An evaluation of the clinical application of three different biodegradable osteosynthesis materials for the fixation of zygomatic fractures

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Objective. The aim of this prospective study was to compare the clinical handling of 3 different biodegradable osteosynthesis materials and to determine whether they can be used for the fixation of all types of zygomatic fractures.

Study design. A total of 54 consecutive patients who presented with displaced fractures of the zygomatic bone between October 2001 and May 2003 were randomly allocated to 3 biodegradable material groups for the fixation of the fractures. A titanium fixation system was used as rescue osteosynthesis whenever biodegradable materials failed.

Results. Seventy-one (75.5%) of 94 fracture sites were fixed with biodegradable osteosynthesis; 23 (24.5%) had to be fixed with titanium plates and screws. No statistically significant difference was found between the 3 biodegradable materials with regard to their suitability for zygomatic fracture fixation (P = .16). Nonstable fixation (n = 7) or the need to fix small fragments (n = 16) were the reasons for using the titanium fixation system as rescue osteosynthesis at these sites. Biodegradable materials were most frequently unfeasible for use at the infraorbital rim and in the zygomaticomaxillary/anterior sinus wall area.

Conclusions. It was possible to stabilize 3 of 4 zygomatic fractures with 1.5- or 1.7-mm biodegradable osteosynthesis. Insufficient fracture stabilization, especially at the infraorbital rim and the zygomaticomaxillary crest/anterior sinus wall, was the main reason to switch to titanium osteosynthesis. The biodegradable screw design is possibly too bulky for these particular bony structures.

Biodegradable materials have been clinically tested for the fixation of facial fractures for about 2 decades. A biodegradable device must be safe as well as effective. It must be sufficiently small and flexible to be applied at various craniofacial bone sites. The materials commonly in use are poly-α-hydroxyl acids. Polymers and copolymers of poly-L-lactic acid (PLLA), poly-D-lactic acid (PDLA), polyglycolic acid (PGA), and polydioxanone-sulphate (PDS). Currently, copolymers of PLLA, PDLA, and PGA are given preference over pure PLA and PGA, which are associated with adverse reactions. A copolymer of PLLA/PGA acid in a ratio of 82/18% (Lactosorb) was the first commercially available material for the fixation of maxillofacial fractures.

The early application of biodegradable materials in maxillofacial trauma included the treatment of zygomatic fractures. One reason for the use of biodegradable devices in this location is that the zygoma is a low-load bearing region of the facial skeleton. Subsequently, owing to the nonoptimal handling and material characteristics of biodegradable devices, several combinations of polymers were developed for this purpose.

Biodegradable materials combine the benefits of rigid fixation with the advantages of biodegradation, obviating the need for their removal, minimizing the risk of other complications such as injuries by hardware in case of refracture, and causing less interference with craniofacial growth in children and with postoperative radiotherapy. Despite the many theoretical benefits that biologic systems may have, the size of the devices, their
adaptability, and other clinical handling properties have been found to be inferior to titanium fixation systems.\textsuperscript{2,3}

The aim of this prospective study was to compare the clinical handling of 3 different biodegradable osteosynthesis materials and to determine whether they are applicable in all cases of zygomatic fracture fixation. To our knowledge, clinical applications of different commercially available biodegradable osteosynthetic materials for the treatment of facial bone fractures have not been previously compared.

**PATIENTS AND METHODS**

Fifty-four consecutive patients who presented at our department with displaced fractures of the zygomatic bone between October 2001 and May 2003 were randomly allocated to 3 different biodegradable fixation materials (group A. LactoSorb, n = 18; group B. BioSorb, n = 18; group C. Delta, n = 18). Exclusion criteria were severely 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. Coronal CT scans were obtained in cases of clinical signs of orbital floor fractures. All patients were treated within 24 hours of presentation. All procedures were carried out by 2 surgeons experienced in handling biodegradable and titanium fixation systems.

**Surgical procedures**

All procedures were performed under general anesthesia with endotracheal intubation. Whenever the Volkmann bone hook did not provide sufficient reduction or primary stability of the replaced zygoma, the fracture site was approached through a marginal gingival incision in cases of zygomaticomaxillary, anterior sinus wall, and parasal bone involvement. The frontozygomatic suture fixation was approached through a lateral eyebrow incision if the fracture was displaced at this site. In cases of displaced orbital floor fractures, the infraorbital margin and the orbital floor were approached through a subciliary incision. Following adequate reduction, the fractures were stabilized with biodegradable plates and screws. Combinations of straight, L-, Y-, and double-Y-shaped plates were used in all groups.

Whenever stable fixation was not possible and/or small fragments could not be fixed with biodegradable plates and screws, a conventional titanium fixation system with 2.0-, 1.5-, or 1.0-mm screws and plates (Martin Corp, Tuttlingen, Germany) was used for fixation of the fracture sites.

