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Stability and morbidity of Le Fort I osteotomy with bioresorbable fixation: a randomized controlled trial

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Abstract. A randomized controlled clinical trial was conducted to compare the use of bioresorbable and titanium mini-plates and screws in Le Fort I maxillary osteotomies for evaluation of clinical morbidity and stability. Forty patients requiring Le Fort I osteotomies were randomly assigned to two groups. One group underwent bioresorbable mini-plate fixation and the other titanium mini-plate fixation. Stability of the maxilla was determined by serial cephalometric analysis at 2 and 6 weeks and at 3, 6 and 12 months postoperatively. Subjective and objective assessment of clinical morbidity was made prospectively. There were no differences in complications between the two fixation materials. Maxillae with bioresorbable fixation were significantly more mobile at the second postoperative week. Bioresorbable plates were initially more easily palpable, but their palpability decreased with time. Titanium plates became significantly more palpable at the 1-year follow-up. There was no difference in neurosensory disturbance between groups. Patients with bioresorbable plate fixation showed significantly more upward displacement in anterior maxilla following impaction and posterior maxilla following downgrafting from the 2nd to 6th postoperative week. The horizontal and angular relapses in the two groups were comparable. Le Fort I osteotomy with bioresorbable fixation results in no greater morbidity than with titanium fixation up to 1 postoperative year.

Key words: bioresorbable fixation; Le Fort I osteotomy; stability; morbidities.

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Internal fixation by plates and screws has become the gold standard for stabilization of bone segments in orthognathic surgery. The dimensions of the plates and screws have been miniaturized for intraoral access, and titanium plates have gradually replaced stainless steel and vitalium plates. Titanium is now widely accepted as the metal with the best biocompatibility and also has good mechanical properties.

Studies have shown that titanium plates implanted in the body for a long time may give rise to problems. Kim et al.[27], in the light of their findings of local macroscopic and microscopic tissue damage around the implanted titanium plates, proposed that all titanium plates should be removed routinely after bone healing. Schmidt

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et al.[37] reported that 10% of patients following Le Fort I osteotomies required plate removal. The reasons for plate removal included palpability, sinusitis, pain, infection, temperature sensitivity and patients' request. Mosbah et al.[34] reported a similar percentage of patients required metal plate removal after orthognathic and trauma surgery. Although routine removal of metal mini-plates has been advocated by some authors, most surgical centres consider prophylactic removal of metal plates necessary only for stainless steel plates, and not for titanium plates.

The feasibility of applying bioresorbable plates and screws for fracture fixation was first demonstrated in orthopaedic surgery[36]. This technique was soon extended to cranio-maxillofacial surgery for fracture and osteotomy fixation[6–10,16–18,20,31]. The fixation devices consist of a combination of different bioresorbable polymers including polylactide, polyglycolide and their co-polymers, so as to achieve a balance between mechanical strength, bendability, miniaturization and resorption time.

There have been a number of clinical reports[3,4,11–15,19,21–23,25,26,28–30,32,33,35,38–42] on bioresorbable plate fixation in orthognathic surgery. These studies were mainly concerned with postoperative morbidities following the use of these materials. Data on maxillary stability following Le Fort I osteotomies have been reported in only a few studies[8,21,35,41]. Randomized controlled trials with adequate follow-up are lacking. The aim of this study was to conduct a randomized controlled clinical trial to compare bioresorbable with titanium mini-plates and screws for fixation in Le Fort I maxillary osteotomies, and to evaluate clinical morbidity and stability.

Table 1. Random errors of maxillary measurements on 40 cephalographs between two time points 1 week apart

Variables	Random error
Horizontal movement of A-point (mm)	0.34
Horizontal movement of P-point (mm)	0.36
Vertical movement of A-point (mm)	0.3
Vertical movement of P-point (mm)	0.24
SN to UI (°)	1.3

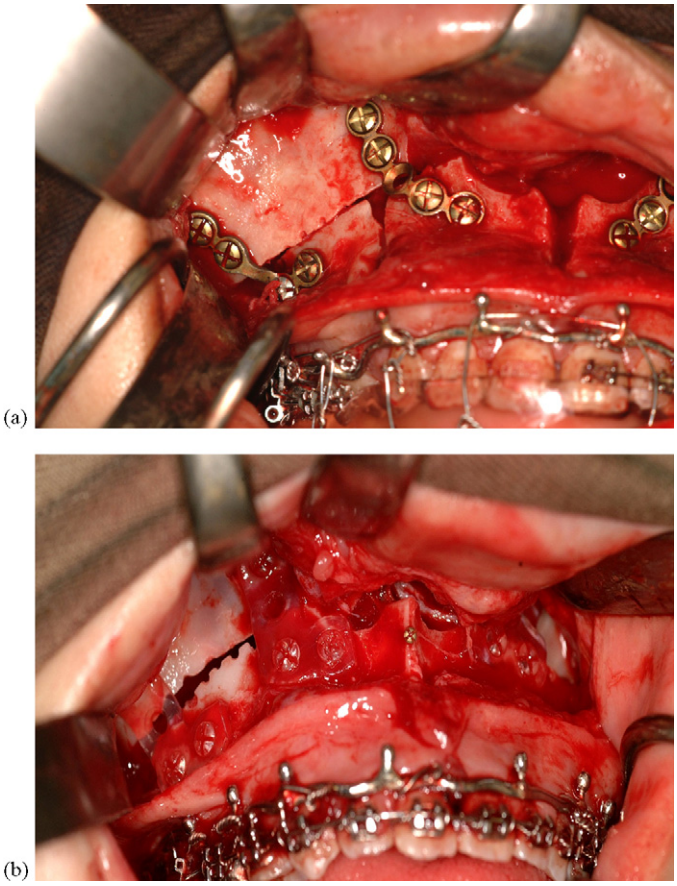

Fig. 1. Mini-plate fixation at the zygomatic buttress and piriform region in Le Fort I osteotomy: (a) titanium plates; (b) bioresorbable plates.

