Fort I osteotomy is needed to determine the site and method of the fixation plate, there is no report on bone healing using 3-dimensional computed tomography (3DCT) after Le Fort I osteotomy.

The purpose of this study was to examine bone healing of the anterior and lateral walls of the maxilla and pterygomaxillary junction regions, after Le Fort I osteotomy in Class III patients, using 3DCT.

### **Patients and Methods**

## **Patients**

The 18 Japanese adults (men:5, women: 13) in this study presented with jaw deformities and diagnosed as mandibular prognathism with/without bi-maxillary asymmetry, maxillary retrognathism or open bite. At the time of the orthognathic surgery, the patients ranged in age from 16 to 42 years, with a mean age of 24.1 years (standard deviation, 7.3 years). Informed consent was obtained from the patients and the study was approved by Kanazawa University Hospital. Fourteen patients underwent Le Fort I osteotomy with bilateral sagittal split ramus osteotomy (SSRO), three patients underwent Le Fort I osteotomy with intraoral vertical ramus osteotomy (IVRO) and one patient underwent Le Fort I osteotomy with SSRO for right side and IVRO for left side (Table 1.).

## Surgical procedure

All patients underwent a standard Le Fort I osteotomy following a periodontal incision at the anterior teeth and a vestibular incision at the posterior teeth to prevent any postoperative scar at the labial gingival tissue, with inter-maxillary fixation screws (Stryker LEIBINGER, Freiburg, Germany or Jeil Medical, Seoul, Korea) implanted in the bimaxillary anterior alveolar bone. The lateral wall of the maxillary sinus was cut using a reciprocating saw, and the nasal septum and lateral nasal walls were sectioned with a chisel. Pterygomaxillary separation was performed without an osteotome. A bone separator was fixed in a thick bony area of the lateral wall of the maxillary sinus, attached with screws implanted in the maxilla, and wired to fracture and pull down the maxillary segment. This method could facilitate the down fracture rather than the conventional method. Furthermore, pulling down the wires made it easier to see and operate in the pterygomaxillary region. The posterior wall of the maxillary sinus, the maxillary tuberosity, and the pterygoid process were then exposed. The maxillary segment was pulled down and forward and small

bone pieces were removed along with surplus sinus membranes, allowing the descending palatine artery to be seen from the pterygopalatine fossa to the nasal wall. The Sonopet UST-2001<sup>TM</sup> ultrasonic bone curette (Miwatec Co., Ltd., Kawasaki, Kanagawa, Japan) was used to remove interference between the pterygoid process and the posterior part of the maxilla without damaging the descending palatine artery or other vessels and nerves. "Artificial fracture" of pterygoid plate could facilitate movement of the maxilla (*Ueki* et al., 2004; *Ueki* et al., 2009). The maxillary segment was then repositioned with an intermediate occlusal splint and fixed with mini-plates and mono-cortical screws.

Two L-type titanium plates at the site of the piriform rim, two straight titanium plates at the site of the zygomatic buttress and screws (Universal Mid-face fixation module, Stryker, Freiburg, German) were used for four patients, Two L-type absorbable plates at the site of the piriform rim, two straight titanium plates at the site of zygomatic buttress and screws (poly-L-lactic acid (PLLA): NEOFIX®, Gunze, kyoto, Japan) were used for four patients and other absorbable plates and screws (uncalcined and unsintered hydroxyapatite and poly-L-lactic acid (uHA/PLLA): super FIXSORB®MX, Takiron Co. Ltd, Osaka, Japan) were used for ten patients, in the same manner (Table.1). Post-operative inter-maxillary fixation was not performed, but traction by elastic was performed in all cases.

# CT assessment

The patients were placed in the gantry with the tragacanthal line perpendicular to the ground for CT scanning. They were instructed to breathe normally and to avoid swallowing during the scanning process. CT scans were obtained in the radiology department by skilled radiology technicians using a high-speed, advantage-type CT generator (Light Speed Plus; GE Healthcare, Milwaukee, WI, USA) with each sequence taken 1.25 mm apart for the 3D reconstruction (120 kV, average 150 mA, 0.7 sec/rotation, helical pitch 0.75). The 3-D image was reconstructed by 3D visualization and measurement software Med View version 5.5 (LEXI Co, Tokyo, Japan). The threshold of the CT value (Hounsfield units: HU) of the measurable maxillary bone was standardized as over 1200 for

both of pre- and postoperative images of all patients. 1 year follow up CT scan was taken for all patients who underwent orthognathic surgery and informed consent was obtained.

