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A randomized controlled trial of resorbable versus titanium fixation for orthognathic surgery

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Objectives. To determine any differences in the intra- and postoperative morbidities and complications between resorbable and titanium plating systems for fixation in orthognathic surgery.
Study design. This prospective randomized clinical trial was conducted in the Oral and Maxillofacial Surgery unit of the University of Hong Kong. Patients with dentofacial deformities were randomly assigned into the titanium and resorbable fixation groups. Intraoperative data such as the surgical procedures, time for fixing each plate, and number of broken plates and screws were recorded. Subjective and objective parameters related to clinical morbidities were assessed postoperatively.
Results. A total of 60 patients with 177 osteotomies were included in this study. Eighty-seven osteotomies fixated with 196 titanium plates and 784 titanium screws were performed in 30 patients, whereas 90 osteotomies fixated with 165 resorbable plates and 658 resorbable screws were done in another 30. The postoperative infection rate was 1.53% (3/196) and 1.82% (3/165) in the titanium and resorbable fixation groups, respectively. These infections were mainly due to loose screws and wound dehiscence. The plate exposure rate was 1.02% (2/196) for the titanium group and 1.21% (2/165) for the resorbable group. The plate removal rate in the titanium and resorbable groups was 1.53% (3/196) and 3.63% (6/165), respectively. Statistically significant difference was shown in the plating time of step (mandibular body) and Hofer (mandibular subapical) osteotomies. There was no significant difference in the subjective clinical parameters such as wound discomfort, clinical stability of the osteotomy segments, palpability of plate, and overall satisfaction of the results between the 2 fixation groups. Similarly, objective parameters including wound dehiscence, rate of infection, plate exposure, occurrence of sinus tract, and palpability assessed by surgeons in both groups also showed no significant difference.
Conclusion. Bioresorbable fixation devices offer similar function as titanium in fixation for orthognathic surgery and do not impose an increase in the clinical morbidities.
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Internal fixation using titanium plates and screws in craniomaxillofacial surgery is regarded as the "gold standard." The metal's high biocompatibility, resistance to corrosion,[1,2] minimal scatter in computerized tomography (CT) scanning, and compatibility with plain radiography and with the use of magnetic resonance imaging (MRI)[3,4] have won its widespread acceptance as the fixation material worldwide.

However, studies have noted problems with titanium fixation that have warranted the removal of the titanium plates or screws after the consolidation of bone segments. These have included the presence of titanium particles in the overlying soft tissues and occasionally in the regional lymph nodes,[5-7] thermal conductivity, possibility of maxillary sinusitis, unacceptable palpability,[8,9] allergic hypersensitivity,[10] chemical carcinogenesis,[11] and infection around the hardware.[12] Francel et al[13] reported that 12% of patients required plate removal in

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their study. Schmidt et al[12] noted that 11% of Le Fort I osteotomy patients had to have their plates removed due to infection and plate exposure. Tuovinen et al[14] recorded a plate removal rate of 11.5% retrospectively in 279 patients with isolated mandibular fractures fixed with titanium miniplates. Matthew and Frame[15] interviewed 23 consultant oral and maxillofacial surgeons and concluded that the incidence of plate removal ranged from 5% to 40%, with a mean removal rate of 13%. Islamoglu and his coworkers[16] reported an overall miniplate and screw removal rate of 7%.

Another recent retrospective study[17] from Glasgow reviewed 658 patients over a 2-year period between January 1993 and December 1994. These patients were treated with titanium plate fixation for either maxillofacial trauma (n = 484) or orthognathic surgery (n = 174). This study showed a plate removal rate of 9% and infection of 5.2% in orthognathic cases (16 out of 174), and 10% in maxillofacial trauma (49 out of 484). In the cases of the 16 orthognathic patients who had plates removed, 9 removals were due to infection, 4 due to pain, 1 due to denture discomfort, and 2 due to palpability. In our center, a total of 780 patients who had received orthognathic surgery over a 10-year period from January 1990 to December 1999 were analyzed retrospectively in 2001.[18] Our infection rate after orthognathic surgery was 5.6% (44 out of 780) and plate removal rate was 1.7% (13 out of 780). In every case the removal of the titanium plates was due to infection. Although the percentage of removal of titanium plates and screws recorded in these studies was not high, the findings were sufficiently striking to prompt some surgeons to experiment with the use of resorbable materials.

Poly-lactide is the most widely used material of this kind, and has been extensively tested both in vitro and in vivo. Studies have reported its successful application in different clinical situations, including maxillofacial fracture,[19-22] orthognathic surgery,[23-30] and pediatric surgery.[31-36] Many researchers were able to demonstrate promising results in terms of clinical morbidities and skeletal stability. However, a prospective clinical trial of comparing titanium and bioresorbable plating systems has not been reported. The aim of this study was to determine any differences in morbidities and complications between resorbable and titanium plating systems for fixation in orthognathic surgery by a randomized controlled trial.

MATERIAL AND METHODS

This prospective study was conducted from July 2001 to April 2003, and was approved by the Ethics Committee of the University of Hong Kong. Subjects selected were patients attending the Orthognathic Assessment Clinic for management of their dentofacial deformities, who had completed their presurgical orthodontic treatment. Patients who presented with any type of intraosseous pathologies such as odontogenic cyst or tumors, as well as any type of craniofacial syndromes such as cleft lip and palate, hemifacial microsomia (Goldenhar syndrome), Crouzon's syndrome, and Treacher Collin Syndrome were excluded from this study. The relevant preoperative information recorded in the protocol included the medical history of the patients, such as diabetes mellitus, wound-healing problems, smoking and drinking habits, diagnosis of the dentofacial deformity, and treatment planning. In each case a standard set of preoperative radiographs was taken, including a panoramic and a lateral cephalograph. After consent was given, patients were randomly assigned immediately before surgery to a resorbable plating group or a titanium plating group, with the aid of a randomization table.[37] The BiosorbFX bioresorbable fixation system (Bionx Implants Inc, Tampere, Finland) was used for the resorbable group. The BiosorbFX system consists of screws of diameter 2 and 2.4 mm, and fixation plates of various designs, which are made of self-reinforced poly-L/DL lactic acid copolymer in a ratio of 70% L-lactide and 30% D-lactide. The Compact 2.0 pure titanium plating system (Mathys Medical Ltd, Bettlach, Switzerland) was used for the titanium group.

