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Comparisons among four types of absorbable plates used for internal fixation of zygomaticomaxillary complex fractures☆

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ABSTRACT

Importance: Conventional plating systems include titanium plates for the fixation of facial bone fractures. However, titanium plates result in artifacts on computed tomography images and appear unstable on magnetic resonance images. Therefore, absorbable plates have been widely used for the fixation of facial bone fractures of late in Asia.

Objective: To compare stability and symmetry among four different absorbable plates used for internal fixation of zygomaticomaxillary complex fractures.

Participants: The subjects were patients with zygomaticomaxillary complex fractures that were diagnosed and treated by internal fixation with absorbable plates between January 2012 and April 2018. Patients aged ≤14 years and ≥76 years were excluded. Patients with other fracture types were also excluded.

All patients underwent surgery within 2 weeks of the injury.

Intervention: Internal fixation was performed with one of four types of absorbable plates, namely Inion®, Polymax®, Osteotrans®, and Biosorb®.

Main outcome measures: The stability of the four plates was investigated by evaluation of the orbital height ratio (A'/A), zygoma angle (a'/a), distance (b'/b) from the midline, and gap (c) of the temporal process on three-dimensional facial computed tomography images obtained before, 3 weeks after, and 3–6 months after surgery. Any plate-associated complications were recorded.

Results: In total, 400 patients were enrolled, and there were 100 patients in each of the four groups. There were no significant differences with regard to postoperative stability and relapse among the four plates. Moreover, facial symmetry showed no changes over time in any group. Complications such as infection and sensory disturbance were not frequent. All plates except Biosorb® were palpable for more than 6 months after surgery, with Osteotrans® remaining palpable for several years.

Conclusions and relevance: Our findings suggest that all four types of absorbable plates are useful for treating isolated zygomaticomaxillary complex fractures. While Biosorb® is unsuitable for severe comminuted fractures. Polymax® and Inion® are not bendable at room temperature. It is important to select an appropriate absorbable plate according to each patient's condition and the fracture severity.

1. Introduction

Zygomaticomaxillary complex fracture (ZMCF) is the most common type of facial fracture after nasal fracture. The aims of surgical treatment include the restoration of any dislocated fragments to their anatomical position, stable fixation, and early functional and esthetic recovery (Gülicher et al., 2006; Paeng et al., 2012). Stable fixation is used to achieve early postoperative recovery of function and esthetics, including mastication, speech,

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and facial expressions (Gülicher et al., 2006; Paeng et al., 2012). Therefore, the choice of fixation plates is an important consideration in the management of facial bone fractures.

Currently, there is no consensus regarding the optimal material for plates used in the repair of ZMCFs. Intraosseous wiring was previously used for this purpose, although titanium plates are currently the gold standard for facial fracture fixation because they are strong, small, inexpensive, and suitable for rigid fixation (Wittwer et al., 2006; Kang et al., 2014; Shadad et al., 2016). However, they can also cause plate-associated complications such as infection, tissue damage, and foreign body reactions (Wittwer et al., 2006; Kang et al., 2014). Moreover, metal plates can cause metal allergies and pain, exhibit sensitivity to temperature changes, cannot be adjusted to account for bone growth in younger patients, and result in artifacts on CT images and appear unstable on MR images. These factors lead patients to request secondary plate removal surgery (Buijs et al., 2012; Shadad et al., 2016).

