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# Maxillary stability after Le Fort I osteotomy using three different plate systems

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*Abstract.* The purpose of this study was to compare postoperative changes in maxillary stability after Le Fort I osteotomy in three groups: with an unsintered hydroxyapatite (u-HA)/poly-L-lactic acid (PLLA) plate; a PLLA plate; and a titanium plate. Subjects comprised 60 Japanese patients diagnosed with mandibular prognathism. All patients underwent Le Fort I osteotomy and bilateral sagittal split ramus osteotomy. All patients were randomized in groups of 20 to a u-HA/PLLA group, a PLLA plate group and a titanium plate group. Changes in postoperative time intervals between the plate groups were compared using lateral and posteroanterior cephalography. The uHA/PLLA group had significantly larger values than the PLLA group regarding change of mx1-S perpendicular to SN between 3 and 12 months (T3) ($P = 0.0269$). The uHA/PLLA group had a significantly larger value than the PLLA group regarding change of S–A perpendicular to SN between baseline and 1 month (T1) ($P = 0.0257$). There was no significant difference in the other measurements. This study suggests that maxillary stability with satisfactory results could be obtained in the u-HA/PLLA, PLLA plate and titanium plate groups, although there was a slight difference between the u-HA/PLLA and PLLA plate systems in Le Fort I osteotomy.

Keywords: Le Fort I osteotomy; unsintered hydroxyapatite (u-HA)/poly-L-lactic acid (PLLA) plate; poly-L-lactic acid (PLLA) plate; titanium plate; stability.

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Comparison of the stability of Le Fort I advancement using biodegradable poly-p-diaxanon thread with titanium miniplates demonstrated good stability of both fixation devices in the anterior–posterior plane, but a tendency to relapse in the vertical dimension.[1]

Poly-L-lactic acid (PLLA) is one of the various absorbable materials that has been used for fixation after Le Fort I osteotomy and sagittal split ramus osteotomy (SSRO). PLLA miniplates promote osteosynthesis of the oral and maxillofacial skeleton, and PLLA screws have been used in patients undergoing orthognathic surgery.[2–4] In a previous study, the authors found that PLLA plates and screws (Fixorb®-MX, Takiron Co., Osaka, Japan) were useful in Le Fort I osteotomy with SSRO and intraoral vertical ramus osteotomy (IVRO), as well as the conventional titanium plate system.[5] The fixation plate system (Super-FIXSORB®-MX, Takiron Co., Ltd., Osaka, Japan) has been newly developed for use in orthopaedic or craniofacial, oral and maxillofacial or plastic and reconstructive surgeries.[6–8] These devices are made from composites of uncalcined and unsintered hydroxyapatite (u-HA) particles and PLLA. They are produced by a forging process, which is a unique compression moulding, and machining treatment. They have a modulus of elasticity close to that of natural cortical bone, and can retain high strength during the period required for bone healing. They can also show optimal degradation and resorption behaviour, osteoconductivity, and bone bonding capability.

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The material character and strength of each plate were different so it is difficult to make comparisons with other studies that used different plate systems. Therefore, it is important to compare different types of plate systems in a study. In the previous study on stability after SSRO, there were no significant differences in postoperative time-course changes between the u-HA/PLLA plate system, PLLA plate system and conventional titanium plate system.[9] There is no report of a study that examined the stability after Le Fort I osteotomy using the u-HA/PLLA plate system. The present study compared time-course changes in maxillary stability after Le Fort I osteotomy with the u-HA/PLLA plate system, PLLA plate system and conventional titanium plate system.

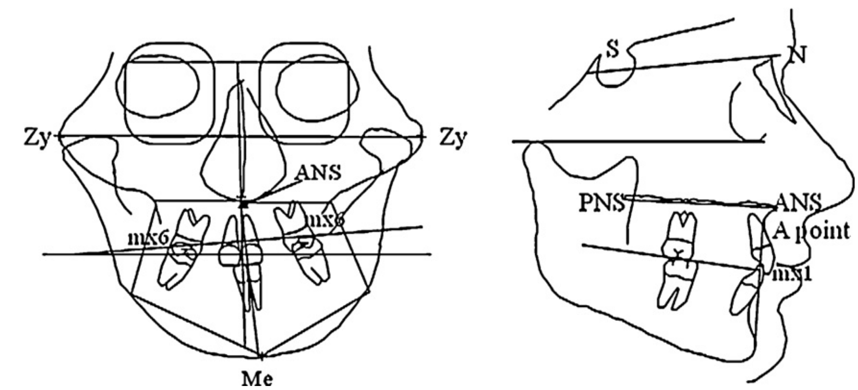


*Fig. 1.* Measurement points on PA and lateral cephalograms.

