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Complications after zygoma fracture fixation: Is there a difference between biodegradable materials and how do they compare with titanium osteosynthesis?

Gert Wittwer, Dr Med Univ, Dr Med Dent,[a] Wasiu Lanre Adeyemo, BDS, FMCDS,[b] Kaan Yerit, Dr Med Univ, Dr Med Dent,[b] Martin Voracek, DSc, PhD,[c] Dritan Turhani, Dr Med Univ,[b] Franz Watzinger, Dr Med Univ, Dr Med Dent,[d] and Georg Enislidis, Dr Med Univ, Dr Med Dent,[a]
Vienna, Austria
MEDICAL UNIVERSITY OF VIENNA

Objective. Biodegradable materials are particularly useful for the fixation of zygomatic fractures. Different systems are commercially available. The aim of this study was to compare the clinical outcome of zygomatic fracture fixation using 3 biodegradable systems and a titanium osteosynthesis system.

Study design. Patients with displaced fractures of the zygomatic bone presenting at our department from October 2001 to May 2003 were randomly allocated to 1 of 3 treatment groups for fracture fixation (study group A: LactoSorb: n = 18; study group B: BioSorb: n = 18; study group C: Delta: n = 18). Treatment outcome and complication rates were compared with a historic patient group with zygomatic fractures fixed with titanium osteosynthesis (control group D: n = 15).

Results. A total of 64 patients (study groups A + B + C: n = 49; control group D: n = 15) were followed for at least 24 months (range: 24 to 44 months). Forty-nine patients in the biodegradable study groups (group A: n = 15; group B: n = 17; group C: n = 17) who had their fractures fixed with biodegradable plates and screws alone or in combination with titanium plates and screws were reviewed postoperatively. Uneventful healing occurred during the entire follow-up period in 39 (80%) out of 49 patients in the biodegradable groups (A + B + C) and in 12 (80%) out of 15 patients in group D. Ten patients in groups A + B + C developed postoperative complications (infection: n = 3; soft tissue dehiscence: n = 2; implant-related tissue reactions: n = 5), compared with 3 patients in group D (soft tissue dehiscence: n = 1; unspecific pain: n = 2) ($P = .97$). Complications occurred in 4 patients in group A and 3 patients each in groups B and C. Smokers developed significantly more postoperative complications than nonsmokers in groups A + B + C ($P = .01$).

Conclusion. There was no significant difference between biodegradable osteosynthesis materials or between biodegradable materials and titanium fixation with respect to fracture healing and postoperative complications. Postoperative complications were of a minor nature and resolved spontaneously or after local therapy. Smoking habits may play a significant role in the incidence of complications with biodegradable materials.

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In the past 10 years, the application of biodegradable materials has gained acceptance in the management of patients with maxillofacial trauma, particularly for fractures of the orbital wall and the midface. These materials combine the benefits of rigid internal fixation with the amenities of biodegradation, obviating the need for their removal and causing less interference with craniofacial growth in children and with postoperative radiotherapy.[1,2] Among the first clinical applications of biodegradable materials in maxillofacial trauma was the treatment of zygomatic fractures.[3] Biodegradable materials are particularly useful for the fixation of

[a]Senior Resident, Oral and Maxillofacial Surgery, University Hospital of Cranio-Maxillofacial and Oral Surgery, Medical University of Vienna, Austria.
[b]Resident, Oral and Maxillofacial Surgery, University Hospital of Cranio-Maxillofacial and Oral Surgery, Medical University of Vienna, Austria.
[c]Resident, School of Psychology, University of Vienna, Austria.
[d]Docent, Oral and Maxillofacial Surgery, University Hospital of Cranio-Maxillofacial and Oral Surgery, Medical University of Vienna, Austria.
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zygomatic fractures because this region is a low load-bearing region of the facial skeleton.[1,4,5]

The first commercially available material for maxillofacial trauma was a copolymer of poly-L-lactic acid/polyglycolic acid (PLLA/PGA; Lactosorb). Other materials currently in use are poly-α-hydroxyl acid homopolymers or copolymers: PLLA, poly-D-lactic acid (PDLA), PGA, and polydioxanone-sulphate (PDS).[6-9] Copolymers of PLLA, PDLA, and PGA are given preference over pure PLA and PGA because of the adverse reactions associated with pure PLA and PGA.[6] To our knowledge, no study focusing on the clinical outcome of commercially available biodegradable osteosynthesis materials for the treatment of facial bone fractures has been published to date.

