Effect of self-setting α-tricalcium phosphate between segments for bone healing and hypoaesthesia in lower lip after sagittal split ramus osteotomy

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Abstract

Purpose. The purpose of this study was to evaluate hypoesthesia of lower lip and bone formation using self-setting α-tricalcium phosphate (Biopex®) between the proximal and distal segments following sagittal split ramus osteotomy (SSRO) with bent absorbable plate fixation.

Subjects and Methods. The subjects were 40 patients (80 sides) who underwent bilateral SSRO setback surgery. They were divided into a Biopex® group (40 sides) and a control group (40 sides). The Biopex® was inserted into the anterior part of the gap between the segments in the Biopex® group. Trigeminal nerve hypoesthesia at the region of the lower lip was assessed bilaterally by the trigeminal somatosensory-evoked potential (TSEP) method. Ramus square, ramus length, and ramus width, the square of the Biopex® at the horizontal plane under the mandibular foramen were assessed preoperatively, immediately after surgery, and 1 year postoperatively by computed tomography (CT).

Results. The mean measurable period and standard deviation were 9.3±15.7 weeks in the control group, 5.3±8.3 weeks in the Biopex® group, and there was no significant difference. Ramus square after 1 year was significantly larger than that prior to surgery and new bone formation was found between the segments in both groups ($P<0.05$). In the Biopex® group, the square of the Biopex® after 1 year was significantly smaller than that immediately after surgery ($P<0.05$).

Conclusion. This study suggested that inserting Biopex® in the gap between the proximal and distal segments was useful for new bone formation and it did not prevent the recovery of lower lip hypoesthesia after SSRO with bent absorbable plate fixation.

Key words:

Self-setting α-tricalcium phosphate (Biopex®), Trigeminal somatosensory-evoked potential (TSEP), Sagittal split ramus osteotomy (SSRO), Computed tomography (CT), Absorbable plate

Introduction

Sagittal split ramus osteotomy (SSRO) is widely used to correct jaw deformities (*Bell*, 1992). In SSRO, it is considered that the large area of bony contact and rigid fixation using the mini-plate or screw can promote early osseous union and healing.

Bony interference between the proximal and distal segments of the mandible can result in lateral displacement of the proximal segment, resulting in condylar rotation and/or displacement. Rotation and/or displacement of the condyle can proceed not only to relapse but also to temporomandibular joint pain, clicking sounds, disc displacement, and condylar resorption (*Hackney et al.*, 1989; *Harris et al.*, 1999). Therefore, it is important to maintain the space between 2 segments (*Hu et al.*, 2000). Bell (1992) proposed that a bone fragment should be inserted into this space to maintain the preoperative position of the proximal segment. *Bettega et al.* (2002) reported that in comparing patient groups with and without an intersegmental bone graft after 1 year of computer-assisted orthognathic surgery, those with a bone grafts showed better results.

On the other hand, we have used the bent plate and screw without bone graft in order to prevent rotation and/or displacement of the condyle. In the previous study *(Ueki et al.*, 2009b) the gap between the proximal and distal segments could fill with new bone after SSRO with both bent titanium and absorbable plates, even if there were few bony contacts between segments. However, a concave outline was observed in some cases in the study, although the square of ramus increased significantly. In other words, the bone defect was found in the anterior part of the ramus after 1year in some cases. Therefore, the use of filling material in of the space between the segments was assumed to be clinically necessary.

However, one of the major complications after SSRO is lower and upper lip hypoesthesia. Standard sensory testing modalities include the following parameters: threshold of light touch perception, two-point discrimination threshold, temperature sensitivity, and trigeminal somatosensory-evoked potentials (TSEP) (*de Beukelaer et al.*, 1998; *Jones & Wolford,* 1990; *Nakagawa et al.*, 1997; *Nakagawa et al.*, 2001; *Nakagawa et* *al.*, 2003). The TSEP method is non-invasive, highly objective and extremely reliable and can be used to investigate trigeminal sensory hypoesthesia of the lower lip after mandibular ramus osteotomy.

It is important evaluate whether the bone substitute material between proximal and distal segment prevent the recovery of inferior alveolar nerve after SSRO.