## Measurements using CT

The frontal and lateral (right and left) 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 36 sides (18 right and 18 left sides) were measured. The defective area was measured in the frontal and lateral views (as 2 dimensional images) made from the 3DCT images using the image software (Scion image, Scion corporation ML, USA) and Med View version 5.5 (LEXI Co, Tokyo, Japan).

The same horizontal plane images parallel to the FH plane at immediately and 1 year post-surgery including the region where the pterygoid plate was fractured or the anterior aspect of pterygoid plate removed were used to evaluate bone healing at the pterygomaxillary junction region.

Evaluation of bone formation between the posterior part of the maxilla and pterygoid plate was set at window width of 2000 and window level of 200. Completion of bone healing at the pterygomaxillary region was judged as bone continuity between the pterygoid plate and the posterior part of the maxillary segments.

All CT images were measured by an author. Fifteen patients were selected randomly and CT images were measured again 10 days later (paired t-test; p>.05). All CT images were measured by an author (K.U.). Fifteen patients were selected for calculations using the Dahlberg's formula (*Dahlberg*, 1940):

$$ME = \sqrt{\sum d^2/2n}$$

where d is the difference between 2 registrations of a pair, and n is the number of double registrations. The random errors did not exceed 0.21 mm for the linear measurements, and  $2.0 \text{ mm}^2$  for the square measurements.

## Statistical analysis

Data were compared between the right and left by paired t-test using the Stat View<sup>TM</sup> version 4.5 software program (Abacus Concepts, Inc., Berkeley, CA, USA). Differences were considered significant at p<0.05.

### Results

No fracture was noted in the upper third of the pterygoid plates, and there was no fracture of the cranial base. Eleven patients (22 sides) underwent an artificial pterygoid fracture or bone removal in the pterygomaxillary region. Intended maxillary movement by simulation surgery could be achieved in all cases by using fore-mentioned ultrasonic bone curette. Therefore, there was no difference between intended maxillary movement and actual post-operative maxillary movement. Blood loss was small and no patient required transfusion.

The titanium plate and uHA/PLLA plate were visible, but the PLLA plate was invisible on the 3DCT image. At 1 year postoperative, the shape of the uHA/PLLA plate did not change in all cases. Therefore, the overlapped area between the bone defect and the plate was not included in the measurement of the area in the cases where the titanium plate and uHA/PLLA plate (Fig.1) were used.

The subjects were divided into three groups (titanium, PLLA, and uHA/PLLA), although the sample number was small. The difference in the area of the defects between immediately after surgery and 1 year after surgery was calculated, and multiple comparisons were performed statistically. However, there were no significant differences in the area of bone defect healing among the plate types.

The results of the statistic analysis without group division showed that the areas of bone defect after 1 year were significantly smaller than that immediately after surgery on the right side (p=0.0145) and left side in the frontal view (p=0.0010) and right side in the lateral view (p=0.0118) (Fig. 2). After 1 year, complete bone continuity between segments could be recognized in 3/18 sides on the right and 5/18 sides on the left in the frontal view, and 4/18 sides on the right and 2 /18 sides on the left in the lateral view (Fig. 3). However,

the area of bone defect after 1 year increased in 6 /18 sides on the right and 3/18 sides on the left in the frontal view, and 2/18 sides on the right and 6 /18 sides on the left in the lateral view (Fig. 4).

Bone healing at the pterygo-maxillary junction was found in all cases without artificial pterygoid plate fracture. In 14 of 22 sides (63.6%) with artificial pterygoid plate fracture, there was bone healing between the pterygoid plate and posterior part of the maxilla (Fig. 5). However, 8 of 22 sides (35.4%) with artificial pterygoid plate fracture did not show bone continuity between the pterygoid plate and posterior part of the maxilla (Fig.6).

