

Comparison of titanium and resorbable copolymer fixation after Le Fort I maxillary impaction

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Introduction: Advances in skeletal stabilization techniques have led to the use of titanium devices for rigid fixation. Their advantages include strength and skeletal stability, but they also have disadvantages. The purpose of this study was to investigate the stability of a resorbable copolymer as a potential alternative to titanium for fixation of Le Fort I maxillary impaction. **Methods:** Fifty consecutive patients underwent maxillary impaction with nonsegmental monopiece Le Fort I osteotomy. Twenty-five patients were treated with titanium fixation; 25 patients were treated with resorbable copolymer fixation (82% poly-L-lactic acid: 18% polyglycolic acid). Lateral cephalograms were obtained 1 week preoperatively, 1 week postoperatively, and a minimum of 8 months postoperatively. Linear and angular measurements were recorded digitally to evaluate 2-dimensional skeletal changes. **Results:** Statistical analysis showed no significant radiographic differences ($P < 0.05$) in long-term stability in or between the 2 groups. No clinical or radiographic evidence of wound healing problems was noted. **Conclusions:** These results support the use of resorbable copolymer fixation for Le Fort I impaction as a viable alternative to titanium fixation. (*Am J Orthod Dentofacial Orthop* 2008;134:67-73)

Advances in skeletal stabilization techniques have led to the use of titanium devices for rigid fixation.¹ Although these devices have proven to be reliable for providing strength and skeletal stability,^{1,2} they also have potential disadvantages.

The concerns expressed in the literature related to metal devices include bone atrophy, palpability, loosening, temperature sensitivity, infections, and interference with radiation therapy and imaging.³⁻⁸ Migration of metal particles to adjacent tissues and regional

lymph nodes has also been shown.^{3,9-11} Any of these factors might ultimately require reoperation for removal of metal plates and screws.

A reliable resorbable fixation system would avoid all these potential complications. If resorbable materials could provide sufficiently rigid fixation to allow for satisfactory bone healing, with the added advantage of elimination by the body, this would be a significant development.

Although research about resorbable fixation dates back over 30 years, recent advances in techniques and material composition have resulted in renewed interest in their use.^{12,13} Lactosorb (Walter Lorenz, Jacksonville, Fla) is a resorbable copolymer composed of 82% poly-L-lactic acid (PLLA) and 18% polyglycolic acid (PGA), and has been in clinical use (approved by the Food and Drug Administration) since 1996.¹⁴ Since that time, various studies have examined this material with regard to clinical application, bone healing, and device degradation.¹⁵⁻¹⁸ A number of resorbable polymers have been developed with varying patterns of resorption and strengths.¹⁶⁻¹⁸

A major requirement of any fixation system in orthognathic surgery is that it must ensure long-term skeletal stability. If a resorbable copolymer is to be considered a viable alternative to the current standard of care for orthognathic surgery (titanium fixation), then long-term, postsurgical stability of the resorbable

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copolymer must be demonstrated for the various orthognathic procedures when the device is used.¹⁹⁻²¹ Most studies about the long-term stability of orthognathic procedures with resorbable copolymer devices concentrated on mandibular advancement surgery,²² with little information about maxillary procedures.²³

MATERIAL AND METHODS

The study comprised 50 consecutively treated patients who satisfied the following inclusion criteria. All patients underwent Le Fort I maxillary impaction procedures with or without a mandibular procedure. Each patient received maxillary impaction of at least 2 mm. All patients required orthognathic surgery for conditions not associated with syndromes. All patients were treated by the same surgeon (J.P.R.) using the same Le Fort I down-fracture technique. Each patient's cephalograms were taken on the same cephalostat under standardized conditions, at the appropriate time intervals. The 50 patients were divided into 2 equal groups. Twenty-five patients were treated with titanium fixation devices only; the others received fixation with Lactosorb, a resorbable copolymer of 82% PLLA and 18% PGA. Each patient received either 2 titanium or 2 resorbable plates to the antero-lateral aspect of the maxilla lateral to the piriform apertures, 1 on the right and 1 on the left. Each plate had at least 2 screws on either side of each osteotomy. If the plates were resorbable, so were the screws; if the plates were titanium, the screws were also titanium. In addition, each patient had an interosseous stainless steel wire placed at the right and left buttress areas.

Patient assignment to treatment groups was not randomized. The patients selected the fixation material through an informed consent process. The first 25 patients who chose titanium fixation and met the inclusion criteria comprised the titanium group. The first 25 patients who chose resorbable fixation and met all inclusion criteria formed the resorbable group. The research protocol was approved by the Committee for Research on Human Subjects of the University of the Witwatersrand, Johannesburg, South Africa, where the study was conducted.

