Skeletal Stability After Mandibular Setback Surgery: Comparisons Among Unsintered Hydroxyapatite/Poly-L-Lactic Acid Plate, Poly-L-Lactic Acid Plate, and Titanium Plate

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Skeletal stability after mandibular setback surgery: comparisons among unsintered hydroxyapatite (u-HA) / poly-L-lactic acid (PLLA) plate, PLLA plate and titanium plate

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Abstract

Purpose:

The purpose of this study is to compare the time-course changes in condylar long axis and skeletal stability after sagittal split ramus osteotomy (SSRO) with unsintered hydroxyapatite (u-HA) / poly-L-lactic acid (PLLA) plate, PLLA plate versus titanium plate.

Patients and Methods:

Of 60 Japanese patients diagnosed of mandibular prognathism, 20 underwent SSRO with u-HA/PLLA plate system and 20 underwent SSRO with PLLA plate system, while the other 20 underwent SSRO with conventional titanium plate system. The time-course changes in condylar long axis and skeletal stability were assessed by axial, frontal, and lateral cephalograms.

Results:

Titanium group was significantly larger than uHA/PLLA group in the change of right condyle angle between initial and 1 month (P=0.0105), intercondylar axes angle between 1 and 3 months (P=0.0013). PLLA group was significantly larger than titanium group (P=0.0043) and u-HA/PLLA group (P=0.0002) in the change of ramus inclination between 1 and 3 months; however, there were no significant differences between the three groups in the other measurements in each time interval.

Conclusion:

This study suggested that there were no significant differences in postoperative time-course changes among u-HA/PLLA plate system, PLLA plate system and conventional titanium plate system.

Key words:

Sagittal split ramus osteotomy

Unsintered hydroxyapatite (u-HA) / poly-L-lactic acid (PLLA) plate

Poly-L-lactic acid (PLLA) plate

Titanium plate

Stability

The use of resorbable materials to stabilize the maxillo-facial skeleton has been reported recently.[1-3] It is no need for a second operation to remove the implant. There is less risk of weakening of the fixed bone because of stress shielding and there is no risk of metallic corrosion. However, several problems remain, including mechanical weakness,[4,5] late foreign body reactions, osteolytic change, and micro-movement of fixed bone caused by a low initial stability.[6,7,8]Poly-L-lactic acid (PLLA) is one of various absorbable materials that has been used for fixation after SSRO. PLLA miniplates promote osteosynthesis of the oral and maxillofacial skeleton, and PLLA screws have been used in patients undergoing orthognathic surgery[9-11]. In our previous study, it was found that PLLA plates and screws (Fixorb®-MX, Takiron Co., Osaka, Japan) was useful in SSRO, as well as the conventional titanium plate system. Furthermore, fixation plate system (Super-FIXSORB®-MX. Takiron Co. Ltd, Osaka) has been newly developed for use in orthopedic or cranio-facial, oral and maxillofacial or plastic and reconstructive surgeries.[12-14] 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.

The purpose of this study is to compare the time-course changes in condylar long axis and skeletal stability after sagittal split ramus osteotomy (SSRO) with u-HA/PLLA plate system, PLLA plate system and conventional titanium plate system.

Patients and Methods

Patients

Sixty Japanese adults (25 men and 35 women) randomly selected in this study presenting with jaw deformities were diagnosed as mandibular prognathism. At the time of orthognathic surgery, the patients ranged in age from 15 to 48 years, with a mean age and standard deviation of 24.8±8.5 years. This study is a retrospective study. Informed consent was obtained from the patients and study was approved by Kanazawa University Hospital.

Surgery

In the u-HA/PLLA group, of the 60 patients, 20 patients (men: 5, women: 15) underwent bilateral SSRO for correction of their mandibular deformities. A mini-plate (28×4.5×1.4 mm) and 4 screws (2×8 mm) (Super Fixorb®-MX, Takiron Co., Osaka, Japan) were placed monocortically in the mandibular angle region in each side through a transcutaneous approach. The patients in the u-HA/PLLA group ranged in age from 15 to 48 years, with a mean age and standard deviation of 29.1±11.2 years.