Materials and methods

The randomized controlled clinical trial was conducted from February 2003 to July 2005. The study was approved by the Ethics Committee of the Faculty of Dentistry, The University of Hong Kong. Patients of age 16 or above presenting with dento-facial deformities requiring Le Fort I osteotomy were recruited. Patients with underlying systemic diseases, congenital craniofacial deformities such as cleft lip and palate, and pathological diseases of the jaws were excluded. Forty patients satisfying the inclusion criteria were selected. Patients were assigned into two groups of 20 patients each according to a randomization table[1]. The patients in the bioresorbable group underwent bioresorbable mini-plate and screw fixation (2.0 compact plating system, Inion Ltd., Tampere, Finland) of the transposed Le Fort I maxilla at the zygomatic buttress and piriform region of each side (Fig. 1b). Four mini-plates and 16 mini-screws were routinely used. The patients in the titanium group underwent titanium mini-plate and screw fixation (Synthes Inc., OH, USA) at the same locations as the bioresorbable group (Fig. 1a).

Preoperative assessment

A standardized protocol was used to record preoperative information such as patients' age, gender, skeletal diagnosis and baseline neurosensory values. The neurosensory status of the infra-orbital nerve was assessed objectively on the infra-orbital skin at an intersecting point 2 cm below the lower eyelid and 2 cm lateral to the alar of the nose on both sides. Objective tests such as static light touch threshold, two points discrimination and pain threshold were used. The static light touch test was performed using a Touch-Test Sensory Evaluator kit (NC12775, North Coast Medical Inc., CA, USA). Individual filaments of ascending diameters were pressed against the infra-orbital skin until they bent. The minimum force that elicited a positive response were recorded. The two points discrimination test was carried out by a disc of paired blunt pins at increasing separation distances. The data of minimum distance that

a patient could identify as two distinct points was recorded. For the pain threshold test, a pin was mounted onto an orthodontic pressure gauge. The minimum force in grams that could trigger a painful sensation in a patient was recorded.

Intraoperative assessment

Standardized Le Fort I osteotomies were performed on all patients under general anaesthesia. The maxillae were downfractured, mobilized and segmentalized according to the surgical plan. The maxillae were guided to the pre-planned position by a custom-made occlusal wafer. The maxillae in both groups were similarly fixed by two mini-plates and screws on each side at the piriform rim and the zygomatic buttress regions. For the bioresorbable group, plates of appropriate shapes were softened by immersion in a warm water bath (55 °C) and then manually bent into the appropriate shape. The final plate adaptation was achieved by pliers. Each hole was drilled and manually tapped before the insertion of screws between 4 and 6 mm long, according to the bone thickness.

Two additional titanium micro-screws (Synthes Inc.) were inserted into the maxillae for radiographic landmark evaluation. One micro-screw was placed at the most concave part of the anterior maxilla at the midline (A-point) and another was fixed to the posterior maxilla above the mesial root of the first molar (P-point).

A standardized intraoperative protocol was used to record any intraoperative complications and the plating time for the Le Fort I osteotomy. Any concomitant mandibular osteotomies performed were recorded.

Postoperative assessment

All patients had their first postoperative follow-up appointment within 2 weeks and were then regularly reviewed at 6 weeks and at 3, 6 and 12 months postoperatively. A standardized postoperative protocol was used to record any post-surgical complications. Neurosensory recordings at the infra-orbital regions were taken at every postoperative follow-up appointment. The subjective degree of mobility of the maxilla, ease of palpability of the plates and degree of pain at the surgical sites were assessed using a visual analog scale ranging from 0 to 10. Clinical mobility and palpability of plates were objectively assessed also by clinicians using the same visual analog scales.

Stability assessment

The skeletal stability or relapse was assessed by serial comparison of lateral cephalographs. Standardized lateral cephalographs were taken preoperatively and at 2 and 6 weeks and 3, 6 and 12 months postoperatively. The cephalometric analysis was modified from CHEUNG et al.[5]. Micro-screws landmarks were compared on serial cephalographs to determine the extent and direction of relapse (Fig. 2). The radiographic landmarks and reference planes for the cephalometric analysis were: sella (S) – the centre of sella turcica; nasion (N) – the suture between the frontal and nasal bone; A-point (A) – the deepest point in the concavity of the anterior maxilla in the midline (marked by a micro-screw); and P-point (P) – above the mesial root of the first molar (marked by a second micro-screw).

