Mandibular, sagittal split osteotomies fixed with biodegradable or titanium screws: A prospective, comparative study of postoperative stability

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Objective. Comparison of skeletal stability following bilateral sagittal split osteotomy (BSSO) advancement of the mandible fixed with titanium or biodegradable bicortical screws.

Study design. Forty consecutive patients underwent mandibular advancement by means of BSSO performed with a standardized technique. In 20 patients rigid fixation was achieved by means of titanium bicortical screws; the other 20 patients were fixed with biodegradable copolymer screws made of poly-L-lactic acid (82%) and polyglycolic acid (18%). Lateral cephalograms were obtained 1 week preoperatively, 1 week postoperatively and after a minimum of 6 months postoperatively. Relevant skeletal points were traced and digitized to evaluate 2-dimensional skeletal change. Changes at each time point were analyzed and compared statistically.

Results. There was no statistically significant difference in long-term stability between the 2 groups. No clinical or radiographic evidence of wound healing problems were noted.

Conclusion. Resorbable poly-L-lactic/polyglycolic acid copolymer bicortical screw fixation of a BSSO is a viable alternative to titanium screws for the fixation of advancement BSSO.

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Therapeutic immobilization of fractures of the human skeleton has been practiced for millennia. Although rigid internal fixation of skeletal fractures has become routine only relatively recently, the modality has advanced rapidly and now provides good results consistently.[1] The lessons learned from the internal fixation of skeletal fractures have been successfully deployed in orthognathic surgery. Although effective in facilitating bone healing, some surgeons advocate the routine removal of titanium plates and screws once healing is complete because they may be palpable or cause infection, thermal and dental sensitivity or allergic reaction and may rarely be carcinogenic. This has been well reviewed by Suuronen.[2] Presently, there is little evidence or consensus regarding the long term local and systemic effects of metal hardware retained in the maxillofacial skeleton, and it may be premature to recommend the routine removal of all intraosseous hardware in the adult patient.[3] Nevertheless, immobilization of skeletal fractures with resorbable internal fixation devices is an attractive idea and the search for a biodegradable material as an alternative to rigid metal fixation has received considerable attention. Thirty years have elapsed since the first reports of biodegradable fixation for immobilization of fractures of the maxillofacial skeleton.[4-6] Resorbable materials for skeletal fixation in craniofacial and orthognathic surgery has been tested in several animal models.[7-11] These trials demonstrated that resorbable plates and screws are biocompatible, are structurally adequate to provide uncomplicated osseous healing, and are completely biodegradable after varying length of time. Moreover, in patients who are growing, the problems of plate transmigration and growth interference may be precluded.[12]

Research efforts have focused primarily on three synthetic high–molecular weight polymers. These are polydioxanone, polylactic acid and polyglycolic acid, of which the latter 2 have been the subject of considerable interest. Fixation of bilateral sagittal split osteotomies (BSSO) in human patients has been accomplished with self-reinforced poly-L-lactide screws.[13,14] Initial results following the clinical application of poly-L-lactide screws and plates were promising.[6,13,15] In due course, however, some of the disadvantages of poly-L-lactic acid have become clear, including foreign body reactions,[16] marked osteolysis around the screws,[17] and a very long degradation period.[18] To overcome these problems, various polymer combinations have been developed in an attempt to improve the physical characteris-

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tics and degradation kinetics of the fixation devices. Considerable work has recently been done on poly-L-lactic/poly-D-lactic acid[10,19] and poly-L-lactic/polyglycolic acid copolymers.[11,20-22] The latter copolymer has been tested for the fixation of Le Fort I and sagittal split osteotomies and has shown to produce uncomplicated bony healing while completely resorbing after 18-24 months.[20-22] There are, however, no data quantifying the skeletal stability following sagittal split osteotomy of the mandible fixed with poly-L-lactic/polyglycolic copolymer screws.

Against this background, a prospective, comparative trial was undertaken to assess skeletal stability following BSSO advancement secured with either copolymer resorbable bicortical screws (poly-L-lactic acid [82%] and polyglycolic acid [18%]) or titanium bicortical screws over a 1-year period.

MATERIAL AND METHODS

The research protocol was approved by the Committee for Research on Human Subjects of the University of the Witwatersrand, Johannesburg. Patients with a Class II skeletal and dental malocclusion requiring BSSO advancement were considered for inclusion in the trial. Several studies have shown that relapse increases as the magnitude of mandibular advancement increases[23,24] and that advancements larger than 9 to 10 mm are considered particularly unstable.[24] Accordingly, patients included in this trial were limited to those requiring not more than 8 mm of mandibular advancement. All patients had preoperative orthodontics. Over a period of 8 months, 40 patients underwent mandibular advancement by means of a bilateral sagittal split osteotomy procedure. No concurrent orthognathic procedure was performed. Twenty consecutive patients received titanium fixation followed by a second consecutive 20 who received copolymer fixation. Orthodontics was resumed 4 weeks after surgery.