The aim of this prospective randomized study was to compare the clinical outcome of zygomatic fracture fixation using 3 biodegradable systems and a titanium osteosynthesis system.

PATIENTS AND METHODS

Patients with displaced fractures of the zygoma who presented at our department from October 2001 to May 2003 were randomly allocated to 1 of 3 different biodegradable fixation material groups (group A, LactoSorb: n = 18; group B, BioSorb: n = 18; group C, Delta system: n = 18). Exclusion criteria were comminuted zygomatic fractures and the presence of infection at the fracture site. Conventional radiographs (orthopantomogram, Water's view, and occipitomental projection) were taken after a clinical examination. In cases of clinical signs of orbital floor fractures, coronal computed tomography (CT) scans were obtained. Informed consent was obtained from each patient or an authorized representative. All patients were treated within 24 hours of presentation. The procedures were carried out by 2 surgeons who were experienced in handling biodegradable and titanium fixation systems.

Biodegradable materials

The LactoSorb 1.5 system is made from a copolymer of PLLA and PGA in an 82:18 ratio (Walter Lorenz Surgical, Inc, Jacksonville, Fl), and we used 5- and 7-mm-long screws of 1.5-mm diameter, and plates (thickness: 0.5 or 1 mm; width: 5.5 mm). The instruments included a drill for the screw hole, custom diameter taps, and a custom screwdriver. The driver consisted of a handle and a distal socket fitted to the hexagonal size of the disposable auxiliary screw heads. The screws could be further tightened with the direct-head driver after disposable auxiliary hex-head separation. The osteosynthesis set also included heat packs containing calcium chloride, which had to be filled with distilled water in order to be activated. Each heat pack provided sufficient heat for approximately 20 minutes. After reduction of the fracture, a flexible template was bent to the contour of the bone. By placing the plates into the folded heat pack, the copolymer was heated above glass transition temperature (approximately 85°C) and the material rendered malleable for 10 to 20 seconds. The plate was then was pressed against the template and molded to its final shape.

The BioSorb FX 1.5 system is made from a self-reinforced copolymer of PLLA and P(L/DL)LA in a 70:30 ratio (Bionx Implants Linvatec Corp, Largo, Fl), and we used 1.0-mm-thick and 5.5-mm-wide plates with screws 1.5 mm in diameter and 4 mm or 6 mm in length. The instruments consisted of a bone drill, bone tap, screwdriver, and bending forceps. Biosorb FX plates did not require heating before use and were basically handled like metal plates.

The 1.7-mm Delta system is made from a copolymer of PLLA, PDLA, and PGA in a 85:5:10 ratio (Stryker Leibinger Corp, Freiburg, Germany), and we used 1.0-mm-thick and 6.0-mm-wide plates with screws 1.7 mm in diameter and 3, 4, 5, or 6 mm in length. Flexible templates, torque-limiting screwdrivers, a water bath system, a contouring pen, and self-drilling taps were included as the armamentarium. After reduction of the fracture, the template was adapted to the contour of the bone. As the next step, the appropriate biodegradable plate was held in contact with the template in the water bath system so that the plate was heated above its glass transition temperature (approximately 70°C). Using this procedure the plate was molded to the shape of the template. The contouring pen was used for in situ contouring of plates.

Surgical procedure

All procedures were performed under general anesthesia with endotracheal intubation. The fracture site was approached through a marginal gingival incision in cases of zygomaticomaxillary, anterior sinus wall, and paranasal bone involvement. Frontozygomatic suture fixation was achieved through a lateral eyebrow incision when the fracture was displaced at this site. In cases of concomitant displaced orbital floor fractures, the infraorbital margin and the orbital floor were approached through a subciliary incision. After reduction, the fractures were stabilized with biodegradable plates and screws.

If stable fixation with biodegradable plates was not possible, ie, if some fragments were too small for the uptake of biodegradable screws, a conventional metal fixation system with 1.0-mm, 1.5-mm, or 2.0-mm screws and plates (Martin Corp, Tuttlingen, Germany) was used as rescue for the fixation of these fracture sites.

