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Clinical Paper
Trauma

Fixation of zygomatic fractures with a biodegradable copolymer osteosynthesis system: short- and long-term results

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Abstract. Biodegradable osteosynthesis devices can be viewed as addition to, not yet replacement for conventional metal osteosynthesis materials. In a series of 65 patients with zygomatic fractures, a short-term complication/sequelae rate of 22.8% and a long-term complication rate of 9.4% were recorded. Lactosorb® plates, panels and screws were the only devices used for osteosynthesis. All complications associated with the biodegradable material could be considered minor and were resolved by the use of minor surgical procedures or conservative measures. The results of this study indicate that treatment of zygomatic fractures with biodegradable osteosynthesis material has no major long-term adverse effects beyond the total material resorption time.

Key words: zygoma; fracture; biodegradable.

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In an effort to overcome the drawbacks of metal osteosynthesis, clinicians and polymer scientists have designed and tested a wide variety of homopolymer and copolymer devices over the past decades. Numerous failures[4–6,13,14] have led to the conclusion that homopolymer devices have unfavourable degradation properties and are likely to cause clinically apparent foreign body reactions, irrespective of the implant location.

In 1996, a new biodegradable osteosynthesis system for craniomaxillofacial surgery became commercially available under the trade-name of Lactosorb®. In 1984, the Lactosorb® copolymer was developed for use as a resorbable ligating clip (Poly-Surgiclip®, U.S.S.C., Norwalk, CT, USA) and since then, the material has been known for its excellent biotolerance.

To date, reports on this material indicate that its biodegradation process is clinically inconspicuous[18,27] in elective surgery. For traumatology, short-term reports[10,12] are promising, however, no long-term trauma study reports with this material have yet been published.

Implantation of biodegradable screws and plates in load-bearing areas such as the zygomaticomaxillary buttress, the infraorbital rim and the frontozygomatic suture seems to be a significant biomechanical challenge to implant stability[1–4]. Biodegradation is dependent on soft tissue coverage, which may be extremely thin in the periorbital region and on the alveolar ridge. To ensure clinically unapparent biodegradation, adequate thickness of tissues around the polymer implants allegedly is mandatory. Concerning the above mentioned, zygomatic fractures would appear to be the most demanding indication for biodegradable osteosynthesis devices.

Material and methods

This prospective study was designed to evaluate the short- and long-term outcome after fixation of zygomatic fractures with a biodegradable osteosynthesis system. A consecutive series of 65 patients (54 males, 11 females; age 9–80 years; mean age 34.48 years) with isolated dislocated unilateral zygomatic fractures was operated from July 1996 to April

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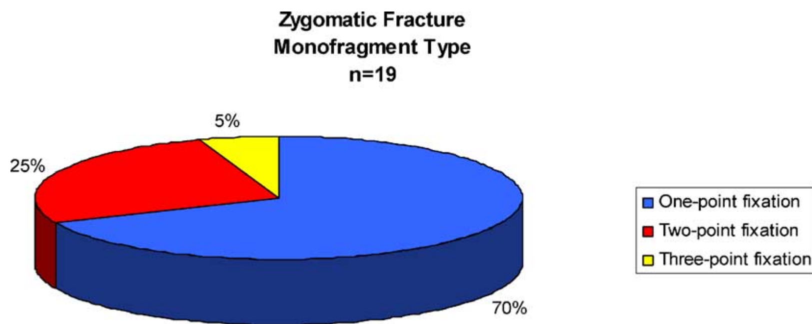

Fig. 1. Points of fixation in zygomatic fractures. I. Monofragment type.

1998 using the Lactosorb® system (Biomet Inc., Warsaw, IN, USA) for internal fixation.

Lactosorb® is the tradename of a biodegradable amorphous copolymer made of 82% L-lactic acid and 18% glycolic acid. It retains 70% of its initial strength for 6–8 weeks and, in an experimental setting[11], totally dissolved after 12–15 months.