In the PLLA group, 20 patientas (men: 10, women: 10) underwent bilateral SSRO. A mini-plate (28×4.5×1.5 mm) and 4 screws (2×8 mm) (Fixorb®-MX, Takiron Co., Osaka, Japan) were placed monocortically in the same region and manner. The patients in the PLLA group ranged in age from 15 to 34 years, with a mean age and standard deviation of 23.5±5.9 years.

In the titanium group, the other 20 patients (men: 10, women: 10) underwent bilateral SSRO with titanium mini-plates and screws (long miniplate: 4 holes/burr 8mm thickness 1.0 mm and 4 screws (2×7 mm) Würzburg titanium miniplate system, Leibinger Co., Freiburg, Germany). The patients in the titanium group ranged in age from 15 to 35 years, with a mean age and standard deviation of 21.7±5.6 years.

At the site of fixation, an osseous step was formed, depending on the amount of setback. Bent plates were used to maintain the condyle in its original position in both groups, so that a small gap remained between the bone fragments at the anterior part of the juncture site space in both fixation methods.[15] After a few days of inter maxillary fixation (IMF), elastic was placed to maintain an ideal occlusion in the same manner in all groups.

Cephalogram assessment

All patients underwent lateral, frontal and axial cephalograms to assess the skeletal changes before operation and at 1 month, 3 months and 1 year postsurgery. Measurements landmarks were according to our previous studies.[11, 15]

One skilled observer performed all digitization so that errors in the cephalometric method were small and acceptable for the purposes of this study. Error analysis by digitization and remeasurement of 10 randomly selected cases generated an average error of less than 0.4 mm for the linear measurements and 0.5 degree for the angular measurements.

Statistical analysis

Data were statistically analyzed with StatView software, version 4.5 (ABACUS Concepts, Inc., Berkeley, CA, USA) Each serial period was defined, and the differences between measurements were calculated as follows.

T1: (Initial to 1 month)

T2: (1 month to 3 months)

T3: (3 months to 1 year)

The data among the groups were then analyzed by multiple comparison method using Bonferroni/Dunn test. Differences were considered significant at $p < 0.05$.

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Result

After surgery no patient experienced any wound infection or severe temporomandibular joint symptoms. The mean setback amount was 6.4±2.6 mm on the right side and 6.3±3.1 mm on the left side in the u-HA/PLLA group, 6.7±3.2 mm on the right side and 6.4±3.2 mm on the left side in the PLLA group and 7.0±2.9 mm on the right side and 6.5±2.6 mm on the left side in the titanium group. There was no significant difference among three groups.

Titanium group was significantly larger than uHA/PLLA group in the change of right condyle angle in T1 (P=0.0105), intercondylar axes angle in T1(P=0.0013). PLLA group was significantly larger than titanium group (P=0.0043) and uHA/PLLA group (P=0.0002) in the change of ramus inclinationin T1. However, there were no significant differences between the three groups in the other measurements in T2 and T3 (Tables. 1-3).

Discussion

Fixorb, bioabsorbable ultra-high-strength PLLA developed for internal fixation of fractures, was fabricated by drawing technique. The bending strength and anti-pull-out strength of Fixorb are higher than those of human cortex and lower than those of titanium plates. In vitro, Fixorb plates can maintain 80% of early bending strength until 12 weeks postoperatively. Fixorb requires a longer period to disappear than PGA/PLA copolymers. However, it has higher strength than PGA/PLA copolymers so that it can be used for loading regions[16, 17]. Maurer et al estimated that the stress of the material was postulated to have reached threshold values for stability. Maximum chewing force was determined by finite element method analysis to be 132N for Fixsorb, 115N for Biosorb, and 46.4N for Lactosorb[18]. Theoretically, it was considered that Fixorb also had sufficient strength to fix mandibular bone in orthognathic surgery.