Once the osteotomy was completed and the occlusion stabilized by surgical occlusal wafers, plates of the appropriate configurations according to the osteotomy types were selected to adapt over the osteotomy cuts. Both the resorbable and titanium plates were bent by a set of mini-bending pliers at room temperature. Once the bent plate was fitted to the bone contour across the osteotomized segments, the screw holes were drilled with specific drill bits. An additional step was required for the resorbable system, involving tapping the hole manually with a screw tap instrument. Screws of appropriate length were then chosen for insertion into the plates and bone, and care was taken to avoid overtightening. Intraoperative information, including details of the surgical procedures, time required for fixing each plate, and the number of broken plates and screws, was recorded. Patients were followed up according to the standard protocol at 2 weeks, 6 weeks, 3 months, 6 months, 1 year, and 2 years postoperatively. A set of standard radiographs was taken at each follow-up. Postoperative assessments were performed subjectively by the patients, using a visual analog scale from 0 to 10, on the wound discomfort (10 as severe pain and 0 as pain free), clinical stability of the osteotomy segment (10 as no mobility and 0 as very mobile), satisfaction level with result (10 as very satisfied and 0 as very unsatisfied), and palpability of the plates. The objective assessment performed by the surgeons included an assessment of

Table I. Osteotomy plating sites and pattern of fixation

Osteotomy types	*Sites for plating*
Le Fort I	-2 anterior plates on pyriform rim
Wunderer and Schuchardt (Maxillary subapical osteotomies)	-2 posterior plates on zygomatic buttress
Hofer (Mandibular subapical osteotomy)	-2 plates across the vertical osteotomy cuts
	-1 plate at the symphysis on splitting of symphyseal midline
Genioplasty	-2 plates across the horizontal osteotomy cut
Step (Mandibular body osteotomy)	-1 plate on each side across the inferior vertical cut (below the mental foramen)
Sagittal split	-1 plate on each side across the anterior vertical osteotomy cut

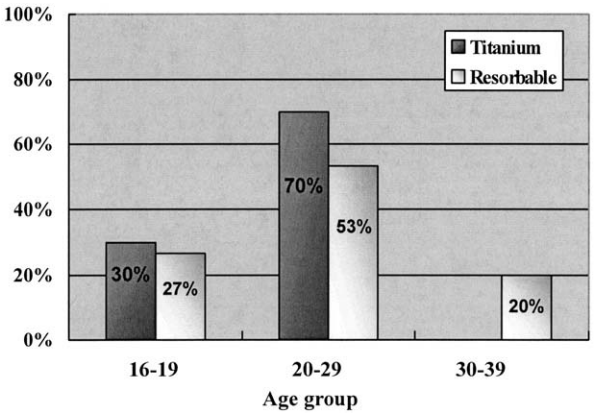

Fig 1. Age distribution of titanium and resorbable groups.

wound dehiscence, pus discharge, sinus formation, and plate exposure. Infection was considered when pain, swelling, and pus discharge were noted. The degree of palpability of plates (scarcely, slightly, moderately, and easily palpable) and the presence of mobility of the osteotomy segments (Yes/No), and the occlusion were also objectively checked by the surgeons. The types of osteotomies performed and the plate fixation sites were standardized in our center (Table I).

The data were analyzed with the use of a Statistical Package for Social Sciences Version 11.0 (SPSS Inc, Chicago, Ill). The means were calculated from the subjective assessment, compared for differences between 2 groups, and tested with the Independent Sample *t*-test (2-tailed). The chi-square test was used to test for the objective assessment results. All the tests were carried out at a significance level of 5%. Sample size calculation was performed with the use of GraphPad StatMate version 1.01 (GraphPad Software, Inc, San Diego, Calif)

RESULTS

Preoperative results

Sixty young adult patients participated in this clinic trial, and no one dropped out from the study before its conclusion. The age of the patients ranged from 16 to 37 years, with a mean age of 22.9 years. The majority of patients (61.7%) were aged between 20 and 29 years, 28.3% between 16 and 19 years, and 10% between 30 and 39 years. The percentage distribution of ages in the titanium and resorbable groups is illustrated in Fig 1. These 60 patients were randomly assigned to the titanium group (n = 30) or the resorbable group (n = 30). The male to female ratio in both groups was 1:2.3 (Table II). All 60 patients were nondiabetics, 2 (3.3%) were smokers, and 13 (21.7%) were social alcohol consumers. None had bleeding or wound-healing problems, or was on steroid therapy. Both smokers happened to be assigned to the titanium group, and of the 13 alcohol consumers, 6 were assigned to the titanium group (20%) and 7 to the resorbable group (23.3%). Forty-eight of 60 patients (80%) were followed up for at least 1 year postoperatively. Of these patients, 24 belonged to the titanium group (50%) and another 24 to the resorbable group (50%). Six patients from the titanium group and 7 patients from the resorbable group were reviewed for at least 2 years.

