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Stability of bioresorbable plates following reduction of mandibular body fracture: Three-dimensional analysis

In-Seok Song [a, 1], Jimi Choi [b, 1], Seong Ryoung Kim [c], Jee-Ho Lee [c, *]

[a] Department of Oral and Maxillofacial Surgery, Korea University Anam Hospital, Republic of Korea
[b] Department of Biostatistics, College of Medicine, Korea University, Republic of Korea
[c] Department of Oral and Maxillofacial Surgery, College of Medicine, University of Ulsan, Asan Medical Center, Republic of Korea

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ABSTRACT

Purpose: The recent development of bioresorbable bone plates and screws allows plates to be applied to the load-bearing regions of the mandible and to remain in place over time without the need for removal. We hypothesized that the stability of composite plates and screws forged from unsintered hydroxyapatite particles and poly-L-lactide (u-HA/PLLA) is comparable to that of standard titanium fixation systems for the reduction of fractures of load-bearing regions of the mandibular body.

Materials and methods: 40 patients underwent open reduction and internal fixation of the fractured mandibular body with either a titanium or u-HA/PLLA bone plate. Cone-beam CT images were obtained immediately postoperatively and at 6-month follow-up, and were analyzed for positional changes of the affected mandible.

Results: There were no significant differences in the postoperative positional changes of reference points between the titanium and u-HA/PLLA miniplates, except for that for the coronoid process (p-value = 0.03). Multivariate regression analysis revealed no significant differences in spatial changes between the immediate postoperative and 6-month follow-up images, after adjusting for age and sex.

Conclusion: The stability of bioresorbable u-HA/PLLA miniplates and screws was comparable to that of titanium miniplates and screws immediately postoperatively and at 6-month follow-up, following surgical reduction of fractures of load-bearing regions of the mandibular body. Bioresorbable osteosynthesis can be considered a viable alternative to titanium osteosynthesis.

1. Introduction

Titanium miniplate fixation is a standard procedure for the reduction and fixation of facial bone fractures. Alternatively, bioresorbable bone plates are now available for growing children and some adults with fractures in non-load-bearing regions of the midface or skull.

Use of bioresorbable plates in load-bearing regions is an area of concern due to their lack of strength compared with standard titanium bone plates (Gaball et al., 2011). The load-bearing regions of the mandibular body require thicker and bulkier bioresorbable plates, thus necessitating longer operation and absorption times, and discomfort on palpation. Moreover, studies have reported complications such as swelling, discharge, and osteolysis related to the absorption of bioresorbable plates (Kim and Kim, 2002).

Recent advances in technology have enhanced the strength and stability of bioresorbable plates. Forged composites of unsintered hydroxyapatite particles and poly-L-lactide (u-HA/PLLA) have high mechanical strength, including bending, shear, and impact strengths, and high bending modulus due to the direct mechanical interlocking between u-HA particles and the PLLA matrix (Shikinami and Okuno, 1999). These materials maintain their bending strength for 24 weeks, which is comparable with human cortical bone *in vivo* (Shikinami et al., 2005; Sukegawa et al., 2015). The PLLA matrix is totally absorbed from the composites after 4 years, followed by the replacement of most u-HA particles by bone after 5.5 years (Kanno et al., 2018).

These u-HA/PLLA bioresorbable plates have been successfully applied (Landes et al., 2014b; Park et al., 2016; Sukegawa et al., 2016, 2017; Kanno et al., 2017); however, no studies have focused on their use in the reduction of fractures of load-bearing regions of the

* Corresponding author. Fax: +82 2 3010 6967.
E-mail address: jeehoman@naver.com (J.-H. Lee).
[1] In-Seok Song and Jimi Choi contributed equally to this work.

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mandibular body. Therefore, we investigated whether the stability of u-HA/PLLA bioresorbable miniplates and screws was comparable with that of titanium miniplates and screws for the reduction of fractures of load-bearing regions of the mandibular body.

