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Self-reinforced biodegradable plates and screws for fixation of zygomatic fractures

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SUMMARY. Purpose: **The aim of this retrospective clinical study was to evaluate zygomatic fracture fixation with the BioSorbFX® osteosynthesis system by assessing stability of reduction as well as complications in the first postoperative year and by conducting a survey to document surgeons' opinions on biodegradable osteosynthesis for this indication.** Material: **From January to September 2003, 25 patients with displaced non-infected unilateral fracture of the zygoma were operated upon (m:f = 20:5; age 17–81 years; mean 39.4 years) using the BioSorbFX® 2.0 and/or 1.5 mm osteosynthesis systems.** Methods: A: **Clinical and radiographic examinations were carried out immediately postoperatively and after 1, 3, 6, 9 and 12 months.** Methods: B: **Surgeons were asked to participate in a survey critically evaluating their experience with biodegradable osteosynthesis systems.** Results: A: **All fractures of the zygoma healed uneventfully. An excessive soft tissue reaction due to the degradation process was not seen. Three minor complications which resolved after local therapy occurred in the immediate postoperative phase.** Results: B: **In the survey, the handling of biodegradable plates in general was rated worse than metal plate osteosynthesis.** Conclusion: **Fixation of fractures of the zygoma with the BioSorbFX® system was simple and safe. The fixations remained stable and bony healing was uneventful. Postoperative complications were few, of a minor nature and not related to the process of biodegradation.** © **2005 European Association for Cranio-Maxillofacial Surgery**

Keywords: **Zygoma; Fracture; Biodegradable**

INTRODUCTION

Ewers and *Förster* (1985) and *Bos* et al. (1987) first reported the use of biodegradable plate and screw prototypes for the fixation of zygomatic fractures in clinical studies. Both observed excessive foreign body reactions (*Ewers* and *Lieb-Skowron*, 1991; *Bos*, 1993) to the implanted materials, which were made of polydioxanone and poly L-lactic acid, respectively. Since these reports, zygomatic fractures have been considered one of the more demanding indications for biodegradable osteosynthesis and there was no further development for years. However, severe complications were only seen in the region of the frontozygomatic suture. Here biomaterials, are implanted under thin soft tissue despite the fact that biodegradation is dependent on thick soft-tissue coverage to ensure proper clearance of degradation products.

Recent reports on improved biodegradation properties of new co-polymers (*Eppley* and *Sadove*, 1995; *Peltoniemi* et al., 2002) encouraged re-evaluation of biodegradable osteosynthesis for zygomatic fractures (*Enislidis* et al., 1998 and 2005; *Eppley*, 2000).

Today, most commercially available biodegradable plates and screws require a set of specially designed instruments for their application, including heating devices to shape the biodegradable plates. By contrast with other materials, BioSorbFX® (Linvatec, Largo, FL, USA) is a biodegradable product made of self-reinforced poly (L-/DL-) lactic acid co-polymer that does not require heating before adaptation to bony contours. The use of BioSorbFX® plates and screws has been reported for simple, single mandibular fractures (*Yerit* et al., 2002) and for orthognathic surgery (*Laine* et al., 2004; *Mazzonetto* et al., 2004) but to date, there is no (published) evidence that this material would also be suitable for the fixation of zygomatic fractures.

The aim of this study was to evaluate zygomatic fracture fixation using the BioSorbFX® osteosynthesis system and to assess stability as well as any complications observed in the first postoperative year.

MATERIAL AND METHODS

From January to September 2003, 25 patients were operated upon (m:f = 20:5; age 17–81 years; mean 39.4 years) using the BioSorbFX® 2.0 and for 1.5 mm osteosynthesis systems.

Inclusion criteria were similar to a former study (*Enislidis* et al., 1998) and focused on unilateral zygomatic fractures with displacement which were not stable after reduction by simple elevation.

BioSorbFX® is the trade name of a biodegradable self-reinforced poly(L/DL)lactic acid (L:DL = 70:30) co-polymer system, which resorbs fully after approximately 4 years.