Table II. Distribution of gender in titanium and resorbable groups

	Titanium (n = 30)	*Resorbable (n = 30)*
Male, n (%)	9 (30)	9 (30)
Female, n (%)	21 (70)	21 (70)
M:F ratio	*1:2.3*	*1:2.3*

According to the presurgical diagnosis of the dentofacial deformities on the maxilla, 60% (36/60) of these deformities were associated with maxillary hypoplasia, 26.7% (16/60) was vertical maxillary excess, and 8.3% (5/60) with maxillary dentoalveolar hyperplasia. Other deformities such as anterior open bite and maxillary hyperplasia accounted for the remaining 5%. The diagnoses of the mandibular deformities in the total subject samples included 30% (18/60) mandibular hyperplasia, 21.7% (13/60) mandibular dentoalveolar hyperplasia, 20% (12/60) unilateral condylar hyperplasia leading to mandibular asymmetry, 13.3% (8/60) mandibular hypoplasia, and 15% (9/60) had a normal mandible. Four patients were concomitantly diagnosed with geniohypoplasia (6.7%).

Table III. Types of osteotomy for titanium and resorbable fixation

Osteotomy	*Titanium (n = 87)*	*Resorbable (n = 90)*	*Total (n = 177)*
Le Fort I, n (%)	25 (28.7)	26 (28.9)	51 (28.8)
Wunderer and Schuchardt (maxillary subapical osteotomies), n (%)	5 (5.7)	3 (3.3)	8 (4.5)
Hofer (mandibular subapical osteotomy), n (%)	20 (23.0)	14 (15.6)	34 (19.2)
Step (mandibular body osteotomy), n (%)	4 (4.6)	2 (2.2)	6 (3.4)
Vertical subsigmoid, n (%)	19 (21.8)	38 (42.2)	57 (32.2)
Sagittal split, n (%)	11 (12.6)	4 (4.4)	15 (8.5)
Genioplasty, n (%)	3 (3.4)	3 (3.3)	6 (3.4)

Table IV. Summary of different plates and screws used and their breakage incidences in different osteotomies

	Titanium plate (n = 196)	*Resorbable plate (n = 165)*	*Titanium screw (n = 784)*	*Resorbable screw (n = 658)*	*Broken resorbable plate (n = 7)*	*Broken resorbable screw (n = 72)*
Le Fort I	100	104	400	415	5	54
Wunderer and Schuchardt (maxillary subapical osteotomies)	20	12	80	47	1	0
Hofer (mandibular subapical osteotomy)	51	35	204	140	1	9
Step (mandibular body osteotomy)	8	4	32	16	0	0
Sagittal split	11	4	44	16	0	8
Genioplasty	6	6	24	24	0	1

Total no. of plates used = 361; Total no. of screws used = 1442.

Of these 60 patients, 54 (90%) underwent bimaxillary osteotomies and 6 patients had single jaw surgery (10%). In the titanium group, all 30 patients (100%) had bimaxillary surgery. In the resorbable group, 24 patients (80%) had bimaxillary procedures and 6 patients (20%) had single jaw surgery. A total of 177 osteotomies were performed on these 60 patients: resorbable fixation was used in 90 osteotomies and titanium fixation was used in 87 osteotomies (Table III).

Intraoperative results

A total of 368 plates and 1514 screws were consumed; 361 plates and 1442 screws were used for fixation in 177 osteotomies and 7 plates (1.9%) and 72 screws (4.8%) were broken during the operation. For the titanium group, 196 plates were used with 784 screws (54%); and for the resorbable group, 165 plates were used with 658 screws (46%). All of the broken plates and screws occurred in the resorbable group; none of the titanium plates and screws broke during the operation. Most of the plates and screws were broken during the Le Fort I plating, which accounted for 71.4% (5/7) of broken plates and 75% (54/72) of the broken screws (Table IV).

Besides the number of intact and broken plates and screws used in the various osteotomies, the occurrence of broken plates and screws at different time periods of surgery was also recorded. Since all broken plates and screws were found in the resorbable group, this part of the analysis was confined to this group. Results revealed that the number of broken plates and screws decreased over time. Three plates and 37 screws were broken during the first 10 operations; 3 plates and 29 screws during the second 10 operations; and only 1 plate and 6 screws during the third 10 operations (Fig 2). The chi-square test showed that the decrease in number of broken plates over time was not statistically significant, whereas there was a significant difference in the reduced number of broken screws ($P < .05$).

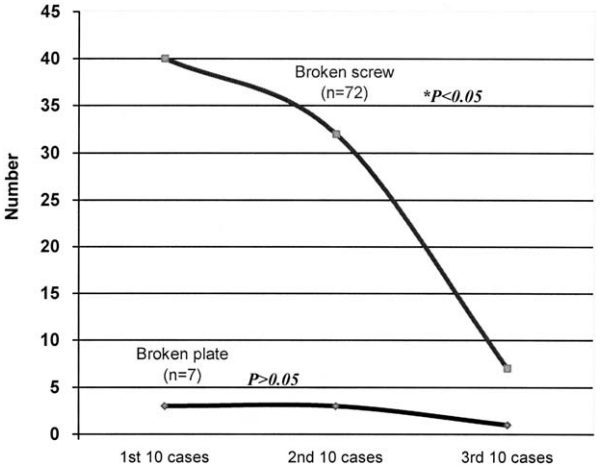

Fig 2. Number of broken plates and screws at different periods.

Table V. The mean plating time and standard deviation for fixing one plate in different osteotomies

	Titanium		Resorbable		
Osteotomy	*Mean min*	*SD*	*Mean min*	*SD*	*P value*
Le Fort I	5.19	2.32	5.51	1.74	.27
Wunderer and Schuchardt (Maxillary subapical osteotomies)	4.80	1.47	5.75	1.60	.10
Hofer (Mandibular subapical osteotomy)	4.61	1.82	5.46	1.41	*.02
Step (Mandibular body osteotomy)	6.38	1.69	4.00	1.41	*.04
Sagittal split	5.73	2.41	6.00	1.15	.83
Genioplasty	5.08	1.11	5.83	0.98	.25

SD = Standard deviation
*P value is statistically significant.