Surgical technique

All patients were operated on by the same surgeon using the same surgical technique. Surgery was performed under general anesthesia via nasotracheal intubation. Osteotomy design was as described by Trauner and Obwegeser[25] as modified by Dal Pont[26] and refined by Epker.[27] After osteotomy, the distal segment was positioned with the teeth in a preplanned occlusion and immobilized by means of intermaxillary fixation without the use of a prefabricated splint. The proximal segment and condyle were positioned by means of a condylar positioner to achieve optimal condyle/fossa relationships. A transosseous wire was placed, maintaining the position of the distal and proximal bone segments during placement of the bicortical screws. Three screws were placed on each side through a transbuccal approach in either a straight-line pattern along the upper border or an inverted-L pattern that avoided the neurovascular bundle engaging both cortices. Copolymer screws (Lactosorb, Walter Lorenz Surgical, Jacksonville, Fla) had a core diameter of 2 mm and an outside thread diameter of 2.5 mm with a self-shear hex head. Titanium screws had an outside thread diameter of 2 mm. Screw lengths were 11, 13 or 15 mm. Before placement of the poly-L-lactic/polyglycolic acid screws, the holes were tapped with a 2.5 mm bone tap and the screws were immediately placed in the hole. Each screw was tightened with a direct-head driver device. After placement of all the bicortical screws the intermaxillary fixation was removed and the occlusion checked. All patients were placed on 2 0.25-in, 3.5-oz Class II guidance elastics. Both groups of patients were placed on a pureed diet for the first 4 postoperative weeks.

Follow-up protocol consisted of postoperative appointments at 1 and 6 weeks, then at 3, 6 and 12 months. All patients underwent a clinical examination of the surgical sites to identify any swelling, discharge, pain, or discoloration of the mucosa and skin.

Panoramic radiographic examination was performed at 1 week, 6 months, and 12 months to assess screw hole ossification and to identify any adverse effects of the degrading copolymer on the surrounding mandible.

Lateral cephalometric radiographs were obtained in centric relation, 1 week preoperatively (T0), 1 week postoperatively (T1), and a minimum of 6 months postoperatively (T2). To evaluate skeletal dimensional changes in the 2 groups of patients, the essential skeletal and dental structures were traced with a sharp 6H pencil onto Ozatex (Ozalid SA [Pty] Ltd, Drawing Office Material, Spartan, Kempton Park, South Africa) 0.05 mm D/matt drafting film paper. The following landmarks were identified and marked: sella, nasion, anterior nasal spine, posterior nasal spine, and supramentale. The same investigator performed all the tracings.

To evaluate postoperative sagittal changes, 2 reference lines were constructed. The lines are (1) from sella to nasion and (2) the palatal plane from the anterior nasal spine to posterior nasal spine on the tracing of the T0 cephalogram. The 2 reference lines were then transferred to the T1 and T2 tracings, which were then superimposed on the T1 and T2 cephalograms. The mandibular landmarks were then transferred from cephalograms to the tracings. Thereafter, a line was drawn from the nasion perpendicular to the line from the anterior nasal spine to the posterior nasal spine. The point of intersection of this line and the palatal plane was designated as N^1. A further line was drawn from the supramentale perpendicular to the line from the

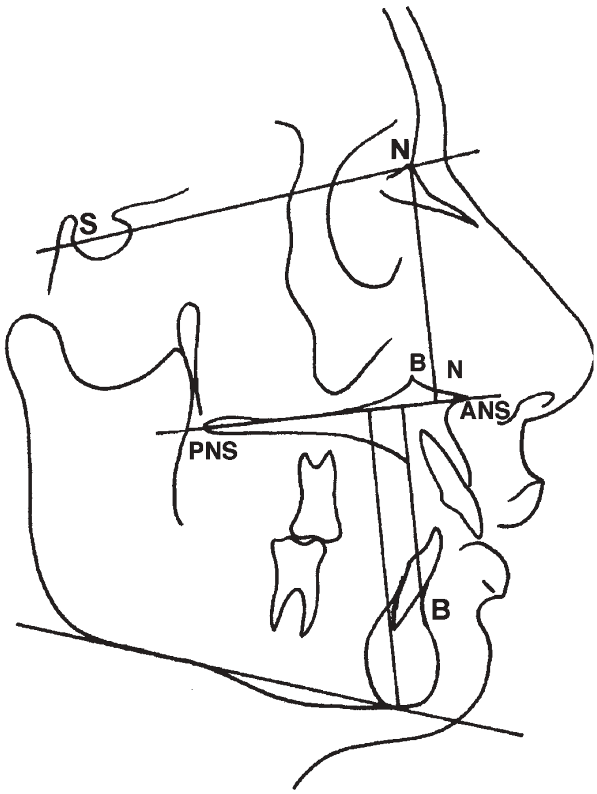

Figure. Cephalometric analysis denoting the relevant landmarks and reference lines.

posterior nasal spine to the anterior nasal spine. The point of intersection with the palatal plane was designated B^1 (Figure).