A horizontal reference plane was constructed at 7° from a linear line connecting the S and N points (SN line). The vertical reference plane was a line drawn perpendicular to the horizontal reference plane and passing through the sella. The shortest distances of the A and P points in relation to the horizontal and vertical reference planes were measured. The intersecting angle formed between the central axis of maxillary central incisor to the SN line (SN to UI) was measured. Lateral cephalographs were serially superimposed, based on the anatomical best fit of the cranial base and SN line. An electronic digital caliper (Digit Cal, Tesa, Renens, Switzerland) with accuracy up to 2 decimal points was used to measure the distances.

Statistical and error analyses

The data obtained were analysed by a Statistical Package for Social Sciences (SPSS 11.5 software, SPSS Incorporation, Chicago, USA). Independent *t*-tests were used to determine the differences in parameters of the bioresorbable and titanium groups.

The errors of cephalometric readings were calculated based on measurements of 40 randomly selected cephalographs from 20 patients who took part in the study. Landmark identifications and tracing of the position of micro-screws were performed and repeated 1 week later by the same investigator. The extent of random error was determined by Dahlberg's formula[24] and reproducibility and reliability were assessed by a paired sample *t*-test. The random errors were small (Table 1) and there were no significant differences ($P > 0.05$) between the tracings at the two different time points, confirming the reliability of the cephalometric measurements.

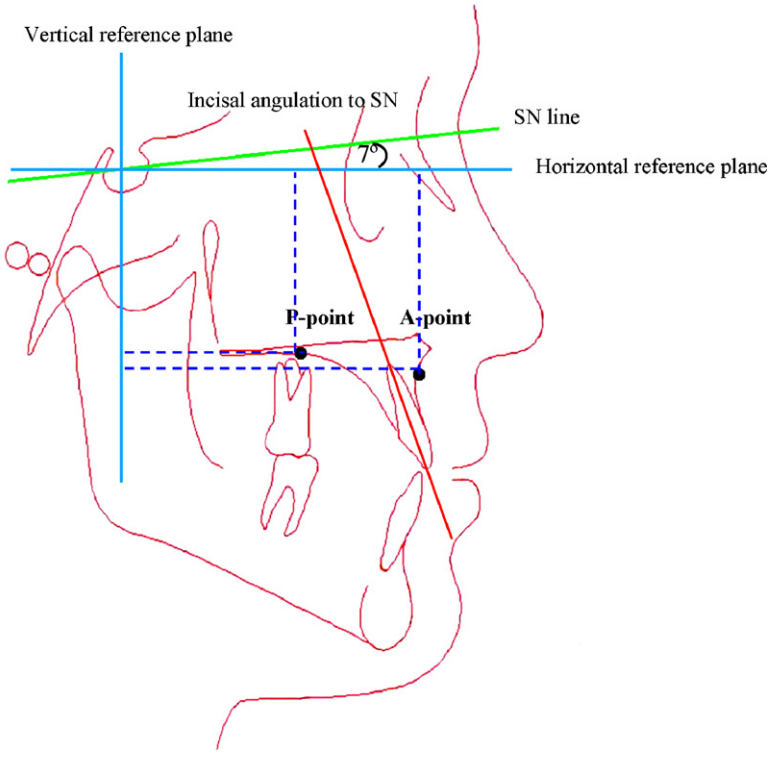

Fig. 2. Reference planes and landmarks used in cephalometric analysis of stability.

Table 2. Maxillary diagnoses of 40 patients

	Bioresorbable fixation ($n = 20$)	Titanium fixation ($n = 20$)
Maxillary diagnosis		
Maxillary hypoplasia in antero-posterior direction	15	16
Vertical maxillary excess	2	3
Dento-alveolar hyperplasia	2	0
Maxillary canting	1	0
Maxillary transverse hypoplasia	0	1

Table 3. Concomitant mandibular osteotomies

	Bioresorbable fixation	Titanium fixation
Hofer (mandibular subapical osteotomy)	10	10
Bilateral vertical subsigmoid	13	10
Bilateral sagittal split	3	1
Combined subsigmoid and sagittal split	1	1
Genioplasty	4	4

Results

Forty patients (17 males, 23 females) participated in this randomized controlled clinical trial. The mean age of the subjects was 22 ± 5.5 in the bioresorbable group and 24 ± 8.4 in the titanium group. All patients received preoperative orthodontic treatment.

Table 2 shows the maxillary diagnoses of the two groups. Most patients were diagnosed with maxillary hypoplasia in the antero-posterior direction (75% of patients in the bioresorbable group and 80% of patients in the titanium group). Segmentalization of the Le Fort I maxillae was performed on 33 patients (83%). The maxillae were segmentalized into four pieces in 21 cases (55%), into two pieces in 11 cases (28%) and into three pieces in 1 case (3%).

Concomitant mandibular osteotomies were performed in all patients (Table 3). More than half the patients (58%) had bilateral vertical subsigmoid osteotomies followed by mandibular subapical osteotomies (50%). Some patients had two or even three mandibular osteotomies at the same time; need was based on the specific diagnoses of dento-facial deformities. There were no statistically significant differences between the background and surgical information of the two groups ($P > 0.05$).

Intraoperative findings

No intraoperative complications were reported and the planned surgical procedures guided by the appropriate surgical wafers were achieved in all cases. All surgical movements of the maxillae were achieved as planned. The mean plating time of the Le Fort I osteotomies was 31.9 min for the bioresorbable plate group and 20.5 min for the titanium plate group. The difference in plating time was found to be statistically significant ($P < 0.01$).