Table VI. The mean score and standard deviation (SD) of wound discomfort at different postoperative periods in the titanium and resorbable groups

Post-operative period	*Titanium*		*Resorbable*		
	Mean	*SD*	*Mean*	*SD*	*P value*
0-2 weeks	4.40 (n = 30)	2.29	3.63 (n = 30)	2.27	.20
3-6 weeks	3.13 (n = 30)	2.26	2.33 (n = 30)	2.16	.17
7-12 weeks	1.47 (n = 30)	1.50	1.20 (n = 30)	1.35	.47
4-6 months	1.42 (n = 30)	1.90	0.65 (n = 30)	1.24	.10
6-12 months	0.67 (n = 24)	1.13	0.46 (n = 24)	1.10	.66
12-24 months	1.00 (n = 6)	2.00	0.29 (n = 7)	0.49	.30

Plating time

Plating time refers to the time required for insertion of 1 plate with 4 screws across the osteotomy segment. The time was measured from when the surgeon started to bend the plate and until he finished placing all 4 screws in that plate. The mean plating time of 1 resorbable or titanium plate in the various osteotomies is listed in Table V. In general, plating of osteotomies using resorbable plates seemed to be more time consuming than titanium plates, but statistical significance was only confirmed in 2 osteotomy types: the Hofer (mandibular subapical osteotomy) and step (mandibular body osteotomy).

Subjective postoperative results

Wound discomfort. All patients suffered a mild to moderate amount of discomfort from the oral wound following the orthognathic surgery. The severity reduced gradually and there was no statistically significant difference between the titanium and resorbable plating groups at the different periods of follow-up (Table VI). Among the subject samples, 48 patients (24 in each group) had follow-up of more than 1 year. The longitudinal changes of wound discomfort in these 48 patients are illustrated in Fig 3.

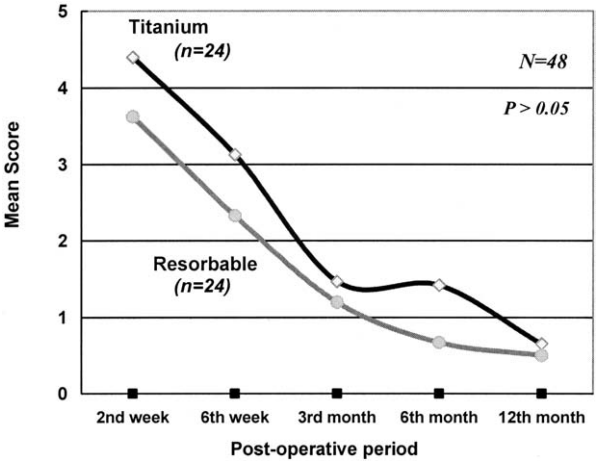

Fig 3. Longitudinal changes of wound discomfort.

Clinical stability. Clinical stability was defined as the extent of mobility of the osteotomy segments that can be detected clinically by bimanual palpation. The stability of the osteotomized segments was found to improve gradually over time, and there was no difference in this respect between the titanium and resorbable fixation (Table VII). The longitudinal changes of the clinical stability in the 48 patients with more than 1-year follow-up are illustrated in Fig 4.

Palpability of plates and screws. Ten out of 30 patients (33.3%) in the titanium group and 11 out of 30 patients (36.7%) in the resorbable group claimed that they could palpate the fixation plates and screws implanted in their jaws in the second postoperative week. The percentage fluctuated throughout the postoperative periods up to 2 years. On longitudinal evaluation of the 48 patients with more than 1-year follow-up, patients in the resorbable group could feel the plates, mostly at the sixth postoperative week. The palpability of the resorbable plates reduced with time, while the palpability of the titanium plates increased with time (Fig 5).

Objective postoperative results

Wound dehiscence. Three patients (10%) in the titanium group and 2 patients (6.7%) in the resorbable group presented with wound dehiscence. All 3 patients in the titanium group had wound dehiscence at the second week postoperatively. In the resorbable group, 1 patient was found to have a dehisced wound at week 2 and the other one at 3 months. One patient in each group with dehisced wounds became infected. All the noninfected wounds closed spontaneously without treatment in less than 6 months postoperatively. All the dehisced wounds in both the titanium and resorbable groups were found in

Table VII. The mean score of clinical stability of osteotomy segments

Postoperative period	*Titanium*		*Resorbable*		
	Mean	*SD*	*Mean*	*SD*	*P value*
0-2 weeks	8.10 (n = 30)	1.79	8.47 (n = 30)	2.18	.48
3-6 weeks	8.50 (n = 30)	1.70	9.07 (n = 30)	1.48	.17
7-12 weeks	8.97 (n = 30)	1.94	9.10 (n = 30)	1.83	.79
4-6 months	8.93 (n = 30)	1.89	9.63 (n = 30)	0.76	.09
6-12 months	9.54 (n = 24)	0.83	9.67 (n = 24)	1.09	.40
12-24 months	8.8 (n = 6)	1.94	9.43 (n = 7)	0.79	.35

SD = Standard deviation

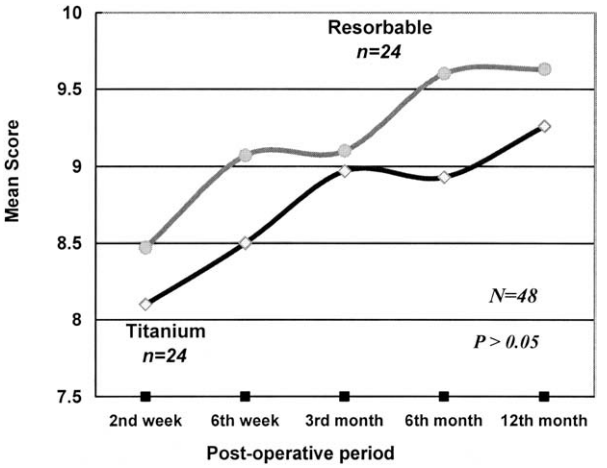

Fig 4. Longitudinal changes of clinical stability.