Ethisorb (Ethicon, Norderstedt, Germany) patches or autogenous bone grafts were applied to the floor of the orbital cavity in cases of herniation of the orbital contents into the maxillary sinus. Surgical wounds were irrigated and closed in layers. All patients were given antibiotic prophylaxis (clindamycin, 1800 mg per day) for 7 days after the operation. Every surgeon completed a questionnaire that registered fracture morphology, the type of materials used, and any complications encountered.

**Biodegradable materials.** From the LactoSorb 1.5 system (Walter Lorenz Surgical, Jacksonville, Fla), which is a copolymer of PLLA and PGA in a ratio of 82/18%, we used screws 1.5 mm in diameter and 5 or 7 mm in length to fix the plates (thickness 0.5/1 mm, width 5.5 mm). The instruments included a drill for the screws, custom diameter taps, and a custom screwdriver. The driver consists 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 includes a heat pack containing calcium chloride, which has to be filled with distilled water in order to be activated. After reduction of the fracture, the flexible template is bent to the contour of the bone. By placing the plates in the folded heat pack, the copolymer is heated above its glass transition temperature (approx. 85°C) and the material rendered malleable for 10-20 seconds. The plate is then held together with the template to achieve the desired shape. An activated heat pack provides sufficient heat for about 20-30 minutes.

From the BioSorb FX 1.5 system (Bionx Implants Linvatec Corp, Largo, Fla), which is a self-reinforced copolymer of PLLA and PDLA in a ratio of 70/30%, we used 1.0-mm-thick and 5.5-mm-wide plates with screws of 1.5 mm diameter and 4 or 6 mm length. The instrumentation consists of an appropriately sized bone drill, a bone tap, a screwdriver, and bending forceps. Biosorb FX plates do not require heating before use and can basically be handled like titanium plates.

From the 1.7-mm Delta system (Stryker Leibinger Corp, Freiburg, Germany), a copolymer of PLLA, PDLA, and PGA in a ratio of 85/5/10%, we used 1.0-mm-thick and 6.0-mm-wide plates with screws 1.7 mm in diameter and 4, 5, or 6 mm in length. The 1.7-mm Delta system was designed for midface fractures; screws for this system are available in a diameter of 1.7 mm but not 1.5 mm. Flexible templates, torque-limiting screw-drivers, a water bath system, a contouring pen, and self-drilling taps are included in the armamentarium. After reduction of the fracture, the desired template is adapted to the contour of the bone, the appropriate biodegradable plate held together in the water bath system, and the plate heated above its glass transition temperature (approx. 70°C). Thus, the plate takes the shape of the template. The contouring pen is used for in situ contouring of plates. The dimensions of the biodegradable
plates are compared with a 2.0-mm titanium plate in Fig 1.

Statistical analysis

All data were analyzed using the SPSS for Windows (version 11.0; SPSS, Chicago, Ill) statistical software package. Descriptive statistics and $\chi^2$ tests were used when appropriate. The significance level was set at $P < .05$.

RESULTS

The patient population consisted of 11 women and 43 men with an average age of 36 years (range 17 to 71 years). Figure 2 shows the distribution of biodegradable/titanium plates and screws for each patient. A combination of biodegradable and titanium plates and screws was necessary for 6 patients in group A and for 2 patients in each of groups B and C. Titanium plates and screws were applied exclusively for 3 patients in group A and 1 patient in each of groups B and C. Overall, biodegradable materials had to be combined with titanium osteosynthesis in 10 of 54 patients (19%) and could not be applied at all in 5 of 54 patients (9%) with zygomatic fractures.

Ninety-four fractured sites (group A, n = 35; group B, n = 30; group C, n = 29) were accessed for osteosynthesis. However, biodegradable osteosynthesis could only be applied at 71 (75.5%) sites (group A, n = 22; group B, n = 25; group C, n = 24). No statistically significant difference was found between the 3 biodegradable materials with regard to their applicability for the fixation of zygomatic fractures ($P = .16$). Insufficient engagement of bone (screw pull-out) ($n = 7$) or the inability to fix small fragments ($n = 16$) were the reasons for using titanium fixation system as rescue osteosynthesis at 23 sites (24.5%). Nineteen (82.6%) of these 23 sites were in the infraorbital region and the zygomaticomaxillary/anterior sinus wall area. In addition, as it was not feasible to treat 11 of 13 fractures at the infraorbital rim successfully with the biodegradable systems, these had to be managed using titanium osteosynthesis.

The most common location in which biodegradable materials could not be used was the infraorbital rim, followed by the zygomaticomaxillary/anterior sinus wall area; the frontozygomatic suture and the paranasal region were less problematic ($P < .01$).

The location of fractures and the materials used for osteosynthesis are shown in Table I. No fracture of biodegradable plates was registered in any of the 3 groups. A total of 24 screws were lost during the procedure (Table II). No statistically significant difference was found in screw failure among the 3 systems. Figure 3 shows the screw and screwdriver design of the 3 biodegradable systems. No immediate postoperative complications were encountered in any of our patients.

