

# Repair of Orbital Floor Fractures Using Bioresorbable Poly-L/DL-Lactide Plates

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**Objective:** To assess the long-term clinical and radiologic findings after insertion of a bioresorbable polylactide plates P(L/DL)LA 70/30 implant (PolyMax) in the repair of orbital floor and wall defects, with special focus on stability and clinical signs of foreign-body reaction.

**Methods:** Forty-six patients who had orbital blowout fractures with at least 1.5-cm<sup>2</sup> bone defects in 1 or 2 walls were included in this retrospective study. Each defect was reconstructed within 2 weeks of injury using a triangle form plate of polylactide. Computed tomography (CT) was performed before the operation and 1 year postoperatively. In 17 patients, additional CT was performed within 2 to 3 years postoperatively. Clinical assess-

ments were performed preoperatively and at 3-, 6-, and 12-month intervals postoperatively.

**Results:** None of the patients showed clinical foreign-body reactions. There was no evidence of infection. Diplopia was seen in 6 patients 3 months postoperatively but normalized in 5 patients at 6 months. Mild enophthalmos was seen in 2 patients postoperatively at 1 year. No sagging of the reconstructed area was found on CT.

**Conclusions:** The P(L/DL)LA 70/30 implant is a well-tolerated, reliable material in orbital repair of relatively large defects. The bioresorbable plate leaves a stable bridge of healed bone or soft tissue after complete degradation.

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**O**RBITAL FLOOR DEFECTS, either isolated or complex, can cause a variety of problems, including diplopia and enophthalmos. To avoid these complications, early reconstruction of the correct 3-dimensional anatomy of the orbit has been advocated.<sup>1,2</sup> A large variety of alloplastic materials and autogenous grafts have been used to reconstruct the normal volume and the contour of the internal orbit.<sup>3-13</sup> Each material has its advantages and disadvantages, but the most important properties of an implant should be its biocompatibility, availability, strength, and user-friendliness.<sup>14-17</sup> Up-to-date calvarial bone grafts and titanium implants have been used successfully in large defects.<sup>18,19</sup> In smaller defects, several researchers<sup>11,12,20</sup> suggest the use of alloplastic resorbable implants strong enough to support the globe during the healing process. Overall, these implants have been gaining popularity owing to the elimination of donor site morbidity, easy handling, and availability. A widely used resorbable implant has been polydioxanone, which loses 50% of its strength within 4 weeks and hydrolyzes totally within 7 to 12 months.<sup>16</sup> These characteristics make polydioxanone an unsuitable implant for

reconstruction of the internal orbit. At present, polydioxanone implants are not approved for internal orbital reconstruction in the United States.<sup>17</sup>

Polylactides were introduced for orbital repair approximately 15 years ago. Since their biomechanical properties were optimized by introducing copolymers, polylactides have experienced a renaissance in craniofacial surgery.<sup>21-30</sup> Early systems consisted of polymerized poly (L-lactide). It was, however, not recommended for orbital wall reconstruction owing to a degradation time longer than 5 years.<sup>31,32</sup> The first clinical assessment of a polylactide plate (LactoSorb; Walter Lorenz Surgical, Jacksonville, Florida) in orbital repair was performed by Enislidis and his team<sup>33</sup> and showed good clinical results in 5 patients. This implant is composed of 82% poly-L-lactic acid and 18% polyglycolic acid and has been in use clinically for approximately 15 years. During the past few years, stereocopolymers, poly-L/D-lactides, have been developed and tested in vivo.<sup>16,34-37</sup> Depending on the ratio of the optic isomer (L/L, D), this material showed different properties. Especially degradation time and, therefore, stability during the healing phase could be optimized by modulating the percentages of D- and L-type isomers of poly-

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**Table 1. Classification of Orbital Wall Defects<sup>a</sup>**

Class	Description
I	Isolated defect of the orbital floor or the medial wall, 1-2 cm <sup>2</sup> , in the anterior two-thirds
II	Defect of the orbital floor or medial wall, >2 cm <sup>2</sup> , in the anterior two-thirds Bony ledge preserved at the medial margin of the infraorbital fissure
III	Defect of the orbital floor or medial wall, >2 cm <sup>2</sup> , in the anterior two-thirds Missing bony ledge medial to the infraorbital fissure
IV	Defect of the entire orbital floor and the medial wall, extending into the posterior third Missing bony ledge medial to the infraorbital fissure
V	Same as class IV, defect extending into the orbital roof

<sup>a</sup>According to the classification of Jaquiéry et al.<sup>19</sup>

lactic acid in the polymer. The numbers that follow the abbreviation of “P(L/DL)LA” indicate the ratio of these isomers; P(L/DL)LA 70/30 demonstrated optimal mechanical properties in vitro and in vivo.<sup>35,37</sup> A recent clinical pilot study<sup>38</sup> assessing the use and outcome of P(L/DL)LA 70/30 implants (PolyMax; Synthes, Oberdorf, Switzerland) showed promising results.