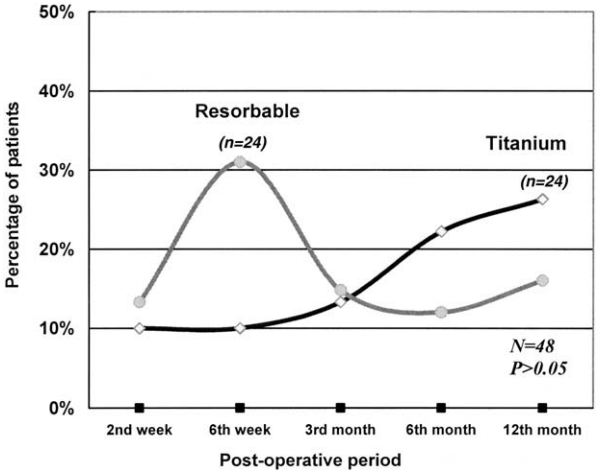

Fig 5. Subjective palpability of plates and screws at various postoperative periods.

the mandibular premolar regions. Three wounds from the titanium group and 1 wound from the resorbable group were noted on the left side, while another wound from the resorbable group was found on the right side.

Infection. Only 3 patients in each group developed infection (10%). One patient became infected in the second week, 1 at the sixth week, and 1 in the third month in the titanium group. However, infections in patients with resorbable plates came relatively late. The first infection was diagnosed in the sixth week, the second in the third month, and the third in the sixth month.

A total of 6 plates (3 in the titanium group and 3 in the resorbable group) became infected. The infection rates were 1.53% (3/196) in the titanium group and 1.82% (3/165) in the resorbable group. The location of the infection is shown in Table VIII. The known causes of infection included loosened screws and wound dehiscence. Both groups included 1 infection due to loosened screws, 1 due to wound dehiscence, and in 1 the cause was unknown. In conclusion, there was no difference in the infection rate between titanium and resorbable plate fixation (P = .67). All the 3 infected plates in the resorbable group were removed in order to resolve the infection, whereas 1 infected plate was removed in the titanium group. The remaining 2 titanium plates were kept in situ and the infection was resolved by wound irrigation and antibiotic therapy.

Plate exposure. Both titanium and resorbable groups had 2 plates exposed between the third and ninth months. Plate exposure rates were 1.02% for the titanium group and 1.21% for the resorbable group. All the plates were found to be exposed at the posterior maxilla (except in 1 titanium case, where the exposure was noted at the mandibular premolar region). None of these exposed plates became infected, but all the exposed plates ultimately required removal.

Sinus tract. Five patients (3 patients in the titanium group and 2 in the resorbable group) developed a non-infected sinus tract. In the titanium group, the sinuses were formed at the sixth postoperative week and the third and sixth postoperative months respectively. Two were found at the maxillary canine region and 1 was found at the mandibular premolar region. In contrast, the resorbable group had sinuses noted at the sixth and twelfth postoperative months. One sinus tract was situated at the mandibular premolar region, and the other at the maxillary molar region. Three tracts in the titanium group and 1 in the resorbable group resolved spontaneously after irrigation only. The remaining patient in the resorbable group required removal of the affected plate connecting to this sinus tract.

Plate removal. In summary, 3 plates (n = 196) in the titanium group and 6 plates (n = 165) in the resorbable group were removed for various reasons (Table IX). The plate-removal rate was 1.53% and 3.36% respectively for the titanium and resorbable groups. There is no

Table VIII. Incidence of infection in titanium and resorbable groups

	Titanium group (n = 196 plates)	*Resorbable group (n = 165 plates)*
Infection, n (%)	3 (1.53)	3 (1.82)
Location of infection		
Maxilla	2 (Left side)	2 (1 left and 1 right side)
Mandible	1 (Left side)	1 (Right side)

P=.67

Table IX. Reasons for plate removal in titanium and resorbable groups

	Titanium group (n = 196)	*Resorbable group (n = 165)*
Infection	1	3
Plate exposure	2	2
Sinus tract	0	1
Total, n (%)	3 (1.53)	6 (3.36)

significant difference between the 2 fixation groups ($P = .47$).

Objective palpability of plate. Titanium plates had no difference in objective palpability when compared with the resorbable plates: 23 patients (76.7%) in the titanium group and 15 patients (50%) in the resorbable group. The palpability of plates was assessed objectively by the surgeons, and longitudinal data showed that most of the titanium plates (80%) were scarcely palpable in the early postoperative period. At around 3 to 6 months, more plates became palpable and most were graded as slightly palpable. In contrast, resorbable plates were more palpable at the early postoperative stage. This palpability decreased with time and the percentage of palpable plates fell below that of titanium at the late postoperative stage. The trend of this longitudinal change in palpability was similar to that of subjective palpability, and is illustrated in Fig 6. The most common site for the palpable plate to occur was at the paranasal region.

Clinical stability. Mobility of the osteotomy segments was detected at the second postoperative week in both groups, affecting 3 patients in the titanium group and 2 patients in the resorbable group. All the mobility was derived from the maxilla, and the degree was very mild. By the sixth week, all the mobile maxillae become stable and firm, and no further mobility was detected in the follow-up period.

Overall satisfaction of patients on surgical results

The mean scores for satisfaction of the results ranged from 7.43 to 8.63. The highest scores were 8.50 in the titanium group and 8.63 in the resorbable group (Table X). The difference between the 2 groups was not statistically significant. The longitudinal evaluation of the 48 patients with more than 1-year follow-up showed a gradual improvement of the satisfactory score over time (Fig 7).