One can readily distinguish between the 1.5 mm panels, which were used in sizes 25 × 50 mm and 50 × 50 mm, and the 2.0 mm plates. The Lactosorb® panel is the biodegradable equivalent to a metallic mesh. Once heated and malleable, this resorbable mesh can be trimmed with a pair of scissors. The thicker plates can be rendered malleable, both panels and plates can be trimmed with a pair of scissors and easily adapted to the bone surface. The plates are generally fixed with 2.0 mm screws (emergency screws: 2.5 mm), and the panels with 1.5 mm diameter screws (emergency screws: 2.0 mm).

Patients with infected midface fractures were excluded from our prospective study. In no patients was there simultaneous use of biodegradable and metallic material in the midface. In our opinion, the data supporting the use of mixed materials is insufficient.

Surgical approach

Under general anaesthesia, the patients first underwent attempted closed reduction with the Langenbeck hook. Whenever adequate reduction and stability of the zygoma were achieved, patients were extubated and excluded from this study. When mobility of the zygomatic complex persisted, open reduction and osteosynthesis of the fragments with the Lactosorb® system were performed. First step was the inspection of the zygomaticomaxillary buttress via an intraoral approach using a gingival margin/crestal incision. The zygomaticofrontal region, the infraorbital region and the orbital floor were surgically approached whenever necessary to achieve correct anatomical repositioning of the zygoma and orbital floor, respectively.

The extent of the surgical procedure varied depending on zygomatic bone integrity. Forty-six patients with multifragment fractures and 19 patients with monofragment fractures were treated by open reduction and fracture fixation using the Lactosorb® system. In 70% of the monofragment fractures, sufficient stabilization (after anatomic reposition) could be achieved via an intraoral approach with one-point-fixation (Fig. 1). In contrast, two thirds of patients with multifragment fractures had to undergo both an intraoral, and at least one extraoral, approach (Fig. 2).

Investigation methods

Phase 1

The first goal of this study was to assess the short-term complication rate after fixation of zygomatic fractures with biodegradable implants. Clinical examinations were performed at 1, 4, 12 and 24 weeks postoperatively with the aim of detecting early osteosynthesis failures and early adverse reactions during biodegradation.

Phase 2

In those patients in whom early complications were seen the follow-up period was extended beyond 24 weeks.

Patients without early complications who underwent non-fracture-related treatment at the clinic after the 6-month postoperative period (e.g., periodontal surgery) were also examined for postoperative complications.

Phase 3

The second aim of this study was to assess the long-term complications of biodegradable osteosynthesis material for stabilization of zygomatic fractures. Patients were contacted a minimum of 5 years after trauma surgery to collect data on the postoperative period and the final outcome. The telephone interview was conducted by a specially trained assistant. The interview protocol was standardized and consisted of three general questions and varying additional questions to complete the database for the complication worksheet.

Results

In our series, 151 plates, panels and 609 screws were used for the fixation of 65 unilateral zygomatic fractures. Biodegradable materials were inserted in seven anatomic locations (Figs. 3 and 4).

Nineteen monofragment zygomatic fractures were fixed with 19 plates and 10 panels using 128 screws (Fig. 3). In these fractures, the 2.0 mm plates were the predominant means of fixation and were placed at the zygomaticomaxillary buttress, which was the first surgical site to be entered via an intraoral approach. Alternatively, a 1.5 mm panel was used on this site when the bone was very thin. Whenever necessary for optimal stabilization, 2.0 mm plates or 1.5 mm

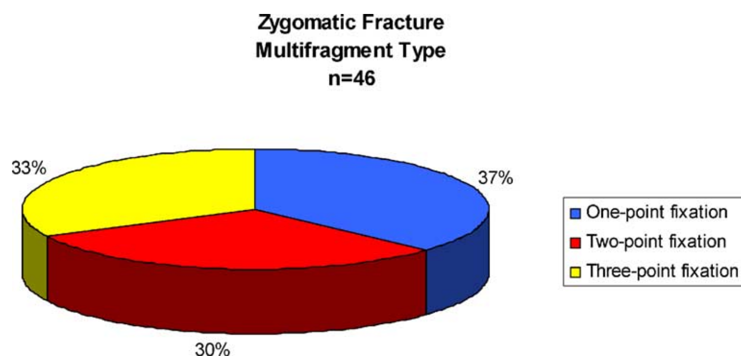

Fig. 2. Points of fixation in zygomatic fractures. II. Multifragment type.