The 2 groups of patients were similar with regard to sex, age, and surgical movements (Tables I and II). An independent samples *t* test showed no significant difference in patient age between the groups ($P = 0.903$), and repeated measures ANOVA showed no significant differences in surgical movements.

The follow-up protocol consisted of postoperative appointments at 1 and 6 weeks, and at 3, 6, and 12 months. At each appointment, patients had a clinical examination of the surgical sites to identify swelling,

Table I. Patient sample

	Titanium fixation (n = 25)	Resorbable fixation (n = 25)	Total sample (n = 50)
Men (n)	8	5	13
Women (n)	17	20	37
Mean age (y) at surgery (SE)	22.9 (1.6)	23.3 (2.0)	23.1 (1.8)

Table II. Comparison of surgical movements (advancement and impaction) in the 2 patient groups

Variable	Titanium (SE)	Resorbable (SE)	Difference	P value
Horizontal (mm)				
A-point	2.45 (0.57)	2.02 (0.39)	0.43	0.375
Vertical (mm)				
A-point	2.14 (0.65)	2.46 (0.71)	0.32	0.167
ANS	2.51 (0.61)	2.42 (0.61)	0.09	0.299
PNS	3.36 (0.43)	2.66 (0.30)	0.70	0.583

discharge, pain, or discoloration of the mucosa and skin. Panoramic radiographic examination was performed at 1 week, 6 months, and 12 months to identify any adverse effects of the titanium devices or degradation of the copolymer on the surrounding bone.

Lateral cephalometric radiographs were obtained in centric relation, 1 week preoperatively (T1), 1 week postoperatively (T2), and a minimum of 8 months postoperatively (T3). To evaluate 2-dimensional skeletal changes in the 2 groups of patients, these radiographs were first scanned (Expression 1680, Epson Canada, Toronto, Ontario, Canada) into digital format (JPEG). The digital cephalograms were then traced directly on the computer screen by using QuickCeph 2000 software (San Diego, Calif).

A custom analysis was created with QuickCeph 2000, based on an x-y cranial-base coordinate reference system. The x-axis was drawn 7° to the sella-nasion line passing through nasion. The vertical axis passed through sella perpendicular to the x-axis (Fig 1). Horizontal, vertical, and angular measurements were then calculated.

The linear distance (mm) of A-point from the y-axis was measured parallel to the x-axis (Fig 2). Forward movement was considered positive. The linear distances (mm) of anterior nasal spine (ANS), A-point, and posterior nasal spine (PNS) from the x-axis were measured parallel to the y-axis (Fig 3). When ANS was surgically removed, the bisection of the thickest portion of the remaining bony protuberance was used as ANS. Superior movement was considered positive. The an-

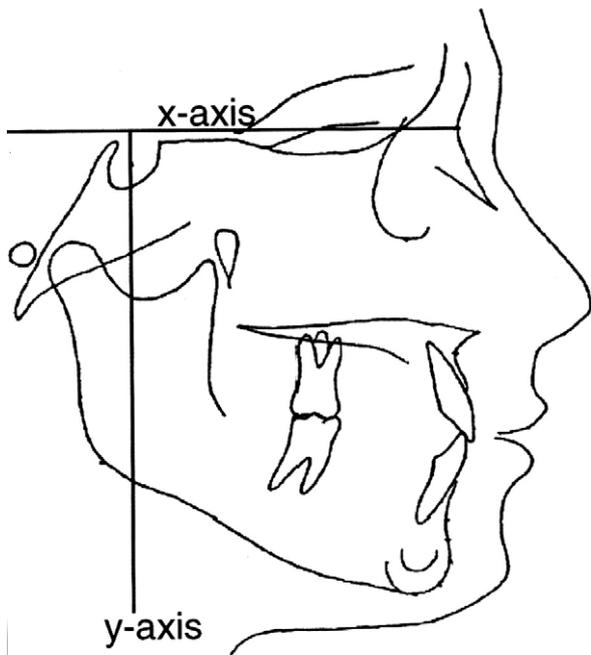


Fig 1. The x-axis was drawn 7° to the sella-nasion line passing through nasion. The vertical axis passed through sella perpendicular to the x-axis.