## Patients and methods

The subjects comprised 60 Japanese adults (16 men, 44 women) presenting with jaw deformities diagnosed as mandibular prognathism with maxillary retrognathism. At the time of orthognathic surgery, the patients were 16–48 years of age, with a mean age and standard deviation of $23.9 \pm 6.9$ years. The operations took place between August 2001 and April 2010. Patients were selected for this study if their pre- and postoperative cephalograms could be obtained and other procedures were not performed. The adequate total sample number calculated by power analysis software (G*Power Version 3.12; program written by Franz Faul, University Kiel, Germany)[10] was more than 54, when the effect size was 0.25. The sample size of 60 in the repeated measure ANOVA in this study was considered to be valid as a prospective study. Informed consent was obtained from the patients and the study was approved by Kanazawa University Hospital. This study was performed according to the guideline of the Helsinki Declaration.

All 60 patients underwent Le Fort I osteotomy and bilateral SSRO (by the Obwegeser method) to advance the maxilla with and without impaction and set back the mandible. The distribution in the direction and amount of maxillary advancement in the three groups was not significantly different. All patients received orthodontic treatment before and after surgery from two orthodontists. All patients underwent surgery performed by two surgeons (K.U. and K.N.).

In 20 (men 9, women 11) of the 60 patients, 2 uHA/PLLA L-type mini-plates (10 mm × 22 mm × 1.4 mm with 4 screws (2 mm × 8 mm), Super-Fixorb®-MX; Takiron Co., Osaka, Japan) and 2 straight uHA/PLLA plates (28 mm × 4.5 mm × 1.4 mm with 4 screws (2 mm × 8 mm), Super-Fixorb®-MX; Takiron Co.) were used to fix the advanced maxilla and 2 uHA/PLLA mini-plates (28 mm × 4.5 mm × 1.5 mm with 4 screws (2 mm × 8 mm), Super-Fixorb®-MX; Takiron Co.) were used for bilateral internal fixation of the mandible (u-HA/PLLA group). The patients in the u-HA/PLLA group ranged in age from 16 to 48 years (mean $26.4 \pm 8.6$ years).

In 20 patients (men 4, women 16), 2 PLLA L-type mini-plates (10 mm × 22 mm × 1.5 mm with 4 screws (2 mm × 8 mm), Fixorb®-MX; Takiron Co., Osaka, Japan) and 2 straight PLLA plates (28 mm × 4.5 mm × 1.5 mm with 4 screws (2 mm × 8 mm), Fixorb®-MX; Takiron Co.) were used to fix the advanced maxilla and 2 PLLA mini-plates (28 mm × 4.5 mm × 1.5 mm with 4 screws (2 mm × 8 mm), Fixorb®-MX; Takiron Co.) were used for bilateral internal fixation of the mandible (PLLA group). The patients in the PLLA group ranged in age from 16 to 34 years (mean $23.8 \pm 6.4$ years).

In the remaining 20 patients (men 4, women 16), 2 L-type titanium mini-plates and 2 straight titanium mini-plates (4 holes/ thickness 0.55 mm with 4 screws (2 mm × 5 mm), Würzburg titanium mini-plate system; Leibinger Co., Freiburg, Germany) were used to fix the advanced maxilla and 2 titanium mini-plates (4 holes/ thickness 0.55 mm with 4 screws (2 mm × 7 mm), Würzburg titanium mini-plate system, Leibinger Co.) were used for bilateral internal-fixation of mandible (titanium group). The patients in the titanium group ranged in age from 16 to 32 years (mean $21.6 \pm 4.4$ years).

After a few days of inter maxillary fixation (IMF), elastic was placed to maintain an ideal occlusion in the same manner in all the groups.

All patients underwent lateral and posteroanterior (PA) cephalography to assess skeletal changes at 1, 3, and 12 postoperative months (Fig. 1). To assess maxillary stability, arbitrary points for the anterior nasal spine (ANS), and posterior nasal spine (PNS), point A and incisor edge were defined and measured from the preoperative images, and subsequently transferred to all remaining radiographs. One skilled observer performed all digitization to minimize errors and this was acceptable for the purposes of this study. Error analysis by digitization and re-measurement of 10 randomly selected cases generated an average error of less than 0.4 mm for the linear measurements and 0.5° for the angular measurements.