All patients were followed up for at least 6 weeks after the operation. There were no drop outs. Most of the patients (78%) were followed up for at least 3 months, and more than half (53%) for at least 6 months. Eleven patients (28%) were followed up for more than 1 year.

Postoperative complications

Maxillary sinusitis was reported in one patient from each group. Sinusitis in the patient with bioresorbable plate fixation occurred within the 2nd week after operation, while the patient with titanium plate fixation presented with sinusitis at the 3-month review appointment. The condition was resolved in both cases following treatment by antibiotics and nasal decongestant.

Subjective and objective clinical evaluation

Mobility of the maxilla

The mobility score, as measured on the 10-point visual analog scale, was low overall (less than 2) (Fig. 3a and b). In both groups, the patients experienced a similar extent of maxillary mobility immediately postoperatively. This may be because they were restricted to a soft diet during this period. During the 6th week and 3rd month patients with bioresorbable fixation felt that their maxillae were more mobile, especially at the 6th postoperative week. No patients reported any mobility at the 1-year follow-up.

When mobility was assessed objectively by clinicians, the maxilla was consistently more mobile in patients with bioresorbable fixation at all postoperative periods than in those with titanium fixation. The differences were largest at postoperative weeks 2 and 6. The differences in objective mobility between the two plating groups became smaller as time progressed. A statistically significant difference was noted only for objective mobility in the 2nd week, when the maxillae of patients in the bioresorbable fixation group were more mobile ($P < 0.05$).

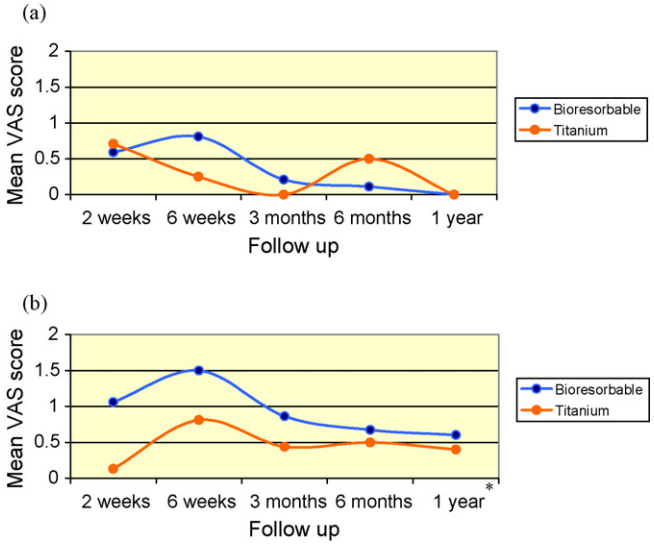

Fig. 3. Mobility of Le Fort I maxilla with internal fixation over time: (a) subjective assessment by patients; (b) objective assessment by clinicians.

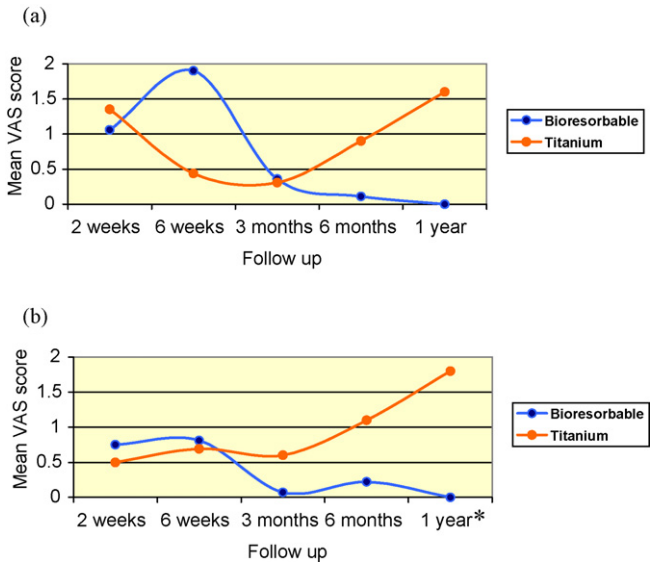

Fig. 4. Palpability of fixation plates and screws in Le Fort I maxilla over time: (a) subjective assessment by patients; (b) objective assessment by clinicians.

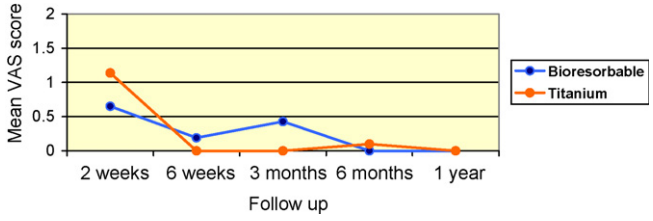

Fig. 5. Pain score of the maxillary surgical wound by bioresorbable and titanium fixation following Le Fort I osteotomy over time.

Palpability of plates

The scores on the visual analog scale regarding palpability of plates were generally also low (Fig. 4a and b). In both subjective and objective evaluation of palpability, the plates were not easily palpable at the 2nd postoperative week. This was perhaps because of residual soft-tissue swelling. At the 6th week after the operation the bioresorbable plates, which are generally more bulky than titanium plates, became more palpable. From the 3rd month onwards the titanium plates became more easily palpable on both subjective and objective evaluation as the postoperative swelling continued to subside. The bioresorbable plates became less palpable over time as they gradually softened before eventually dissolving. There was a statistically significant difference in palpability between the two groups at the 1-year follow-up ($P < 0.01$).