The purpose of this study was to evaluate hypoesthesia of lower lip with TSEP and bone formation using self-setting α-tricalcium phosphate (Biopex®) between the proximal and distal segments after SSRO with bent absorbable plate fixation.

Patients and Methods

Patients

Forty Japanese adults (men: 13, women: 27) in this study presented with jaw deformities diagnosed as mandibular prognathism with and without maxillary deformity. At the time of orthognathic surgery, the patients ranged in age from 16 to 50 years, with a mean age of 27.5 years (standard deviation, 11.2 years). Informed consent was obtained from the patients and the study was approved by Kanazawa University Hospital.

Surgery

The study group comprised 40 patients (80 sides) who had mandibular prognathism (20; 40 sides, the Biopex® group; 20; 40 sides, the control group). The groups were randomized to show similar distribution in preoperative SNB. All the patients underwent BSSO setback by the Obwegeser method. At the time of fixation, the dental arch of the distal segment was secured to the maxillary arch with an interpositional splint and a 0.4-mm wire. In both groups, a mini-plate (28×4.5×1.5 mm) and 4 screws (2×6 or 2×8 mm) (Super-Fixorb®-MX, Takiron Co., Osaka, Japan) were placed in the mandibular angle region.

When the proximal and distal segments are fixed with straight plates after setback surgery, the proximal segments containing the condylar head cause internal rotation. Thus, it was assumed that the use of bent plates was the most efficient and simple method to prevent internal rotation of the proximal segments (Fig. 1) (*Ueki et al.*, 2001).

In the Biopex® group, Biopex® was inserted at the anterior part of the gap between the segments after plate fixation.

After day 1 of surgery, an elastic was placed to maintain ideal occlusion. All patients received orthodontic treatment before and after surgery. A CT scan was obtained for all patients preoperatively, immediately after surgery and 1 year after surgery.

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. The scanning was performed 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 3D reconstruction (120 kV, average 150 mA, 0.7 sec/rotation, helical pitch 0.75). The resulting images were stored in the attached workstation computer (Advantage workstation version 4.2; GE Healthcare, Milwaukee, WI, USA) and the 3D reconstruction was performed using the volume rendering method. ExaVision LITE version 1.10 medical imaging software (Ziosoft, Inc, Tokyo, Japan) was used for 3D morphologic measurements.

Measurement of ramus using CT

The RL line was determined as the line between the most anterior points of the bilateral auricles. The horizontal plane under the mandibular foramen parallel to the FH plane was identified, and the ramus area was measured pre- and postoperatively and bilaterally (Figs. 2 and 3). The threshold of the CT value (Hounsfield units: HU) of the measurable bone was standardized as over 1200 for both of pre- and postoperative images of all patients. It was difficult to distinguish between cortical bone and the Biopex by the CT values. However, the Biopex material that was inserted could be identified as a radiopaque image at windows level of 500 and windows width of 4000 as shown in Fig.2-4. The setting was determined after attempt to change the window level and width randomly.

1) Ramus length: the distance between the most anterior point and most posterior point of ramus.

2) Ramus width: the distance between the most medial point and the cross point between the lateral outline of ramus and the line through the most medial point parallel to the RL line.

3) Ramus square: the square that showed the total area of the proximal plus distal segments when the image was measured immediately after surgery.

4) Length of Biopex®: the distance between the most anterior point and most posterior point of Biopex®

5) Width of Biopex®: the distance between the most medial point and the most lateral point of Biopex®

6) Square of Biopex®: the square that showed the total area of the anterior part of ramus

All CT images were measured by an author (K.U.). Fifteen patients were selected and the calculation performed using Dahlberg's formula (*Dahlberg,* 1940):

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

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 mm^2 for the square measurements.

Trigeminal nerve hypoesthesia was assessed bilaterally by the TSEP method. The methodology and values of TSEP have been described previously in our preliminary studies (*Nakagawa et al.*, 1997; *Nakagawa et al.*, 2001; *Nakagawa et al.*, 2003). The electrodes were placed exactly under the highest point of the vermilion border and on the mucosa of the lower lip. An electroencephalograph recording system (Neuropack Sigma™; Nihon Koden Corp., Tokyo, Japan) was used to measure the potentials. The right and left sides were measured separately so that a total of 80 sides could be assessed. Each patient was evaluated pre-operatively and then post-operatively at 1 and 2 weeks, 1, 3 and 6 months and 1 year.