In cases of herniation of the orbital volume into the maxillary sinus, an Ethisorb (Ethicon, Norderstedt, Germany) patch or an autogenous bone graft was

applied to the floor of the orbit. All patients were given intravenous antibiotic prophylaxis (clindamycin, 3 × 600 mg/d) for 7 days after surgery. The patients were asked to report for postoperative assessments at 1, 3, 6, 12, 18, and 24 months after the surgical procedure. In addition to a clinical examination, radiographs (conventional radiographs and CT scans) were taken immediately after surgery, and at 6, 12, and 24 months postsurgery.

For comparison of results, we evaluated a consecutive series of 15 patients (group D: control group) treated from January to October 2000, who had suffered zygomatic fractures and had been treated with titanium osteosynthesis.

Statistical analysis

Data were analyzed using the statistical software package SPSS for Windows (version 11.0; SPSS Inc, Chicago, Ill). Descriptive statistics and test of significance were used, and the significance level was set at $P < .05$.

RESULTS

The mean age (and SD) of the patients in groups A, B, and C (34.6 ± 14.8 years; range: 17 to 71 years) corresponded well with that of the historic titanium control group D (35.5 ± 15.9 years; range: 18 to 69 years). The male-to-female ratio was 37:12 in the former and 12:3 in the latter sample. A total of 49 patients in the biodegradable study groups (group A: n = 15; group B: n = 17; group C: n = 17) who had their fractures fixed with biodegradable plates and screws alone or in combination with titanium plates and screws were reviewed postoperatively. Biodegradable plates and screws alone were applied in 9 patients in group A and in 15 patients each in groups B and C. A combination of biodegradable and titanium plates and screws was used in 6 patients in group A and in 2 patients each in groups B and C. In 3 patients in group A and in 1 patient each in groups B and C, titanium plates and screws were applied exclusively and these patients were excluded from the study groups (Table I). In the biodegradable study groups, uneventful healing during the entire follow-up period was observed in 39 patients (80%), whereas 10 patients (20%) developed postoperative complications (infection: n = 3; soft tissue dehiscence: n = 2; implant-related tissue reactions: n = 5). These were found in 4 patients in group A and in 3 patients each in groups B and C ($P = .7$) (Table II).

Table I. Osteosynthesis materials used in study groups (group A: n = 18; group B: n = 18; group C: n = 18)

	Group A	*Group B*	*Group C*
Only biodegradable	9	15	15
Biodegradable and titanium	6	2	2
Only titanium	3	1	1

Study groups

Group A (LactoSorb). One patient developed mild infection at the zygomaticomaxillary location after 4 weeks, which was treated with oral antibiotics. Another patient developed intraoral dehiscence, necessitating removal of the biodegradable plate and screws (Fig. 1). Two patients experienced swelling and pain at the supraorbital rim (implant-related tissue reaction) after 4 weeks. In one of these patients, the implant-related tissue reaction persisted for 5 months (Table III).

Group B (BioSorb). An intraoral soft-tissue dehiscence was observed at the zygomaticomaxillary region in one patient 4 days postoperatively; the wound was irrigated and resutured. Two patients experienced pain and swelling (implant-related tissue reaction) after 4 weeks. The first patient had symptoms in the zygomaticomaxillary region, which persisted for 11 months. The second patient complained of mild swelling at the supraorbital rim even 23 months after surgery (Table III).

Group C (Delta system). Primary infection leading to intraoral soft tissue dehiscence in the zygomaticomaxillary region necessitated removal of the plates and screws in 2 patients within 1 month after surgery (Fig. 2). Another patient had a mild swelling at the supraorbital rim (implant-related tissue reaction) after 4 weeks. This, however, resolved after 8 weeks (Table III).

Control group

Twelve (80%) patients experienced uneventful healing and 3 (20%) developed postoperative complications. Intraoral dehiscence was seen in one patient within 1 month after surgery; the patient was a heavy smoker. The osteosynthetic material was exposed and had to be removed (Table III). At the 3-month follow-up visit, one patient reported painful sensations at the supraorbital rim and another patient in the zygomaticomaxillary region. In both cases the plates were removed 12 months after trauma surgery (Table III). During removal we observed that the screws in the zygomaticomaxillary region had loosened; this may have been the reason for painful sensations.

Regarding postoperative complications, there was no statistically significant difference between study groups (A + B + C) and the control group (D) ($P = .97$) or between different biodegradable groups and the control group (group A vs group D, $P = .67$; group B vs group D, $P = .87$; and group C vs group D, $P = .87$).