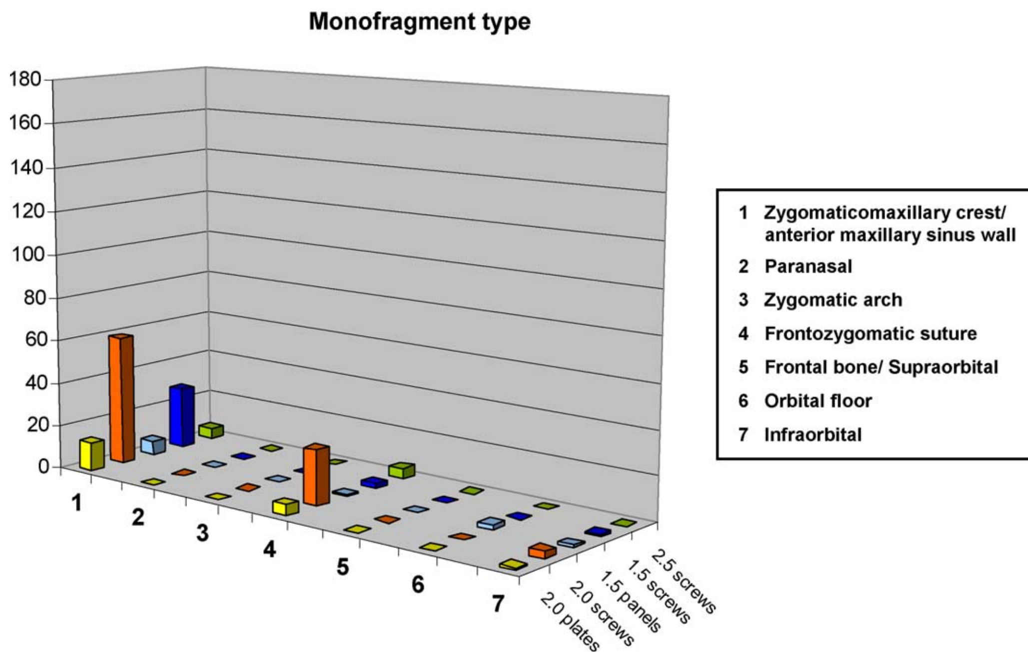

Fig. 3. Distribution of plates, panels and screws in zygomatic fractures. I. Monofragment type.

panels were employed at the frontozygomatic suture.

Forty-six multifragment zygomatic fractures were stabilized with 65 plates and 57 panels using 481 screws (Fig. 4). The 2.0 mm plates served as fixation at the zygomaticomaxillary buttress, but, in contrast to the monofragment fractures, 1.5 mm panels were more frequently used as an alternative, especially in cases of severe comminution. For 2- and 3-point fixation, 2.0 mm plates were predominantly used at the frontozygomatic suture and 1.5 mm panels or 2.0 mm plates—depending on degree of communication and bone thickness—in the infraorbital area.

Nineteen panels were used to bridge 18 orbital floor defects (2 in monofragment and 17 in multifragment cases). The irregular number of panels arises from the fact that two panels had to be used in one multifragment patient to bridge the orbital floor defect.

In 5 of these 18 sites, the panels simultaneously served as fixation for fractures of the infraorbital rim, using a technique previously described[9]. However, these panels were only counted once, namely in the ''infraorbital rim'' section.