The PLLA plates could be easily bent with a forceps at room temperature and stayed in the desired position without use of a heating device. PLLA plates are therefore easy to use for fixation of bone segments after osteotomy. Even after the PLLA plate was bent, it was strong enough to fix bone segments after mandibular osteotomy. However, the stability and strength of bent PLLA plates remain unclear. The fact that the PLLA plate was easily bent at room temperature suggests that after bending slight distortion may occur in vivo, although data supporting this assumption are lacking. On the other hand, the u-HA/PLLA could be bent with a forceps in 60 ºC hot water. The stability of bent u-HA/PLLA seemed to be higher than bent PLLA, although this study could not detect the difference between the materials in themselves.

u-HA/PLLA plate system (Super-FIXSORB®-MX) which have completed clinical tests in orthopedic, oral and maxillofacial surgeries exhibit total resorbability and osteological bioactivity such as the ability to directly bond to bone and osteoconductivity[19] as well as good biocompatibility and high stiffness retainable for a long period of time to achieve bone union.[20] The screw and plate of the u-HA/PLLA system contain 30 and 40 weight % of u-HA in each. The u-HA/PLLA system The u-HA/PLLA plate (Super-FIXSORB®-MX) was higher than the PLLA plate (Fixorb®-MX) and human cortical bone in the bending strength (u-HA/PLLA: 200-270 MPa, PLLA: 200-250 MPa, Cortical bone: 100-200MPa) and the shearing strength(u-HA/PLLA: 120-145 MPa, PLLA: 90-95 MPa, Cortical bone: 100 MPa). Shikinami et al. documented the complete process of bioresorption and bone replacement of rods made of forged composites of unsintered hydroxyapatite particles/poly L-lactide (F-u-HA/PLLA) implanted in the femoral medullary cavities of rabbits.[14] From the results, it was found that morphological changes during biodegradation and bone replacement in the proximal medullary cavity up to 4.5 years, and molecular weight and the bending strength had decreased to 50 KDa and 200 MPa after 6 months. Therefore, if the strength of the absorbable plate decreases and the bony healing between segments is not complete at least 6 months after osteotomy, the skeletal stability can not sustain for a long time. However, 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, because of containing the HA. Furthermore, the u-HA/PLLA plate and screw could be recognized in the computed tomography image, although the PLLA plate was radiolucent completely. Therefore, it is easy to judge whether the u-HA/PLLA plate or screw break or displace. However, it was thought that breakage of screw head by driver of system device in the u-HA/PLLA was more frequently than PLLA system. Perhaps containing of u-HA might reduce elasticity of the screw.

When rigid fixation is used, changes in intercondylar angle and width after BSSO advancement or setback may influence TMJ function.[21-26] Intercondylar width tends to decrease after mandibular setback and to increase after mandibular advancement. This trend becomes clearer with rigid fixation. A change in axial inclination involving either a medial or lateral rotation of the axis was found, with inward rotation more frequently occurring on mandibular retropositioning and with rigid-screw fixation. To prevent internal rotation of the condylar axis, we have previously proposed the use of a bent plate to intentionally create a step at the cortical bone between the anterior aspects of the proximal and distal segments. A previous study showed that a bent plate was more effective than a straight plate for postoperative TMD[15]. In that study, however, titanium plates and screws were used for fixation. In our study, three types of material were applied in a similar manner. Statistically, there was significant difference between the titanium group and u-HA/PLLA group in right condylar angle and intercondylar axes angle in T1. However, in postoperative condylar change there was no significant difference. The change of measurement was mainly surgical factors such as setback amount and direction. Therefore, this difference in T1 might cause by the difference in bilateral setback amount. Ramus inclination in PLLA group showed larger postoperative change than that in u-HA/PLLA and titanium group. Only PLLA plate could be bent at room temperature with forceps. Therefore, slight stretching of bent PLLA plates immediately after surgery may have pushed proximal segments near the mandibular angle posteriorly, though the distal segment was fixed by intermaxillary traction with elastics.

However, there were no significant differences between the three groups in the other lateral and frontal cephalometric measurements in each time interval. Patients in three groups underwent intermaxillary traction with elastics immediately after surgery to stabilize distal segments and the occlusion. This procedure might account for the lack of a difference in postoperative skeletal stability between the three groups.

In conclusion, this study suggested that there were no significant differences in postoperative time-course changes among uHA/PLLA plate system, PLLA plate system and conventional titanium plate system.