The lateral cephalometric analysis involved the following measurements. S–A parallel to SN: distance between point A and sella parallel to SN plane. S–A perpendicular to SN: distance between point A and sella perpendicular to SN plane. S–PNS parallel to SN: distance between the arbitrary PNS and sella parallel to SN plane. S–PNS perpendicular to SN: distance between the arbitrary PNS and sella perpendicular to SN plane. mx1–S parallel to SN: distance between the incisor edge and sella parallel to SN plane. mx1–S perpendicular to SN: distance between the incisor edge and sella perpendicular to SN plane. S–ANS parallel to SN: distance between the arbitrary ANS and sella parallel to SN plane. S–ANS perpendicular to SN: distance between the arbitrary ANS and sella perpendicular to SN plane.

The PA cephalometric analysis involved the following measurements. Mx–Md midline: angle between the ANS-Menton line and the line perpendicular to the bilateral zygomatic frontal suture line. Right mx6 to Zy–Zy: distance between the most buccal point at the right molar crown and the line connecting the most lateral points of the bilateral zygomatic arches (Zy–Zy). Left mx6 to Zy–Zy: distance between the most buccal point at the left molar crown and Zy–Zy. Occlusal cant: angle between Zy–Zy and the line from the most buccal point at the right first molar crown to the most buccal point at the left molar crown.

#### Statistical analysis

Data were statistically analysed 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: T1 (baseline to 1 month); T2 (1 month to 3 months); T3 (3 months to 1 year).

The statistical calculation with repeated measure analysis of variance (ANOVA) was performed using class category (uHA/PLLA group, PLLA group and titanium group) and time-course (T1, T2 and T3). Comparisons between the three groups in each time period (T1, T2 and T3) were performed using Scheffe's method. Differences were considered significant at $P < 0.05$.

### Results

After surgery, no patient experienced complications such as wound infection or dehiscence, bone instability, or long-term malocclusion. There was no significant difference between the three groups in the distribution of men and women using the $\chi^2$ test. There was no significant difference between the three groups in age using the $\chi^2$ test (Table 1). Mean setback was $6.5 \pm 3.5$ mm on the right and $6.1 \pm 3.7$ mm on the left in the uHA/PLLA group, $5.9 \pm 3.1$ mm on the right and $6.1 \pm 2.5$ mm on the left in the PLLA group, and $6.3 \pm 3.5$ mm on the right and $6.0 \pm 2.6$ mm on the left in the titanium group. There was no significant difference between the three groups using Student's *t*-test.

From the results of repeated measure ANOVA, significant differences were identified among the three groups in S–A perpendicular to SN (between subjects; $F = 11.310$; df = 2; $P < 0.0001$), mx1–S perpendicular to SN (between subjects; $F = 5.712$; df = 2; $P = 0.0055$) and S–ANS perpendicular to SN (between subjects; $F = 4.867$; df = 2; $P = 0.0112$) (Fig. 1 and Tables 2 and 3).

From the multiple comparison in each time period, the uHA/PLLA group had a significantly larger value than the PLLA group regarding change of mx1–S perpendicular to SN between 3 and 12 months (T3) ($P = 0.0269$). The uHA/PLLA group had a significantly larger value than the PLLA group regarding change of S–A perpendicular to SN between baseline and 1 month (T1) ($P = 0.0257$).

No significant differences were identified among the three groups in the other measurements on lateral cephalometric analysis and in all measurements in the PA cephalometric analysis (Fig. 1 and Tables 2 and 4).

### Discussion

Most studies on stability in Le Fort I osteotomy with SSRO have suggested that no appreciable difference exists in wire versus plate and screw fixation for single-piece maxillary impactions and/or advancements.[11–14] Inferior repositioning of the maxilla has been shown to be an unstable move regardless of the fixation method used.[1,12,15] Many studies have shown that mandibular surgery in combination with maxillary surgery does not affect maxillary stability.[14,16–19]

Norholt et al.[20] found significant differences in vertical positioning of the maxilla in a lateral cephalometric analysis after 6 weeks as the position became more superior compared with the postoperative situation in a study using Lactosorb® (Lorenz Surgical, Jacksonville, FL, USA). In the study by Cheung et al.,[21] maxilla with bioresorbable plate fixation (2.0 compact plating system, Inion Ltd., Tampere, Finland) were confirmed to have minimal relapse compared to titanium plate fixation starting from the sixth postoperative week, but vertical instability occurred in the early postoperative period. Costa et al.,[22] found that superior displacement of the maxilla occurred mainly within the first 8 postoperative weeks in the study with Lactsorb®. In the authors' previous study using the PLLA plate (Fixsorb®-MX), they found that the maxilla was stable in the horizontal plane but tended to displace superiorly following Le Fort I osteotomy with SSRO or IVRO.[5] The plate systems used in each study were different so it was difficult to compare the results, but it seemed that superior displacement at the anterior part of the maxilla could occur after Le Fort I osteotomy with an absorbable plate.