Both plates and panels were generally well accepted by surgeons; 1.5/5 mm screws were most commonly used for the fixation of 1.5 mm panels, and 2.0/7 mm screws for the 2.0 mm plates. In

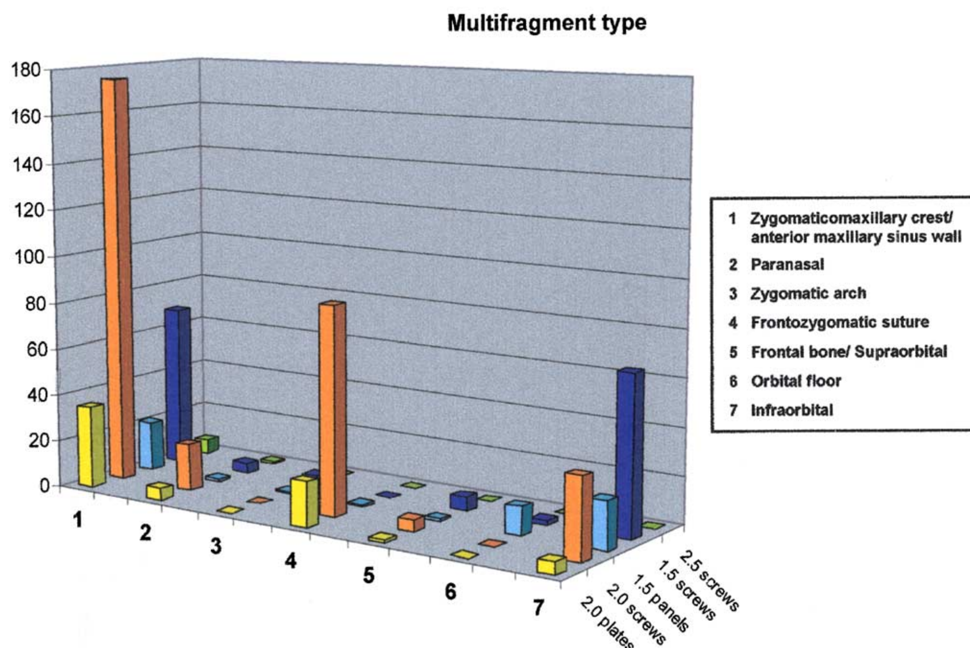

Fig. 4. Distribution of plates, panels and screws in zygomatic fractures. II. Multifragment type.

exceptional cases, 2.5 mm emergency screws had to be used when a 2.0 mm screw did not engage in bone due to stripping of the screwhole during tapping.

Intraoperative complications were generally easy to handle. There were three types of technical difficulties associated with the Lactosorb® screws: incomplete screw insertion, screw breakage and stripping of the screw holes.

First, inadequate tapping resulted in inability to fully seat nine screws. This problem was encountered most often in 2.0 and 2.5 mm screws that were greater than 7 mm length. In order not to risk screw breakage, we left these screws in place.

Second, the intraoperative breakage of nine screws, predominantly of 2.0 and 2.5 mm diameter and of more than 7 mm length, was observed; the screw failures were estimated to be mainly caused by insufficient pre-tapping and consequently excessive friction between bone and screw, overpowering the copolymer material stiffness. Whenever stability could be obtained by fixing the plate or panel with the other screws, the remnant thread particle was left in place.

Third, 11 screws were registered as spinners, meaning that they were unable to engage bone and press the plate or panel against the bony surface. In most cases, these screws still were capable of at least helping to retain the osteosynthesis plate or panel, and were therefore left in place despite being loose. When better fixation was needed, the spinners were removed and replaced with emergency screws.

In our clinical concept, the presence of an experienced surgeon was imperative for successful completion of the operative procedures. In Vienna, the author and/or specially trained co-workers were present in the operating theatre, either performing surgery themselves or assisting with the operation. After 5–10 assisted procedures, colleagues were able to perform operations with the Lactosorb® system on their own. This oversight allowed for quality management, systemized the indications for surgery, and standardized intraoperative handling of the Lactosorb® osteosynthesis system for all procedures.

Follow-up

In our analysis, a distinction was made between posttraumatic sequelae and postoperative complications. The records of phases 1–3 are listed in Table 1 and Fig. 5.