Sample size analysis

This randomized controlled clinical trial was designed with the aim of comparing the clinical morbidities between titanium and resorbable fixation. The infection rate obtained in this study, based on the individual plate (361 plates) was 1.53% (3/196) in the titanium group and 1.82% (3/165) in the resorbable group. The percentages of infection remain unchanged if the samples include both the plates and screws of the titanium and resorbable groups. The infection rate would then be 1.53% (15/980) and 1.82% (15/823), respectively. The sample size required to detect a 1% difference in infection rate would be 900 with 60% statistical power. Since our sample consisted of 980 in the titanium group and 823 in the resorbable group, this sample size was considered adequate.

DISCUSSION

To our knowledge, this is the first prospective randomized clinical controlled trial to compare the clinical morbidities of titanium and bioresorbable fixations in orthognathic surgery. Inclusion and exclusion criteria were properly incorporated. Previous articles on clinical morbidities were mainly retrospective studies of the occurrence of postoperative infection and short-term clinical skeletal relapse. Studies from Kallela et al[22] and Haers and Sailer[38] attempted to analyze the skeletal stability of resorbable plate fixation by cephalometric measurements prospectively, but there was no comparison with titanium plate fixation. Ferretti and Reyneke[29] conducted a prospective, comparative study of the stability of mandibular advancement, but they assigned their subjects deliberately rather than randomly. Besides assessing the postoperative infection rate, our study was also able to explore and compare the subjective and objective parameters of wound healing and its relationship with the internal fixation.

Infection rates in terms of individual plate were 1.53% (3/196) in the titanium group and 1.82% (3/165) in the resorbable group. Rates in terms of the individual patient were higher, at 10% in each group (3/30 in both groups). The infection rates reported in previous studies were usually based on the individual patient rather than on the plate itself. Tuovinen and his colleagues[14] showed an infection rate of 3.6% in terms of number of cases rather than plates. Zijderveld et al[39] reported 27.8% postoperative infection cases. Earlier studies in the 1970s and

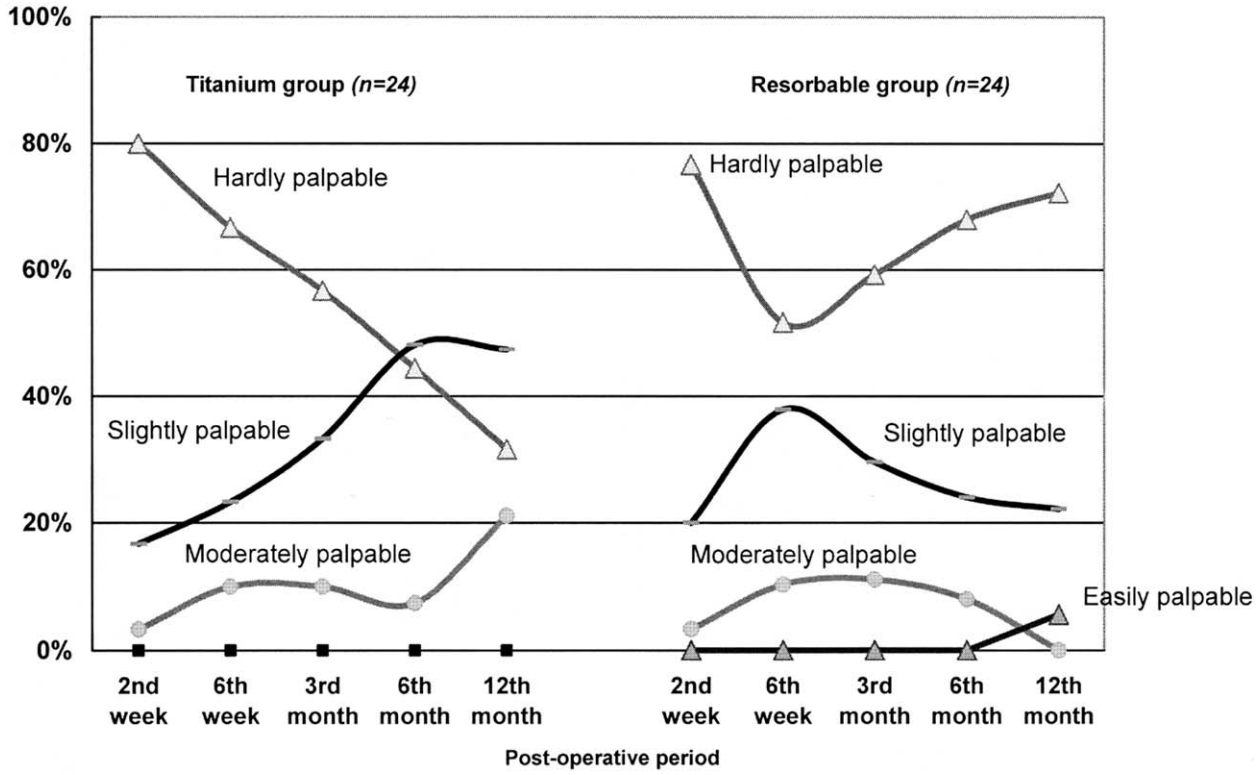

Fig 6. Longitudinal changes in objective palpability of titanium group versus resorbable group.

1980s also reported infection rates based on the number of cases.[40-45] The study by Rosenberg et al[5] was the only one to address the infection rate (2.5%, 1/39 plates) in terms of number of plates.