The most commonly used polymers are homopolymers of PLLA and polyglycolides (PGA) and copolymers of polyglycolide–polylactide (PLGA) or copolymers of L- and D-lactide, poly-L/D-lactide (PLDLA).[23] There are methods of obtaining strong malleable devices from PLLA or PLDLA, such as self-reinforced (SR) composite (Biosorb FX, Bionximplants Ltd., Tampere, Finland), as polymerized PLLA and drawn PLLA (Fixorb®-MX).[24,25]

Fixorb®-MX, bioabsorbable ultra-high-strength PLLA developed for the internal fixation of fractures, was fabricated by a drawing technique developed by Matsusue et al.[24,25] 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 the early bending strength until 12 weeks postoperatively. Fixorb requires a longer period to disappear than PGA/PLA copolymers, but it has a higher strength than PGA/PLA copolymers such that it can be used for loading regions.[24,25] To produce the PLLA for use in the miniplate system, after dissolution and moulding of the PLLA as a biomechanical polymer (molecular weight, about 400 kDa), it was mechanical processed into rods made through uniaxial extension into various forms. The bending strength of PLLA used was 240 MPa, and the bending modulus was 13 GPa.[24] This strength is considerably greater than that of PLLA used in other system.[26] Maurer et al. estimated that the stress of the material was thought to have reached threshold values for stability. Maximum chewing force as determined by the finite element method analysis was 132 N for Fixsorb®, 115 N for Biosorb® (Bionximplants Ltd., Tampere, Finland), and 46.4 N for Lactosorb®.[27] Theoretically, it was thought

*Table 1*. Patient demographic data.

| | Number | | | Age (years) | | | |
|---|---|---|---|---|---|---|---|
| | Total | Men | Women | Mean | SD | Minimum | Maximum |
| uHA/PLLA group | 20 | 9 | 11 | 26.4 | 8.6 | 16 | 48 |
| PLLA group | 20 | 4 | 16 | 23.8 | 6.4 | 16 | 34 |
| Titanium group | 20 | 4 | 16 | 21.6 | 4.4 | 16 | 32 |

There was no significant difference among the three groups in the distribution of men and women, and age.

*Table 2*. Cephalometric measurements.