2. Materials and methods

2.1. Study design and sampling

This retrospective cohort study involved a total of 40 participants (12 females and 28 males) who underwent open reduction and internal fixation of a mandibular body fracture under general anesthesia with either standard titanium (Optimus MF System®; Osteonic Ltd., Seoul, South Korea) or bioresorbable u-HA/PLLA miniplates and screws (Osteotrans MX®; Teijin Medical Corporation Ltd., Osaka, Japan) at a single oral and maxillofacial surgery clinic. The patients were assigned haphazardly to each group, and operations were performed. A single surgeon performed all procedures. The patients underwent cone-beam CT immediately postoperatively and at a 6-month follow-up appointment.

Individuals with fractures in other parts of the mandible, including the angle, condyle, or coronoid process, and those in whom fixations were performed with only screws or wire were excluded. The study protocol was reviewed and approved by the institutional review board of the Asan Medical Center (IRB approval No. 2018-1420).

First, local anesthetic agents were injected. Then, an intraoral vestibular incision was made and periosteal dissection was performed, allowing the surgeon to locate the fracture line on the body of the mandible. Intermaxillary fixation was performed, followed by application of either a titanium or bioresorbable miniplate, according to the manufacturers' instructions (Fig. 1). Two straight 4-hole plates (1.0-mm thickness) were bent or twisted at room temperature, adapted to the upper and lower portion of the fractured mandible, and fixed according to the AO concept (Champy et al., 1978). Postoperative care involved elastic-guided occlusion for 1 month. All the patients received a soft diet for 2–4 weeks postoperatively. There were no reported surgical complications such as infections or screws fractures.

2.2. 3D analysis of positional change in the anatomical landmarks of the affected mandible

The positions of each mandible landmark were calculated digitally using a three-dimensional (3D) simulation software tool (OnDemand3D®; Cybermed, Seoul, Republic of Korea). Positional changes in landmarks were presented as 3D coordinates (x, y, z), including distance (mm) and direction (x-axis: medial (−) to lateral (+), y-axis: anterior (−) to posterior (+), z-axis: lower (−) to upper (+)) (Fig. 2A). Anatomical landmarks were selected and defined to estimate plate stability as follows: Cl (lateral pole of condylar head) was the most prominent point of the lateral surface of the mandibular condyle. Cm (medial pole of condylar head) was the most prominent point of the medial aspect of the mandibular condyle. Cc (center of the mandibular condyle) was the midpoint between Cl and Cm. Cr (tip of coronoid process of the mandible) was the most prominent point of the coronoid process. A (angle of the mandible) was the most prominent point of the mandibular angle (Fig. 2B). Spatial changes between the immediate postoperative and 6-month follow-up stages were estimated by subtracting the immediate postoperative measure from the 6-month measure for these anatomical landmarks (Lee et al., 2012, 2014).

2.3. Statistical analysis

SAS software (version 9.4, SAS Institute Inc., Cary, NC, USA) was used for all statistical analyses. Results were presented as either mean ± standard deviation, as number (%), or as median (IQR). Intra-rater and inter-rater reliability were measured using the intraclass correlation coefficient, which showed that all the values were over 0.976, indicating high reliability (Supplementary Table 1). The positional changes in the landmark points between the immediate postoperative and 6-month follow-up stages were assessed using the Student's t-test or Mann–Whitney U-test for continuous variables, and the chi-square test or Fisher's exact test for categorical variables. A p-value < 0.05 was considered significant.

3. Results

Table 1 shows the characteristics of the included patients. The mean participant age was 34.7 ± 18.0 years in the titanium group and 31.8 ± 17.0 years in the bioresorbable group (Table 1). Male patients were more likely to undergo surgery than females in both groups (9 vs 3 in the titanium group and 19 vs 9 in the bioresorbable group). There were no significant differences in sex or mean age between the titanium or bioresorbable miniplate groups ($p = 0.73$ and 0.63, respectively).