Pain of surgical wounds

The pain score was highest at the 2-week postoperative point (Fig. 5). For patients with titanium fixation, pain became minimal at the 6th week. For the bioresorbable fixation group, there was an initial reduction of pain at the 6th week, but a higher level of pain at the 3rd month. This may be due to an inflammatory reaction related to the resorption of the bioresorbable plates. There were no statistically significant differences between the two groups at any time point ($P > 0.05$).

Neurosensory evaluation

Static light touch threshold

Although patients with titanium plate fixation seemed to have a lower sensation of touch during the 2nd week, the mean minimum force to elicit a positive response was less than 0.4 g (Fig. 6a). The light touch threshold was so small that it could be considered as within the normal range. From the 6th week onwards, the light touch results of both groups were essentially the same. There was no statistically significant difference between the two groups at the different time points ($P > 0.05$).

Two points discrimination

The minimum distance that the patients could distinguish was marginally higher in patients with bioresorbable fixation within the first 6 weeks postoperatively (Fig. 6b). At the 3rd month the two groups had similar proprioception at the infra-orbital regions. From the 3rd month onwards, patients with bioresorbable fixation had increased sensitivity of the cheeks, but there was no statistically significant difference between the two groups ($P > 0.05$).

Pain threshold

In both groups the minimum force required to stimulate a painful response decreased postoperatively and became constant from the 3rd month onwards (Fig. 6c). This suggests that the infra-orbital nerves developed hyperesthesia after osteotomy, although none of the patients made any complaint in this respect. There was no significant difference between the two groups ($P > 0.05$).

Stability of the maxilla

The mean changes of different landmarks were analysed according to the different time periods: T1, preoperative to postoperative 2 weeks; T2, 2 to 6 weeks; T3, 6 weeks to 3 months; T4, 3 to 6 months; T5, 6 months to 1 year. The surgical movements are listed in Table 4.

Horizontal changes

For the anterior maxilla, there were minimal postoperative horizontal displacements following either advancement or

Table 4. Surgical movements in different directions of the maxilla at the radiographic A-point and P-point with bioresorbable and titanium plate fixation

	A-point		P-point	
	Bioresorbable	Titanium	Bioresorbable	Titanium
Advancement	3.43 (2.03)	4 (2.45)	2.93 (2.08)	3.9 (2.04)
Retrusion	1.12 (1.12)	1.59 (0.84)	1.36 (0.8)	1.3 (1.4)
Impaction	2.65 (2.05)	3.27 (1.84)	2.49 (1.19)	2.79 (2)
Downgraft	2.87 (1.94)	1.45 (1.1)	2.41 (1.77)	1.23 (1.17)

Values are in mm (SD).

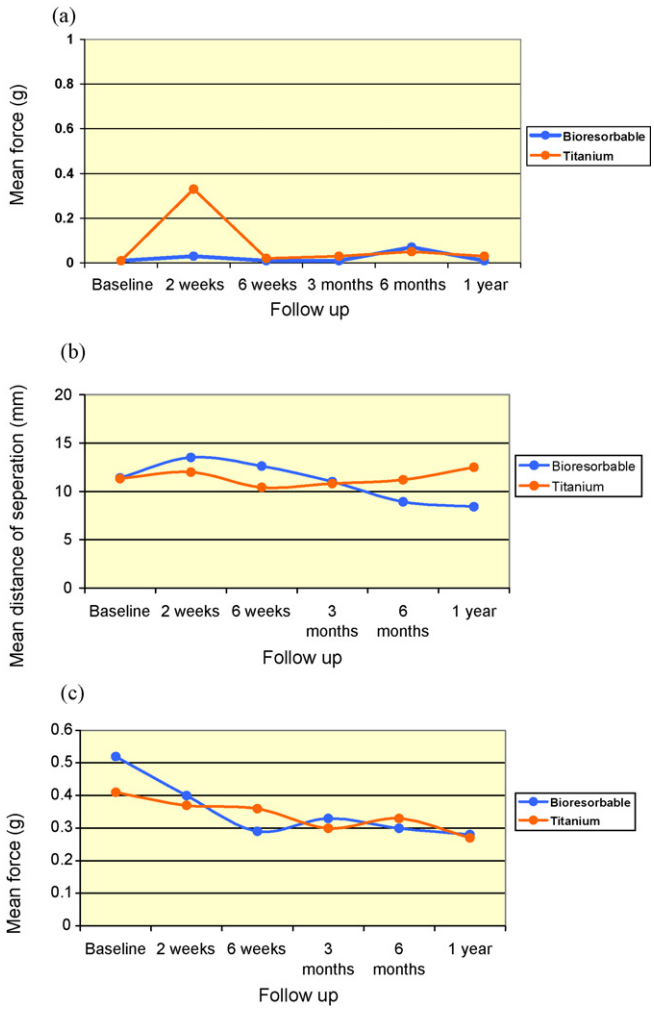

Fig. 6. Results of neurosensory function tests on the infra-orbital skin following Le Fort I osteotomy over time: (a) static light touch threshold; (b) two points discrimination; (c) pain threshold.

retrusion up to 1 year (Fig. 7a). The sample size for anterior maxillary retrusion was much smaller with only five patients from each group (Fig. 7b). The retrusive movements at the anterior maxilla were mainly for correction of dento-alveolar hyperplasia.