| | Baseline | | 1 month | | 3 months | | 1 year | |
|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | Mean | SD | Mean | SD |
| uHA/PLLA group | | | | | | | | |
| SNA (°) | 81.6 | 2.8 | 82.9 | 3.6 | 83.2 | 2.7 | 83.3 | 3.3 |
| S–A parallel to SN (mm) | 59.9 | 4.0 | 62.1 | 4.8 | 62.3 | 4.3 | 62.8 | 4.9 |
| S–A perpend to SN (mm) | 64.8 | 4.6 | 65.5 | 5.0 | 64.4 | 4.2 | 64.9 | 4.2 |
| S–PNS parallel to SN (mm) | 16.2 | 2.5 | 17.0 | 2.7 | 17.6 | 2.9 | 18.0 | 3.8 |
| S–PNS perpend to SN (mm) | 49.7 | 3.8 | 48.1 | 4.6 | 47.9 | 3.6 | 48.6 | 4.8 |
| mx1–S parallel to SN (mm) | 62.5 | 6.2 | 64.5 | 5.6 | 65.5 | 5.7 | 65.5 | 6.5 |
| mx1–S perpend to SN (mm) | 69.6 | 2.9 | 69.9 | 2.6 | 69.7 | 2.7 | 70.3 | 2.9 |
| S–ANS parallel to SN (mm) | 65.4 | 4.3 | 68.2 | 4.9 | 68.0 | 4.5 | 68.7 | 5.2 |
| S–ANS perpend to SN (mm) | 57.8 | 3.5 | 57.9 | 3.6 | 57.1 | 3.1 | 57.8 | 3.2 |
| Mx–Md midline (°) | −2.1 | 5.6 | −1.0 | 1.8 | −1.3 | 2.1 | −0.9 | 1.9 |
| Right mx6 to Zy–Zy (mm) | 49.5 | 5.9 | 46.8 | 5.3 | 47.4 | 4.2 | 48.5 | 5.5 |
| Left mx6 to Zy–Zy (mm) | 49.9 | 5.8 | 47.5 | 4.7 | 48.7 | 5.2 | 49.8 | 6.1 |
| Occlusal cant (°) | 1.4 | 2.6 | 1.5 | 1.7 | 1.9 | 2.2 | 1.9 | 2.1 |
| PLLA group | | | | | | | | |
| SNA (°) | 80.2 | 5.2 | 81.2 | 2.7 | 82.4 | 2.9 | 82.7 | 3.8 |
| S–A parallel to SN (mm) | 54.5 | 5.7 | 57.0 | 4.9 | 57.9 | 5.1 | 56.9 | 5.0 |
| S–A perpend SN (mm) | 61.2 | 4.6 | 58.6 | 5.3 | 58.6 | 5.1 | 57.2 | 5.0 |
| S–PNS parallel to SN (mm) | 12.9 | 4.2 | 15.2 | 4.3 | 15.0 | 3.8 | 15.0 | 3.2 |
| S–PNS perpend to SN (mm) | 47.7 | 3.5 | 45.1 | 4.0 | 45.5 | 4.0 | 45.5 | 3.7 |
| mx1–S parallel to SN (mm) | 57.6 | 7.0 | 60.3 | 6.1 | 61.4 | 6.9 | 59.8 | 6.3 |
| mx1–S perpend to SN (mm) | 65.6 | 3.7 | 65.5 | 4.1 | 65.1 | 3.7 | 64.2 | 3.8 |
| S–ANS parallel to SN (mm) | 57.6 | 5.1 | 59.6 | 4.4 | 60.5 | 4.8 | 59.9 | 5.2 |
| S–ANS perpend to SN (mm) | 54.5 | 3.9 | 53.3 | 5.2 | 52.5 | 4.6 | 51.8 | 4.5 |
| Mx–Md midline (°) | 1.5 | 4.5 | 0.1 | 2.0 | 0.2 | 2.0 | 0.2 | 2.3 |
| Right mx6 to Zy–Zy (mm) | 47.3 | 5.1 | 45.1 | 5.7 | 44.3 | 5.6 | 43.6 | 5.9 |
| Left mx6 to Zy–Zy (mm) | 48.1 | 4.6 | 46.5 | 5.7 | 45.9 | 4.6 | 44.6 | 6.7 |
| Occlusal cant (°) | −0.1 | 2.4 | 2.4 | 2.8 | 2.1 | 3.0 | 2.4 | 1.8 |
| Titanium group | | | | | | | | |
| SNA (°) | 80.7 | 3.6 | 82.9 | 4.0 | 83.2 | 4.1 | 83.5 | 3.7 |
| S–A parallel to SN (mm) | 58.1 | 6.6 | 60.8 | 6.6 | 61.2 | 6.4 | 61.3 | 6.0 |
| S–A perpend to SN (mm) | 62.7 | 4.0 | 61.8 | 4.7 | 62.6 | 5.0 | 63.0 | 4.5 |
| S–PNS parallel to SN (mm) | 14.1 | 3.7 | 15.9 | 3.6 | 15.7 | 3.4 | 14.9 | 2.6 |
| S–PNS perpend to SN (mm) | 49.3 | 4.0 | 48.0 | 4.6 | 48.2 | 4.2 | 48.6 | 4.4 |
| mx1–S parallel to SN (mm) | 61.8 | 6.6 | 64.6 | 7.1 | 65.4 | 7.6 | 65.0 | 7.3 |
| mx1–S perpend to SN (mm) | 61.4 | 7.1 | 60.8 | 7.3 | 60.7 | 7.9 | 61.0 | 7.3 |
| S–ANS parallel to SN (mm) | 61.1 | 7.5 | 63.4 | 7.1 | 63.6 | 6.8 | 63.9 | 6.5 |
| S–ANS perpend to SN (mm) | 56.9 | 3.9 | 56.1 | 4.2 | 56.7 | 4.5 | 57.0 | 4.3 |
| Mx–Md midline (°) | 2.6 | 7.5 | 1.2 | 2.0 | 0.7 | 2.0 | 1.5 | 1.7 |
| Right mx6 to Zy–Zy (mm) | 45.8 | 5.8 | 44.4 | 6.9 | 46.2 | 5.4 | 45.1 | 5.9 |
| Left mx6 to Zy–Zy (mm) | 47.4 | 7.2 | 45.9 | 6.8 | 46.7 | 5.0 | 46.4 | 5.1 |
| Occlusal cant (°) | −0.2 | 3.5 | 1.5 | 1.9 | 1.2 | 2.0 | 0.8 | 1.6 |

that Fixorb also had sufficient strength to fix the maxilla-mandibular bone in orthognathic surgery.