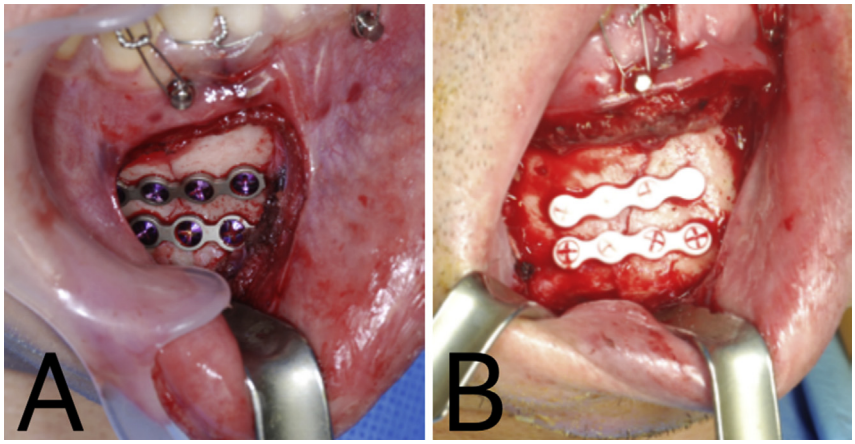

Fig. 1. Plate positioning in open reduction and internal fixation of a mandibular body fracture. Each fractured mandible was reduced with either two straight four-hole standard titanium or bioresorbable u-HA/PLLA miniplates and screws.

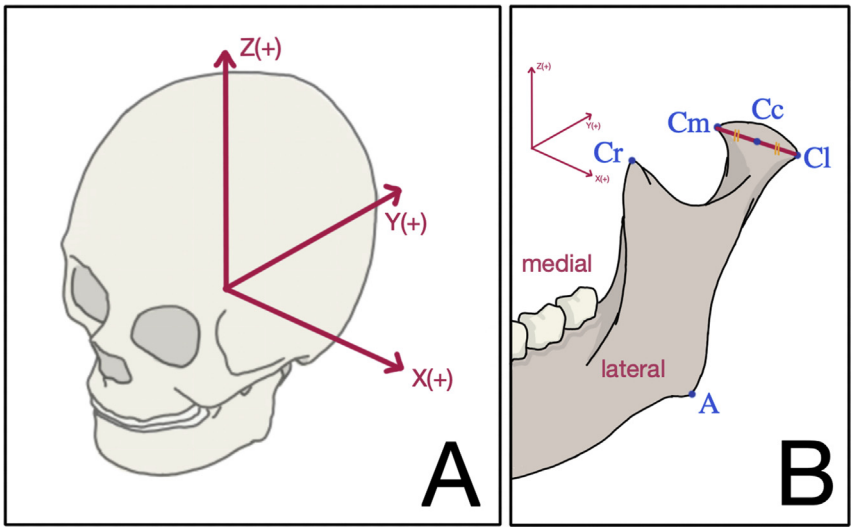

Fig. 2. Schematic models of three-dimensional (3D) coordinated systems. (A) The positional changes were presented as 3D coordinates (*x*, *y*, *z*), including distance (mm) and direction (*x*-axis: medial (−) to lateral (+), *y*-axis: anterior (−) to posterior (+), *z*-axis: lower (−) to upper (+)). (B) Anatomical landmarks were defined on the 3D model reconstructed using CT images in the 3D coordinate system. (Cl = lateral pole of condylar head, Cm = medial pole of condylar head, Cc = center of the mandibular condyle, Cr = tip of coronoid process of the mandible, A = angle of the mandible).

Table 1
Patients' characteristics.

	T (n = 12)	B (n = 28)	p-value
Gender, n (%)			0.73[a]
Male	9 (75.0)	19 (67.9)	
Female	3 (25.0)	9 (32.1)	
Age, mean (SD) (years)	34.7 (18.0)	31.8 (17.0)	0.63[b]

T, titanium group; B, bioresorbable u-HA/PLLA group.
[a] p-value according to Fisher's exact test.
[b] p-value according to Student's t-test.

The comparison of surgical time between the titanium and bioresorbable groups is shown in Table 2. There was no significant difference between surgical times ($p = 0.76$).

The mean (SD) change in displacement (in mm) of the titanium and bioresorbable plates was 1.15 (0.41) and 1.00 (0.78) for the mandibular angle, 1.04 (0.55) and 1.06 (0.53) for the condyle (lateral), 0.95 (0.45) and 1.21 (0.68) for the condyle (medial), 0.72 (0.31) and 0.67 (0.40) for the center of the condyle, and 0.82 (0.41) and 1.25 (0.83) mm for the coronoid process, respectively. There were no significant differences in postoperative positional changes in reference points between the titanium and bioresorbable miniplates, with the exception of the coronoid process (Table 3). The bioresorbable plates were more likely to displace the coronoid process laterally along the *x*-axis than the titanium plates ($p = 0.03$).