Of late, absorbable plates are in frequent use for the fixation of facial bone fractures (Buijs et al., 2012). Ewers and Förster (1985) and Bos et al. (1987) first reported the use of biodegradable plate and screw prototypes for ZMCF fixation in clinical studies (Shadad et al., 2016). Absorbable plates show biocompatibility, strength, and ductility; degrade without late inflammatory complications; and do not interfere with bone growth in children (Michael et al., 2014; Choi and Lee, 2016; Hyun et al., 2016). Moreover, the plates are not palpable a few months or years after surgery, and because they degrade within the body, there is no requirement for secondary surgery (Bergsma et al., 1993; Kim et al., 2012; Choi and Lee, 2016). In previous studies, absorbable plates were found to be capable of providing adequate strength and immobilization when they were compared with titanium fixation systems for the fixation of facial fractures (Buijs et al., 2012; Michael et al., 2014; Choi; Lee, 2016). Although they are expensive and difficult to use in cases of unstable comminuted fractures because of their lower strength compared with that of metal plates, the use of absorbable plates is increasing because of benefits such as no metal allergies, tolerable pain, insensitivity to temperature changes, no artifacts on CT images, and the ability to degrade within the body (Enislidis et al., 2005; Park et al., 2011; Liya et al., 2013; Frankie et al., 2017). Inion® (INION, Finland), Polymax® (DePuySynthes, Pennsylvania, USA), Osteotrans® (C.I. TAKIRON, Japan), and Biosorb® (OSTEONIC, Korea; Fig. 1) plates exhibit these properties and are commonly used; therefore, we used these plates for internal fixation of ZMCFs in our clinic.

Absorbable plates are composed of macromolecular chains forming a single polymer and are manufactured with differing ratios of poly-L-lactic acid (PLLA) and poly-DL-lactic acid (PDLLA) in order to produce a robust fixation plate. The biodegradation of absorbable plates comprises a hydrolysis phase and a metabolic phase. In the hydrolysis phase, water molecules permeate the absorbable plate and degrade the long macromolecules into polymeric chains, which are then phagocytosed by macrophages before transportation to the liver. Thereafter, in the metabolic phase, the macromolecules are broken down into carbon dioxide (CO_2) and water. In this regard, inflammation can occur when the metabolism exceeds the capabilities of the body or when debris particles exceed the wound healing capacity (Choi and Lee, 2016; Hyun et al., 2016).

The aim of the present study was to evaluate and compare stability and symmetry among Inion®, Polymax®, Osteotrans®, and Biosorb® through a review of medical records and follow-up of three-dimensional (3D) facial CT images.

2. Material and Methods

In order, Inion®, Polymax®, Osteotrans® and Biosorb® plates were used in patients diagnosed with ZMCF between January 2012 and April 2018 irrelevant to sex and age, without any statistical bias. The study was conducted with IRB approval (IRB file No. KNUMC 2018-04-026). Patients aged ≤14 years are not grown to adult size; therefore, they were excluded in order to minimize measurement errors. Moreover, patients aged >75 years were excluded to avoid errors due to soft tissue changes or the presence of diseases such as osteoporosis. All fractures were diagnosed using 3D facial CT and physical examinations, and patients with additional fractures other than ZMCFs were excluded. All patients exhibited displacement requiring surgical treatment, which was performed by the same surgeon within 2 weeks of the injury.

A three-point fixation method was used. The zygomaticomaxillary buttress was accessed via a marginal buccal–gingival incision, the inferior orbital rim was accessed via a subciliary incision, and the frontotemporal suture area was accessed via a Dingman incision. During surgery, the absorbable plates were bent to fit the shape of the facial bones.

Symmetry and stability were analyzed using 3D facial CT before, 3 weeks after, and 3–6 months after surgery. The orbital height ratio (A'/A) was measured to verify the vertical alignment of ZMC. A horizontal baseline was defined as the line connecting the margins of the supraorbital rim on the fracture and contralateral sides, and A and A′ were defined as the distances from this horizontal baseline to the lowermost point of the infraorbital rim margin on the fracture side and contralateral side, respectively. The zygoma angle (a'/a), distance (b'/b) from the midline (hereafter referred to as distance), and gap (mm) of the temporal process (hereafter referred to as gap) were measured to verify the horizontal alignment of ZMC. The zygoma angle (a'/a) was defined as the angle between the midline and the malar prominence at the nasal tip (a': contralateral side, a: fracture side). The distance was defined as the perpendicular distance from the midline to the malar prominence (b': contralateral side, b: fracture side), and the gap was defined as the distance from the outer cortex of the zygomatic arch to the deepest part of the fracture (Fig. 2).