The system is available with screw diameters of 1.5 and 2.0 mm. Plates from the 2.0 mm system have a thickness of 1.2 mm, whilst plates of the 1.5 mm system have a thickness of 0.8 mm (cranial plates) or 1.0 mm (mid-facial plates, x-plates). The plates can be cut and trimmed to the desired shape (e.g. shortening a 7-hole plate) with standard surgical scissors. BioSorbFX® plates can be bent at room temperature and do not require heat to become malleable.

Surgical approach

All patients were treated under general anaesthesia. Closed reduction with a hook was first attempted. Whenever adequate reduction and stability of the zygomatic complex was not achieved, open reduction and fixation of the zygoma was undertaken. Generally, this would begin with stabilization of the zygomatico-maxillary crest via an intraoral marginal or crestal incision. The fronto-zygomatic suture and infraorbital rim as well as the orbital floor were generally approached whenever the intraoral fixation alone did not provide sufficient stability or whenever open reduction from the intraoral approach was impossible. The latter was checked intraoperatively by digital palpation at the infraorbital margin and the fronto-zygomatic suture. Any gap or step in these locations was interpreted as incorrect bony alignment and was an indication for rigid internal fixation at the corresponding sites. Indications for bridging orbital floor fractures were based on preoperative CT scan evaluation.

Postoperative follow-up

During the first postoperative week, all patients were referred to the department of ophthalmology for re-evaluation of vision, fundus, globe position and eyeball mobility. Clinical and radiographic examinations were carried out immediately after surgery and then after 1, 3, 6, 9 and 12 months (Figs 1–3). Special emphasis was laid on clinical signs of degradation such as soft-tissue swelling and induration.

Survey amongst operating surgeons

Twelve of 15 operating surgeons took part in a survey (Table 4) to assess clinical experience with different osteosynthesis systems.

RESULTS

Surgery on 25 patients with unilateral dislocated zygomatic fractures was performed by 15 surgeons. Overall, 45 plates and 208 screws (15 plates and 65 screws 2.0 mm system, 30 plates and 143 screws

Fig. 1 – Preoperative radiograph (Water's view): dislocated zygomatic fracture on the right side.

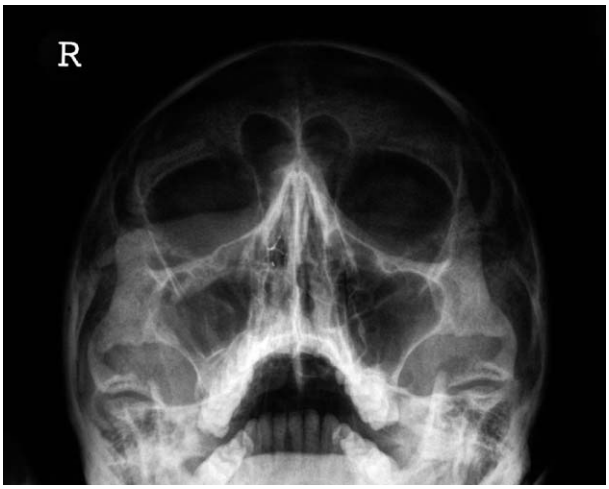

Fig. 2 – Immediate postoperative radiograph.

Fig. 3 – Six-months postoperative radiograph.

1.5 mm system) were used for fixation of these fractures. Biodegradable osteosynthesis materials were inserted in 4 anatomic locations (Table 1). Additionally, orbital floor fractures of small or medium size (smaller than 2.5 cm^2; *Baumann* et al., 2002) were bridged with biodegradable material (Ethisorb® patch, Johnson & Johnson, Norderstedt, Germany or Delta® mesh, Stryker-Leibinger, Kalamazoo, MI, USA) in two patients. Large orbital floor defects of more than 2.5 cm^2 were not encountered in this series.

Hardware distribution

Six out of the 25 fractures were stabilized by fixation at one site (zygomatico-maxillary crest), 14 by two-site fixation (zygomatico-maxillary crest plus fronto-zygomatic suture or infraorbital rim), 5 fractures were fixed by three-site fixation (zygomatico-maxillary crest and fronto-zygomatic suture and infraorbital rim). The choice of surgical access (Fig. 4) indirectly reflects fracture morphology and degree of comminution. Simple monobloc fractures were usually only stabilized at the zygomatico-maxillary crest; comminuted fractures usually required two- or three-site fixation.