The positional changes in reference points between the immediate postoperative and 6-month follow-up evaluations were assessed using multivariate analysis, as presented in Table 4. Although some discrepancies in coefficients were found between the titanium and bioresorbable groups, there were no significant differences in spatial changes between the immediate postoperative and 6-month follow-up stages, after adjustment for age and sex.

The positional changes in reference points during the immediate postoperative and 6-month follow-up periods were examined according to sex. The bioresorbable plates displaced the coronoid process more in males, while the titanium plates displaced the mandible angle more in females ($p = 0.01$ and 0.04, respectively) (Table 5).

Finally, the tendency for changes between the immediate postoperative and 6-month postoperative stages was assessed for each anatomical landmark. The bioresorbable miniplates were more likely to cause the lateral condyle point to displace backward along the *y*-axis, and the coronoid process to displace upward along the *z*-axis ($p = 0.003$ and 0.02, respectively), compared with standard titanium miniplates (Table 6).

Table 2
Comparison of surgical time between bioabsorbable and titanium plates (min).

	n	mean	SD	median	(IQR)	p-value[a]
B	28	87.0	70.2	68.5	(25.5–123.25)	0.760
T	12	83.1	78.2	53.5	(23.0–117.3)	

[a] p-value according to Mann–Whitney test.

4. Discussion

Bioresorbable miniplates and screws possess comparable stability to titanium miniplates and screws. None of the reference points used in our study showed significant differences between the bioresorbable and titanium plate groups, except for the coronoid process. The coronoid process (in males), and the angle (in females), showed significant differences in displacement. However, the differences disappeared after adjusting for age and sex.

This study confirms the stability of the u-HA/PLLA bone plates for the reduction of bone fractures. Previous studies have supported the stability of u-HA/PLLA for orthognathic surgery (Landes et al., 2014b; Park et al., 2016), midface or malar fractures (Hayashi et al., 2013; Landes et al., 2014a), naso-orbital-ethmoid fractures (Kanno et al., 2017; Sukegawa et al., 2017), and mandibular fractures (Sukegawa et al., 2015, 2016).

To the best of our knowledge, this is the first clinical report that clearly demonstrates the stability of u-HA/PLLA bone plates for reduction of mandibular body fractures. Various plate formulations have been tried previously, but have failed to achieve sufficiently reliable clinical outcomes (Kim and Kim, 2002; Ashammakhi et al., 2004; Lovald et al., 2007). For example, a self-reinforced P(L/DL)LA form was developed in an attempt to impart greater strength, with

Table 3
Changes in reference points between the immediate postoperative and 6-month follow-up stages.