All collected data were statistically analyzed using SPSS ver. 12.0 (SPSS, Chicago, IL, USA). The mean values for each group were compared using one-way analysis of variance, and a *P*-value of <0.05 was considered statistically significant.

3. Results

In total, 400 patients were included in this study, with 100 patients each in the Inion®, Polymax®, Osteotrans®, and Biosorb® groups. The mean age of patients and male:female ratio in each group were as follows: Inion® group, 39.2 ± 16.8 years and 80:20, respectively; Polymax® group, 39.4 ± 17.4 years and 83:17, respectively; Osteotrans® group, 37.1 ± 17.1 years and 82:18, respectively; and Biosorb® group, 42.2 ± 16.4 years and 80:20, respectively. The mean interval between trauma and surgery ranged from 5.6 to 6.4 days. There were no statistically significant differences in the patient demographics and interval between trauma and surgery among the four groups ($P > 0.05$).

At 3 weeks after surgery, the four groups showed no significant differences in the horizontal and vertical symmetry parameters ($P > 0.05$). The mean orbital height ratios (A'/A) in the Inion®, Polymax®, Osteotrans®, and Biosorb® groups were 0.98, 0.97, 0.97, and 0.98, respectively. The mean zygoma angles (a'/a) were 1.01, 1.02, 1.02, and 1.02($P > 0.05$), respectively, the mean distances (b'/b) were 1.08, 1.05, 1.04, and 1.06, respectively ($P > 0.05$), and the mean gaps were 0.87, 0.81, 0.72, and 0.74 mm ($P > 0.05$), respectively. Thus, the immediate postoperative stability was similar for the four plates ($P > 0.05$; Table 1).

At 3–6 months after surgery, the Inion® group exhibited a mean orbital height ratio (A'/A) of 0.97, angle (a'/a) of 1.01, distance (b'/b)

