Self-Reinforced Biodegradable Screw Fixation Compared With Titanium Screw Fixation in Mandibular Advancement

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Purpose: This report compares the skeletal stability and treatment outcomes of 2 similar cohorts undergoing bilateral sagittal osteotomies of the mandible for advancement. The study groups included patients stabilized with 2-mm self-reinforced polylactate (PLLDL 70/30), biodegradable screws (group B), and 2-mm titanium screws placed in a positional fashion (group T).

Materials and Methods: Sixty-nine patients underwent bilateral sagittal osteotomies of the mandibular ramus for advancement utilizing an identical technique. There were 34 patients in group B and 35 patients in group T. Each patient had preoperative, immediate postoperative, splint out, and 1-year postoperative cephalometric radiographs available for analysis. The method of analysis and treatment outcomes parameters are identical to those previously used. Repeated measures analysis of variance was performed with means of fixation as the between-subject factor and time as the within subject factor. The level of significance was set at .01.

Results: There were no clinical failures in group T and a single failure in group B. The average difference in stability between the groups is small and subtly different at the mandibular angle. The data documented similarity of the postsurgical changes in the 2 groups with the only statistically significant difference being the vertical position of the gonion ($P < .001$) and the mandibular plane angle ($P < .01$) with greater upward remodeling at gonion in group T.

Conclusions: Two-mm self-reinforced PLLDL (70/30) screws can be used as effectively as 2-mm titanium screws to stabilize the mandible after bilateral sagittal osteotomies for mandibular advancement. The difference in 1-year stability and outcome is minimal.

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Biodegradable internal fixation has become increasingly popular in many orthopedic applications and has gained wide acceptance in pediatric craniofacial surgery, where heavy loading of the osteotomy sites rarely occurs and therefore the initial strength of the material is not a major consideration.[1,2] Initial reports suggested that biodegradable fixation might not have enough strength for orthognathic procedures, and there has been reluctance to apply this technology to orthognathic surgery because of concerns about the strength of the material, the added time necessary to place it, and the possibility of inflammation or complications related to the degradation process.[3,4] The major advantages of biodegradable fixation are that functional stress is gradually transferred to the bone as it remodels and matures, which allows bone to heal to its original strength. The materials almost never require surgical removal, and potentially can be used as a vehicle to release bone healing mediators.[5] It appears that implantable copolymers now have adequate strength to maintain most osteotomy sites in approximation while initial bone healing occurs, making them suitable for orthognathic surgery.[6,7]

Although titanium is the standard for bone plates and screws for human use, it has been reported that the material can be found in local and regional lymph nodes years after placement.[8,9] The pathologic con-

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Table 1. DEMOGRAPHIC AND SURGICAL CHARACTERISTICS OF PATIENTS IN THE BIODEGRADABLE AND TITANIUM SCREW FIXATION GROUPS

	Biodegradable (n = 34)		Titanium Screw (n = 35)	
	N	%	N	%
Female	18	53	24	69
Genioplasty	7	21	9	26
Advancement				
<5 mm	10	29.4	20	57.1
5–10 mm	24	30.6	14	40
>10 mm	0	0	1	2.9
	Mean	SD	Mean	SD
Age at surgery	27.5	13.0	26.8	11.2
Mandibular plane angle	32.0	6.3	32.0	8.4
Advancement at B Point	5.4	2.6	5.0	2.6

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sequence, if any, is unknown and the titanium debris has never been definitively linked to a disease. Once the titanium serves the purpose of maintaining the position of bone segments during healing, it is no longer necessary. The most common reasons for removing it, as usually is done in multiple European countries, are concerns of infection and thermal sensitivity. In the United States, sinus symptoms, infection, or the desire of the patient because the plate or screw is palpable are the primary reasons for removal and the incidence has been reported to be 10%.[10] In our unit patients are counseled that there is about an 8% chance of necessary removal because of symptoms or infection. Another reason for removal is concern about shielding the bone from normal functional stress, which ultimately influences bone strength, but whether this is clinically significant for orthognathic surgery is not known. Removal of titanium is not always easy. Sometimes osseointegration occurs, and when this happens, removal of bone is necessary to free the material. Breakage during removal can occur, and when this happens the surgeon must decide if it is more prudent to leave the remaining material or continue with removal.

The exact composition of biodegradable materials varies among manufacturers, and the low-grade inflammatory response to biodegradation that occurs is dependent on many factors. These include the exact material used, the method used to form the material, the sterilization process, how it was handled clinically, the amount of material used, and the perfusion of tissues overlying the materials once implanted.[11] Polylactate is the principal polymer used in most biodegradable bone plates and screws, with other polymers (usually polyglycolate) added to alter strength and degradation characteristics, and other

Table 2. BIODEGRADABLE FIXATION GROUP (GROUP B): DESCRIPTIVE STATISTICS FOR HORIZONTAL MOVEMENT

	Surgical Change (n = 34)		Fixation Change (n = 30)		Net Change to 1 Year (n = 34)	
	Mean	SD	Mean	SD	Mean	SD
ANS	0.24	0.75	0.08	0.66	−0.20	1.77
PNS	0.13	0.47	0.07	0.59	0.64	2.24
B	5.20	2.37	0.29	1.80	0.54	3.25
Pg	6.19	3.40	−0.22	1.91	0.26	3.68
Go	1.81	2.37	0.69	2.10	1.88	4.34
Me	6.27	3.79	−0.25	2.09	0.34	4.04
Co	0.18	1.81	−0.86	1.87	−1.06	2.37
XI	0.07	1.00	0.40	0.99	0.21	2.74
MI	5.20	2.79	0.59	1.39	0.47	2.75
XM	1.02	2.68	−0.04	1.61	0.20	2.73
MM	5.44	2.62	0.67	1.86	0.11	2.40

NOTE. Minus sign indicates posterior movement.

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