## **Discussion**

In Le Fort I osteotomy, incomplete ossification of osteosynthesis is one of the major problems (*Proffit* et al., 2003). If the size of the defect between the advanced inferior maxillary segment and the superior segment exceeded 3mm at the levels of the piriform rim and zygomaticomaxillary junction following Le Fort I osteotomy, use of a bone graft can become necessary for stabilization. Furthermore, bone recovery would be inadequate if there is a defect of more than 3 mm between the segments along the line of osteosynthesis. The line of osteosynthesis would involve a fibrous tissue rather than osseous tissue. In this instance, resistance to relapse would be via this fibrous tissue and the initial plate and screw rather than a robust osseous tissue (*Holmes* et al., 1988; *Proffit* et al., 2003). However, there has been no well-controlled study in which the maxilla is advanced to a large distance with and without bone grafting.

In orthognathic surgery, bone fragments are usually fixed with the use of metallic plates and screws. Recently, the use of resorbable materials to stabilize the maxillofacial skeleton has been reported (*Ueki* et al., 2005, *Ueki* et al., 2006). In this study, there was no significant difference between the titanium plate, PLLA plate and uHA/PLLA plate. It has been proven that the uHA/PLLA plate produced osteoconductivity in vitro (*Shikinami* et al., 2005). However, in this study, the finding was that new bone formation surrounding

the uHA/PLLA plate was not found in the 3DCT image at1 year postsurgery.

Currently, several studies have reported the interpretation of the 3DCT and multiplanar reconstructed images by CT as supplying more information than axial (2D) images, providing more reliable diagnosis, effective therapeutics, evaluation of treatment, and consequently reducing the manifestation of sequelae (*Albrecht & Blomley*, 1998; *Cavalcanti* et al., 1999; *Chacon* et al., 2003, *Ueki et al.*, 2009b). When the 3DCT reconstruction was performed and evaluated, the threshold of the CT value was very important to judge whether it was matured bone or soft tissue. *Lettry* et al. (2003) reported that the CT values of mandibular cortical bones in 10 cadavers ranged from 976 HU to 1478 HU, with a mean of 1183.9 HU (SD 112.1). However, there is no report regarding the anterior and lateral walls of the maxillary bone that will allow CT values be determined as over 1200 HU. Although immature bone tissue might not be detected in this study, this determination of CT value was considered acceptable, because the detection of just hard bone tissue to keep the skeletal strength and stability was necessary for this study.

The areas of bone defect after 1 year were significantly smaller than that immediately after surgery in the right and left anterior wall and right lateral wall of the maxilla. However, the area of bone defect increases in some cases. The patient who underwent 5 mm maxillary advancement had the largest bone gap between the segments in this study, but complete bone healing at the anterior and lateral walls could occur after 1 year. On the other hand, although bone contact between segments could be established in the maxillary impaction cases intra-operatively, there were cases where complete bone healing could not be achieved after 1 year. This suggested that thin bone at the edge along the osteotomy line could be resorbed after 1 year postsurgery.

In our previous report, there was no difference in the stability following Le Fort I osteotomy without bone graft between a titanium plate group and an absorbable plate group in most frontal and lateral cephalometric measurements. However, a significant difference in the A point in the lateral cephalometric measurements was found between the two groups (*Ueki* et al., 2006). This suggested that the difference between titanium and the absorbable plate could affect the stability following Le Fort I osteotomy. On the other hand, in the

animal study of Calhoun et al., the healing findings provided only a qualitative evaluation of differences in the stages of healing (*Calhoum* et al., 1989). The finding of better healing with semi-rigid fixation than with rigid fixation suggested that a small amount of movement between bone segments might stimulate healing. Actually, the absorbable plate is weaker than the titanium plate. However, it was proved that PLLA and uHA/PLLA plates were stronger rather than the surrounding cortical bone (*Shikinami* et al., 2005; *Marumo* et al., 2006). Furthermore, this study showed that there were no significant differences in the area of bone defect among the plate types. It was considered that various factors such as preoperative bone thickness, occlusion, inter-maxillary traction, moving direction and amount, age and gender etc. were associated with the healing at the anterior and lateral wall of maxilla. The change in the stress distribution at the region of the space between segments might also affect the change in the bone area. At least, use of bone graft or an alternative material may not be decided on the basis of only the amount of bony gap by movement of the maxillary segment.