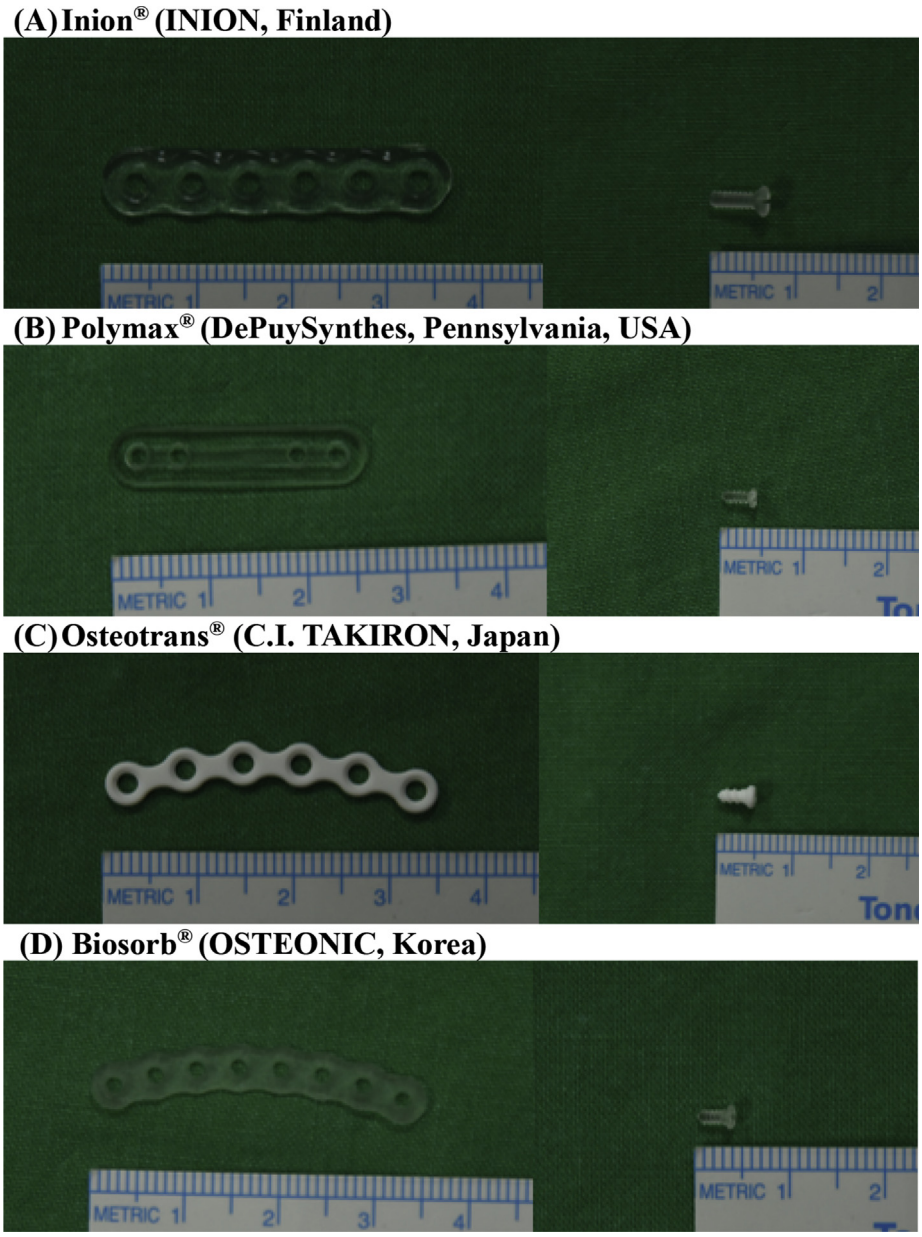

Fig. 1. Images of four absorbable plates and screws used for internal fixation of zygomaticomaxillary complex fractures.

of 1.09, and gap of 0.86 mm, with no significant differences from the values at 3 weeks ($P > 0.05$). The values in the Polymax® group also showed no significant differences from those at 3 weeks; the mean orbital height ratio (A'/A), angle (a'/a), distance (b'/b), and gap were 0.97, 1.02, 1.05, and 0.81 mm, respectively ($P > 0.05$). These values were 0.98, 1.02, 1.05, and 0.71 mm, respectively, in the Osteotrans® group and 0.99, 1.02, 1.06, and 0.72 mm, respectively, in the Biosorb® group; both groups showed values similar to those at 3 weeks ($P > 0.05$). Thus, all four absorbable plates maintained their stability over time (Table 1).

With regard to postoperative complications, the rate of positive palpability was significantly different between Biosorb® and the other plates ($P < 0.05$), with Biosorb® showing almost no palpability after surgery in all but 1 patient. Osteotrans® remained palpable for several years after surgery. A representative case of Osteotrans® fixation is shown in Fig. 2. At 2 years after surgery, the plate can be seen in its original position without any bioresorption. There were no significant differences among groups with regard to other complications, including infection, foreign body reaction, fistula formation, paraesthesia, exposure, malocclusion, and relapse (Table 2).

4. Discussion

In the present study, we evaluated the properties of Inion®, Polymax®, Osteotrans®, and Biosorb® plates and found that all four plates have their own unique characteristics and are suitable for internal fixation of ZMCFs.

