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Preliminary assessment of skeletal stability after sagittal split mandibular advancement using a bioresorbable fixation system

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SUMMARY. **We studied skeletal stability during the first year after mandibular advancement and fixation with bioresorbable self-reinforced poly-L-lactide (SR-PLLA) screws in 11 patients by cephalometric measurements. We compared these with a cohort of 11 patients, in whom titanium screws were used for fixation. We found no significant difference between the two groups in the median preoperative cephalometric values and the median changes after operation. There was also no significant difference between the two groups regarding the median extent of relapse 1-year after operation. We conclude that bioresorbable SR-PLLA screws are comparable to metallic screws for fixation of bone after sagittal split mandibular advancement.**

Keywords: **Skeletal stability; SR-PLLA; Craniofacial**

INTRODUCTION

During the past decade, metallic plates and screws have become the routine method of stabilising the craniofacial skeleton. They are reliable and have a low incidence of complications. Disadvantages of metal fixation, however, include unacceptable palpability, exposure intraorally, passive migration, and distortion of future magnetic resonance images (MRI) and computed tomograms (CT). Titanium particulate matter may be shed into the adjacent tissues and has also been found in regional lymph nodes.[1]

The ideal bioresorbable material should not only support the bony fragments during healing but also resorb fully once healing is completed. The resulting metabolites should not cause any local or systemic disorders.

LactoSorb is a copolymer of poly-L-lactic and polyglycolic acid, in a ratio of 82:18%. The copolymer is structured to provide adequate strength for 6–8 weeks and to allow a resorption time of 9–15 months. It is metabolised in the citric acid cycle and eventually excreted by the lungs as carbon dioxide and water.

The use of resorbable materials to stabilise the facial skeleton was first reported by Cutright *et al.*[2] Since then, considerable alterations have been made in the composition of the resorbable materials to modify their clinical properties. Various polymers have been investigated including polylactic acid (PLA) and polyglycolic acid (PGA). Biodegradable fracture-fixation devices have been used in the maxillofacial region.[3–8] In comparative studies of resorbable plates and metallic plates, bony union with callus formation was accomplished within 6 weeks with both methods of fixation in all but one osteotomy (in the metallic fixation group).[4] No plates failed.

Self-reinforced poly-L-lactide (SR-PLLA) screws were used for fixation of sagittal split mandibular osteotomy in nine patients. Healing at 15 months after operation was normal. No long-term complications were encountered.[5]

Self-reinforced poly-L/DL-lactide plates and screws were used for fixation in 10 consecutive bimaxillary osteotomies. The stability of the fixation was assessed 6 weeks later and was comparable to the "gold standard" of titanium plates and screws.[9]

A PLA/PGA plating system was used for fixation of 29 Le Fort I osteotomies,[10] with a follow-up period between 2 weeks and 1 year. The fixation devices were evaluated postoperatively for wound healing, stability, signs of infection, and patient satisfaction. No complications were reported.

The clinical effectiveness of resorbable copolymeric screws for mandibular sagittal split ramus osteotomies were investigated and the authors concluded that the

clinical results were comparable to those after metallic screw fixation.[11,12]

PATIENTS AND METHODS

We studied 22 patients who were referred to our unit for correction of their mandibular retrognathism. All patients had bilateral sagittal split mandibular osteotomies. In 11 patients, bioresorbable SR-PLLA screws were used for fixation of the mandibular segments and the remaining 11 had titanium screw fixation. Six patients in each group underwent simultaneous maxillary osteotomies. The median follow up period was 14 months (range 12–24). All patients had lateral cephalograms taken immediately before operation, immediately after operation and after at least 12 months. These were used to assess changes resulting from the operation and stability. Patients who had simultaneous maxillary surgery or genioplasty were not excluded from the study. Patients were included in the study after obtaining ethics committee approval and signed consent from the patient.

The planned advancement in all cases was within 8 mm, the median being 5.9 mm (range 3–8 mm). The mean age of patients in the bioresorbable group was 29 years (range 21–44) and in the control group 32 years (18–46). All patients were female and underwent preoperative and postoperative orthodontic treatment.

The Dal Pont-Hunsuck modified Obwegeser sagittal split osteotomy was used. After completion of the bone cuts and splitting of the mandible, the distal part was advanced and positioned with the help of a prefabricated occlusal wafer. Intermaxillary fixation was then applied, after the surgeon was sure that the heads of the mandibular condyles were correctly seated in their fossae. Burr holes were drilled before screws were inserted. Fragments were fixed using two or three titanium or pre-tapped positional SR-PLLA Biofix screws (Fig. 1) placed above the neurovascular bundle on both sides.