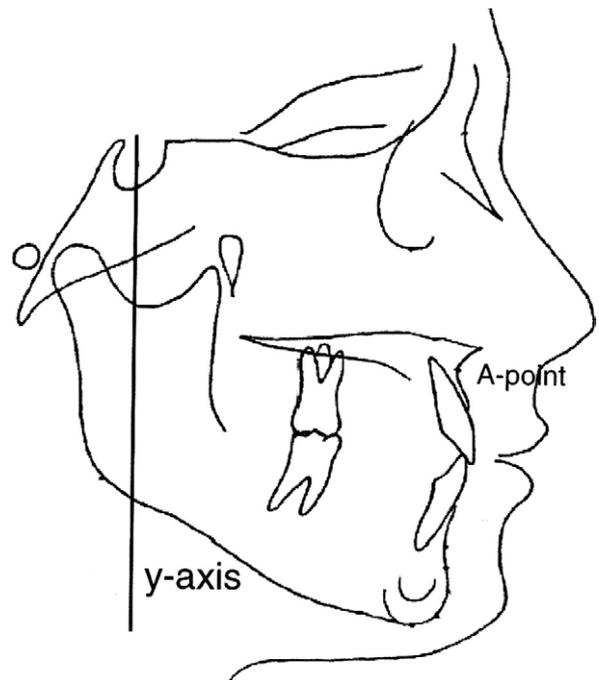


Fig 2. The linear distance of A-point from the y-axis was measured parallel to the x-axis.

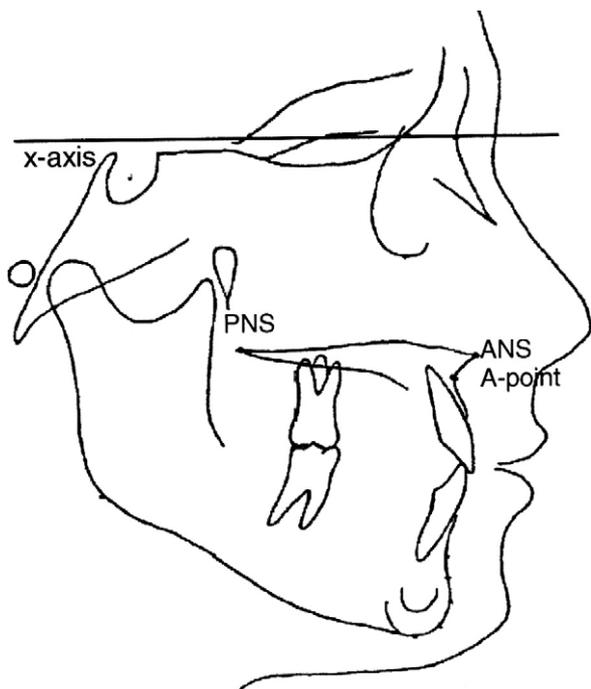


Fig 3. The linear distance of ANS, A-point, and PNS from the x-axis was measured parallel to the y-axis.

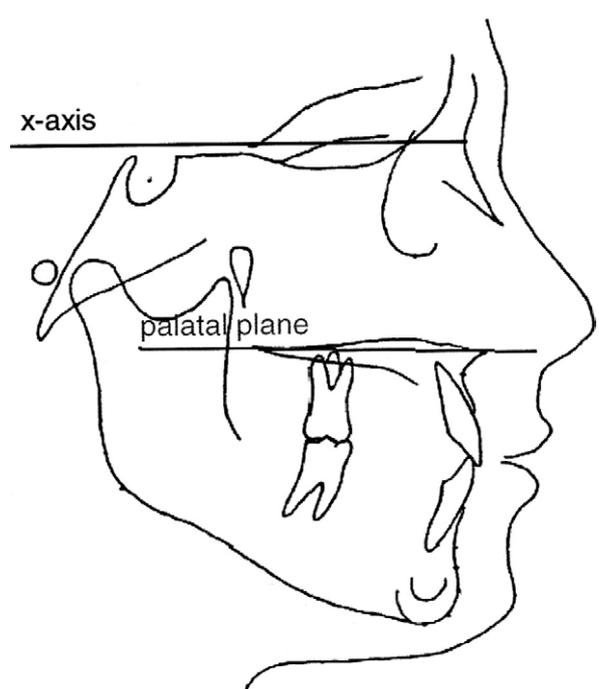


Fig 4. The angular relationship of the palatal plane (PNS-ANS) to the x-axis was measured. Clockwise movement was considered positive.