The orbital height ratio (A'/A), which represents horizontal symmetry, and the zygoma angle (a'/a) and distance (b'/b), which represent vertical symmetry, showed postoperative values that were close to 1 for all four plates. This finding indicated good bilateral symmetry of the zygomatic bones. We believe that these outcomes were achieved because the frontotemporal suture area

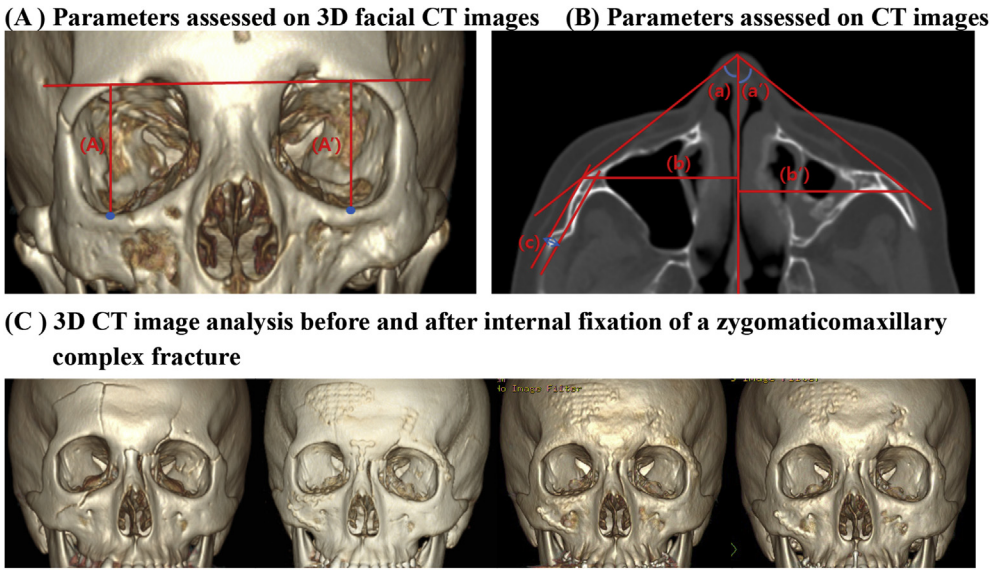

Fig. 2. 3D facial CT images. A. Orbital height ratio (A'/A): A horizontal baseline is defined as the line joining the margins of the supraorbital rims on the fracture side and contralateral side. A and A′ are defined as the distances from the horizontal baseline to the lowermost point of the infraorbital rim margin on the fracture side and contralateral side, respectively. B. Zygoma angle (a'/a): Angle between the midline and the malar prominence at the nasal tip (a': contralateral side, a: fracture side), Distance (b'/b): Perpendicular distance from the midline to the malar prominence (b': contralateral side, b: fracture side), Gap (mm; c): The distance from the outer cortex of the zygomatic arch to the deepest part of the fracture. C. 3D CT image analysis before and after internal fixation of a zygomaticomaxillary complex fracture with Osteotrans® (C.I. TAKIRON, Japan), Postoperative analyses were performed at 3 weeks, 1 year, and 2 years after surgery. 3D: three-dimensional, CT: computed tomography.

Table 1
Three-dimensional computed tomography parameters for patients with zygomaticomaxillary complex fractures treated by internal fixation with absorbable plates.

	Inion® (n = 100)	Polymax® (n = 100)	Osteotrans® (n = 100)	Biosorb® (n = 100)	*P*-value
Orbital height ratio (A'/A)					
Before Surgery	0.87	0.88	0.87	0.89	$P > 0.05$
Three weeks after surgery	0.98	0.97	0.97	0.98	$P > 0.05$
3–6 months after surgery	0.97	0.97	0.98	0.99	$P > 0.05$
P-value	$P > 0.05$	$P > 0.05$	$P > 0.05$	$P > 0.05$	
Zygoma Angle (a'/a)					
Before Surgery	1.10	1.12	1.09	1.11	$P > 0.05$
Three weeks after surgery	1.01	1.02	1.02	1.02	$P > 0.05$
3–6 months after surgery	1.01	1.02	1.02	1.02	$P > 0.05$
P-value	$P > 0.05$	$P > 0.05$	$P > 0.05$	$P > 0.05$	
Distance (b'/b)					
Before Surgery	1.15	1.11	1.17	1.16	$P > 0.05$
Three weeks after surgery	1.08	1.05	1.04	1.06	$P > 0.05$
3–6 months after surgery	1.09	1.05	1.05	1.06	$P > 0.05$
P-value	$P > 0.05$	$P > 0.05$	$P > 0.05$	$P > 0.05$	
Gap (mm)					
Before Surgery	2.45	2.31	2.81	2.56	$P > 0.05$
Three weeks after surgery	0.87	0.81	0.72	0.74	$P > 0.05$
3–6 months after surgery	0.86	0.81	0.71	0.72	$P > 0.05$
P-value	$P > 0.05$	$P > 0.05$	$P > 0.05$	$P > 0.05$	