Twenty-three intraoral plates were used to stabilize the fractures at the zygomatico-maxillary crest (the relation of 2.0 mm to 1.5 mm was 8 to 15). Furthermore, two plates were placed paranasally (2.0 mm:1.5 mm = 2:0) to stabilize incomplete fractures at the Le-Fort-I level. A total of 16 plates (2.0 mm:1.5 mm = 5:11) were placed via a lateral eyebrow incision for fixation of the fronto-zygomatic suture, and 4 plates were used to stabilize the infaorbital rim (2.0 mm:1.5 mm = 0:4). In 4 patients, the infaorbital rim could only be stabilized with titanium microplates due to severe comminution (Table 1).

2.0 mm vs 1.5 mm

There was a clear preference for the 1.5 mm system over the 2.0 mm system. This may be attributed to the fact that the smaller plates were easier to handle because of their lower profile, which also made the plates less palpable postoperatively.

Screw lengths

Among the 2.0 mm screws, the most commonly used length was 6 mm at the zygomatico-maxillary crest, the fronto-zygomatic suture and paranasally. As an alternative, 4 mm screws were used at the zygomatico-maxillary crest and 8 mm screws at the fronto-zygomatic suture in a few cases (Table 2).

For the 1.5 mm system, 6 mm screws were most often used. Alternatively, 4, 7 and 8 mm screws were used at the zygomatico-maxillary crest, 5 and 8 mm screws at the fronto-zygomatic suture and 5 mm screws at the infaorbital rim.

Overall, the majority of surgeons opted for a screw length of 6 mm in all three implantation sites.

Intraoperative complications

All intraoperative complications were generally easy to manage: In cases of screw breakage, the remnants were removed and easily replaced with a new screw. There was no excessive build-up of friction during insertion of screws which would have led to incomplete insertion and consequent suboptimal fixation of osteosynthesis plates. None of the screws was unable to engage bone and press the plate against the bony surface. Generally, there was little need for the use of emergency screws.

Follow-up

On the postoperative radiographs, the alignment of fragments was anatomically correct in the first instance and the position of the zygoma remained stable. Clinical evaluation revealed symmetrical appearance of the midface in all patients. Revisional surgery would have been indicated in cases of postoperative malalignment of fragments, malposition, de novo dislocation of the zygomatic bone, or zygomatic asymmetry.

The postoperative ophthalmologic examinations demonstrated normal globe position in all cases. Revisional surgery would have been indicated in cases of en-/exophthalmos and/or inferior displacement of the globe of more than $+/-2$ mm by Hertel measurement, deterioration of vision and/or restriction of eye mobility.

Two cases of local infection with swelling in the upper oral vestibule in the early postoperative period were managed by antibiotics, incision and drainage. There were no clinically or radiographically apparent adverse reactions to the biodegradation process. One other patient had an intraoral wound dehiscence which resolved after debridement and resuture (Table 3).

Results of survey

Amongst biodegradable osteosynthesis materials, there was a clear preference of surgeons for Bio-SorbFX® because this material was malleable without heat. The handling of biodegradable osteosynthesis in general was rated worse than metal osteosynthesis because of the need for pretapping before screw insertion and occasional screw breakage. However, 8 of the 12 surgeons interviewed realize the advantages for the patients offered by degradable hardware and would prefer to have their own fracture fixed by means of resorbable rather than metallic osteosynthesis (Table 4).

Table 1 – Fixation of biodegradable osteosynthesis plates according to anatomical locations

	2.0 mm screw system				1.5 mm screw system			Other	
Patient no	Zygomatico-maxillary crest	Front-zygomatic suture	Infraorbital rim	Paranasally	Zygomatico-maxillary crest	Fronto-zygomatic suture	Infraorbital rim (incl. Paranasally)	Orbital floor fracture	Infraorbital rim (titanium microplate)
1	1					1			
2					1	1		1 (Ethisorb)	2
3	1	1							
4					1	1			
5					1	1			
6					1				1
7					1	1			
8					1				
9					1				1
10					1	1			
11					1				
12	1	1		1					
13					1				
14					1	1	1		
15	1						1	1 (Delta mesh)	
16	1								
17	1	1							
18	1					1			
19	1								
20					1	1			
21						1	1		
22		1							
23				1	1				
24					1	1			1
25		1			1		1		
Total	8	5	0	2	15	11	4	2	5

DISCUSSION

Biodegradable osteosynthetic materials are known for their advantages over metal osteosynthesis due to their disappearance over time, which obviates any desire for implant removal and minimizes the risk of complications from remaining hardware.