The PLLA plates could be easily bent with forceps at room temperature and stayed in the desired position without use of a heating device. PLLA plates are 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. The stability and strength of bent PLLA plates remains unclear. The fact that the PLLA plate bent easily 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 forceps in 60 °C 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.

There remain some problems, such as those given below, which still need to be resolved in the search for better resorbable devices. The rigidity should be increased, although the bending strength is sufficiently high in some devices. The degradation rate of high strength PLLA devices should be enhanced and the period of time until complete resorption should be shortened. Bioactivity, such as bone conduction and bone bonding capability, should be made available by using other bioactive materials. u-HA/PLLA (Super-Fixsorb®-MX) was developed to overcome these problems.[7]

u-HA denotes an inorganic compound which is neither calcined at 800–900 °C nor sintered at 1000–1400 °C. It is a raw material of a HA ceramic, and has almost the same composition as natural bone. Sintered HA is surface bioactive, but not bioresorbable. On the other hand, u-HA is bioabsorbable so that the u-HA/PLLA plate and screw could be absorbed *in vivo*. u-HA/PLLA plate systems that have completed clinical tests in orthopaedic, oral and maxillofacial surgeries exhibit total resorbability and osteological bioactivity such as the ability to bond to bone directly and osteoconductivity[8,28,29] as well as

*Table 3*. The results of repeated measure ANOVA.

| | Degree of freedom | Sum of squares | Mean sum of squares | *F*-Value | *P*-Value |
|---|---|---|---|---|---|
| S–A perpendicular to SN | | | | | |
| Class | 2 | 79.950 | 39.975 | 11.310 | <0.0001* |
| Groups residual | 57 | 201.474 | 3.535 | | |
| Category for time course | 2 | 24.161 | 12.080 | 1.076 | 0.344 |
| Category for time course × class | 4 | 102.999 | 25.750 | 2.294 | 0.064 |
| Category for time course × groups residual | 114 | 1279.000 | 11.224 | | |
| mx1–S perpendicular to SN | | | | | |
| Class | 2 | 15.311 | 7.655 | 5.712 | 0.0055* |
| Groups | 57 | 76.394 | 1.340 | | |
| Category for time course | 2 | 2.473 | 1.239 | 0.311 | 0.733 |
| Category for time course × class | 4 | 22.060 | 5.515 | 1.384 | 0.244 |
| Category for time course × groups residual | 114 | 454.192 | 3.984 | | |
| ANS–S perpendicular to SN | | | | | |
| Class | 2 | 34.846 | 17.423 | 4.867 | 0.0112* |
| Groups | 57 | 204.053 | 3.580 | | |
| Category for time course | 2 | 15.921 | 7.961 | 1.019 | 0.364 |
| Category for time course × class | 4 | 30.563 | 7.641 | 0.978 | 0.423 |
| Category for time course × groups residual | 114 | 890.612 | 7.812 | | |

* Significant differences (between subjects) were identified among the three groups.

good biocompatibility and high stiffness retainable for a long period of time to achieve bone union.[30] The u-HA/PLLA system screw and plate contain 30 and 40 wt.% of u-HA in each respectively. The u-HA/PLLA plate was higher than the PLLA plate (Fixorb®-MX) and human cortical bone in bending strength (200–270; 200–250; and 100–200 MPa, respectively) and shearing strength (120–145; 90–95; 100 MPa, respectively). Shikinami et al. documented the complete process of bioresorption and bone replacement of rods made of forged composites of unsintered HA particles/poly-L-lactide (F-u-HA/PLLA) implanted in the femoral medullary cavities of rabbits.[6] From the results, it was found that morphological changes during biodegradation and bone replacement in the proximal medullary cavity took up to 4.5 years, while molecular weight and bending strength had decreased to 50 kDa and 200 MPa, respectively, after 6 months. Therefore, if the strength of the absorbable plate decreases and the bony healing between segments is not complete by at least 6 months after osteotomy, skeletal stability cannot be sustained for long. They have a modulus of elasticity close to that of natural cortical bone, and they can retain high strength during the period required for bone healing. They can also show optimal degradation and resorption behaviour, osteoconductivity, and bone bonding capability, because of the HA content. The u-HA/PLLA plate and screw could be recognized in computed tomography (CT) images, although the PLLA plate was completely radiolucent. Therefore, it is easy to judge whether the u-HA/PLLA plate or screw breaks or has become displaced. It was thought that breakage of the screw head by the driver of the system device in the u-HA/PLLA occurred more frequently than with the PLLA system. Perhaps the u-HA content might reduce the elasticity of the screw.