A total of 400 patients were stratified into four groups of 100 patients each according to the absorbable plate used for internal fixation: Inion® (INION, Finland), Polymax® (DePuySynthes, Pennsylvania, USA), Osteotrans® (C.I. TAKIRON, Japan), and Biosorb® (OSTEONIC, Korea).
The four groups show no significant differences in the orbital height ratio, zygoma angle, distance, and gap at all time points. For all absorbable plates, there are no significant differences between the orbital height ratio, zygoma angle, distance, and gap at 3 weeks after surgery and those at 3–6 months after surgery.

and inferior orbital rim were fixed using a Dingman incision and a subciliary incision, respectively, under direct observation.

On preoperative 3D facial CT images, the four groups showed no significant differences in the orbital height ratio (A'/A), zygoma angle (a'/a), distance (b'/b), and gap (mm). This indicated similar levels of preoperative displacement in all groups. Even at three weeks after surgery, there were no statistically significant differences in symmetry, indicating similar immediate postoperative stability for all four plates. When we compared the orbital height ratio (A'/A), angle (a'/a), distance (b'/b), and gap (mm) at 3 weeks with those at 3–6 months after surgery, there were no significant differences between the two time points for any of the absorbable plates. This means that fixation remained steady for a given duration of time, and that time-dependent stability was well maintained. In other words, all absorbable plates result in similar outcomes with regard to time-dependent stability and relapse.

Although some patients experienced initial postoperative numbness, this was thought to be caused by retraction during surgery. In all patients, the numbness disappeared within 3 months after surgery. The reported infection rate for absorbable plates is approximately 4.26%, although the infection rate in our cohort was only 1%. The incidences of foreign body reactions and paraesthesia were also negligible, with only 1–2 cases per group. However, the rate of postoperative palpability was higher for Inion®, Polymax®,

Table 2
Complications associated with different absorbable plates used for internal fixation of zygomaticomaxillary complex fractures.

	Inion® (n = 100)	Polymax® (n = 100)	Osteotrans® (n = 100)	Biosorb® (n = 100)
Infection	1	1	2	0
Foreign body reactions	1	2	2	1
Fistula formation	0	0	0	0
Palpability	20	17	35	1
Paraesthesia	2	1	2	1
Exposure	0	0	1	0
Malocclusion	0	0	0	0
Relapse	0	0	0	0

A total of 400 patients were stratified into four groups of 100 patients each according to the absorbable plate used for internal fixation: Inion® (INION, Finland), Polymax® (DePuySynthes, Pennsylvania, USA), Osteotrans® (C.I. TAKIRON, Japan), and Biosorb® (OSTEONIC, Korea).
There is a significant difference between Biosorb® and the other three plates with regard to postoperative palpability. There are no differences among the plates with regard to the other complications.

Table 3
Comparisons among absorbable plates for internal fixation of zygomaticomaxillary complex fractures.