The amount of advancement and postoperative stability for the posterior maxilla followed a similar trend when compared to the anterior maxilla (Fig. 8a). For posterior maxillary retrusion, there were again only five patients from each group (Fig. 8b). The difference in horizontal relapse between the two groups was again not statistically significant at all postoperative time points.

Vertical changes

Anterior maxilla for both groups demonstrated further upward displacement up to 1 year following impaction (Fig. 9a). The bioresorbable group had more upward displacement up to 6 months postoperatively and the difference at T2 was statistically significant ($P < 0.01$). After downgrafting of the anterior maxilla, the amount of superior displacement in the bioresorbable group was greater at T2 (Fig. 9b). The difference in superior displacement was not statistically significant between the two groups.

The vertical displacements of posterior maxillae followed a similar trend after impaction and downgrafting. Following downgrafting, there was more upward displacement at T2 for the bioresorbable group (Fig. 10b), and the difference in vertical displacement between the two groups was statistically significant ($P < 0.01$). The differences in vertical displacements in other postoperative periods were not statistically significant between the two groups.

Angular changes of upper central incisor

There was a decrease in SN to UI angle in both groups after the osteotomies (Fig. 11). This was likely related to the surgical up-righting of the anterior maxilla from segmentalization or change of occlusal plane. Overall, there was no statistical significance in the angular changes at the different time points ($P > 0.05$).

Discussion

The stability of Le Fort I osteotomies with bioresorbable fixation has been the subject of only a few studies. Edwards & Kiely[11] mentioned that all maxillae were stable by the 4th week with no further notable occlusal changes, but there were no quantitative measurements of maxillary stability. Haers & Sailer[21] reported stability data of 10 patients with bioresorbable plate fixation. Unfortunately, there was no control group for comparison and the stability data were available only for the postoperative period up to 6 weeks. The most informative study was carried out by Norholt et al.[35]. Their randomized controlled trial covered a total of 60 patients who were followed up to 1 year postoperatively, but they only presented stability data up to 6 weeks and merely reported that the maxillae were stable afterwards. The present randomized controlled clinical trial is the first study reporting the post-surgical stability and morbidity of bioresorbable plate fixation for Le Fort I osteotomies. The stability data were recorded at regular periods exceeding 1 year.

Maxillae with bioresorbable plate fixation were confirmed to have minimal relapse compared to titanium plate fixation starting from the 6th postoperative week onwards, but vertical instability occurred in the early postoperative period. These findings are consistent with a recent study by Ueki et al.[41], in which the investigators found that the maxillae were stable in the horizontal plane but tended to displace superiorly following Le Fort I osteotomy when combined with either sagittal split or intraoral vertical ramus osteotomy. The results of the present study indicate that this upward displacement occurs during the 2nd to the 6th postoperative weeks. In another study by Costa et al.[8], similar superior displacement of the maxilla occurred mainly within the first 8 postoperative weeks. These authors noticed a weak but significant relapse in the horizontal plane which was also related to the extent of maxillary advancement; this relationship could not be demonstrated in the present study.

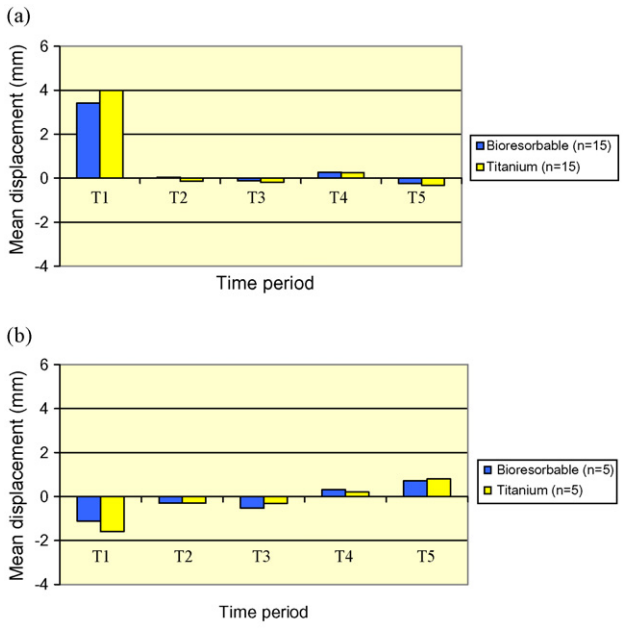

Fig. 7. Horizontal changes of the anterior maxilla at A-point with bioresorbable and titanium fixation: (a) changes following maxillary advancement; (b) changes following maxillary retrusion.

Norholt et al.[35] also demonstrated a mean superior displacement of the maxilla shortly following Le Fort I osteotomies with bioresorbable fixation. The amount of vertical displacement was less than 1 mm and considered clinically unnoticeable. In contrast, the mean vertical changes at both anterior and posterior maxilla in this study were more than 1 mm following maxillary impaction and 2 mm after downgrafting. This amount of maxillary displacement would influence the upper incisal exposure and would be clinically noticeable. Proportional overcorrection of the osteotomy is hence recommended in this directional movement.