Trigeminal hypoesthesia was assessed by the latency of P1 and N2 in the recorded TSEP spectra. An earlier pilot study in healthy volunteers showed that these peaks produced an accurate figure and tended to result in better reproducibility. Measurable periods of TSEP were defined as periods before the peaks of N1 (N13), P1(P17), N2(N27), P2(P36) and N3(N46) that were identified clearly as early components of the TSEP wave. Actual data was recorded as the latency period (msec) in each peak.

The measurable period was determined as the time when TSEP was first measurable post-operatively. Measurement of TSEP after surgery was continued until TSEP became measurable.

Statistical analysis

Data were statistically analyzed with StatView software, version 4.5 (ABACUS Concepts, Inc., Berkeley, CA, USA) and Dr. SPSSII (SPSS Japan Inc., Tokyo, Japan). Total time-course changes from before surgery to 1 year after surgery were examined by analysis of variance (ANOVA). Comparisons between groups in each time period were performed and adjusted using Bonferroni correction. The differences were considered significant at $p<0.05$.

Results

After surgery no patient had wound infection or dehiscence, bone instability or non-union, or long-term malocclusion.

The mean setback amount was 6.4 ± 2.6 mm on the right side and 6.1 ± 3.5 mm on the left side in the control group, and 7.0 ± 2.4 mm on the right side and 6.1 ± 3.5 mm on the left side in the Biopex® group. These differences were not significant. There was no case that showed significant relapse or postoperative mal-occlusion in both groups.

Comparisons of the two groups in each period revealed that ramus length , ramus width, and ramus square in the Biopex® group were larger than that in control group immediately after surgery (ramus length: $P=0.025$, ramus width: $P=0.0048$, ramus square: $P<0.0001$) and after 1 year (ramus length: $P=0.014$, ramus square: $P<0.0001$).

There were significant differences between the two groups in the time-course changes

(F=9.699; df=1; P=0.0026), within subjects (F=100.513; df=2; P<0.0001), and between subjects (F=6.206; df=2; P=0.025) regarding ramus length. There were significant differences between the two groups in the time-course changes (F=4.579; df=1; P=0.0361), within subjects (F=157.025; df=2; P<0.0001), and between subjects (F=4.433; df=2; P=0.0234) regarding ramus width. There were significant differences between the two groups in the time-course changes (F=19.764; df=1; P=<0.0001), within subjects (F=57.887; df=2; P<0.0001), and between subjects (F=16.739; df=2; P<0.0001) regarding ramus square.

The length, width and square of the Biopex$^{®}$ after 1 year were smaller than immediately after surgery in the Biopex$^{®}$ group (P<0.0001, P=0.0052 and P<0.0001) (Table 1).

In the control group, TSEP was measurable within 1 week in 16 of 40 (40.0%) sides of the lower lip, within 2 weeks in 25 sides (62.5%), within 1 month in 30 sides (75.0%), within 3 months in 35 sides (87.5%) and within 1 year in 39 sides (97.5%). Recovery of TSEP was negative response 1 year post-operatively in the remaining 1 side.

In the Biopex$^{®}$ group, TSEP was measurable within 1 week in 24 of 40 (60.0%) sides of the lower lip, within 2 weeks in 28 sides (70.0%), within 1 month in 32 sides (80.0%), within 6 months in 33 sides (82.5%) and within 1 year in 39 sides (97.5%). Recovery of TSEP was negative response 1 year post-operatively in the remaining 1 side.

In the latency period in P1, N2 and P2, there were no significant differences between control and Biopex$^{®}$ group, however, there was significant difference in N1 (P=0.0388). The value in post-operative measurable period were significantly shorter than the value in pre-operative period in the latency period in all of N1, P1, N2 and P2 in both groups (the control group, N1; P=0.0005, P1; P=0.0003, N2; P=0.0021, P2; P=0.0067) (the Biopex$^{®}$ group, N1; P=0.0092, P1; P=0.0324, N2; P=0.0018, P2; P=0.0100) (Table 2).