	Inion®	Polymax®	Osteotrans®	Biosorb®
Composition	L-Lactide, D,L-Lactide, Polyglycolide, Trimethylene Carbonate	85:15 poly (L-lactide-co-glycolide)	hydroxyapatite (u-HA; 30 wt% in screws and 40 wt% in plates) combined with poly L-lactide (PLLA)	82:18 L-lactide, glycolide
Thickness	1.5 mm	1.5 mm	1.4 mm	0.8 mm
Strength (Bending force)	1.9 N*cm	1.8 N*cm	1.5 N*cm	0.8 N*cm
Flexibility	Malleable at temperatures >55 °C	Can be contoured after immersion in hot water	Bends at room temperature	Bends at room temperature
Biodegradability (Stability)	70% of the plate remains at 9 weeks after implantation	70% of the plate remains at 8 weeks after implantation	70% of the plate remains at 6 months after implantation	70% of the plate remains at 8 weeks after implantation
Bioresorption	2–4 years	1 year	3–5 years	1 year

and Osteotrans® than for Biosorb®. Among patients from the out-patient department, at approximately half the thickness, Biosorb® showed almost no palpability in all but 1 patient, whereas Osteotrans® was palpable in several patients, and it remained palpable for several years after surgery, which was investigated by physical examination.

Even though Inion®, Polymax®, and Osteotrans® have similar thicknesses, Osteotrans® contains hydroxyapatite, which makes it a little harder than the others; this probably explains the long-term palpability of this plate.

All the absorbable plates used in this study undergo hydrolysis and are metabolized by the body to form CO_2 and water. Inion® comprises a polymer of L-lactide, D,L-lactide, polyglycolide, and trimethylene carbonate. It has a thickness of 1.5 mm and is strong, with a bending force of 1.9 N*cm. However, it is not bendable at room temperature, although it remains stable, with 70% of the plate remaining after nine postoperative weeks. The plate is fully bioresorbed after 2–4 years. Polymax® (DePuySynthes, Pennsylvania, USA) comprises an 85:15 poly (L-lactide-co-glycolide) polymer. It is strong and has a thickness of 1.5 mm and a bending force of 1.8 N*cm. Like Inion®, it does not bend at room temperature, although it remains stable, with 70% of the plate remaining after 8 postoperative weeks. Moreover, it shows rapid bioresorption, which is completed in approximately 1 year. Osteotrans® (C.I. TAKIRON, Japan) is made of hydroxyapatite (u-HA; 30 wt% in screws and 40 wt% in plates) combined with a poly L-lactide (PLLA) polymer. It has a thickness of 1.4 mm, is strong, and exhibits a bending force of 1.5 N*cm. It can be readily bent at room temperature and remains stable, with 70% of the plate remaining after 6 postoperative months. However, complete bioresorption requires 3–5 years. Biosorb® (OSTEONIC, Korea) comprises an 82:18 L-lactide, glycolide polymer. It has a thickness of 0.8 mm, because of which it is barely palpable after surgery. The bending force is 0.8 N*cm, and, like Osteotrans®, it can be readily bent at room temperature, which is convenient during surgery. It maintains stability, with 70% of the plate remaining after 8 postoperative weeks. Moreover, complete bioresorption is relatively fast, taking approximately 1 year (Table 3).

5. Conclusion

Our findings suggest that all four absorbable plates assessed in this study are useful for treating isolated fractures of ZMC. While Polymax® and Inion® cannot be bent at room temperature, Osteotrans® and Biosorb® are easily bendable at room temperature, which makes them slightly more convenient to use. With the exception of Biosorb®, all plates are strong but somewhat thick, because of which they are often palpable even after 3–6 postoperative months. In particular, Osteotrans® was palpable after surgery in the majority of young female patients, and it did not show complete resorption even after several years. Biosorb® rapidly undergoes complete bioresorption within 1 postoperative year, but it is not as strong as the other plates and is consequently unsuitable for severe comminuted fractures. Nevertheless, it can be safely used for isolated ZMCFs, considering we observed no significant differences in immediate postoperative or time-dependent stability between Biosorb® and the other stronger plates. Thus, each absorbable plate has distinct characteristics, and it is important to select the appropriate plate on the basis of the patient's condition and the severity of the fracture.

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