Recent reports on the use of BioSorbFX® for elective surgery such as for mandibular and maxillary osteotomies and cranioplasties (*Haers* and *Sailer*, 1998; *Haers* et al., 1998; *Serlo* et al., 2000 and 2001; *Turvey* et al., 2002) have been promising; reports with a follow-up time well beyond the biodegradation period (*Suuronen* et al., 1999 and 2000; *Laine* et al., 2004) showed excellent long-term results. In 2002, *Yerit* et al. (2002) and *Kim* and *Kim* (2002) reported excellent results with BioSorbFX® plates and screws for fixation of mandibular fractures in 22 and 49 patients, respectively. Their findings were encouraging for the use of this material in other types of maxillofacial fractures.

In this study, the use of BioSorbFX® for fixation of displaced non-infected unilateral zygomatic fractures was evaluated in 25 patients. Intraoperative handling was rated as superior to other biodegradable systems in a survey conducted amongst 12 of 15 operating surgeons. While conventional biodegradable plates require heating for bending (Fig. 5), BioSorbFX® plates can be adapted to the bony surface at room temperature without heating. This shortens the learning curve for surgeons who are already familiar with the use of metallic osteosynthesis plates in the craniofacial area. Unfortunately, bending of conventional biodegradable plates at room temperature will result in surface cracks and consequent plate failure (Fig. 6), as has been seen in overload situations (*Kasrai* et al., 1999; *Kosaka* et al., 2003). To the best of our knowledge, BioSorbFX® is the only commercially available biodegradable osteosynthesis system which can be shaped at room temperature without risk of fracture (Fig. 7).

In this sample, there was a clear preference amongst surgeons for the 1.5 mm over the 2.0 mm system. The obvious reason for this may be to avoid placement of visible and/or palpable hardware as well as the ease of fixing smaller fragments. The fact that the 1.5 mm system was preferred did not influence stability of reduction and overall treatment outcome.

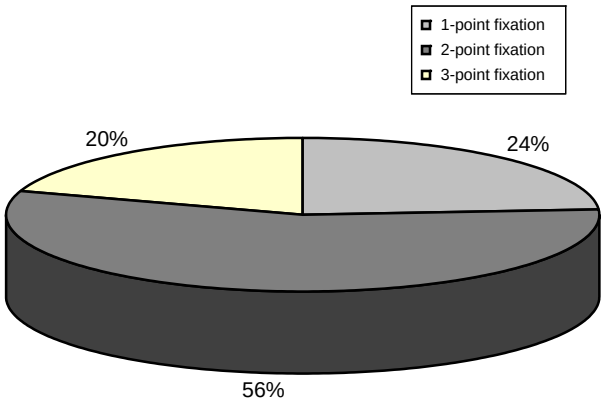

Fig. 4 – Percentage of one-, two- and three-site fixation in study sample.

Table 3 – Complications in 25 patients treated with BioSorbFX® biodegradable osteosynthesis system

Inflammation/infection	2
Wound dehiscence	1
Sterile sinus formation	0
Local osteolysis	0
Hypertrophic scar	0
Exposed implant	0
Malposition	0
Non-union	0
Malocclusion	0
Persistent sensory disturbance	0
Motor deficit	0
Ectropion	0
Ex/enophthalmos	0