Infection rates regarding the use of the resorbable plate for fixation also varied from study to study and were generally quite low, ranging from 1.4% to 10%.[28,29,38,46] Again, nearly all cases were based on the individual patient. Some studies showed no infection related to the use of the resorbable plate and screw fixation in various clinical situations.[22,26,27,47-57]

The large difference between the infection rate based on the individual patient and that based on the individual plate is probably due to the small sample size of patients. With a small sample, an increase in 1 patient would produce a significant overall percentage change. The multiple osteotomies performed in orthognathic surgery require a larger number of plates and screws than the comparatively straightforward fixation in fractured jaw treatment with few plates and screws used. However, the overall infection rate could be higher in the fracture patients than the orthognathic patients, because of additional predisposing factors such as wound contamination, pattern of fracture (eg, compound or comminuted fractures), etc. It would therefore be more reasonable to use the plate and screw as the unit for calculation, because an infection will occur if any single component fails. The study found no difference in the rate of infection between titanium and resorbable fixation regardless of whether an individual patient or individual plate was considered. In addition, we found that when infection occurred in patients with resorbable fixation, its onset was later than in those with titanium fixation. Infections in the resorbable group were diagnosed at the 6-week, 3-month, and 6-month postoperative periods, whereas those in the titanium group were diagnosed at the 2-week, 6-week, and 3-month periods. This observation was not proven of statistical significance.

Although infection has been demonstrated in many studies,[28,29,38,46] the details, including causes, sites, and

Table X. Satisfaction of patients with surgical results

Postoperative period	*Titanium fixation*		*Resorbable fixation*		
	Mean	*SD*	*Mean*	*SD*	*P value*
0-2 weeks	7.60 (n = 30)	1.45	7.53 (n = 30)	1.53	.86
3-6 weeks	7.43 (n = 30)	2.05	8.00 (n = 30)	1.53	.23
7-12 weeks	8.07 (n = 30)	1.72	8.27 (n = 30)	1.36	.62
4-6 months	8.30 (n = 30)	1.86	8.47 (n = 30)	1.43	.83
6-12 months	8.50 (n = 24)	1.84	8.63 (n = 24)	1.44	.80
12-24 months	8.00 (n = 6)	2.37	7.57 (n = 7)	2.50	.94

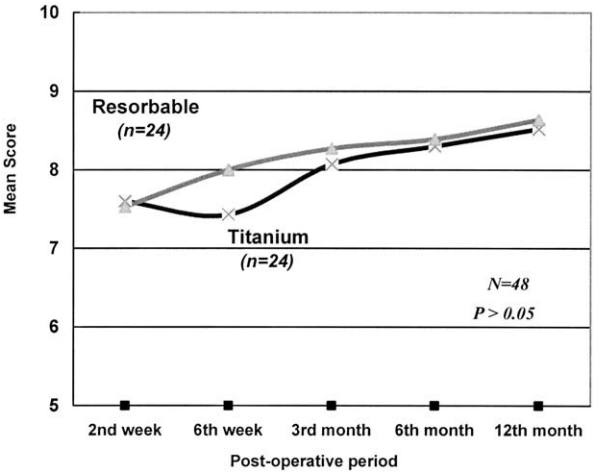

Fig 7. Longitudinal satisfaction level of surgical results over time between the resorbable and titanium groups.

treatment of infection, were generally not mentioned. In our study, we found that the main causes of infection were loose screws (1 patient in each group) and wound dehiscence (1 patient in each group). These results indicate that the chance of a loosened screw or wound dehiscence is no greater with resorbable fixation than with titanium fixation.

Not all dehisced wounds become infected later.[52] In our study groups, 3 patients in the titanium group and 2 in the resorbable fixation group presented with wound dehiscence. Only 1 patient in each group actually became infected, ultimately requiring the associated plates and screws to be removed. The other dehisced wounds required no intervention, and eventually closed spontaneously. All the dehisced wounds were located at the mandibular premolar region, where the greatest wound tension was at wound closure due to the mandibular arch curvature.

The most common site for plate exposure was at the posterior maxilla, and results showed that all the exposed plates (2 in the titanium group and 2 in the resorbable group) were located there. This may be related to the thin mucosa in the maxilla. Secondly, the oblique osteotomy cut of Le Fort I, with the posterior cut in a more inferior position, leaves the posterior plate more prone to exposure. Eppley[52] also found that a patient in his study had plate exposure over the posterior maxilla.

Plate removal rates were 1.53% (3/196) and 3.63% (6/165) in the titanium and resorbable groups, respectively. These rates are slightly lower than the reported rates for the titanium plating system (5% to 20%) in previous studies.[12-17,58,59] The reasons for plate removal in this study were plate exposure (2 in each group), infection (1 patient in the titanium group and 3 patients in the resorbable group), and nonpurulent sinus tract (1 patient in the resorbable group). Although the percentage of plate removal was higher in the patients who received resorbable fixation, it was not statistically significant ($P > .05$) when compared with the titanium group.

Previous studies have generally provided few details on the patients' acceptance and satisfaction, wound discomfort, and the subjective palpability and stability of osteotomy segment. In this study, particular attention was paid in quantifying these parameters. As far as subjective wound discomfort was concerned, there was no significant difference between the titanium and resorbable groups. The mean scores in the titanium and resorbable groups at the second postoperative week were 4.40 and 3.63 respectively, and the scores continued to drop throughout the study periods. This suggested that patients initially experienced only moderate pain, and that pain from the wound (unsurprisingly) decreased over time, to the point where patients were nearly free of pain (12 months postop). It is interesting that the mean scores of wound discomfort in the resorbable group were slightly lower than those of the titanium group at each postoperative period. This suggests that the patients who received resorbable plates suffered less pain from their wounds than patients in the titanium group, but this cannot be confirmed statistically.

The mean score of subjective clinical stability of osteotomy segments was quite high at the early postoperative periods: 8.10 in titanium group and 8.47 in the resorbable group. This stability increased slowly during the postop periods to 9.54 and 9.67 at 12 months in the titanium and resorbable fixation groups, respectively. This implies that the initial stability of the osteotomy segments was good, and that it continued to improve over time. Again, the stability scores were also higher in the resorbable group throughout the whole postoperative period. It seems that resorbable fixation apparently had slightly better clinical stability than titanium fixation, although the difference was not statistically significant.