Thirty-seven patients (groups A, B, C: n = 27; group D: n = 10) were moderate to heavy smokers (more than 10 cigarettes per day), while 27 (group A, B, C: n = 22; group D n = 5) were nonsmokers (Table IV). Overall,

Table II. Distribution, location, number, and percentage complication of implants in the biodegradable groups (groups A, B, and C) and the control group (group D)

	Total no. of implants (no. of patients)	*Location of plate*	*No. of implants*	*No. of patients/implants with complications*	*Percentage complication*
Group A		Zygomaticomaxillary anterior sinus wall	12	2	
	22 (15)	Zygomaticofrontal	10	2	18
		Infraorbital	—	—	
		Paranasal	—	—	
Group B		Zygomaticomaxillary anterior sinus wall	13	2	
	25 (17)	Zygomaticofrontal	7	1	12
		Infraorbital	2	—	
		Paranasal	3	—	
Group C		Zygomaticomaxillary anterior sinus wall	15	2	
	24 (17)	Zygomaticofrontal	7	1	13
		Infraorbital	—	—	
		Paranasal	2	—	
Group D		Zygomaticomaxillary anterior sinus wall	15	2	
	31(15)	Zygomaticofrontal	8	1	10
		Infraorbital	6	—	
		Paranasal	2	—	

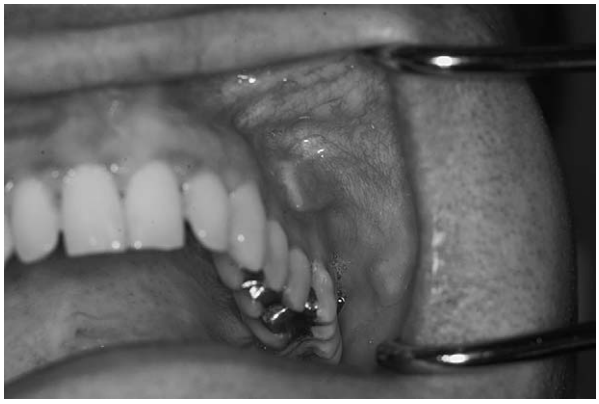

Fig. 1. Beginning of extrusion of a Lactosorb plate through the mucosa in the left zygomaticomaxillary region 4 weeks after trauma surgery; the hardware had to be removed.

more postoperative complications were seen in smokers than in nonsmokers (P = .12). In the study groups, significantly more postoperative complications were observed in smokers than in nonsmokers (P = .01), whereas no such difference was observed in the control group (P = .17).

Despite the complications observed, clinical and radiographic evidence of satisfactory bone healing was registered in all patients 2 years after fixation. No case of malunion or nonunion was observed, while occlusion and facial appearance were satisfactory in all patients of both the biodegradable and the titanium osteosynthesis groups. No complication was associated with the combined use of titanium and biodegradable materials.

DISCUSSION

Biodegradable materials were found to be useful for the fixation of maxillofacial fractures.[7,9-15] The advantage lies in the avoidance of secondary surgery for the removal of hardware. If not removed, metal implants may be painful and irritating.[6,7] In addition to being palpable and/or visible, metal fixation systems are sensitive to temperature and pose difficulties for imaging techniques such as CT or MRI. Biodegradable devices are a most convenient option in growing children, as they do not interfere with growth.[6]

To our knowledge, this is the first clinical report comparing the treatment outcome with 3 different commercially available biodegradable materials for the fixation of zygomatic fractures. Forty-nine (91%) of 54 patients who participated in the biodegradable study group could benefit from biodegradable materials alone or in combination with a titanium fixation system. Biodegradable devices could not be used in cases of poor stability of fixation or in the presence of small bone fragments. The clinical handling characteristics of the 3 biodegradable materials used in the present study have previously been reported.[14]

The majority (80%) of patients treated with biodegradable fixation had no complications up to 24 months after fixation. Ten (20%) patients had minor complications during the follow-up period; an identical

Table III. Types and distribution of postoperative complications among patients (groups A, B, and C) and control group D