Postoperatively, light guiding elastics were placed as intermaxillary fixation in all patients for 4–5 weeks. Postoperative review appointments were at weekly intervals for the first 6 weeks. Thereafter, patients were seen at 3 and 6 months, and at 1 year.

Radiographic assessment

The radiographs were digitised in a darkened room using special software (PCDIG Version 5.0, Center for Dental Technology and Biomaterials, Karolinska Institute, Stockholm), installed on a personal computer (Viglen, Genie Executive 4DX33) attached to a digitiser (Digi-Pad controller type 5A, GTCO Corporation, USA). The anatomical landmarks used to assess mandibular surgical movement and relapse were: genion, sella, nasion, articulare, anterior nasal spine, posterior nasal spine, and A-point. Genion point is defined as the most posterior and superior point of the upper genial tubercle on the lingual cortex. This anatomical landmark is not affected by genioplasties and can be used as an internal reference point.[13] The mandibular position was assessed in two radiographically constructed planes: the lower border of the mandible and the posterior border of the mandible (Fig. 2).

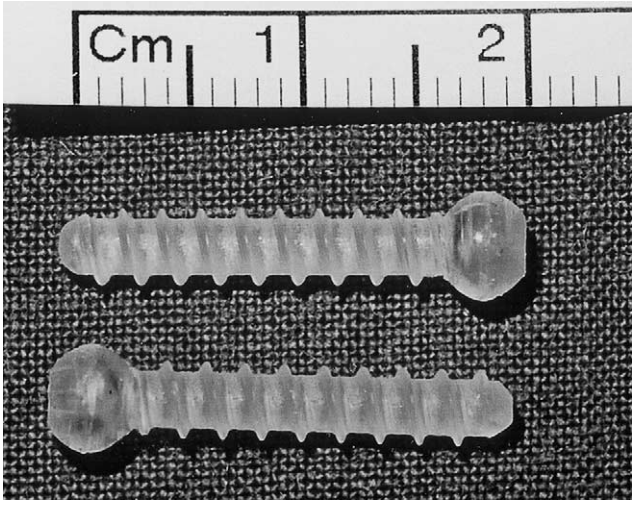

Fig. 1 SR-PLLA Biofix screw 3.5 mm in diameter and 20 mm long.

The points sella and nasion were marked with a pin hole on the preoperative radiograph. These points were then transferred to the immediate postoperative radiograph and the follow-up radiograph after about a year. We used two methods to analyse the radiographs. In addition to routine linear and angular measurements the x and y co-ordinates of the anatomical landmarks were measured. The sella-nasion plus 7° line was used as the horizontal reference line and the plane perpendicular to this line passing through sella as the vertical reference line.

Errors of the method

To minimise both systematic and random errors of the method, we digitised all the radiographs twice, 1 week apart. All the radiographic measurements were adjusted to eliminate magnification.

Statistical evaluation

The reliability and reproducibility of the cephalometric analysis were established using Student's t test to assess random error, and the coefficient of reliability was used to test for systematic error. Within the two groups, the mean postoperative change was examined by application of Student's t test. The magnitude of surgical movement and postoperative changes were also assessed with