Table 1. Postoperative complications in 16 of 53 patients (observation period >5 years)

Complication	n
Dehiscence without implant exposure	4
Dehiscence with implant exposure	1
Temporary swelling	2
Maxillary sinusitis	2
Hypertrophic scar	2
Temporary ectropion	3
Long-term ectropion	5
Total	19

Phase 1 (from 0 to 6 months postoperative)

Clinical examinations up to 24 weeks were performed in 65% of patients ($n = 42$). Twenty-three patients were lost to clinical follow-up during the first 6 months; the complications they suffered until their drop-out, however, were added to our count.

Fifteen of these 23 patients were recontacted in phase 3 and the data on complications was added to the 6 month complication rates.

Conventional radiographs were taken immediately postoperatively and at the 24-week-follow-up visit; patients number 1–30 underwent additional axial and coronal CT scanning at the first postoperative evaluation and after 6 months. Although the stabilization material could not be seen in the scans excellent skeletal stability during the first 6 months was consistently found. As a consequence of this finding, it was decided to alter the study protocol and omit the 6-month CT scan for the subsequent patients.

Clinically, the postoperative position of zygomaticomaxillary complexes remained symmetrical in all cases. Adverse reactions to biodegradation were not observed.

Combining the 42 patients followed for 6 months with the 15 reached after 5 years, information on posttraumatic complications in 57 patients was analysed.

Fourteen percent ($n = 8$) out of these 57 patients complained of posttraumatic sequelae (hypaesthesia or dys/paraesthesia lasting longer than 6 months). An additional 22.8% ($n = 13$) of the 57 patients had a total of six sequelae (hypaesthesia or dys/paraesthesia lasting longer than 6 months) and 15 early postoperative complications (four intraoral dehiscences without implant exposure, one dehiscence with implant exposure, three temporary ectropia, five long-term ectropia and two hypertrophic scars).

The four intraoral dehiscences without implant exposure occurred 2, 2, 4 and 13 weeks postoperatively and all resolved after 1–4 weeks without treatment.

The intraoral dehiscence with implant exposure occurred 15 weeks after trauma surgery and lasted 20 weeks. All attempts at secondary wound closure by suturing failed; healing of the dehiscence could only be induced by repetitive local removal of polymer debris and topical application of antibiotic ointments.

A total of eight cases of ectropion after subciliary approach were documented; one of the temporary ectropia was resolved by early surgical correction, since the patient insisted on the procedure; the outcome was favourable (Patient No. 8). The diagnosis of persistent (long-term) ectropion was established and documented as a complication 6 months after onset and confirmed to still be present by telephone interview after a minimum of 5 years.

Phase 2 (6 months to telephone interview)

Two patients suffered from temporary swelling which occurred at 12 months after trauma surgery and lasted 3 months in the first case and started 13 months after trauma surgery and lasted 2 weeks in the second case. Additionally two cases of symptomatic maxillary sinusitis on the operated side were registered, one of them occurring concomitantly with the temporary swelling of the first case mentioned above. The sinusitis lasted 4 weeks in both patients and was treated successfully with antibiotics.

Another patient suffered a second trauma during a game of basketball. He was hit on the infraorbital rim 12 months after infraorbital fracture fixation with the Lactosorb® osteosynthesis system. Clinically, there were no signs of refracture, however, he developed what appeared to be a haematoma in the medial aspect of the infraorbital rim; the patient further reported recurring oedema in the infraorbital region in the morning. After 10 weeks of observation, the haematoma resolved spontaneously. The instance was registered as postoperative finding but not as complication.