	T ($n = 12$)			B ($n = 28$)			Difference (B − T)		p-value[a]
	mean (SD)	95% CI for mean	median (IQR)	mean (SD)	95% CI for mean	median (IQR)	mean (SD)	95% CI for mean	
Angle (affected)									
d*x*	0.82 (0.38)	(0.58–1.06)	0.80 (0.58–1.06)	0.68 (0.79)	(0.37–0.99)	0.47 (0.27–0.74)	0.14 (0.70)	(−0.35–0.62)	0.46
d*y*	0.58 (0.37)	(0.34–0.81)	0.61 (0.28–0.78)	0.39 (0.46)	(0.21–0.57)	0.22 (0.06–0.56)	0.19 (0.44)	(−0.12–0.49)	0.23
d*z*	0.38 (0.29)	(0.19–0.56)	0.33 (0.14–0.55)	0.34 (0.23)	(0.26–0.43)	0.28 (0.2–0.5)	0.03 (0.25)	(−0.14–0.21)	0.70
Diff	1.15 (0.41)	(0.89–1.41)	1.13 (0.92–1.5)	1.00 (0.78)	(0.69–1.30)	0.75 (0.57–1.41)	0.15 (0.7)	(−0.34–0.64)	0.43
Cond (lat, affected)									
d*x*	0.68 (0.52)	(0.35–1.01)	0.60 (0.32–0.99)	0.59 (0.41)	(0.43–0.75)	0.61 (0.21–0.88)	0.09 (0.44)	(−0.22–0.40)	0.57
d*y*	0.32 (0.23)	(0.17–0.47)	0.29 (0.13–0.49)	0.45 (0.36)	(0.31–0.59)	0.33 (0.17–0.58)	−0.13 (0.33)	(−0.36–0.10)	0.27
d*z*	0.54 (0.48)	(0.24–0.85)	0.41 (0.17–0.93)	0.59 (0.47)	(0.41–0.77)	0.55 (0.38–0.68)	−0.045 (0.47)	(−0.38–0.29)	0.78
Diff	1.04 (0.55)	(0.69–1.39)	1.03 (0.66–1.48)	1.06 (0.53)	(0.86–1.27)	0.90 (0.72–1.37)	−0.019 (0.54)	(−0.39–0.35)	0.92
Cond (med, affected)									
d*x*	0.47 (0.37)	(0.24–0.71)	42 (0.16–0.69)	0.56 (0.5)	(0.37–0.75)	0.49 (0.22–0.76)	−0.087 (0.47)	(−0.41–0.24)	0.59
d*y*	0.5 (0.43)	(0.23–0.77)	0.37 (0.16–0.79)	0.49 (0.45)	(0.32–0.67)	0.36 (0.19–0.69)	0.01 (0.45)	(−0.30–0.32)	0.97
d*z*	0.46 (0.33)	(0.25–0.67)	0.38 (0.28–0.74)	0.65 (0.71)	(0.38–0.93)	0.41 (0.18–0.88)	−0.19 (0.62)	(−0.63–0.24)	0.38
Diff	0.95 (0.45)	(0.66–1.23)	1.03 (0.49–1.40)	1.21 (0.68)	(0.94–1.47)	1.10 (0.77–1.59)	−0.26 (0.62)	(−0.70–0.18)	0.23
Center of condyle[b]									
d*x*	0.34 (0.26)	(0.18–0.50)	0.35 (0.06–0.56)	0.33 (0.23)	(0.24–0.42)	0.28 (0.13–0.51)	0.01 (0.24)	(−0.16–0.18)	0.90
d*y*	0.44 (0.31)	(0.24–0.64)	0.33 (0.18–0.69)	0.31 (0.24)	(0.21–0.40)	0.23 (0.11–0.45)	0.13 (0.26)	(−0.05–0.32)	0.15
d*z*	0.3 (0.26)	(0.14–0.46)	0.22 (0.07–0.52)	0.37 (0.4)	(0.22–0.53)	0.26 (0.06–0.49)	−0.07 (0.36)	(−0.33–0.18)	0.56
Diff	0.72 (0.31)	(0.52–0.92)	0.74 (0.63–0.94)	0.67 (0.4)	(0.52–0.82)	0.71 (0.38–0.85)	0.05 (0.38)	(−0.21–0.31)	0.70
Cor (affected)									
d*x*	0.34 (0.3)	(0.15–0.53)	0.20 (0.12–0.54)	0.74 (0.82)	(0.42–1.05)	0.56 (0.34–0.87)	−0.4 (0.71)	(−0.89–0.10)	0.03
d*y*	0.45 (0.42)	(0.18–0.71)	0.32 (0.13–0.61)	0.5 (0.41)	(0.34–0.66)	0.43 (0.18–0.68)	−0.05 (0.41)	(−0.34–0.24)	0.74
d*z*	0.44 (0.28)	(0.26–0.61)	0.35 (0.31–0.51)	0.59 (0.54)	(0.38–0.8)	0.48 (0.23–0.82)	−0.15 (0.48)	(−0.49–0.18)	0.24
Diff	0.82 (0.41)	(0.55–1.08)	0.66 (0.56–1.14)	1.25 (0.83)	(0.93–1.57)	1.05 (0.78–1.41)	−0.43 (0.73)	(−0.94–0.08)	0.03