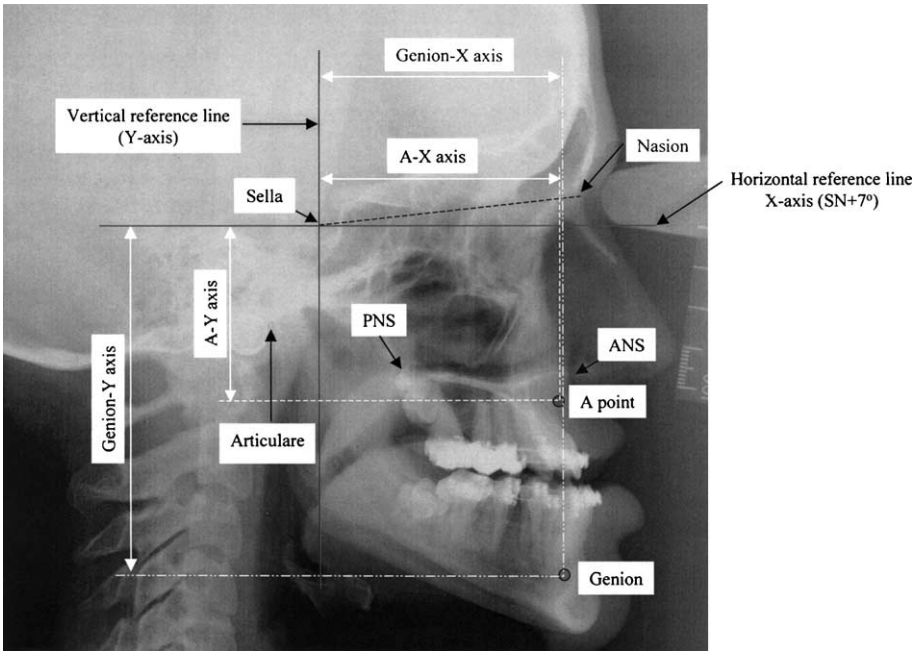

Fig. 2 Diagram showing reference planes and angular measurements to assess mandibular position.

Student's *t* test. Probabilities of less than 0.05 were accepted as significant. Data are presented as median.

RESULTS

Of the 22 patients in the study, two reported persistent paraesthesiae of the lower lip 1-year after operation. One resorbable screw extended through the oral mucosa and two patients reported pain and clicking of the temporomandibular joints 9–12 months postoperatively. There were no fractures or failures of the fixation. In the resorbable fixation group, one patient reported discomfort from the over extended screw beyond the lingual cortex and one developed from a sterile abacus around the screw. No surgical intervention was needed and the symptoms gradually improved.

The methods used for analysis of the radiographs were reproducible and reliable. This is indicated by the high coefficient of reliability (ranging from 0.99 to 0.96), which shows that the random errors were small. Systematic errors were also sought by comparisons of the two digitisations, which were made a week apart, and there was no significant difference. The accuracy of the cephalometric analysis was 0.5 mm for linear measurements and 0.5° for angular measurements.

There was no significant difference between the two groups regarding the mean preoperative cephalometric values (Table 1). The main postoperative change in the two groups was the downward and forward movement of the

Table 1 Mean preoperative measurements for each group of patients

	Metal screws ($n = 11$)		Bioresorbable screws ($n = 11$)	
	Median	Interquartile range	Median	Interquartile range
Co-ordinates (cm)				
Genion–*y* axis	10.3	9.7–10.9	10.2	9.7–10.8
Genion–*x* axis	3.6	3.2–4.4	3.2	2.7–3.7
A–*y* axis	6	5.9–6.5	6.0	5.8–6.3
A–*x* axis	6.7	6.5–6.9	6.2	5.8–6.5
Angular measurements (°)				
Saddle angle	92.3	82.9–97.9	93.1	92.4–96.4
Gonial angle	128.7	122.1–130.9	125.5	120.6–125.2
SN-MAX angle	8.9	7.9–9.4	9.5	8.3–11.3
Linear measurements (cm)				
Mandibular length	9.4	9.3–9.7	9.3	8.6–9.9

There was no significant difference between the groups using the Mann–Whitney's test.

Table 2 Differences from preoperative measurements immediately after operation

	Metal screws ($n = 11$)		Bioresorbable screws ($n = 11$)	
	Median	Interquartile range	Median	Interquartile range
Co-ordinates (cm)				
Genion–*y* axis	4.5	1.5 to 5.0	4.5	2.0 to 6.0
Genion–*x* axis	4.0	3.0 to 8.0	4.0	0.0 to 5.0
Angular measurements (°)				
Saddle angle	−3.7	−7.0 to 0.0	−2.7	−5.3 to 0.0
Gonial angle	1.5	1.0 to 8.0	4.2	2.2 to 8.8
Linear measurements (mm)				
Mandibular length increase	5.5	3.5 to 5.5	5.0	3.0 to 6.0

There was no significant difference between the groups. Minus value indicates posterior or superior shift.

Table 3 Differences from preoperative measurements 12 months after operation

	Metal screws ($n = 11$)		Bioresorbable screws ($n = 11$)	
	Median	Interquartile range	Median	Interquartile range
Co-ordinates (mm)				
Genion–*y* axis	−1.0	−2.0 to 0.0	−2.5	−3.5 to 0.0
Genion–*x* axis	0.0	−4.3 to 3.0	0.5	−1.5 to 1.5
Angular measurements (°)				
Saddle angle	−1.6	−1.7 to 1.4	−1.0	−1.9 to 0.0
Gonial angle	1.0	−1.0 to 2.5	1.0	−1.0 to 3.3
Linear measurements (mm)				
Mandibular length	−1.0	−1.5 to 1.5	−1.0	−2.5 to 0.0

There was no significant difference between the groups. Minus value indicates posterior or superior shift.

mandible, a clockwise rotation of the inferior mandibular segment (Table 2). This was accompanied by an increase in mandibular length and gonial angle (the angle formed between the line representing the posterior border of the mandible and the inferior border of the mandible), and reduction of the saddle angle. There was also a downward and forward rotation of the maxilla in the bimaxillary cases. There was no significant difference in the magnitude of the postoperative changes between the two groups.