Micro-screws were used as landmark identification to facilitate easy comparisons of serial lateral cephalolographs. This method minimized the error in landmark identification and overcame the problems of remodelling of the landmarks such as the A-point and anterior nasal spine. Moreover, if dental landmarks are used, their positions are likely to be changed by postoperative orthodontics.

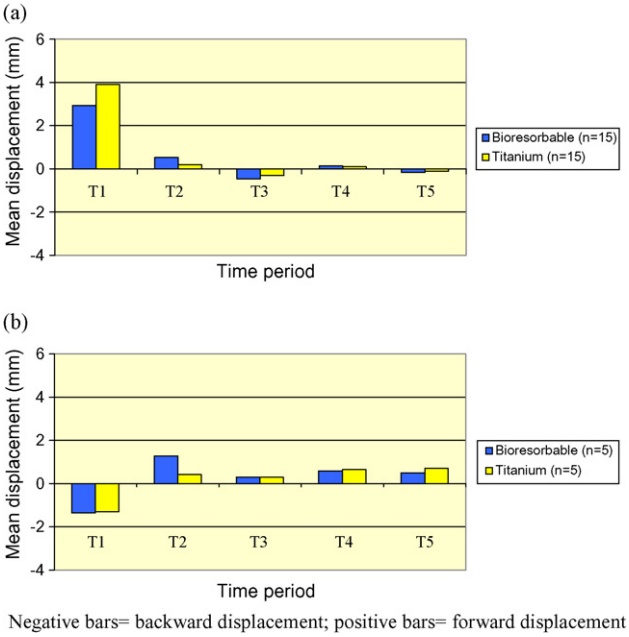

Fig. 8. Horizontal changes of the posterior maxilla at P-point with bioresorbable and titanium fixation: (a) changes following maxillary advancement; (b) changes following maxillary retrusion.

Several investigators found that after fixation with bioresorbable plates the maxillae had slight mobility immediately postoperatively[11,14,35,38,40]. This degree of mobility was not usually quantified. In the present study, on a 10-point visual analog scale, the mean subjective mobility was less than 1 at all time points, regardless of the method of fixation. The low mobility scores may be because the patients were advised to restrict themselves to a soft diet for at least 6 weeks after the operation, or they had intermaxillary fixation for vertical subsigmoid osteotomies. The mean scores for mobility were almost doubled when assessed by clinicians, especially during the 6th week. The maxillae in the bioresorbable group were found to be significantly more unstable at the early time points. These findings suggest that, although the maxillae were clinically mobile after the operation, the degree of mobility experienced by the patients was usually well tolerated.

This study found a low incidence of complications in relation to internal fixation. Maxillary sinusitis was diagnosed in two patients, but the infection was resolved following treatment with antibiotics. It was difficult to prove whether the sinusitis was caused by the presence of mini-plates or by the osteotomy itself.

Three patients presented with wound dehiscence and another three with plate exposure at the mandibular premolar regions. All these complications occurred within 3 months postoperatively. Fortunately, none of these wounds became infected. In bioresorbable plate fixation, when there are signs of wound dehiscence, swelling and redness of the wound, clinicians will be concerned as to whether these complications are related to foreign body reactions caused by the materials. Bergsma et al.[2] investigated the degradation features of bioresorbable plates in fixation of zygoma fractures. They found that all patients presented with painless swellings at the site of implantation during follow-up. These swellings may be caused by an increase in tissue volume after the materials degrade. The bioresorbable plates they used consisted of poly L-lactide, which is known for its incompleteness in resorption. In a review article on the complications regarding bioresorbable

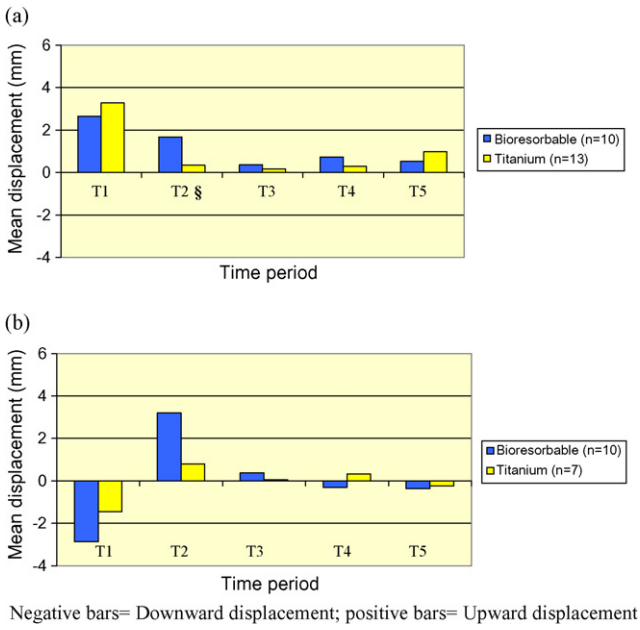

Fig. 9. Vertical changes of the anterior maxilla at A-point with bioresorbable and titanium fixation: (a) changes following maxillary impaction; (b) changes following maxillary downgrafting.