Table 2 – Number of screws per anatomical location

Screw type	Length (mm)	Number of screws				
		Zygomatico-maxillary crest	Fronto-zygomatic suture	Infraorbital rim	Paranasally	Total
2.0 mm screw	4	6	1	0	0	7
	5	0	0	0	0	0
	6	24	17	0	10	51
	7	0	0	0	0	0
	8	2	4	0	0	6
	10	1	0	0	0	1
Total 2.0 mm screws		33	22	0	10	65
1.5 mm screw	4	15	0	1	0	16
	5	9	4	6	0	19
	6	45	35	12	0	92
	7	4	0	0	0	4
	8	2	9	1	0	12
	10	0	0	0	0	0
Total 1.5 mm screws		75	48	20	0	143
Grand total		108	70	20	10	208

Table 4 – Survey amongst surgeons operating on study patients

1. How many zygomatic fractures have you operated until now?	Less than 10	10–20	More than 20	
	2	2	8	
2. How many zygomatic fractures did you treat with resorbable osteosynthesis materials?	Less than 5	5–10	More than 10	
	4	4	4	
3. Comparing resorbable and metal osteosynthesis materials: how do you judge the handling of the resorbable materials?	Better than metal	Same as metal	Worse than metal	n.a.
	1	3	7	1
4. Which biodegradable osteosynthesis systems have you used already?	Biosorb	Lactosorb	Delta	Others
	12/12	8/12	9/12	2/12
5. How would you rate these systems in respect to their ease of use? (only surgeons with experience on all three materials, $n = 7$)	1,1,1,1,1,1,1	2,2,3,3,3,3,3	3,2,2,2,2,2,	
6. What are the reasons for your rating? (answers were rated according to their frequency of nomination)	(1) Biosorb needs no heating (2) Biosorb screws do not break too often			
7. What do you think are the greatest advantages of the use of resorbable osteosynthesis for the surgeon?	No second operation			
8. What do you think are the greatest problems in the use of resorbable osteosynthesis materials for the surgeon? (answers were rated according to their frequency of nomination)	(1) Handling difficulties: •Screw breakage •Tapping necessary •Stiff plates (2) Difficult fixation of comminuted fractures			
9. Comparing resorbable osteosynthesis with metal osteosynthesis: is the application of resorbable osteosynthesis material an advantage or a disadvantage for the patient?	Advantage	No difference between resorbable and metal	Disadvantage	
	8	3	1	
10. Why? (answers were rated according to their frequency of nomination)	PRO resorbable: (1) No second operation (2) No remaining foreign body CONTRA resorbable: (1) Bulky material contours are aesthetically compromising			
11. In which year of your surgical speciality training are you currently?	First year	Second year	Third year	Surgical training completed
			6	6
11. If it was you who had a zygomatic fracture and if you could be treated by an experienced surgeon: Would you choose metal or resorbable osteosynthesis material for the treatment of your own fracture?	Resorbable	Metal	Indifferent	n.a.
	8	2	1	1

n.a. – no answer.

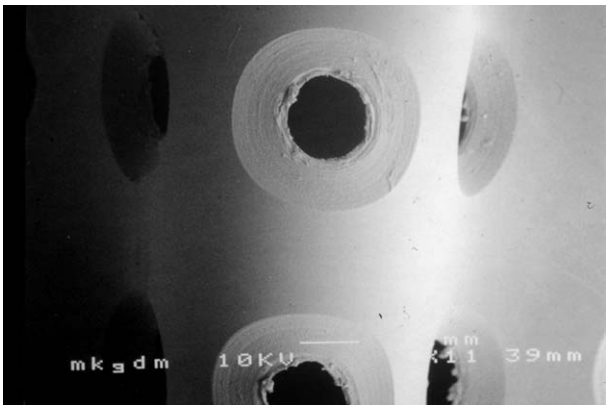

Fig. 5 – Scanning electron micrography (SEM) of Lactosorb® panel after bending in heated condition.

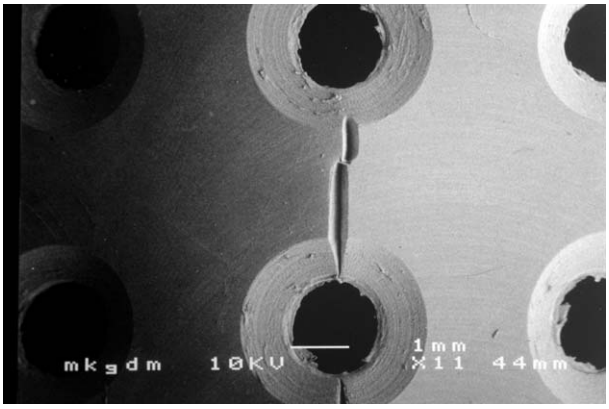

Fig. 6 – SEM of Lactosorb® panel after bending in cold condition.