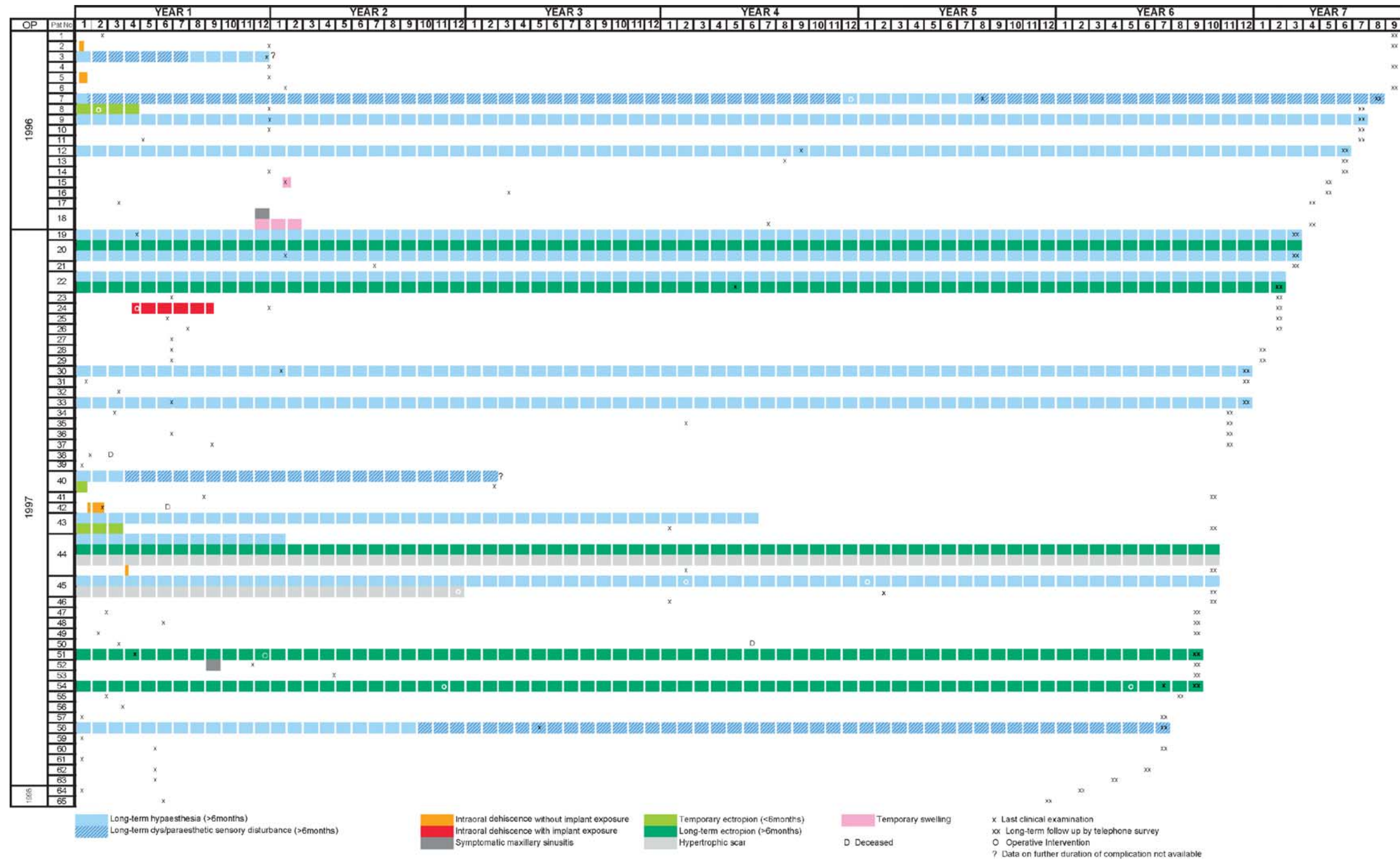

Fig. 5. Posttraumatic sequelae/postoperative complications.

Overall, the average clinical follow-up was 14.2 months (1–67 months).

Phase 3 (telephone interview after a minimum of 5 years after trauma surgery)

81.5% ($n = 53$) of all patients were reached by telephone in phase 3 (minimum follow-up of 5 years after trauma surgery; mean postoperative follow-up 72.7 months; range 60–81 months) (Fig. 5).

Eight of 53 patients (15.1%) suffered from long-term posttraumatic hypaesthesia or dys/paraesthesia, which were counted as posttraumatic sequelae.

An additional 5 of 53 patients (9.4%) had a total of two long-term posttraumatic sequelae (hypaesthesia) and six long-term postoperative complications (five persistent ectropia and one persistent hypertrophic scar). No biodegradation-related complications were found.