T, titanium group; B, bioresorbable u-HA/PLLA group; d*x*, positional changes (in millimeters) between postoperative and preoperative time-points along *x*-axis; d*y*, positional changes (in millimeters) between postoperative and preoperative time-along *y*-axis; d*z*, positional changes (in millimeters) between postoperative and preoperative time-points along *z*-axis; Diff, distance (in millimeters) between postoperstive and preoperative landmarks in 3D coordinated system.
[a] *p*-value by Student's t-test.
[b] Middle point between Cond (lat) and Cond (med).

less volume, into a bioresorbable system (Lovald et al., 2009; Lee et al., 2010). In one study, a bioresorbable mandibular bone plate design using a P(L/DL)LA (70:30 in composition) copolymer, with a bar width of 2.49 mm and a plate thickness of 2.68 mm, was shown to be optimal (Lovald et al., 2009). However, these forms were still bulky and palpable, and carried an increased risk of foreign body reactions or late-stage infections. Our study used two thin (1.0 mm) miniplates (40 wt% u-HA particles) with 2.0-mm-diameter screws (30 wt% u-HA particles) and achieved high stability, similar to that of standard titanium miniplates, without significant complications.

Table 4
Multivariate analysis of changes in reference points between the immediate post-operative and 6-month follow-up stages.

	Coefficient for T vs B	Standard error	*p*-value[a]
Angle (affected)			
d*x*	0.10	0.24	0.69
d*y*	0.19	0.15	0.20
d*z*	0.04	0.09	0.69
Diff	0.12	0.24	0.62
Cond (lat, affected)			
d*x*	0.05	0.15	0.73
d*y*	−0.13	0.12	0.27
d*z*	−0.03	0.17	0.86
Diff	−0.04	0.19	0.84
Cond (med, affected)			
d*x*	−0.10	0.17	0.56
d*y*	−0.03	0.15	0.86
d*z*	−0.22	0.22	0.31
Diff	−0.31	0.21	0.14
Center of condyle			
d*x*	0.00	0.08	0.96
d*y*	0.12	0.09	0.19
d*z*	−0.10	0.12	0.40
Diff	0.02	0.12	0.88
Cor (affected)			
d*x*	−0.41	0.25	0.11
d*y*	−0.03	0.14	0.81
d*z*	−0.15	0.17	0.38
Diff	−0.44	0.26	0.10

T, titanium group; B, bioresorbable u-HA/PLLA group.
[a] *p*-value according to multiple linear regression, adjusting for age and gender.

The lateral condyle was displaced backward along the *y*-axis, while the coronoid process was displaced upward along the *z*-axis in the bioresorbable u-HA/PLLA group. Similarly, a previous study found that torsion moments drove the mandibular angle outward, and shear forces displaced the proximal segment upward when bioresorbable PLLA was used to fix mandibular body fractures (Tams et al., 1999). The muscles attached to the ramus (including the masseter, temporal, and medial pterygoid) dislocated the proximal segment medially and upward when the fractures were horizontally and vertically unfavorable (Fonseca et al., 2013). The u-HA/PLLA plate might be able to withstand muscle forces from the pterygomasseteric sling, but other minor movements seemed unavoidable.

We also found that the coronoid process was displaced more in males, while the angle was displaced less in females within the u-HA/PLLA group, compared with the titanium group. According to Table 5, Female showed less Diff in angle (affected) in Bioresorbable group (0.63) compared to titanium group (1.37) with statistical significance (p-value is 0.04). A previous study showed that maximum molar bite forces were 1.6 times greater in males than in females (Waltimo and Kononen, 1993) because of differences in the diameter of the masseter muscles (Tuxen et al., 1999). Also, the male temporalis muscle forces were significantly higher than the corresponding female forces during exercise (Reynolds et al., 2016). Because the temporal muscles attach to the coronoid process and pull upward when opening and closing the mouth, a strong male temporal muscle may displace the coronoid process upward. This would be less frequently observed with female temporal muscles.

Table 5
Changes in reference points between the immediate postoperative and 6-month follow-up stages, by sex.