Table III. Intra-examiner reliability

	Variable	Intraclass correlation
Horizontal (mm)	A-point	0.9949
Vertical (mm)	A-point	0.9822
	ANS	0.9651
	PNS	0.9782
Angular (°)	Palatal plane	0.9835

Table IV. Surgical and postsurgical maxillary movement in titanium fixation group

Variable	T2-T1		T3-T2		P value	
	Mean	SE	Mean	SE		
Horizontal (mm)	A-point	2.45	0.57	-0.80	0.43	0.063
Vertical (mm)	A-point	2.14	0.65	-0.64	0.57	0.264
	ANS	2.51	0.61	-0.32	0.50	0.520
	PNS	3.36	0.43	-0.28	0.35	0.429
Angular (°)	Palatal plane	2.36	0.74	0.00	0.69	1.000

gular relationship of the palatal plane (PNS-ANS) to the x-axis was measured (Fig 4). Clockwise movement was considered positive.

All measurements were made for each patient at T1, T2, and T3. The differences from T1 to T2 showed the surgical movements. The differences from T2 to T3 measured change (relapse) during the postoperative observation period.

Fifteen radiographs were chosen at random and traced by the same investigator (W.S.D.) on two separate occasions, one month apart. Reliability coefficients were calculated for each measurement used in the study to determine intra-examiner reliability.

Statistical analysis

Descriptive statistics consisting of means and standard errors were calculated for the various measurements in each group. Repeated measures ANOVA was used to assess significant changes in the cephalometric measurements in the groups (within-group differences) from T2 to T3 and any significant differences between the groups (between-group differences). Statistical tests were 2-tailed at the 5% significance level ($P < 0.05$). In addition, clinically significant thresholds of 1 mm for linear measurements and 1° for angular measurements were used to test for clinical significance of postsurgical changes. Results were considered significant only if they were both statistically and clinically significant.

Table V. Surgical and postsurgical maxillary movement in resorbable fixation group

Variable	T2-T1		T3-T2		P value	
	Mean	SE	Mean	SE		
Horizontal (mm)	A-point	2.02	0.39	-0.20	0.43	0.639
Vertical (mm)	A-point	2.46	0.71	-0.12	0.57	0.834
	ANS	2.42	0.61	-0.04	0.50	0.936
	PNS	2.66	0.30	-0.24	0.35	0.498
Angular (°)	Palatal plane	0.99	0.84	-0.04	0.69	0.954

Table VI. Difference in postsurgical maxillary movement between titanium and resorbable groups

Variable	Mean (T3-T2) difference		SE	P value
	Mean	SE		
Horizontal (mm)	A-point	0.60	0.60	0.321
Vertical (mm)	A-point	0.52	0.80	0.520
	ANS	0.28	0.70	0.690
	PNS	0.04	0.50	0.936
Angular (°)	Palatal plane	0.04	0.97	0.967

RESULTS

The results of the precision study show a high level of intra-examiner reliability (Table III).

For the titanium fixation group, the surgical movements (T2-T1) and results (T3-T2) are summarized in Table IV.

Horizontal changes included a mean surgical advancement at A-point of 2.45 ± 0.57 mm, and a mean relapse occurred posteriorly but had a clinically and statistically insignificant value of 0.80 ± 0.43 mm.

Vertical changes included a mean surgical impaction at ANS of 2.51 ± 0.61 mm; mean relapse was in an inferior direction, clinically and statistically insignificant at 0.32 ± 0.50 mm. The mean surgical impaction at PNS was 3.36 ± 0.43 mm, and mean relapse was in an inferior direction, with a clinically and statistically insignificant value of 0.28 ± 0.35 mm.

Angular changes included a mean sagittal rotation of the palatal plane of $2.36^\circ \pm 0.74^\circ$ in a clockwise manner (posterior impacted more than anterior), and mean relapse of the palatal plane angle was essentially zero.

In the resorbable fixation group, the surgical movements (T2-T1) and results (T3-T2) are summarized in Table V.

Horizontal changes included a mean surgical advancement at A-point of 2.02 ± 0.39 mm. Mean relapse occurred in a posterior direction but had a

clinically and statistically insignificant value of 0.20 ± 0.43 mm.

Vertical changes included a mean surgical impaction at ANS of 2.42 ± 0.61 mm. Mean relapse was in an inferior direction, with a clinically and statistically insignificant value of 0.04 ± 0.50 mm. The mean surgical impaction at PNS was 2.66 ± 0.30 mm. Mean relapse was in an inferior direction, with a clinically and statistically insignificant value of 0.24 ± 0.35 mm.

Angular changes included a mean sagittal rotation of the palatal plane of $0.99^\circ \pm 0.84^\circ$ in a clockwise manner (posterior impacted more than anterior). Mean relapse of the palatal plane angle was $0.04^\circ \pm 0.69^\circ$ in a counterclockwise direction; this was clinically and statistically insignificant.

Table V summarizes the differences of relapse values (T3-T2 changes) between the 2 groups for each measurement. The difference in relapse between the groups was insignificant for each measurement.