In the previous study with CT after Le Fort I osteotomy, exact separation of the pterygomaxillary junction at the posterior nasal spine level was found in only 18 of 74 sides (24%). In 29 of 74 sides (39.2%), separation occurred anteriorly to the descending palatine artery. In 29 of 74 sides (39.2%), complete separation between the maxillary tuberosity and the lateral and/or medial pterygoid plate did not occur at the pterygomaxillary junction at the posterior nasal spine level. However, exact separation occurred more frequently at the lower level, with no complications (*Ueki* et al., 2009a).

It remains unclear whether bone healing could occur at the region of the pterygo-maxillary junction after artificial pterygoid fracture of the anterior part of the pterygoid plate. Bone healing at the pterygo-maxillary junction was found in all cases without artificial pterygoid plate fracture. This result might be due to the fact that the amount of the maxillary advancement or impaction was comparatively small in this study. Furthermore, in 14 of 22 sides (63.6%) with artificial pterygoid plate fracture, there was bone healing between the pterygoid plate and posterior part of maxilla. However, 8 of 22 sides (35.4%) with artificial pterygoid plate fracture did not show bone continuity. We did

not use an osteotome to separate the pterygomaxillary junction, suggesting a green stick fracture occurred in most cases when the maxillary segment was fractured down in the previous study. Pterygomaxillary dysjunction was found in only 24% of cases, so the pterygomaxillary junction might not always be adequate to separate the segments at the posterior nasal spine level. Thus, the separation pattern at the pterygomaxillary junction varied greatly indicating that the pattern of bone healing could vary. Removal volume of the pterygoid plate or posterior part of the maxilla and the distance between the pterygoid plate and maxillary segment might be related to healing at this region after 1year. If the mechanical stress stimulation at the pterygomaxillary region increases according to recovery of the occlusal force after more than 1 year, bone healing volume may increase there.

### Conclusion

This study suggested that bony healing could occur in the space between the segments of the maxilla and pterygomaxillary regions as well as at the region of anterior and lateral wall in maxilla, but it is not always complete within 1 year after Le Fort I osteotomy. However, further examination using a large sample number will be necessary.

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## Legends

Fig.1 Measurements of the area of bone defects on 3DCT image. A: frontal view, B: lateral view. Red area shows bone defect. A uHA/PLLA plate was used in this case, so that the plate was visible.

Fig. 2 The area of defects between segments. Error bars show the standard deviation. \* indicates a significant difference at P<0.05.

Fig. 3 Frontal view of the case where a PLLA plate was used. A: immediately after surgery. The bone defect was recognized. B: 1 year after surgery. The bone healing completed. The PLLA plate was not visible on the 3DCT.

Fig. 4 Frontal view of the case where a PLLA plate was used. A: immediately after surgery. The bone defect was recognized. B: 1 year after surgery. Although bone continuity between segments at the lateral wall region was found, the bone defect increased at the frontal wall of the maxilla. The PLLA plate was not visible on the 3DCT.

Fig. 5 Horizontal plane of CT at the pterygomaxillary junction. A: immediately after surgery. The anterior part of pterygoid plate was removed and pterygoid fracture was performed. Red arrows show the space between the maxillary segments and pterygoid plate. B: 1 year after surgery. Bone healing with continuity between the maxillary segments and pterygoid plate completed.

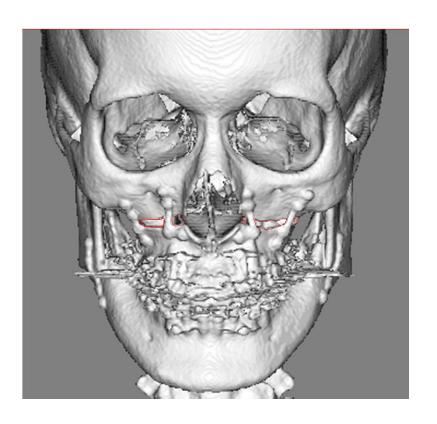
Fig. 6 Horizontal plane of CT at the pterygomaxillary junction. A: immediately after surgery. The anterior part of the pterygoid plate was removed and pterygoid fracture was performed. Fracture of the posterior wall of the maxilla could be observed. Red arrows showed the space between the maxillary segments and pterygoid plate. B: 1 year after