	Male			Female		
	T ($n = 9$)	B ($n = 19$)	p-value[a]	T ($n = 3$)	B ($n = 9$)	p-value[a]
	Median (IQR)	Median (IQR)		Median (IQR)	Median (IQR)	
Angle (affected)						
dx	0.71 (0.61–0.90)	0.61 (0.33–0.92)	0.29	1.11 (0.25–1.13)	0.40 (0.21–0.49)	0.19
dy	0.60 (0.33–0.68)	0.33 (0.10–0.72)	0.35	0.64 (0.07–1.29)	0.03 (0.01–0.24)	0.09
dz	0.32 (0.21–0.47)	0.28 (0.20–0.53)	0.94	0.43 (0.03–0.89)	0.27 (0.12–0.45)	0.79
Diff	1.11 (0.91–1.15)	0.87 (0.65–1.48)	0.79	1.37 (0.92–1.70)	0.63 (0.44–0.67)	0.04
Cond (lat, affected)						
dx	0.67 (0.55–1.01)	0.43 (0.19–1.03)	0.31	0.27 (0.03–0.50)	0.64 (0.23–0.82)	0.22
dy	0.33 (0.17–0.53)	0.31 (0.15–0.53)	0.96	0.23 (0.01–0.42)	0.35 (0.27–0.94)	0.29
dz	0.39 (0.18–0.46)	0.56 (0.48–0.66)	0.15	0.66 (0.15–1.19)	0.44 (0.13–0.70)	0.59
Diff	1.10 (0.72–1.60)	0.87 (0.73–1.37)	0.66	0.75 (0.16–1.36)	0.98 (0.65–1.36)	0.53
Cond (med, affected)						
dx	0.61 (0.17–0.72)	0.57 (0.21–0.77)	0.94	0.22 (0.14–0.48)	0.36 (0.23–0.75)	0.42
dy	0.59 (0.11–0.93)	0.60 (0.19–0.92)	0.83	0.30 (0.23–0.43)	0.26 (0.08–0.36)	0.72
dz	0.42 (0.36–0.87)	0.38 (0.19–1.13)	0.79	0.25 (0.04–0.30)	0.44 (0.06–0.80)	0.53
Diff	1.17 (0.97–1.41)	1.24 (0.77–1.88)	0.51	0.54 (0.40–0.57)	0.82 (0.76–1.30)	0.09
Center of condyle						
dx	0.32 (0.08–0.46)	0.38 (0.17–0.60)	0.497	0.61 (0.04–0.68)	0.14 (0.13–0.27)	0.65
dy	0.60 (0.18–0.70)	0.34 (0.11–0.60)	0.35	0.20 (0.16–0.40)	0.13 (0.11–0.23)	0.48
dz	0.37 (0.17–0.67)	0.30 (0.06–0.74)	0.77	0.12 (0.03–0.27)	0.19 (0.05–0.39)	0.72
Diff	0.76 (0.71–0.97)	0.80 (0.39–0.92)	0.96	0.69 (0.21–0.79)	0.44 (0.36–0.50)	0.59
Cor (affected)						
dx	0.18 (0.12–0.46)	0.55 (0.32–0.89)	0.05	0.36 (0.12–1.00)	0.57 (0.39–0.84)	0.72
dy	0.30 (0.10–0.46)	0.42 (0.12–0.52)	0.64	0.63 (0.26–1.53)	0.50 (0.30–0.94)	0.72
dz	0.35 (0.29–0.49)	0.44 (0.13–0.81)	0.79	0.55 (0.32–1.21)	0.54 (0.46–0.82)	0.86
Diff	0.62 (0.49–0.67)	1.02 (0.76–1.23)	0.01	1.37 (1.08–1.67)	1.19 (0.79–1.47)	0.59

T, titanium group; B, bioresorbable u-HA/PLLA group.
[a] p-value according to Mann–Whitney U-test.

This study did not report any significant complications associated with u-HA/PLLA plate use. Due to its bioactive and bioconductive properties, foreign body reactions or soft tissue thickening were scarce. However, long-term follow-up is necessary because delayed complications with the u-HA/PLLA plate could occur, and such complications might affect plate stability. One study reported that minor, but resolvable, complications healed spontaneously at 1–12 months after surgery (Landes et al., 2014a).