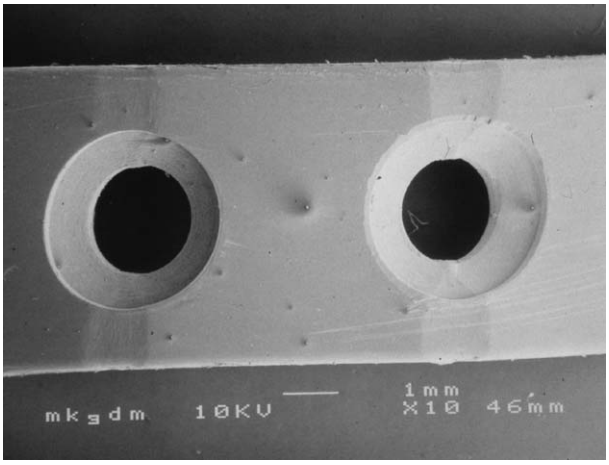

Fig. 7 – SEM of BioSorbFX® plate after bending in cold condition. Note absence of cracks.

The hypothesis that multi-fragment fractures of the zygoma (*Zingg* et al., 1992) may be a significant challenge to implant stability because the osteosynthesis material is load-bearing was not confirmed in this study sample. The 1.5 mm material was used approximately twice as often as the 2.0 mm system hardware for fracture fixation at the zygomatico-maxillary crest and at the fronto-zygomatic suture. For the infaorbital rim, either the 1.5 mm BioSorbFX® system or, in cases of severe comminution, one or two metallic titanium microplates were used. This is a drawback and means that biodegradable osteosynthetic devices can only be viewed as an addition to, and not yet a replacement for conventional metal plates and screws in this location.

Overall, biomechanical stability was not found to be compromised by biodegradable fixation. Plate fractures and consecutive dislocation of fragments were not observed. In this series, all zygomatic fractures healed uneventfully. An excessive body reaction to the degradation process was not seen. This would be clinically apparent by a temporary swelling or other signs of local inflammatory reaction. Three minor local complications occurred in the immediate postoperative phase but it was felt that any association with the biodegradable process could be excluded.

CONCLUSION

Fixation of zygomatic fractures with the BioSorbFX® system is simple and safe. Fixation results remained stable and bony healing was uneventful. Postoperative complications were few, of a minor nature and not related to biodegradation. Although clinical and radiographic results were excellent, the surgical acceptance of biodegradable materials is still clouded by the fact that intraoperative handling is not quite as simple as that of metallic fixation devices. However, there is general agreement that biodegradable materials have a clear advantage for the patient. Randomized, prospective long-term studies should be conducted to compare the results of biodegradable vs metallic osteosynthesis for fixation of zygomatic fractures.

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References

Baumann A, Burggasser G, Gauss N, Ewers R: Orbital floor reconstruction with alloplastic resorbable polydioxanone sheet. Int J Oral Maxillofac Surg 51: 367–373, 2002

Bos R: Late complications from to bioresorbable poly(L-lactide) plate osteosynthesis. J Oral Maxillofac Surg 51: 190–191, 1993

Bos R, Boering G, Rozema F, Leenslag J: Resorbable poly(L-lactide) plates and screws for the fixation of zygomatic fractures. J Oral Maxillofac Surg 45: 751–753, 1987

Enislidis G, Pichorner S, Lambert F, Wagner A, Kainberger F, Kautzky M: Fixation of zygomatic fractures with a new biodegradable copolymer osteosynthesis system: preliminary results. Int J Oral Maxillofac Surg 27: 352–355, 1998