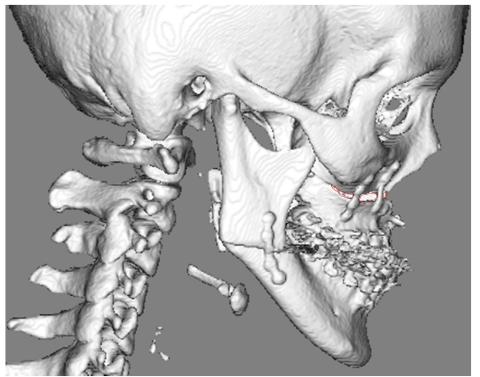
surgery. The area of bone healing increased and fracture of the posterior wall of the maxilla healed, but bone continuity between the maxillary segments and pterygoid plate did complete.

Table. 1. Table I. Patient data. SSRO: sagittal split ramus osteotomy, IVRO: intraoral vertical ramus osteotomy, L1:Le Fort I osteotomy, PLLA: poly-L-lactic acid (absorbable) plate. uHA/PLLA: uncalcined and unsintered hydroxyapatite and poly-L-lactic acid (absorbable) plate

Case number	Diagnosis	Age (yrs)	Sex	Procedures	Setback right Setback left		Plate	Osteotomy in	Maxillary movement
					(mm)	(mm)		pterygoid process	
1	bi-maxillary asymmetry, mandibular prognathia	20	F	L1,IVRO	3	0	titanium	bilateral	2 mm side shift to the right, right 4 mm up
2	mandibular prognathia, open bite	28	F	L1,SSRO	8	8	PLLA	bilateral	whole 8 mm up
3	mandibular prognathia	21	M	L1,SSRO	10	10	PLLA	bilateral	4 mm up at the postrior teeth
4	mandibular prognathia, maxillary retrognathism	18	F	L1,SSRO	8	9	titanium	n	5 mm advance
5	bi-maxillary asymmetry, mandibular prognathia	34	F	L1,SSRO	9	2	titanium	bilateral	right 3 mm up and left 3 mm down
6	bi-maxillary asymmetry, mandibular prognathia	42	F	L1,SSRO	6	5	uHA/PLLA	n	right 3 mm down and left 3 mm up
7	bi-maxillary asymmetry, mandibular prognathia	17	F	L1,SSRO	6	5	uHA/PLLA	bilateral	2 mm advance, right 3 mm down and left 3 mm up
8	mandibular prognathia, maxillary retrognathism	16	F	L1,SSRO	8	8	uHA/PLLA	n	4 mm advance
9	bi-maxillary asymmetry, mandibular prognathia	24	M	L1,SSRO,IVRO	4	3	titanium	bilateral	right 8 mm up and left 5 mm up
10	mandibular prognathia, maxillary retrognathism	16	F	L1,SSRO	6	6	uHA/PLLA	n	4 mm advance, right 3 mm up and left 4 mm up
11	mandibular prognathia, open bite	23	F	L1,SSRO	4	2	uHA/PLLA	bilateral	whole 8 mm up
12	bi-maxillary asymmetry, mandibular prognathia, open bite	21	M	L1,SSRO	3	3	uHA/PLLA	bilateral	2 mm advanve, right 3 mm up and left 5 mm up at the posterior teet
13	mandibular prognathia, maxillary retrognathism	20	M	L1,SSRO	8	6	uHA/PLLA	n	2 mm advance and 4 pieces segmental osteotomy
14	bi-maxillary asymmetry, mandibular prognathia	28	F	L1,SSRO	8	7	uHA/PLLA	n	right 8 mm up and left 3 mm up
15	bi-maxillary asymmetry, mandibular prognathia	37	F	L1,IVRO	1	1	PLLA	n	whole 4 mm up
16	bi-maxillary asymmetry, mandibular prognathia	26	M	L1,IVRO	4	1	uHA/PLLA	bilateral	right 4 mm up
17	bi-maxillary asymmetry, mandibular prognathia	24	F	L1,SSRO	1	1	uHA/PLLA	bilateral	3 mm down at the anterior teeth and 8 mm up at the posterior teeth
18	mandibular prognathia	19	F	L1,SSRO	5	5	PLLA	bilateral	left 4 mm up
average		24.1			5.7	4.6			
sd		7.3			2.7	3.1			