DISCUSSION

Biodegradable materials for the fixation of maxillofacial fractures are becoming popular among surgeons worldwide. These materials combine the benefits of rigid fixation with the advantages of biodegradation, obviating the need for implant removal, minimizing the risk of other complications such as injuries by hardware in cases of refracture, and causing less interference with craniofacial growth in children and with postoperative radiotherapy.$^{3,7}$

To our knowledge, this is the first prospective study comparing 3 different biodegradable systems for the fixation of zygomatic fractures.

Ninety-four fracture sites were accessed, but stable fixation with biodegradables could be achieved only at 71 (75.5%) sites. At the remaining 23 (24.5%) sites, the surgical staff decided to switch to titanium osteosynthesis for stable fixation. The impossibility to engage thin bone structures and/or to fix small fragments of bone was the main reason for using titanium plates and screws as a rescue form of fixation. This circumstance was encountered almost equally often with the 3
systems. The bulk and diameter of the currently available biodegradable materials are the main factors hindering their use for the fixation of small bone fragments. Small fragments of bone can be fixed better with metal implants. The need to reduce the bulk of the biodegradable materials without compromising on their strength has been emphasized earlier.

An analysis of those cases in which the biodegradable materials could not be used revealed that the infraorbital margin and the zygomaticomaxillary crest/anterior sinus wall were the most problematic zones and accounted for 82.6% of intraoperative switches to titanium osteosynthesis. Consequently, the frontozygomatic suture was found to be the optimum location for the placement of biodegradable osteosynthesis; most appropriate anchorage of screws and most stable fixation were achieved at this site. In this respect, biodegradable osteosynthesis is best placed at the frontozygomatic suture in cases of 1-, 2-, or 3-point fixation. When it comes to fixation of fractures at the infraorbital margin or at the zygomaticomaxillary suture, biodegradables are still useful in monobloc fracture types, but the limitations of biodegradable materials may become obvious in multifragment cases. As a clinical concept, it might be preferable to combine biodegradables at the frontozygomatic suture with titanium osteosynthesis for all other locations of comminuted fractures. The patient would benefit from this combination because removal of hardware is less invasive and scarring at the eyebrow may be minimized.

Generally, intraoperative handling of biodegradable materials is subject to a learning curve. A small number of surgeons were involved in the present study and the team was experienced in handling biodegradable osteosynthesis materials. There was no apparent difference in the handling characteristics of the 3 biodegradable plates used in this study, with the exception of the Lactosorb and Delta plates, which required heating before application, whereas the BioSorb plates could be easily bent with forceps at room temperature. None of the plates failed during surgery or in the early postoperative period. Patients in group A required fixation at the infraorbital rim more frequently than those in any of the other groups; a thorough data analysis revealed that this patient sub-group had comminuted fractures at the infraorbital rim which needed fixation to reconstruct the infraorbital rim. The fact that more patients with infraorbital fractures were allocated to group A was considered a limitation of this study.

Table I. Location of fractures and osteosynthetic materials applied

<table>
<thead>
<tr>
<th>Fracture site</th>
<th>Zygomaticomaxillary ant. sinus wall</th>
<th>Zygomaticofrontal</th>
<th>Infraorbital</th>
<th>Parasagittal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B</td>
<td>T</td>
<td>B</td>
<td>T</td>
</tr>
<tr>
<td>Group A</td>
<td>12</td>
<td>4</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>Group B</td>
<td>13</td>
<td>2</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>Group C</td>
<td>15</td>
<td>2</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>40</td>
<td>8</td>
<td>24</td>
<td>3</td>
</tr>
</tbody>
</table>

B, Biodegradable system; T, titanium system.

Table II. Total number of screws applied for each system and screw failures registered during the surgical procedures

<table>
<thead>
<tr>
<th>Used screws</th>
<th>Lost screws</th>
<th>Total screws</th>
</tr>
</thead>
<tbody>
<tr>
<td>LactoSorb 1.5</td>
<td>104</td>
<td>7</td>
</tr>
<tr>
<td>BioSorb FX 1.5</td>
<td>137</td>
<td>14</td>
</tr>
<tr>
<td>Delta 1.7</td>
<td>118</td>
<td>3</td>
</tr>
</tbody>
</table>

Fig 3. Biodegradable screws with appropriate screw-drivers. A, LactoSorb 1.5. B, BioSorb FX 1.5; C, 1.7-mm Delta.
stripping. Breakage beneath the screw head during insertion occurred in some cases.

In conclusion, it was possible to stabilize 3 out of 4 zygomatic fractures (75.5%) with 1.5-mm or 1.7-mm biodegradable materials. Overall, 5 of 54 patients (9%) received only titanium osteosynthesis and 10 patients (19%) were treated with a mix of biodegradable material and titanium. Insufficient fracture stabilization, particularly at the infraorbital margin and the zygomatico-maxillary crest/anterior sinus wall, was the main reason for having to switch to titanium osteosynthesis. This may be because the biodegradable screw designs are too bulky for these bone structures. Further improvement of design and handling properties is needed before zygomatic fractures can be fixed exclusively with biodegradable osteosynthesis materials.

REFERENCES

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