In this study, the predictor variables were three types of plate (uHA/PLLA, PLLA, titanium plate) and cephalometric measurements in each time interval. Age, gender and race were considered as the confounding variables. There was no significant difference in the distribution of age, gender, race and setback amount so that the effects of confounding variables could be excluded. Differences in the preoperative skeletal pattern and advancement amount in the maxilla could not be identified among the three groups (Tables 2 and 4). Therefore, it could be considered that three groups with similar skeletal pattern were randomly selected in this study.

In the lateral cephalometric analysis, there were significant differences in the time course changes in S–A perpendicular to SN, mx1–S perpendicular to SN and S–ANS perpendicular to SN among the three groups. This could suggest that postoperative superior displacement at the anterior part of the maxilla tended to occur in the PLLA group. The uHA/PLLA group had a significantly larger value than the PLLA group regarding change of S–A perpendicular to SN between baseline and 1 month. This suggested that the maxillary movement in the PLLA group contained maxillary advancement with impaction. In the other time interval, except for mx1–S perpendicular to SN in T3, there was no significant difference among the groups, and differences in the changes were not clinically appreciable.

Analysis of the PA cephalography can be used to measure dentofacial asymmetry and determine occlusal cant, although advance movement was dominant in all patients in this study. A line was drawn connecting the most buccal points of the left and right maxillary first molars. Standard PA cephalometric analyses do not include evaluation of the relationships of the occlusal plane to the horizontal. This represents an important deficiency, as levelling the occlusal plane, when necessary, should be a goal of surgical and orthodontic therapy. Occlusal cant alone is insufficient to evaluate asymmetry, so Mx–Md midline was also added for a more accurate evaluation. In the time-course of change in the result of the PA cephalogram, no significant differences were identified among the three groups. This suggests that uHA/PLLA and PLLA plates are as strong as a titanium plate to fix the maxillary segment from the frontal view.

The bone strength of the maxilla should be considered when stability after Le Fort I osteotomy is examined. The authors' previous study showed that there were no significant differences in area of bone defect between the segmental gap after Le Fort I osteotomy among the plate types using three-dimensional CT.[31] Various factors such as preoperative bone thickness, occlusion, inter-maxillary traction, moving direction and amount, age and gender were considered to be associated with healing at the anterior and lateral walls of the maxilla. The change in stress distribution in the region of the space between the segments might also affect the change in bone area. At least, use of

*Table 4.* Time interval value for cephalometric data.