Table. 1





A

Fig. 1

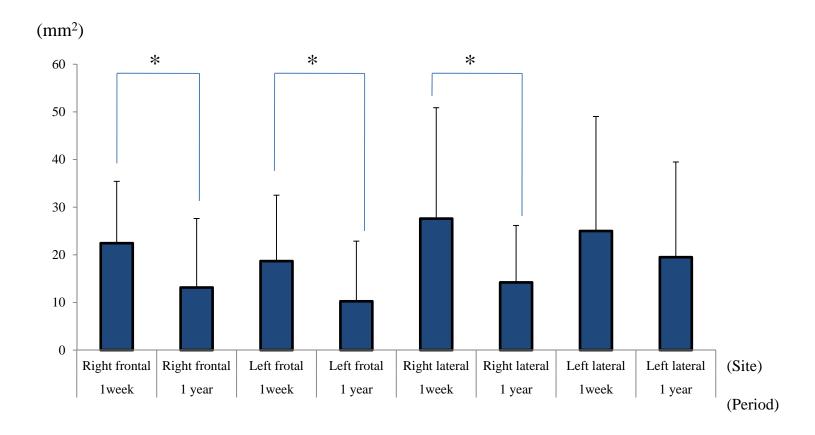


Fig. 2

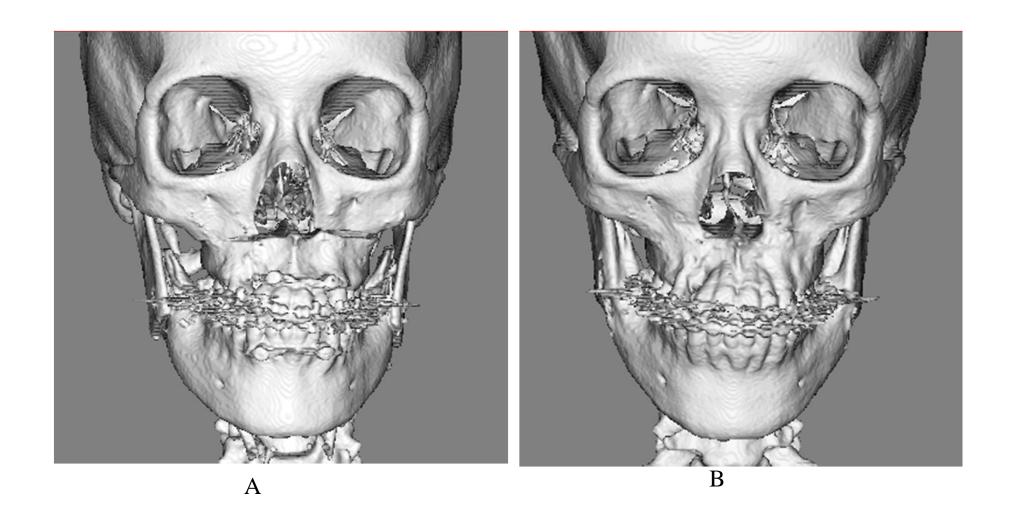
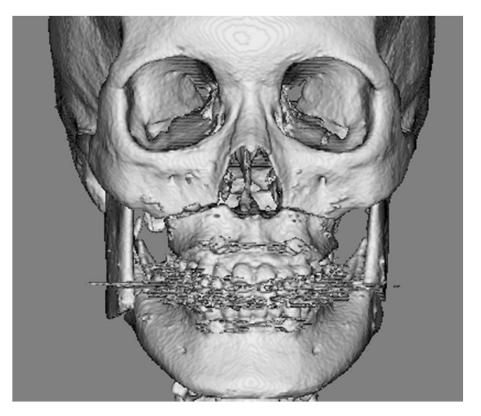
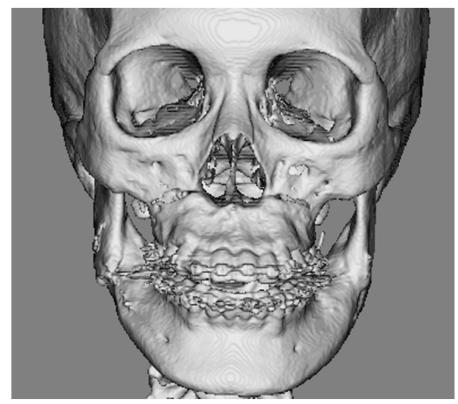