Discussion

Miniplate removal following trauma surgery is indicated in approximately 10% of cases and is mainly caused by infection and/or dehiscence, pain, interference with denture position, screw or plate failure, and palpability[21]. There is no evidence to support routine removal of titanium maxillofacial plates due to corrosion up to a period of 13 years[19].

The benefits of bioabsorbable osteosynthesis materials, such as obviating the need for implant removal, minimizing the risk for complications by remaining hardware, less interference with craniofacial growth in children and postoperative radiotherapy, no disturbance in post-operative imaging, no sensitivity in cold weather, gradual transfer of stress to bone and easy placement of dental implants clearly outweigh possible complications in modern commercially available systems.

Polymer science is at a point where pure experimental work on prototypes is being superceded with an increasing number of clinical reports[7,9,12,15–18,20,24,25,27,28] using commercially available products. Early complications with biodegradable materials are mostly caused by inappropriate surgical technique, whereas late complications are related to the biochemical composition of the material. One of the exceptions to this rule may well be the late appearance of soft tissue swelling, which may partly be due to inappropriate soft tissue coverage over the implants.

The causes for soft tissue swelling in the course of degradation are generally not well understood. Two pathogenesis theories have been proposed: first, as mentioned above, inadequate soft tissue thickness around the implants and hence poor absorption of degradation products.

Second, sudden increase of degradation products, possibly caused by unnoticed minimal secondary trauma to the implantation site, causing disintegration of implanted materials and scattering of polymers into the adjacent tissues, thereby overwhelming the local clearance mechanisms.

It can be stated that the individual morphology of the patient at a particular anatomical site, for example, the infraorbital rim, should dictate whether or not to implant a biodegradable osteosynthesis material and if so, whether to use a rapidly or slowly degrading one.

Rapid degradation may contribute to an increased demand for body clearance and thereby may be hazardous in situations with insufficient soft tissue coverage. On the other hand, slowly degrading devices are said to seldom overpower the local clearance capacity.

Exposure of biomaterials is thought to have a similar pathogenesis; insufficient soft tissue coverage could be one of the main reasons. Interestingly, this complication occurred only intraorally in our sample. Our complication rate of 1.9% compares favourably with the 1.7% rate of exposure of titanium miniplates[21].

Fibrous encapsulation is normal in polymer degradation. Numerous macrophages and multinucleated giant cells digest the polymer debris in the connective tissue capsule.

Hypertrophic scarring, as seen twice in our sample, was not associated with excessive fibrous reaction to degradation and therefore not an implant-related complication.

Apart from temporary swelling and intraoral exposure of biomaterials the late onset of maxillary sinusitis in 3.8% was considered to be the third implant-associated complication seen. Zingg et al.[29] reported a 2.2% incidence of symptomatic maxillary sinusitis in his series of zygomatic fractures with metallic fixation.

Telephone interview was chosen for assessment of long-term outcome; specific questions were formulated after evaluation of the complications expected. Sensory disturbance, ectropion, scarring, and inflammatory reactions were clearly identified and described by our patients.

Clinically unapparent complications such as temporary intrabony sinus formation could not be detected; their assessment, however, may have limited value for health care.

The detection of complications noticeable to the patients was our main goal. Any radiological or clinical follow-up was deliberately omitted and our utmost efforts were directed toward long-term (>5 years) patient recall.

There was no distinction made between scleral show and ectropion, because the difference could not be assessed by telephone interview. Neither was it possible to assess globe malposition or midface asymmetry. This is a weakness of telephone interviews. However, short-term clinical follow-up would have shown any posttraumatic dysmorphology; moreover, patients tend not to distinguish between ectropion and scleral show since both alike lead to an untoward aesthetic appearance clearly detected by the patient. In our series, we found 10.7% (3 of 28 subciliary approaches) had temporary and 17.9% (5 of 28 subciliary approaches) had long-term ectropion after a subciliary approach. In the literature, rates for transient ectropion vary from 6 to 37% and from 0 to 28% for permanent ectropion/scleral show with the subciliary approach[8].