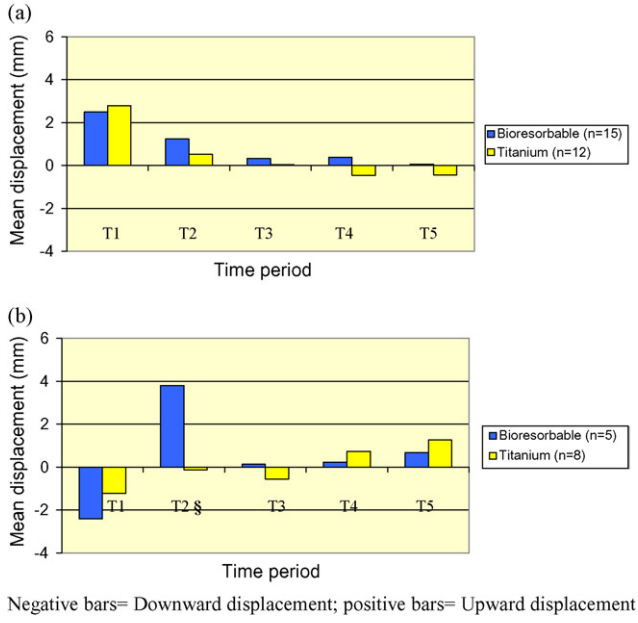

Fig. 10. Vertical changes of the posterior maxilla at P-point with bioresorbable and titanium fixation: (a) changes following maxillary impaction; (b) changes following maxillary downgrafting.

fixation in orthognathic surgery, Laine et al.[29] reported that two patients with sagittal split osteotomies (1 month postoperatively) and another two patients with Le Fort I osteotomies (4 and 17 months postoperatively) presented with a granulation-type tissue over the plating area. All these tissue responses were found to be associated with loose screws. In Landes & Krriener's[30] study, two patients were confirmed to have foreign body granuloma at the plating area following sagittal split osteotomy with fixation of bioresorbable plates at the 3rd and 4th month postoperatively. The specimens obtained from other symptom-free patients confirmed that foreign body reaction occurred around the plates at different times. These examples indicate that it is difficult to assess whether a foreign body reaction will produce a significant undesirable tissue response, and if so when it will happen. Mandibular wound dehiscence and plate exposure in the bioresorbable fixation group in the present study did not seem to be related to a foreign body reaction. All cases occurred in the early postoperative period and no granulation tissue reaction was observed. It was likely that the plates were placed too close to the dento-alveolus, or directly over the incision line of the surgical wounds. There is a need to further evaluate the soft-tissue response to degradation of bioresorbable materials by having a longer follow-up period with soft-tissue biopsies at different times.

The plating time was significantly longer for bioresorbable than for titanium mini-plate fixation, due to the need for manual tapping of the screw holes before screw insertion in the former procedure. One way to reduce the plating time is to use self-tapping screws or the Tacker pistol system developed by Inion Ltd. The Tacker pistol can only be used in thin bones; in thick bone, the screws cannot be shot in completely and further tightening by screwdriver is difficult. For standardization of technique, it was decided to tap the holes manually, which produced more consistent screw insertion stability than the tacking technique.

The palpability of the bioresorbable and titanium plates was similar during the early postoperative period. They were hardly palpable initially due to the expected postoperative swellings. Around the 6th week, when there was considerable reduction in swelling, the bioresorbable plates became easily palpable because they were bulkier than the titanium plates. From the 3rd month onwards the bioresorbable plates became less palpable due

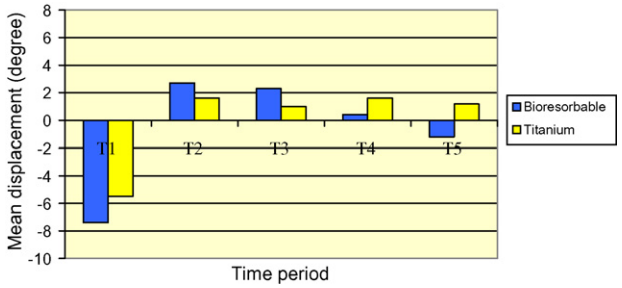

Fig. 11. Change in SN to upper incisor angulation at different postoperative time points.

to softening and gradual resorption. The pattern of changes in the palpability of bioresorbable versus titanium mini-plates in this study was similar to a previous clinical trial of the Biosorb system[4].

It was reassuring that the neurosensory findings had returned to the baseline reading as early as 6 weeks after Le Fort I osteotomy. The neurosensory function in the infra-orbital region was similar for the different fixation materials used. This confirmed that the degradation of bioresorbable plates and screws did not lead to any increase in clinical neurosensory impairment. As the resorption process of bioresorbable materials may take years to complete, it is necessary to further evaluate the effect of material degradation on neurosensory function with a longer follow-up.

In conclusion, bioresorbable plate fixation is confirmed to be an acceptable alternative to conventional titanium mini-plate fixation in Le Fort I osteotomy. There were no significant differences in morbidity in the 1st year following the operation. Although bioresorbable plates are expected to be more easily palpable in the early postoperative period, they become less palpable over time. The Le Fort I maxilla with bioresorbable fixation is expected to be slightly mobile within the first 6 postoperative weeks but will firm up uneventfully afterwards with associated superior displacement of the maxilla. The resorbable fixation tends to cause more vertical relapse following vertical movements than titanium fixation in the early postoperative period. The long-term stability of Le Fort I osteotomy in horizontal and vertical planes was similar for bioresorbable and titanium mini-plate fixation.

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