The mean measurable period and standard deviation were 9.3±15.7 weeks in the control group, 5.3±8.3 weeks in the Biopex® group, and there was no significant difference.

Discussion

It was unclear whether the insertion of the bone alternative material could affect the bone healing and the recovery of inferior alveolar nerve in the gap between the proximal and distal segment in SSRO with bent absorbable plate fixation. This study was performed to evaluate the combined use absorbable plate system and bone substitute material from the view of morphological change in ramus region and sensory disturbance of lower lip.

Our previous study using rabbit suggested that the use of an absorbable plate (Super FIXSORB$^{®}$-MX) in combination with Biopex$^{®}$ was useful and both Super FIXSORB$^{®}$-MX and Biopex$^{®}$ could provide adequate bone regeneration and maintain strength and stability in the surgical bone space (*Okabe et al.*, 2010). The resorbable bone fixation devices have been developed for use in orthopedic or cranio-facial, oral and maxillofacial or plastic and reconstructive surgeries (*Shikinami & Okuno,*1999; *Shikinami & Okuno,*2001; *Shikinami et al.*, 2005). These devices are made from composites of uncalcined and unsintered hydroxyapatite (u-HA) particles and poly-L-lacted (PLLA), and they are produced by a forging process, which is a unique compression molding, and machining treatment. They have a modulus of elasticity close to that of natural cortical bone, and they can retain a high strength during the period required for bone healing. They can also show optimal degradation and resorption behavior, osteoconductivity, and bone bonding capability. In this study, the absorbable plate remained after 1 year as confirmed by CT imaging, although characteristic material changes were not observed.

On the other hand, *Monma et al.* (1988) have originally developed a self-setting cement-type calcium phosphate material consisting of α-TCP, dicalcium phosphate dibasic (DCPD) and tetracalcium phosphate monoxide (TeCP). According to their extensive studies, this cement-type material could be refined, demonstrating better biocompatibility and direct integration to bone without any participation of peripheral soft tissue (*Kurashina et al.*,1997a,b; *Yamamoto et al.*, 1998; *Yuan et al.*, 2000). As it is free of the infiltration over time of residual monomers of methacrylate resin, which has long been used for orthopedic treatment, this self-setting cement came to be rapidly targeted for clinical use in Japan.

In this study, 2-dimensional CT evaluation could give valid results clinically as well as our previous studies that described regarding mandibular ramus morphology including inferior alveolar nerve after SSRO *(Nakagawa et al., 2003; Hashiba et al., 2008; Ueki et al., 2009)* and pterygoid plate in maxilla *(Ueki et al., 2009)*, although the 3-dimensional reconstruction was used in the other previous studies *(Ueki et al 2008; Ueki et al, 2009; Ueki et al, 2010).* In this study, ramus square in the Biopex group was significantly larger than the control group immediately after surgery and after 1 year. In fact, a concave outline at the anterior part in ramus was observed in some cases in the control group, although the bone formation was found at the middle and posterior par in the ramus in all cases. This suggested that insertion of Biopex® in the anterior part of ramus increased the total volume of the ramus and that it can prevent invasion of mucosal endothelial cells into the gap between segments. In other words, the Biopex was inserted t to make the bone formation at the anterior part between the segmental gap. The Biopex just played a role to prevent invasion of the mucosal endothelial cells as a barrier so that small amount of the Biopex at the anterior part in ramus could be effective significantly. A significant decrease in the square of the Biopex® after 1 year suggested that Biopex® is likely absorbed. Although it was difficult to judge the segmentation new bone and the Biopex® accurately, remnant Biopex® could be identified as a block at windows level of 500 and windows width of 4000. Actually, small particles at the surrounding of the remnant Biopex could not be detected. However, surrounding of the blocks of the Biopex that decreased the square was filled with bone tissue after 1 year in all cases.