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uHA/PLLA group		T1 Mean	SD	T2 Mean	SD	T3 Mean	SD
Right condyle angle	(dg)	-1.6	4.7	2.8	4.0	-3.3	4.5
Left condyle angle	(dg)	-0.7	4.0	-0.1	6.4	0.8	5.3
Intercondylar axes angle	(dg)	1.9	6.3	-2.7	7.3	2.6	5.9
SNB	(dg)	-2.9	2.1	0.2	1.1	0.0	1.3
ANB	(dg)	3.7	3.3	0.3	1.1	-0.3	1.2
Gonial angle	(dg)	-1.5	4.6	1.3	4.2	1.4	5.6
Ramus inclination(FH)	(dg)	2.0	4.3	0.0	3.3	-0.5	4.9
Interincisal Angle	(dg)	4.1	8.7	-1.5	8.2	1.4	5.6
Pog-N Parallel to SN	(mm)	4.8	4.7	-0.6	2.3	-0.5	2.6
Pog-N Perpend to SN	(mm)	-1.6	3.3	0.1	2.4	0.2	2.4
Occlusal Plane - SN	(dg)	0.9	4.0	-0.9	2.3	0.8	2.5
Convexity	(mm)	3.8	3.6	0.3	1.2	-0.6	1.5
Me-Ag Right	(mm)	2.7	5.5	1.8	5.2	-0.1	4.0
Me-Ag Left	(mm)	2.4	6.1	1.7	5.4	-0.7	4.3

Table 1. Results of changes in u-HA/PLLA group. SD indicates standard deviation.

PLLA group		T1		T2		T3	
		Mean	SD	Mean	SD	Mean	SD
Right condyle angle	(dg)	2.3	6.7	0.2	5.3	-0.9	5.4
Left condyle angle	(dg)	-0.4	5.0	-0.6	4.6	-0.2	4.5
Intercondylar axes angle	(dg)	-1.6	6.7	0.4	8.2	0.5	7.2
SNB	(dg)	-2.9	4.0	0.2	1.5	0.5	2.2
ANB	(dg)	3.7	2.7	-0.3	2.3	-0.6	2.0
Gonial angle	(dg)	-4.9	5.7	0.7	4.6	1.8	3.3
Ramus inclination(FH)	(dg)	7.8	5.4	-0.7	4.4	-2.3	3.7
Interincisal Angle	(dg)	1.0	6.4	0.7	4.3	-0.3	3.5
Pog-N Parallel to SN	(mm)	5.2	9.1	-0.1	3.5	-0.6	4.4
Pog-N Perpend to SN	(mm)	-1.4	4.7	-0.6	1.7	-0.8	3.6
Occlusal Plane - SN	(dg)	0.5	5.2	-0.8	2.0	-0.2	2.8
Convexity	(mm)	3.8	3.3	-0.2	2.6	-0.5	2.2
Me-Ag Right	(mm)	2.2	4.7	1.5	5.0	-2.2	4.7
Me-Ag Left	(mm)	1.9	4.8	0.3	5.0	-2.1	5.8

Table 2. Results of changes in PLLA group. SD indicates standard deviation.

Titanium group		T1		T2		T3	
		Mean	SD	Mean	SD	Mean	SD
Right condyle angle	(dg)	3.1	5.4	-0.5	4.5	-0.7	2.8
Left condyle angle	(dg)	3.0	5.7	1.1	5.8	0.9	4.6
Intercondylar axes angle	(dg)	-6.1	9.0	-0.6	7.3	-1.5	8.1
SNB	(dg)	-2.9	3.1	0.4	2.2	-0.1	1.7
ANB	(dg)	3.8	2.8	-0.3	1.6	0.2	1.6
Gonial angle	(dg)	-2.4	3.2	1.8	3.5	-0.1	2.4
Ramus inclination(FH)	(dg)	3.5	3.6	-1.5	2.7	0.2	2.9
Interincisal Angle	(dg)	2.7	7.6	-1.2	3.8	1.6	5.3
Pog-N Parallel to SN	(mm)	5.1	6.9	-0.6	5.2	-0.3	4.1
Pog-N Perpend to SN	(mm)	-3.7	5.5	0.4	2.8	1.4	4.5
Occlusal Plane - SN	(dg)	-2.1	5.4	-0.4	2.5	-1.0	3.1
Convexity	(mm)	3.8	3.2	-0.2	1.7	-0.1	1.9
Me-Ag Right	(mm)	-0.9	6.5	1.7	4.4	0.6	5.5
Me-Ag Left	(mm)	-1.1	6.5	1.8	5.1	0.1	4.4

Table 3. Results of changes in titanium group. SD indicates standard deviation.