Fig. 3





A

Fig. 4

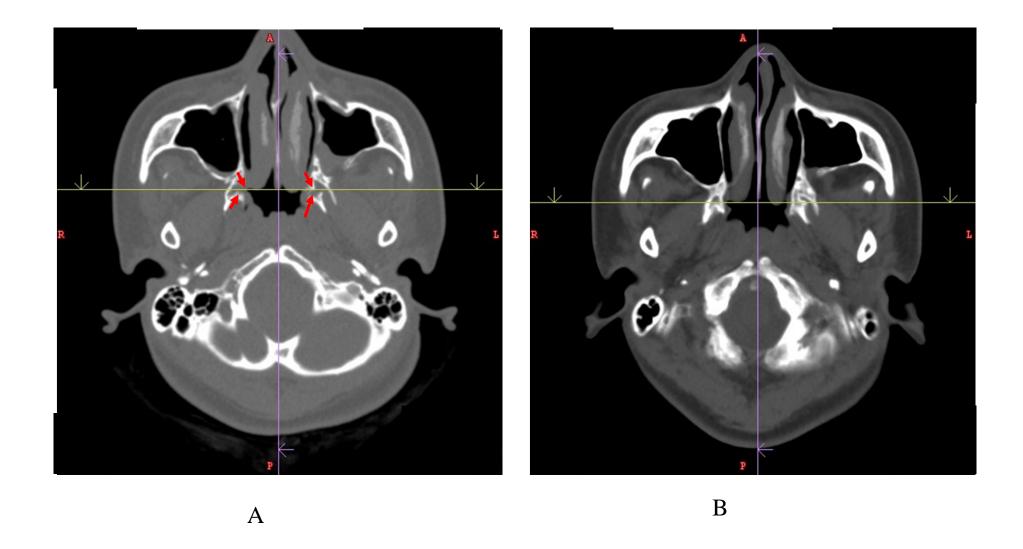


Fig. 5

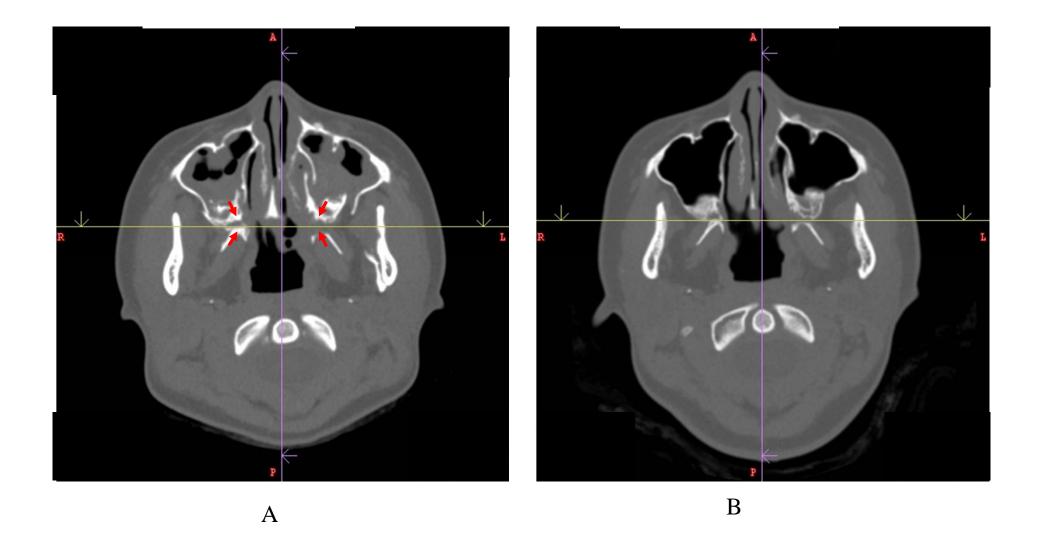


Fig. 6