	4 days			*1 month*			*3 months*			*6 months*			*12 months*			*18 months*			*24 months*		
	I	*D*	*ITR*	*I*	*D*	*ITR*	*I*	*D*	*ITR*	*I*	*D*	*ITR*	*I*	*D*	*ITR*	*I*	*D*	*ITR*	*I*	*D*	*ITR*
LactoSorb 1.5 system	0	0	—	1	1	2	0	0	1*	0	0	1*	0	0	0	0	0	0	0	0	0
BioSorb FX 1.5 system	0	1	—	0	0	2	0	0	2†	0	0	2†	0	0	2†	0	0	1‡	0	0	1‡
Delta system	0	0	—	2§	2§	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	I	*D*	*USP*	*I*	*D*	*USP*	*I*	*D*	*USP*	*I*	*D*	*USP*	*I*	*D*	*USP*	*I*	*D*	*USP*	*I*	*D*	*USP*
Control group D	0	0	0	0	1‖	0	0	1‖	2¶	0	1‖	2¶	0	0	2¶	0	0	0	0	0	0

I, Infection; *D,* dehiscence; *ITR,* implant-related tissue reaction; *USP,* unspecific pain.
*One of the patients (Lactosorb group) who developed ITR at 1 month postoperatively.
†The same patients (Biosorb group) who developed ITR at 1 month postoperatively.
‡One of the 2 patients (Biosorb group) whose ITR persisted until 24 months postoperatively.
§The same patients (Delta system group) developed infection, which eventually led to dehiscence.
‖The same patient.
¶The same patients.

complication rate (20%) was observed in a control group of patients treated with a titanium fixation system. No statistically significant difference was found in the number of postoperative complications among the 3 biodegradable study groups (LactoSorb, BioSorb, and Delta system), or between the biodegradable groups and the titanium control group. Of 5 complications that were not related to implant tissue reactions, seen in 5 patients, only 2 (infection and dehiscence) could be treated conservatively. In the remaining 3 patients (group A: n = 1; group C: n = 2) the complications necessitated removal of the biodegradable device, although renewed fixation was not required. Apart from implant-related tissue reactions, all complications occurred within 1 month after trauma surgery.

One of the limitations of this study was that comparability in-between groups A, B, and C may have been compromised by the fact that more patients were treated with a combination of metal and biodegradable osteosynthesis in the Lactosorb group compared with the Biosorb and the Delta groups, which was reported and analyzed earlier.[14]

With regard to the number of complications, a statistically significant difference was registered between smokers and nonsmokers in the individual study groups, whereas no such difference was found in the control group.

Yerit et al.[7] reported 3 complications among 22 patients who had their mandibular fractures fixed with a biodegradable fixation system made of self-reinforced polylactic acid copolymer (SR-P[L/DL]LA [70/30]) (BiosorbFX 2.0 system, Bionx Implants, Inc, Tampere, Finland). Two of the 3 complications were managed easily; in the third case the biodegradable implant material had to be removed and replaced with titanium plates and screws because of disturbed healing and infection. No implant-related tissue reactions were recorded during the entire follow-up period of 49.1 weeks (range, 22 to 78 weeks). Enislidis and colleagues[15] used the LactoSorb biodegradable fixation system and reported uneventful healing of bone, confirmed clinically and radiographically, in patients after zygomatic fracture fixation. All complications were minor in nature and were easily treated.

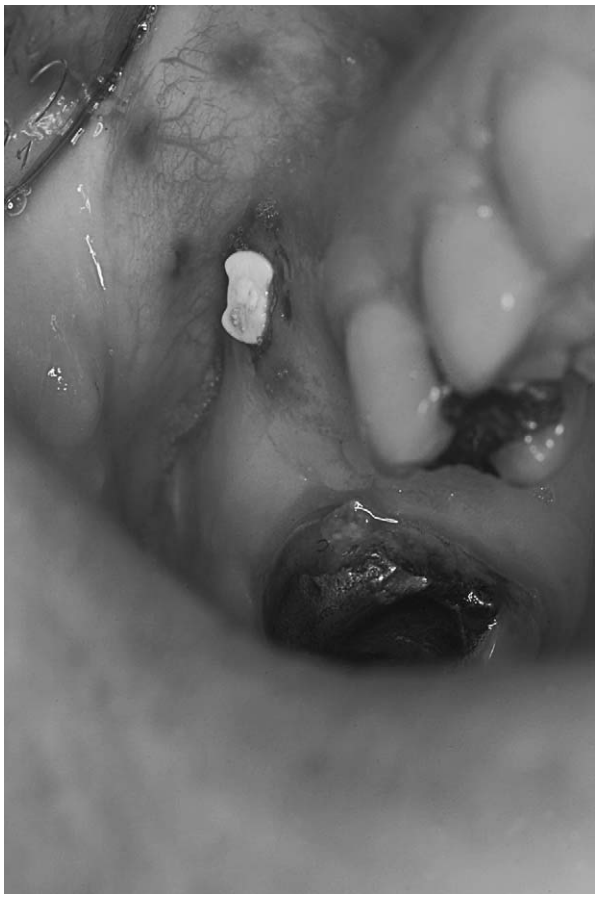

Fig. 2. Intraoral dehiscence in the right zygomaticomaxillary region, leading to infection and subsequent removal of the Delta plate and screws.