Table 6
Changes between the immediate postoperative and 6-month follow-up stages.

	T ($n = 12$)		B ($n = 28$)			p-value
n (%)	Negative[c]	Positive[d]	Negative[c]	Zero	Positive[d]	
Angle (affected)						
x	7 (58.3)	5 (41.7)	15 (53.6)	0 (0.0)	13 (46.4)	0.78[b]
y	7 (58.3)	5 (41.7)	15 (53.6)	2 (7.1)	11 (39.3)	1.00[a]
z	6 (50.0)	6 (50.0)	21 (75.0)	0 (0.0)	7 (25.0)	0.15[a]
Cond (lat, affected)						
x	8 (66.7)	4 (33.3)	18 (64.3)	0 (0.0)	10 (35.7)	1.00[a]
y	10 (83.3)	2 (16.7)	9 (32.1)	0 (0.0)	19 (67.9)	0.003[b]
z	7 (58.3)	5 (41.7)	22 (78.6)	0 (0.0)	6 (21.4)	0.25[a]
Cond (med, affected)						
x	6 (50.0)	6 (50.0)	15 (53.6)	0 (0.0)	13 (46.4)	0.84[b]
y	8 (66.7)	4 (33.3)	16 (57.1)	1 (3.6)	11 (39.3)	0.81[a]
z	3 (25.0)	9 (75.0)	13 (46.4)	1 (3.6)	14 (50.0)	0.50[a]
Center of condyle						
x	7 (58.3)	5 (41.7)	15 (53.6)	0 (0.0)	13 (46.4)	0.78[b]
y	7 (58.3)	5 (41.7)	19 (67.9)	0 (0.0)	9 (32.1)	0.72[a]
z	6 (50.0)	6 (50.0)	15 (53.6)	0 (0.0)	13 (46.4)	0.84[b]
Cor (affected)						
x	6 (50.0)	6 (50.0)	18 (64.3)	0 (0.0)	10 (35.7)	0.49[a]
y	3 (25.0)	9 (75.0)	12 (42.9)	0 (0.0)	16 (57.1)	0.48[a]
z	12 (100.0)	0 (0.0)	17 (60.7)	0 (0.0)	11 (39.3)	0.02[a]

[a] p-value according to Fisher's exact test.
[b] p-value according to chi-square test.
[c] Negative if primary value > secondary coordinate.
[d] Positive if primary value < secondary coordinate.

Hayashi et al. reported one case of bulging and another case of late postoperative infection after bioresorbable fixation (Hayashi et al., 2013). Soft tissue thickening or swelling due to incompletely absorbed plates or dissolved materials has been reported, even 2 years postoperatively (Landes et al., 2014a). Therefore, great cares should be taken, for up to several years, until biodegradation of the u-HA/PLLA plate is complete.

There are some limitations to this study. First, the cohort used was relatively small. Second, the authors assigned the patients to each group haphazardously. Haphazard assignment to one or the other therapy could lead to bias. Third, the authors did not consider or classify the surgical or postoperative complications prior to the operations. Strictly speaking, the complications were not assessed analytically. Fourth, the study stated that there were no complications, but only examined stability of the bone plates for 6 months, because this was considered sufficient time for fracture bone healing and strength reacquisition without plate systems. Furthermore, large-scale prospective randomized trials are required to elucidate safety issues such as delayed infection or soft tissue thickening, which could affect the stability of the bone plates. Finally, this study has several advantages. It clearly demonstrated that u-HA/PLLA bone plates withstood repetitive masticatory forces, irrespective of age or sex. Also, the results explained the paths of displacement within the affected mandible according to 3D coordinates, helping to elucidate possible mechanisms involved in these actions.

5. Conclusion

The stability of u-HA/PLLA bioresorbable miniplates and screws was comparable to that of titanium miniplates and screws up to 6 months postoperatively. Even considering this study's limitations, u-HA/PLLA bioresorbable miniplates and screws appear to be reliable for open reduction and internal fixation of mandibular body

fractures. Bioresorbable osteosynthesis can be considered a viable alternative to titanium osteosynthesis.

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Disclosure of potential conflicts of interest

There are no conflicts of interest for this study.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jcms.2019.07.033.

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