As far as the objective clinical stability was concerned, 3 patients (10%) in the titanium group and 2 patients (6.7%) in the resorbable group presented with mild mobility of the maxillary osteotomy segments in the second postoperative week, but all segments became firm at the sixth postoperative week. No further segment mobility was noticed during the remaining study period. This result was similar to the study of Shand and Heggie.[28] Again there was no significant difference between the 2 groups. Bioresorbable plates and screws therefore appear to offer the same fixation ability as their titanium counterparts. Although there was mobility in the bone segments from the surgeons' point of view, patients' evaluation showed a good stability of the segments even at the early postoperative period.

As far as the palpability of plates was concerned, there was no significant difference between the 2 materials, which is consistent with Majewki et al's research.[56] We initially assumed that resorbable plates would be more palpable than titanium plates, since they were wider, longer, and thicker. On subjective assessment, the number of patients with palpable plates was similar in both groups at the second week, while the number of patients with palpable plates in resorbable groups increased at the sixth week. This was probably because postsurgical edema was quite marked at the early postsurgical period, the overlying soft tissue swelling might have camouflaged the palpable plates. After the edema subsided, these plates then became more palpable. It was interesting to note that the number of palpable plates in the resorbable group decreased in the later postoperative periods and fell below that of the titanium group in the sixth and twelfth months. In contrast, titanium plates became more palpable plate at the later periods. This could be related to the softening and reduction in mass of the resorbable plates over time. The objective assessment on plate palpability showed the same clinical pattern of change between the 2 groups. The number of patients identified with palpable resorbable plates objectively was 26 out of 30 patients (76.7%) in our study, which was higher than that reported in Montag et al's study[48] (26% , 9/35). However, similar results on the changes of palpability over time were noted in previous studies.[50,60,61] Goldenstein[59] and Losken et al[60] found that the palpability of resorbable plates decreased markedly at around 3 to 9 months postop to virtually nonpalpable status. Indeed, the surgeons noted a higher incidence of plate palpability than the patients, and most of the plates were only slightly palpable. Most of these plates were found at the paranasal region in our study, which is consistent with the findings of Edwards and Kiely's study.[24] Both groups of patients were quite satisfied with the surgical results, with the mean satisfaction score of 7.60 for titanium plate patients and 7.53 for resorbable plate patients at the second week, and the scores gradually increased to 8.5 and 8.63 at the twelfth month. Longitudinal data have shown that the mean scores of satisfaction in the resorbable group were invariably higher than in the titanium group. However, statistical significance could not be proven.

No study has drawn attention to the plating time of the bioresorbable system, although it is well known that the placement of resorbable screws required pretapping of the drilled hole. In contrast, the titanium screws were self-tapping and insertion of these screws was quite straightforward. This study confirmed that the time was almost doubled at the earlier cases, while we were gaining experience in using the plates. Once our surgeons became familiar with this technique, they were able, in some cases (eg, plating of mandibular body osteotomy), to fix the resorbable plates quicker than the titanium plates. In most orthognathic procedures, resorbable plate fixation was nearly as quick as titanium plate fixation, with a time difference of within 1 to 2 minutes.

There were also some drawbacks in the resorbable plating system. The plate was relatively bulky, being about 15% to 20% larger than the titanium plates. Its larger size resulted in increased palpability at the early postoperative period. The individual packing of screws and plates together with the delivery system were not user-friendly, and increased the cost of operations significantly. Once a plate is opened from its package, it has to be used straight away, since resterilization is not possible. The unique property of glass transition temperature possessed by the poly-lactide (PLLA) means that the traditional sterilization method by autoclaving would have a detrimental effect on its mechanical property.

In addition, the variable quality of the screw heads predisposed to warpage, leading to difficulty in screw holding and tapping by the screwdriver. As a result, a number of screws fractured or had to be discarded. In our study, the number of broken plates and screws was low in which only 7 plates and 72 screws were recorded, accounting for 1.9% and 4.8% of the overall consumed plates and screws. The percentage of broken screws was slightly higher than that reported in Haers and Sailer's study,[38] which was about 3.9%, and they have no plate breakage in their case series. Most of the breakage of plates and screws occurred in the early stage of our research, and a marked decrease in the number was noted later in the study after all our surgeons became accustomed to use the resorbable plates and screws. Although there was breakage of the screws during the fixation, it could be easily overcome by simply redrilling and retapping and fixing a new screw into a freshened screw hole.

In order to reduce the chances of breakage and warpage of screws, a special screw-loading device together with a piston-like tacker has been developed by Inion, Ltd (Tampere, Finland). This technique does not require pretapping of the screw hole, and the screw can be simply fastened to the plate by pressure. This should result in a shorter plating time with easier handling and lower wastage rate of screws. In our preliminary experience with this fixation system, this device worked quite well in fixing the plates to the maxilla, but difficulty was encountered on the mandible due to the thick buccal cortical bone. The screws were either incompletely seated or, in some cases, could not be inserted at all. A conventional pretapping technique was

still required to insert the screws on the mandible at this stage of development.

Although this study concentrated mainly on the clinical morbidities of the 2 fixation systems, we noted that there was no difference in clinical stability between the use of resorbable and titanium plates and screws. No cases in this series recorded any occlusal relapse in the resorbable group. However, one case in the titanium group with an advancement of 7 to 8 mm of the mandible developed a late occulsal relapse, around 1 year after the operation. It is well known that the greater the magnitude of mandibular advancement, the higher the relapse rate.[62,63] In order to investigate any differences in skeletal stability between titanium and resorbable fixation, a future prospective clinical trial is under way to study the stability of Le Fort I osteotomy specifically.

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