To assess sagittal changes, the length in millimeters from B^1 to N^1 was recorded and deemed negative if relapse was opposite to the direction of surgical advancement and positive if it was in the same direction as the surgical advancement. For statistical analysis, positive and negative denotations were discarded. Ten radiographs were randomly selected, retraced, redigitized, and remeasured after 10 days and compared with the original data to ensure intraexaminer accuracy. All reference points were digitized using a Kentron MOP video plan computer system. The amount of relapse was measured in millimeters from T1 to T2. The variance of the relapse between the 2 fixation methods was tested with Bartlett's test for equal variance. The mean postoperative change for the 2 methods was compared by a Student *t*-test. The results were confirmed with a Mann-Whitney *U*-test. A *P* value of .05 was considered significant.

RESULTS

Analysis of the data with 2 sample t-tests for both equal and unequal variances confirmed that the 2 groups did not differ significantly with regards to age, sex and degree of advancement. The mean advancement for the copolymer group was 5.67 mm (standard deviation [SD] 1.70 mm; range, 2.57 – 7.59 mm) and for the titanium group 4.80 mm (SD 1.33 mm; range, 2.49 – 6.68 mm). The mean long-term relapse (T2) for the copolymer group was 0.83 mm (SD 1.25; range, –3.73 to +1.24) and 0.25 mm (SD 1.38, range, –3.19 to +2.25) for the titanium group. The mean relapse between the 2 treatment groups was not statistically significant (*P* = 0.18) (Table). Clinical examination of all surgical incisions revealed no abnormal pain, swelling, discharge, or mucosal discoloration during the postoperative period. All screw holes were visible at 12 months by radiographic examination, but no osteolytic changes were noted. Four patients were examined at 24 months, and the screw holes, although less evident, were still visible.

Table. Comparison of the 2 treatment groups

	Titanium *n = 20*	*PLLA/PGA* *n = 20*	P *Value*
Advancement (mm)	4.7 ± 1.3	5.5 ± 1.7	.345
Range	2.4 - 6.6	2.56 - 7.58	
Relapse (mm)	0.25 ± 1.38	0.83 ± 1.25	.176
Range	(–)3.19 to (+)2.25	(–)3.73 to (+)1.24	
Relapse (%)	5.32 ± 29.8	16.2 ± 38.6	.158
Range	(–)70.19 to (+)64.09	(–)84.92 to (+)12.35	

PLLA/PGA, poly-L-lactic/polyglycolic acid.

DISCUSSION

Resorbable devices for osteosynthesis are being increasingly, and successfully, deployed in maxillofacial surgery. They have been tested in Le Fort I[19,21,22,28] BSS[13,15,19,20] and genioplasty[29] osteotomies with promising results. Although these copolymers have all allowed for bony healing to occur, poly-L-lactic acid copolymer screws have caused excessive osteolysis around the screw hole and excessively slow degradation.[17,18] Whether this is clinically significant is unclear at present. Our results have shown that BSSO fixed with poly-L-lactic/polglycolic acid copolymer screws relapsed 0.83 mm as compared to 0.25 mm for titanium fixation. This change is both statistically and clinically insignificant. This corresponds to a 16.2% relapse rate at B point and compares favorably with relapse rates for BSSO secured with metal screws, reported to range from 5.2% to 26%.[12] Moreover, BSSO advancement osteotomies immobilized with self-reinforced poly-L-lactic acid bicortical screws reported relapse of 15% and 17% at pogonion and supramentale respectively.[12]

No evidence of wound healing complications was noted at the follow-up visits in any of the patients. This concurs with previous studies that poly-L-lactic/polyglycolic acid copolymer fixation in orthognathic surgery provides uncomplicated bone and overlying soft tissue healing.[20-22,28,29] Radiographic examination of selected patients 2 years after surgery showed the presence of screw holes indicative of incomplete copolymer degradation, but no signs of perifixation osteolysis were noted. In contrast, a recent report has published radiographic evidence of complete degradation of poly-L-lactic/polyglycolic acid screws in 68% of screw holes in the mandible 18 to 24 months after surgery.[22] This suggests that degradation rates for poly-L-lactic/polyglycolic acid fixation devices are subject to interpatient variations due to factors that at present are unclear.

We do not advocate the routine removal of titanium fixation hardware and therefore believe it is premature to recommend the habitual application of resorbable fixation, bearing in mind the technical disadvantages (albeit minor) over titanium and the cost implications. These initial results show that for the BSSO advancement of less than 8 mm, resorbable poly-L-lactic/polyglycolic acid screw fixation is a viable alternative to titanium screws. Its use in larger advancements awaits the results of further studies.

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