The median changes at 12 months after operation are shown in Table 3. There is a tendency for relapse in the vertical plane with the anterior aspect of the mandible moving upwards and posteriorly with a counter-clockwise rotation of the mandibular plane, with reduction of the ramus (saddle angle).

There was still a slight *forward* displacement of the mandible, but it was the posterior relapse that was seen in most of them. The variability of the magnitude and direction of relapse was pronounced more in the metal screw group. However, the median relapse in antero-posterior direction was similar in the two groups. There was limited change (relapse) in the mandibular length (1 mm) and gonial angle (1°), which suggests a positional relapse of the mandible rather than an alteration in the relation between the proximal and distal segment. The angle of the ramus, which is the angle between the sella-nasion line (anterior cranial base) and a line along the posterior part of the ramus of the mandible, is an indicator of the position of the posterior segment. There was no significant difference in this value at any time interval between the two groups. There was no significant difference in the magnitude of the mandibular or maxillary relapse between the two groups.

DISCUSSION

Permanent metal implants when used in the maxillofacial region may require removal secondary to implant loosening, migration, unacceptable palpability, breakage or tissue irritation which can result in localised growth restrictions in the paediatric skeleton and being radio-opaque, may interfere with therapeutic and imaging applications of irradiation. To address these concerns, in recent years there has been both growing availability and acceptance of the use of absorbable polymer fixation devices.[15–17]

The most commonly used absorbable polymers in clinical practice today are based on alpha-hydroxy acids such as D-lactic and L-lactic acid, glycolic acid and paradioxanone.[18,19] The implants degrade hydrolytically, and then there is a macrophage cellular response that converts the polymer debris to water and carbon dioxide. This occurs concurrently with healing. Some of the many factors that affect the rate of degradation are the chemical identity of the polymer, its molecular weight, crystalline:amorphous ratio and size and shape of the

implant. By altering the properties of the copolymers through judicious selection of the identity and ratio of the monomeric constituents therefore, the overall behaviour of the implant may be manipulated to improve either its strength (L-lactide), absorption (glycolide) or contourability (D-lactide).

There are few reports of long-term stability in orthognathic surgery using resorbable fixation. Shand and Heggie reviewed 31 patients who underwent orthognathic surgery using this type of fixation. Eight patients had maxillary osteotomies, nine had mandibular osteotomies and 14 had bimaxillary procedures. The follow-up period ranged from 2 to 8 months. No immediate postoperative complications were reported, except in one who developed a localised buccal space infection. In the early postoperative period, six patients had slight mobility of the maxilla, but stability was within normal limits at 6 weeks postoperatively. The authors concluded that technique was an important determinant of success and that LactoSorb was a good fixative for maxillo-mandibular repositioning.[14]

We found that there was no significant difference in the magnitude of the relapse between the resorbable and the metallic fixation groups over the period studied. There was no change in the position of the maxilla in those patients who had had simultaneous Le Fort I maxillary osteotomy. The inclusion of patients who had simultaneous genioplasty procedures and the variable reproducibility of B point on consecutive lateral cephalometric radiographs meant that genion was selected as our stable internal reference point on the outline of the mandible.

Resorbable screws are radiolucent and consequently are not visible radiographically. This may be one of the main disadvantages of the system. The burr holes are radiographically the only sign of these screws (Fig. 3). The diameter of the resorbable screws is larger than the standard 2-mm titanium screws. This may cause some difficulty in inserting three screws above the neurovascular bundle at the upper border of the ramus. In our experience, two screws seemed to be sufficient to provide satisfactory fixation of the bony segment.

If a third screw is required it is best placed below the neurovascular bundle toward the inferior border of the mandible.

Fig. 3 Panoramic radiograph showing the burr hole at the site of the resorbable screws on the upper border of the ramus.

CONCLUSION

The stability of mandibular sagittal split advancement osteotomy using resorbable SR-PLLA screws is comparable to that obtained with metallic screws. Longer-term follow up is recommended to confirm the complete absorption of the screws and full bony in-fill in their sites without any adverse effects.

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