Table IV. Patient sex and distribution of complications among smokers and nonsmokers in the biodegradable study groups and the titanium control group

	Gender		*Smoking habits*		*Complications*	
	M	*F*	*Smokers*	*Nonsmokers*	*Smokers*	*Nonsmokers*
Study groups						
Group A	12	3	7	8	3	1
Group B	13	4	11	6	3	0
Group C	12	5	9	8	3	0
Total	**37**	**12**	**27**	**22**	**9**	**1**
Control group						
Group D	12	3	10	5	1	2
Grand Total*	49	15	37	27	10	3

M, Male; *F,* female.
*Study groups plus control group.

In 1997, Eppley and Prevel[16] reported their experience with the Lactosorb biodegradable fixation system in a series of 30 patients with midfacial fractures. In the first postoperative year, no patient experienced any implant-related complications, including infection, erythema of the overlying skin, fracture instability, relapse, or radiographic evidence of osteolysis. In patients who underwent periorbital fixation, the devices were no longer palpable, and the fracture lines showed radiographic evidence of healing. Complete absorption of the device was also demonstrated in one patient who underwent ectropion lower lid repair 13 months after primary surgery. Other authors[3,6,17] have also reported satisfactory results after using biodegradable fixation plates and screws for the fixation of zygomatic fractures.

Implant-related tissue reaction was the most common complication (50%) seen in the biodegradable study groups. This was manifested by recurrent pain and swelling around the implant sites. The 5 cases of implant-related tissue reaction were almost equally distributed in the 3 groups and all of these were observed at the 1-month follow-up visit. At the end of 2 years after fracture fixation, these reactions had completely subsided in the Lactosorb and the Delta system groups, but persisted in the patient from the Biosorb group.

Poly-L-lactic acid (PLLA) plates and screws were the first biodegradable materials tested for the fixation of zygomatic fractures.[3,6] However, several years after surgery the patients experienced foreign body reactions in the operated area, causing notable swelling and necessitating surgical removal of the hardware.[18,19] Pure PLLA and PGA are no longer used because of their numerous adverse reactions. The majority of the commercially available biodegradable fixation systems now consist of amorphous copolymers. Nevertheless, many authors still believe that implant-related tissue reaction may occur long after implantation.[1,18,19]

The 3 biodegradable plate-and-screw systems used in the present study contain different quantities of PLLA. The main mode of degradation of PLLA biomaterials is hydrolysis.[20,21] The tissue reaction is thought to be the result of its inability to absorb the degradation products resulting from rapid hydrolysis. In contrast to PLLA, polyglycolic acid undergoes more rapid hydrolysis and therefore causes greater inflammatory reactions. The morphology of polymers is also believed to be a factor contributing to tissue reaction. Polymers dominated by indigestible crystalline components are known to elicit more tissue reactions than those with more easily resorbed amorphous components.[1,22-24] Other factors that may influence the resorption of these materials, and hence the tissue reaction, are the size and shape of the implants, their molecular weight, the site of implantation, and the purity of the implant material.[6,25-27] One or a combination of the above-mentioned factors may be responsible for the tissue reactions seen in our patients, particularly, in the Biosorb group. The Delta system, a relatively new biodegradable material of 3 polymers, incited a relatively mild tissue reaction in our study. This may have been due to the PLLA/PDLA/PGA ratio of this copolymer.

CONCLUSION

Concerning fracture healing and postoperative complications, there was no significant difference in-between biodegradable osteosynthesis materials or between biodegradable materials and titanium fixation. Postoperative complications were of a minor nature and resolved spontaneously or after local therapy. Further research is needed to determine whether biodegradable fixation is contraindicated in smokers.

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Reprint requests:
Gert Wittwer, DDS, MD
University Hospital of Cranio-Maxillofacial and Oral Surgery
Medical University of Vienna
Waehringer Guertel 18-20
A-1090 Vienna, Austria
gert.wittwer@meduniwien.ac.at