However, the presence of remnant Biopex® after 1 year also suggested that the resorption of the Biopex® was comparatively slow. In the study of *Hao et al.* (2004) using rabbit femoral cortical bone, a range of osteoclasts accumulated on the surface of the Biopex®, whilst many osteoblasts were localized on the surface opposing the Biopex® from days 5 to 10. However, remnants of the Biopex® particles were present in the new bone with a profile of compact bone on days 30 and 40. The Biopex® was so hard that the osteoclasts could not resorb it rapidly. In orthognathic surgery, use of Biopex can compensate the strength and rigidity between segments from the early post-surgery period.

It was considered that the slow replacement of the Biopex® could also contribute to maintaining the strength of the mandible after surgery.

These results suggested that the combined use of segmental fixation with the absorbable plate system and filling in the space between the segments were useful and void of any hindrance.

Postoperative hypoesthesia after SSRO is a known complication, caused by direct or indirect intra-operative damage to the inferior alveolar nerve. The induction of neural impairment is thought to be influenced by multiple causal factors, including fixation methods (*Westermark et al.*, 1998; *Pratt et al.*, 1996; *Lemke et al.*, 2000), patient age (*Yikontiola et al.*, 2000; *Van Sickels et al.,* 2002) postoperative swelling (*Jones & Wolford,* 1990), and surgical procedures, particularly a bad split (*Brusati et al.*, 1998; *Augaust et al.*, 1998).

With regards to the effect of the fixation method, *Lemke at al.* (2000) reported that rigid fixation resulted in more anesthesia in the mental nerve distribution than wire fixation when tested with the brush stroke direction. *Fujioka et al.* (1998) also reported that mono-cortical osteosynthesis caused less damage to the inferior alveolar nerve. Some surgeons have suggested that compressive forces can occur when fixing the 2 mandibular segments together, resulting in the nerve being sandwiched.

However, the results of our previous study with TSEP suggested that mono-cortical or bi-cortical fixation methods did not influence the recovery period from hypoesthesia, and recovery period of hypoesthesia of lower lip following SSRO was strongly associated with sagittal split area and the distance between the plate (the most medial point of screw) and the mental foramen (*Hashiba et al.*, 2007; *Hashiba et al.*, 2008).

TSEP, a somatosensory evoked potential of the peripheral nerves has been used previously to investigate the causal factors of trigeminal sensory hypoesthesia that occurs after SSRO. This method is highly objective and reliable as the potential changes of cerebral origin can be detected on the scalp in human subjects following electrical stimulation of the peripheral nerves. SEP data is collected directly from the electroencephalography derived from the cerebral cortex making data of TSEP more objective and reliable. Thus, difference between objective and subjective assessment may occur. Furthermore, there may also be differences between the actual return of sensation and registration of nerve conduction. Advancements in the field of neurophysiology have revealed posttraumatic change in the central nervous system. Functional disturbance in the central nervous system after peripheral nerve injury is known as central sensitization (*Coderre et al.*, 1993; *McQuay et al.*, 1994). In this study, it was considered that the result of data using TSEP was valid and reliable.

In this study the subjects ranged from 16 to 50 were randomly selected, however the age was not correlated to the recovery period of TSEP. Although 6 and 8 mm screws were selected and used to fit the thickness at the fixation part of the proximal segment, the difference between 6 and 8 mm screw did not affected the result of TSEP. In both groups, post-operative latency period was significantly shorter than preoperative value. This suggested that lower lip could have higher discrimination in the recovery process of hypoesthesia in the measureable period in both groups. The measurable period meant that the first time that peak of TSEP wave could be identified post-operatively, so that the lower lip could be more sensitive in this time. However, there was no significant difference between two groups regarding the recovery period of lower lip hypoesthesia, in this study. The volume and site of insertion of the Biopex® could be related to the result. The material was inserted into the gap carefully not to contact the surrounding bone tissue of the mandibular canal. This might be one of the reasons that lead such a result.

Conclusion

This study could prove that inserting Biopex® in the gap between the proximal and distal segments was useful for new bone formation and it did not prevent the recovery of lower lip hypoesthesia after SSRO with bent absorbable plate fixation.