In our series, long-term sensory disturbance of the infraorbital nerve in 10 of 53 cases (18.9%) was recorded. According to the literature, the incidence of long-term neurosensory deficits in zygomatic fractures ranges from 10 to 50%[26]. Our data compares favourably with the numbers given by Rohrich & Watumull[23] (19.1% decreased cheek sensation after a mean follow-up period of 2.6 years) and Zingg et al.[29], who recorded 30.9% sensory disturbance in monofragment and 22.6% in multifragment fracture types after a mean follow-up period of 1.5 years.

Overall, our complication rate compares favourably with the literature, although a selection bias, which rather reflects the worst-case situation, occurred during phase 3. Patients lost to follow-up are rather free of complications/sequelae, as can be derived from the data of the 15 patients who were recontacted in phase 3 (5 years after having lost them in phase 1); none had suffered any adverse event.

Early complications, occurring before bony healing, were easily treated conservatively with anti-inflammatory local measures, whereas late complications,

taking place after bony healing, required aggressive measures, for example, the removal of exposed biomaterials. The use of systemic antibiotic treatment was generally not required, unless there were clear signs of bacterial infection like in maxillary sinusitis.

Apart from untoward biodegradation properties, i.e. adverse reactions in the course of biodegradation to zero remnant, clinicians are primarily interested in the handling properties of surgical devices and in the universal applicability of one material for all age groups and anatomic skull regions. The latter is questionable, since the biochemical and biomechanical properties of one biodegradable material cannot be suitable for all purposes. The individual choice of material should be made on a case by case basis selecting from currently available product lines. Surgeons will therefore have to undergo continuing education to become acquainted with the demands of the various commercially available biodegradable osseofixation materials; it is generally accepted that polymer material differences have a far greater clinical significance than those of metals[22].

From a technical standpoint, the 1.5 mm panels can be adapted to the bony surface of the zygomaticomaxillary butress and anterior sinus wall like a corset. In cases of bony comminution, the individual fragments can be screwed to the panel with the 1.5 mm screws to form a puzzle-like mosaic beneath the sheltering panel. The cranial aspect of the panel is then fixed to the body of the zygoma while the caudal end is fixed to the alveolar bone. In retrospect, this was the easiest method for reconstruction of the vertical dimension of the zygomaticomaxillary buttress in cases of gross disruption. The disadvantage of this method lies in potential postoperative dehiscences at the mucogingival border above the caudal end of the panel. Whether the intraoral dehiscences with implant exposure were induced physically (i.e. by mechanical pressure from the dental prosthesis), chemically, or just a result of poor oral hygiene cannot be determined in retrospect.

The curved 6-hole 2.0 mm plate was the predominant form of osteosynthesis along the zygomaticofrontal suture; adaptation in this area is easy, and stability of osteosynthesis most important. The bony structures will easily accept the 2.0/7 mm screws. In our series, surgeons deliberately refrained from reducing the plate size and from shaping the plate surface, which is sometimes advocated to decrease the postoperative transcutaneous palpability; in our follow-up, plate contours were not palpable after the first postoperative year.

The infraorbital rim fractures were rather stabilized with a 1.5 mm panel than with a 2.0 mm plate. In some cases, the panel bridging an orbital floor defect was bent over the infraorbital rim[9] and used for osteosynthesis of the fractured infraorbital rim as well.

In summary, the intraoperative handling of biodegradable osteosynthesis involved a learning curve, however, intraoperative complications were of minor nature and could easily be solved. The incidence of postoperative complications which are not related to degradation was found to be similar to zygomatic fractures fixed with metallic osteosynthesis. Postoperative complications related to biodegradation occurred as expected during the degradation period, were rare and of minor nature. The results of this study indicate that treatment of zygomatic fractures with Lactosorb® biodegradable osteosynthesis material has no major long-term adverse effects related to biodegradation.

Acknowledgments. The author wishes to dedicate this article to Professor Rolf Ewers, head of the Vienna University Clinic for Oral and Maxillofacial Surgery, on occasion of his 60th anniversary. Over the years, Professor Ewers has fostered dozens of innovative projects and thereby has contributed significantly both to international research and development as well as to improvement in patient care.

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