Enislidis G, Lagogiannis G, Wittwer G, Glaser C, Ewers R: Fixation of zygomatic fractures with a biodegradable

copolymer osteosynthesis system: short- and long-term results. Int J Oral Maxillofac Surg 34: 19–26, 2005
Eppley B: Zygomaticomaxillary fracture repair with resorbable plates and screws. J Craniofac Surg 11: 377–385, 2000
Eppley B, Sadove A: A comparison of resorbable and metallic fixation in healing of calvarial bone grafts. Plast Reconstr Surg 96: 316–322, 1995
Ewers R, Förster H: Fracture and osteotomy treatment by means of resorbable osteosynthesis materials – experimental and clinical results. Abstract issue. Am Assoc Oral Maxillofac Surg 67: 23, 1985
Ewers R, Lieb-Skowron J: Bioabsorbable osteosynthesis materials. Facial Plast Surg 7: 206–214, 1991
Haers P, Sailer H: Biodegradable self-reinforced poly-L/DL-lactide plates and screws in bimaxillary surgery orthognathic: short-term skeletal stability and material related failures. J CranioMaxillofac Surg 26: 363–372, 1998
Haers P, Suuronen R, Lindqvist C, Sailer H: Biodegradable polylactic acid plates and screws in orthognathic surgery. J CranioMaxillofac Surg 26: 87–91, 1998
Kasrai L, Hearn T, Gur E, Forrest C: A biomechanical analysis of the orbitozygomatic complex in human cadavers: examination of load sharing and failure patterns following fixation with titanium and bioresorbable plating systems. J Craniofac Surg 10: 237–243, 1999
Kim Y-K, Kim S-G: Treatment of mandible fractures using bioabsorbable plates. Plast Reconstr Surg 110: 25–31, 2002
Kosaka M, Uemura F, Tomemori S, Kamiishi H: Scanning electron microscopic observations of ''fractured'' biodegradable plates and screws. J CranioMaxillofac Surg 31: 10–14, 2003
Laine P, Kontio R, Lindqvist C, Suuronen R: Are there any complications with bioabsorbable fixation devices? A 10 year review in orthognathic surgery. Int J Oral Maxillofac Surg 33: 240–244, 2004
Mazzonetto R, Paza AO, Spagnoli DB: A retrospective evaluation of rigid fixation in orthognathic surgery using a biodegradable self-reinforced (70L:30DL) polylactide. Int J Oral Maxillofac Surg 33: 664–669, 2004
Peltoniemi H, Ashammakhi N, Kontio R, Waris T, Salo A, Lindqvist C, Grätz K, Suuronen R: The use of bioabsorbable osteofixation devices in craniomaxillofacial surgery. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 94: 5–14, 2002
Serlo W, Ashammakhi N, Törmälä P, Waris T: Case report: a new technique for correction of trigonocephaly in an infant – application of an absorbable endocranial plate. Childs Nerv Syst 16: 595–597, 2000
Serlo W, Kaarela O, Peltoniemi H, Merikanto J, Ashammakhi N, Lassila K, Pohjonen T, Tormala P, Waris T: Use of self-reinforced polylactide osteosynthesis devices in craniofacial surgery: a long-term follow-up study. Scand J Plast Reconstr Surg Hand Surg 35: 285–292, 2001
Suuronen R, Haers P, Lindqvist C, Sailer H: Update on bioresorbable plates in maxillofacial surgery. Facial Plast Surg 15: 61–72, 1999
Suuronen R, Kallela I, Lindqvist C: Bioabsorbable plates and screws: current state of the art in facial fracture repair. J Craniomaxillofac Trauma 6: 19–27, 2000
Turvey T, Bell R, Tejera T, Proffit W: The use of self-reinforced biodegradable bone plates and screws in orthognatic surgery. J Oral Maxillofac Surg 60: 59–65, 2002
Yerit K, Enislidis G, Schopper C, Turhani D, Wanschitz F, Wagner A, Watzinger F, Ewers R: Fixation of mandibular fractures with biodegradable plates and screws. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 94: 294–300, 2002
Zingg M, Laedrach K, Chen J, Chowdhury K, Vuillemin T, Sutter F, Raveh J: Classification and treatment of zygomatic fractures. J Oral Maxillofac Surg 50: 778–790, 1992

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