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Legends

Fig 1. Simulation of plate bending. The plates were bent to prevent the proximal segments from rotating internally. Note the gap between the osteotomy surfaces on both sides.

Fig 2. Immediately after horizontal CT image at the level under the mandibular foramen in the Biopex® group.

Fig 3. 1 year after horizontal CT image at the level under the mandibular foramen in the Biopex® group.

Fig 4. Measurements of ramus on a horizontal CT image.
1) Ramus length: the distance between the most anterior point and most posterior point of ramus. 2) Ramus width: the distance between the most medial point and the cross point between the lateral outline of ramus and the line through the most medial point parallel to the RL line. 3) Ramus square: the square that showed the total area of the proximal (3a) plus distal (3b) segments, when the image immediately after surgery was measured. 4) Length of Biopex®: the distance between the most anterior point and most posterior point of Biopex®. 5) Width of Biopex®: the distance between the most medial point and the most lateral point of Biopex®. 6) Square of Biopex®: the square that showed the total area at the anterior part of ramus

Table 1. Results of the measurements of ramus and Biopex®. SD indicates standard deviation.

Table 2. Latency period in each peak in TSEP wave. SD indicates standard deviation.

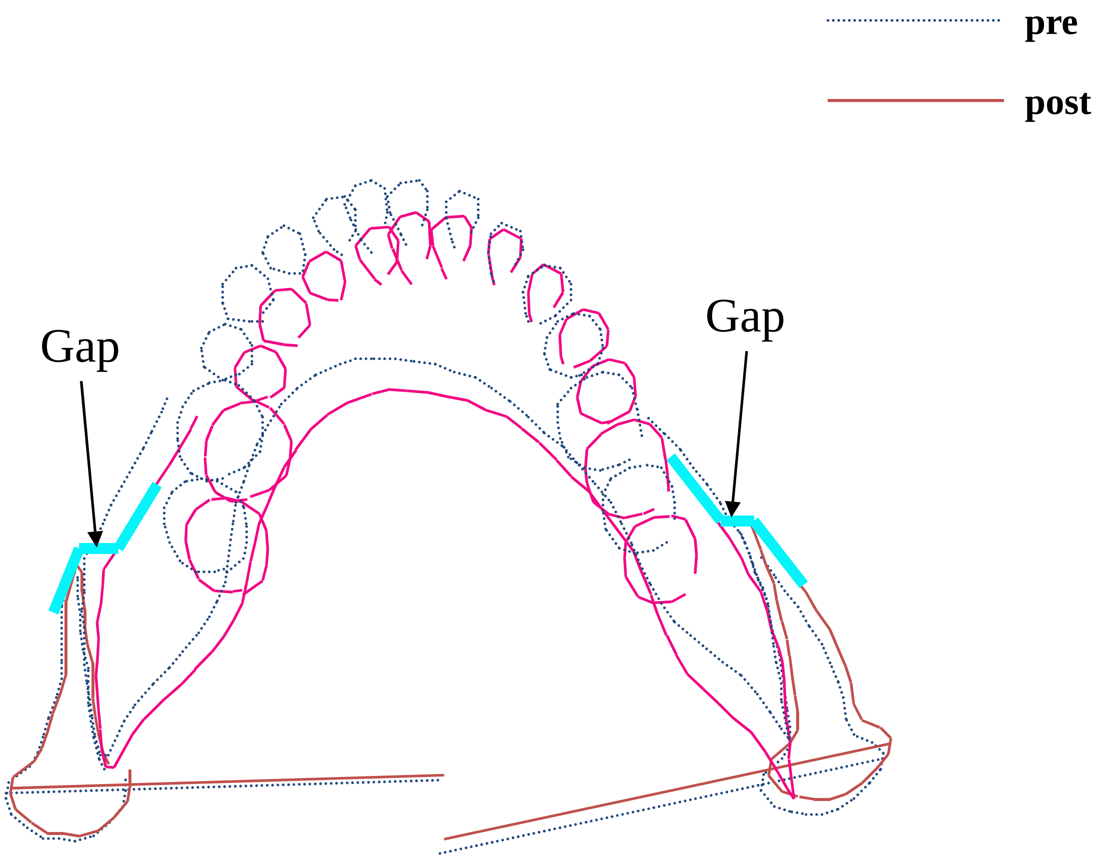

Fig. 1.