DISCUSSION

The use of resorbable fixation devices for osteosynthesis was first investigated over 3 decades ago.^{12,13} Renewed interest in their use has been spawned by potential concerns about metal devices and has led to advances in techniques and material composition.^{14,16,18}

A resorbable copolymer of 18% PGA and 82% PLLA (Lactosorb) has shown promise as an alternative to metal for fixation of maxillofacial osteotomies.¹⁹⁻²¹ These resorbable devices are being used increasingly for orthognathic surgery, with reports of successful application in Le Fort I osteotomy^{19,23,24} and bilateral sagittal split osteotomy.^{25,26} Various human trials have demonstrated, qualitatively, the ease of application, strength, and the stability of surgical results with resorbable copolymer devices.^{15,19,20,25,26} To date, there have been no reports of healing complications related to this material.

Until recently, no data quantified the skeletal stability of orthognathic procedures when resorbable copolymer was used. Ferretti and Reyneke²² were the first to carry out such a study. Their prospective trial assessed the skeletal stability of bilateral sagittal split osteotomy advancement and compared 20 patients with titanium screws with 20 patients in whom resorbable copolymer screws were used. Their results showed that, after 1 year, bilateral sagittal split osteotomy fixed with resorbable copolymer screws relapsed 0.83 mm compared with 0.25 mm for titanium fixation. These changes were both statistically and clinically insignificant.

The purpose of our study was to similarly examine Le Fort I maxillary impaction procedures. A previous

study examined the stability of maxillary procedures fixated with a resorbable copolymer.²³ Norholt et al²³ reported a statistically significant difference in the vertical position of the maxilla after 6 weeks in Le Fort I osteotomies fixated with a resorbable copolymer, as the position became slightly more superior than the immediate postoperative position with an average of 0.6 mm. No such changes were noted in the titanium group, and the changes in maxillary position were not clinically noticeable in either treatment group.²³

Our study accurately and reliably measured parameters from lateral cephalometric radiographs of each patient at T1, T2, and T3.

Horizontal, vertical, and angular measurements showed no significant statistical or radiographic evidence of relapse in either the titanium or the resorbable group. Differences between the groups were similarly insignificant (Tables IV-VI).

Compared with previous stability studies²⁷⁻²⁹ of Le Fort I procedures, this study was unique, and its design had numerous advantages. All operations were performed by 1 surgeon, using the same technique for all patients. The sample was gathered prospectively over a relatively short period (18 months) and included consecutively treated patients who met specific inclusion criteria. The indications for surgery were kept narrow by restricting the study groups to patients who required nonsegmental maxillary impaction procedures with minimal anteroposterior changes. All cephalometric radiographs were obtained with the same cephalostat under standardized conditions. Also, the cephalometric analysis focused on pertinent skeletal landmarks to examine maxillary position and ignored extraneous landmarks to improve the statistical power of the study.

Our primary goal was to determine whether resorbable copolymer plates and screws offer sufficient stability for fixation of Le Fort I impaction procedures. Radiographically, the results indicate sufficient strength and stability from resorbable copolymer plates and screws to resist relapse forces such as occlusal or muscular forces.

Clinical examinations of the surgical sites were carried out postoperatively at 1 and 6 weeks, and at 3, 6, and 12 months. Signs of swelling, discharge, pain, or discoloration of the mucosa and skin were monitored as indicators of complications during healing. There was no evidence of wound healing complications at these follow-up visits for any patient. Panoramic radiographic examinations were performed at 1 week, 6 months, and 12 months, again to identify any adverse effects of the fixation devices on the surrounding bone. No evidence of healing complications were noted. However, Norholt et al²³ found 2 patients with infec-

tion and wound dehiscence in their resorbable copolymer group of 30 patients, whereas titanium osteosynthesis was more often palpable after 6 to 12 months and required removal in 3 of the 30 patients.

Our results support the use of resorbable copolymer devices as a viable alternative to titanium for fixation in Le Fort I maxillary impaction.

Future studies should examine the stability of other orthognathic procedures, particularly those that are inherently more susceptible to relapse such as inferior repositioning of the maxilla, maxillary segmental surgery, and mandibular setback procedures. We assessed only the stability of single piece or single fragment nonsegmental Le Fort I level osteotomies. These results might not apply to segmental Le Fort I osteotomies or Le Fort I osteotomies with major anteroposterior repositioning. In addition, different copolymer material compositions, the use of self reinforcement, the incorporation of bone-stimulating factors into the polymers, and the use of cyanoacrylate or rivets to replace screws for plate fixation need further investigation.^{18,30-33}

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