| | T1 | | T2 | | T3 | |
|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | Mean | SD |
| uHA/PLLA group | | | | | | |
| SNA (°) | 1.3 | 2.6 | 0.3 | 1.9 | 0.0 | 2.0 |
| S–A parallel to SN (mm) | 2.2 | 1.6 | 0.2 | 2.0 | 0.5 | 2.7 |
| S–A perpend to SN (mm) | 0.6* | 3.2 | −1.1 | 2.1 | 0.4 | 1.9 |
| S–PNS parallel to SN (mm) | 0.8 | 2.3 | 0.6 | 2.9 | 0.4 | 4.2 |
| S–PNS perpend to SN (mm) | −1.6 | 1.9 | −0.1 | 1.9 | 0.6 | 2.1 |
| mx1–S parallel to SN (mm) | 2.0 | 1.9 | 1.1 | 2.0 | 0.0 | 3.1 |
| mx1–S perpend to SN (mm) | 0.3 | 1.2 | −0.3 | 1.5 | 0.6* | 1.7 |
| S–ANS parallel to SN (mm) | 2.8 | 1.8 | −0.2 | 2.5 | 0.6 | 2.6 |
| S–ANS perpend to SN (mm) | 0.1 | 2.1 | −0.8 | 1.7 | 0.7 | 1.7 |
| Mx–Md midline (°) | 1.1 | 5.2 | −0.3 | 2.0 | 0.4 | 1.9 |
| Right mx6 to Zy–Zy (mm) | −2.7 | 4.9 | 0.6 | 3.2 | 1.1 | 3.1 |
| Left mx6 to Zy–Zy (mm) | −2.4 | 5.2 | 1.2 | 3.9 | 1.1 | 4.2 |
| Occlusal cant (°) | 0.2 | 3.0 | 0.3 | 2.5 | 0.0 | 2.2 |
| PLLA group | | | | | | |
| SNA (°) | 1.1 | 4.5 | 1.2 | 2.5 | 0.3 | 2.3 |
| S–A parallel to SN (mm) | 2.5 | 2.6 | 0.8 | 3.2 | −1.0 | 1.3 |
| S–A perpend to SN (mm) | −2.6* | 4.7 | 0.0 | 2.1 | −1.4 | 1.5 |
| S–PNS parallel to SN (mm) | 2.3 | 3.5 | −0.2 | 2.7 | 0.0 | 2.3 |
| S–PNS perpend to SN (mm) | −2.7 | 2.9 | 0.4 | 1.2 | 0.1 | 1.1 |
| mx1–S parallel to SN (mm) | 2.8 | 3.3 | 1.0 | 3.0 | −1.5 | 2.2 |
| mx1–S perpend to SN (mm) | −0.1 | 2.9 | −0.4 | 1.1 | −0.9* | 1.6 |
| S–ANS parallel to SN (mm) | 2.0 | 2.2 | 0.9 | 3.0 | −0.7 | 2.1 |
| S–ANS perpend to SN (mm) | −1.3 | 4.1 | −0.8 | 2.5 | −0.8 | 1.6 |
| Mx–Md midline (°) | −1.4 | 3.9 | 0.1 | 1.6 | −0.1 | 1.9 |
| Right mx6 to Zy–Zy (mm) | −2.2 | 4.5 | −0.8 | 2.9 | −0.7 | 6.3 |
| Left mx6 to Zy–Zy (mm) | −1.6 | 5.1 | −0.6 | 3.7 | −1.3 | 6.6 |
| Occlusal cant (°) | 2.5 | 3.8 | −0.3 | 3.1 | 0.2 | 2.5 |
| Titanium group | | | | | | |
| SNA (°) | 2.2 | 2.9 | 0.3 | 3.5 | 0.3 | 2.7 |
| S–A parallel to SN (mm) | 2.7 | 2.6 | 0.4 | 3.5 | 0.2 | 3.1 |
| S–A perpend to SN (mm) | −0.8 | 2.9 | 0.7 | 3.2 | 0.4 | 3.6 |
| S–PNS parallel to SN (mm) | 1.8 | 4.0 | −0.2 | 2.8 | −0.8 | 2.2 |
| S–PNS perpen to SN (mm) | −1.3 | 2.1 | 0.2 | 1.3 | 0.4 | 2.1 |
| mx1–S parallel to SN (mm) | 2.9 | 2.6 | 0.7 | 3.9 | −0.4 | 2.8 |
| mx1–S perpend to SN (mm) | −0.6 | 1.8 | −0.1 | 1.3 | 0.3 | 2.1 |
| S–ANS parallel to SN (mm) | 2.2 | 2.6 | 0.2 | 3.4 | 0.4 | 2.6 |
| S–ANS perpend to SN (mm) | −0.8 | 2.4 | 0.6 | 3.2 | 0.3 | 2.6 |
| Mx–Md midline (°) | −1.4 | 6.7 | −0.4 | 2.1 | 0.8 | 1.9 |
| Right mx6 to Zy–Zy (mm) | −1.4 | 7.1 | 1.7 | 4.3 | −1.0 | 4.1 |
| Left mx6 to Zy–Zy (mm) | −1.5 | 8.6 | 0.7 | 4.7 | −0.3 | 3.8 |
| Occlusal cant (°) | 1.6 | 3.5 | −0.3 | 2.3 | −0.4 | 2.0 |

* Significant difference between groups at $P < 0.05$.

bone graft or an alternative material may not be decided solely on the basis of the amount of bony gap by movement of the maxillary segment. It will also be necessary to examine the relationship between new bone formation and type of plate.

In conclusion, this study suggested that there was no significant difference time course changes in most measurements among three groups, although there was significant difference in mx1–S perpendicular to SN in T3 between the u-HA/PLLA plate system and PLLA plate system in Le Fort I osteotomy. Clinically, maxillary skeletal and occlusal stability with satisfactory results could be obtained in the u-HA/PLLA group, PLLA plate group and titanium plate group without complications.

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