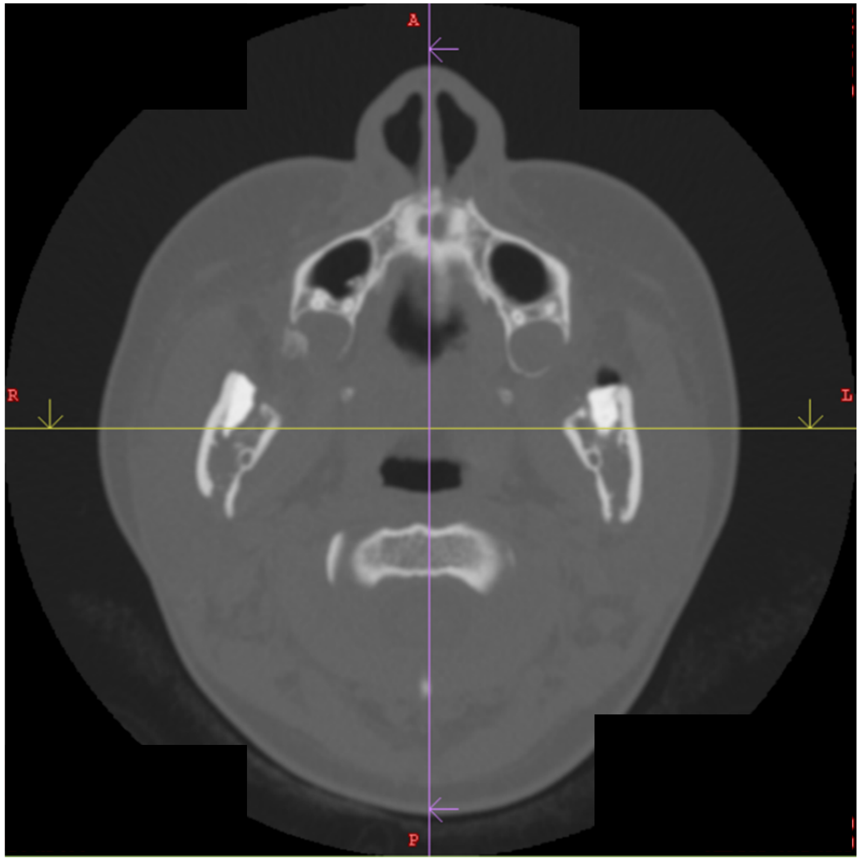

Fig. 2.

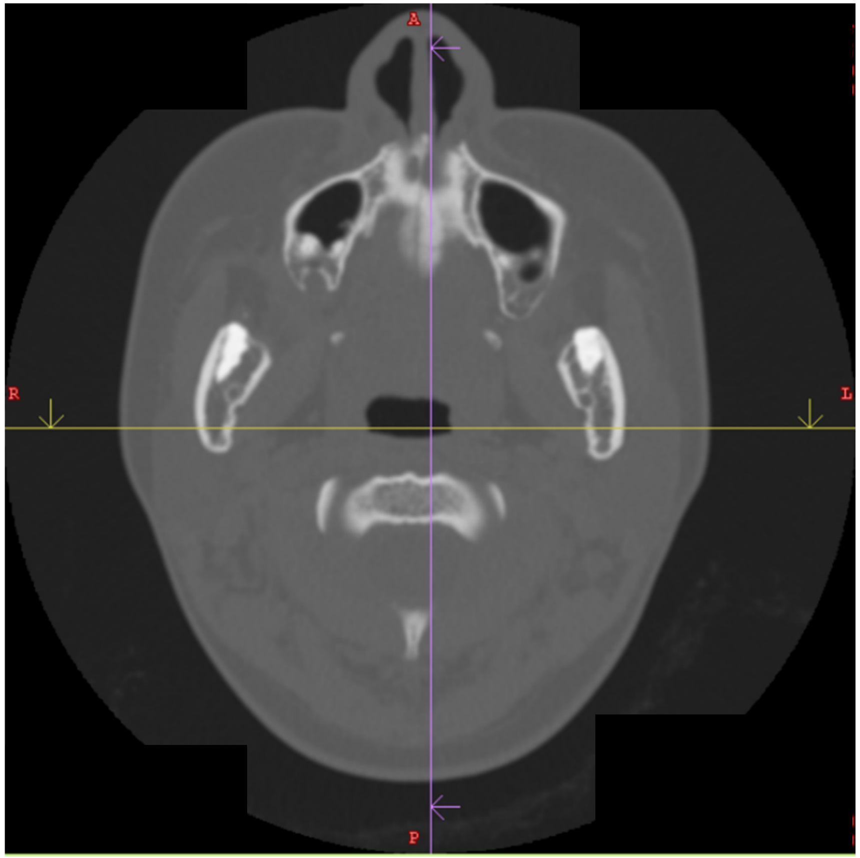

Fig. 3.

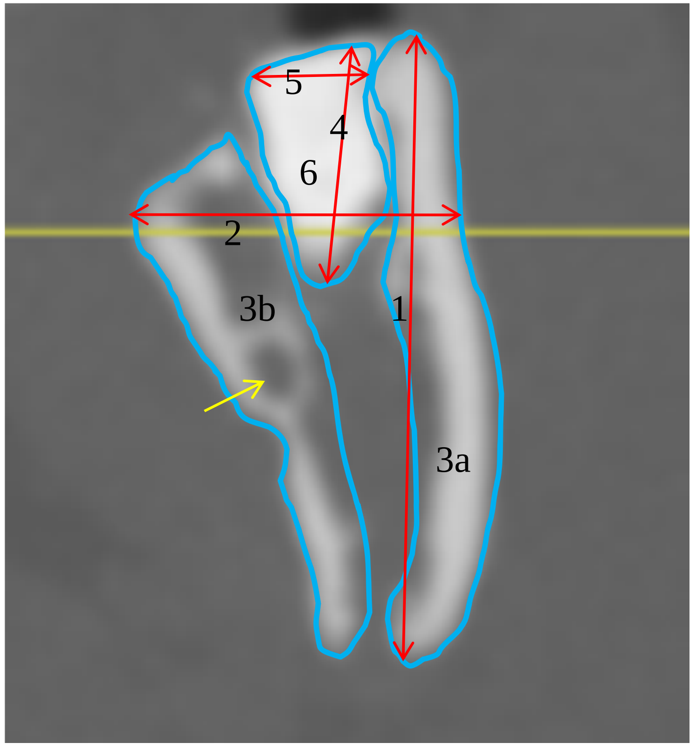

Fig. 4.

		Pre-operation		Immediately after		After 1 year	
		Mean	SD	Mean	SD	Mean	SD
Control group	Ramus length(mm)	30.4	3.0	33.6	4.2	30.2	4.2
	Ramus width(mm)	12.4	1.7	15.5	2.0	14.5	2.0
	Ramus square(cm^2)	2.1	0.4	2.2	0.4	2.4	0.5
Biopex group	Ramus length(mm)	31.8	3.0	36.6	4.4	33.5	4.7
	Ramus width(mm)	12.5	1.6	16.8	2.0	15.3	1.8
	Ramus square(cm^2)	2.3	0.3	2.7	0.5	2.9	0.5
Biopex group	Length of Biopex®(mm)			10.8	3.6	9.0	3.8
	Width of Biopex®(mm)			5.3	1.4	4.6	1.3
	Square of Biopex®(cm^2)			0.4	0.2	0.3	0.2

Table 1.

		N1		P1		N2		P2	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD
Control group	Pre-operation	15.1	1.8	19.3	2.2	28.8	2.7	38.0	2.8
	Post-operation	13.8	1.9	17.7	2.2	27.0	3.2	36.4	3.6
Biopex group	Pre-operation	14.3	1.5	18.5	2.1	28.8	2.4	38.7	2.9
	Post-operation	13.5	1.2	17.6	1.4	27.6	1.9	37.2	3.0

Table 2.