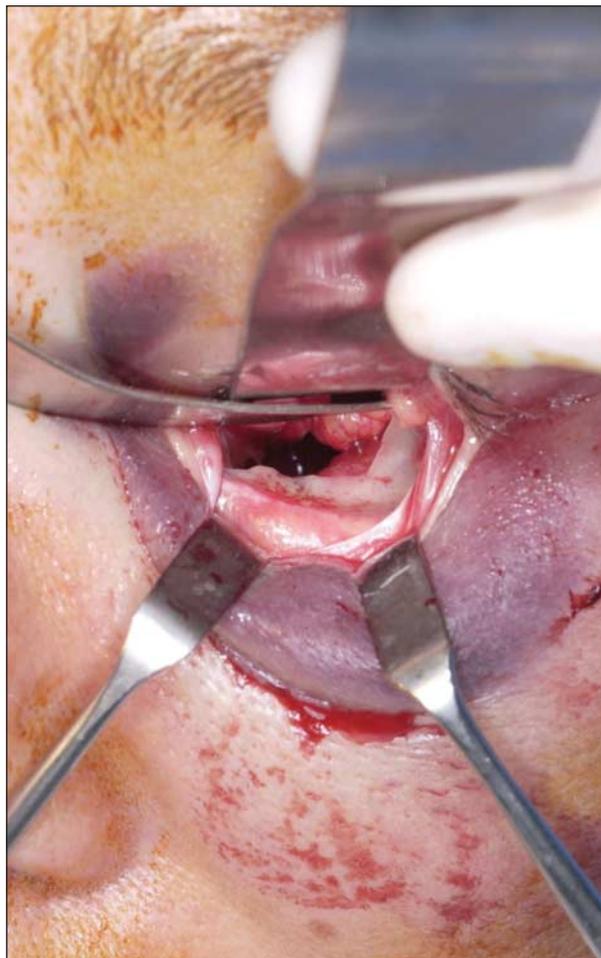
According to the engineers of AO (Arbeitsgemeinschaft Osteosynthesefragen), the polylactide plate used in this study (P(L/DL)LA 70/30 [PolyMax]) retains approximately 68% of its initial bending strength at 8 weeks, approximately 30% at 6 months, and completely resorbs at approximately 24 months, depending on the accurate duration of the sterilization cycle.<sup>39</sup> Amorphous 70/30 poly-L/DL-lactide copolymer plates sustain continuous hydrolysis through water penetration into the implant body during the first 6 months in situ.<sup>35</sup> This breaks copolymer chains into smaller particles, which later become degraded through phagocytotic cells. This process is associated with a transient foreign-body reaction.

In a study by Kontio et al,<sup>37</sup> visible degradation in vivo was detected in this product within 7 months. They also found that mesh sheet-frame structures, containing different poly-L/D-lactide ratios, such as in the plate used in this study, proved to be mechanically adequate for orbital repair. It retained its shape for 7 months and seemed not to possess any intrinsic memory. Another advantage of this copolymer blend is its mechanical properties, which allow repeated bending without deterioration.<sup>38</sup> All these properties seem to make this plate an ideal implant for small (classes I and II), middle-sized (class III), and even large (classes IV and V) defects. There are, however, no data in the English literature regarding clinical long-term outcome after orbital repair using such plates.

The purpose of this study was, therefore, to assess the long-term clinical and radiologic findings after insertion of a bioresorbable P(L/DL)LA 70/30 implant (PolyMax) in the repair of orbital defects, with special focus on stability and clinical signs of foreign-body reaction.

## METHODS

Between July 1, 2005, and December 31, 2006, a total of 54 patients underwent surgical reconstruction of the orbit using



**Figure 1.** Exploration of an orbital floor defect via the transconjunctival approach.

P(L/DL)LA 70/30 plates. Of these 54 patients, 8 underwent surgical reconstruction of the orbit using the P(L/DL)LA 70/30 implant owing to craniofacial deformities or tumor resection. The remaining 46 patients (>18 years old) had sustained a facial injury that caused an orbital wall fracture and were included in this retrospective assessment. At the University Hospital of Bern, Bern, Switzerland, the indications for surgical reconstruction are the presence of diplopia, enophthalmos, restricted globe motility, and fracture size of at least 1.5 cm<sup>2</sup>. Before surgery, the patients were routinely evaluated by a maxillofacial surgeon (O.L., B.S., and J.Z.) regarding bone and soft-tissue lesions, diplopia, and eye mobility. Preoperative computed tomography (CT) was used to analyze the size and location of the defect and the extent of muscle entrapment. The fractures were classified according to the scores introduced by Jaquiéry et al (**Table 1**).<sup>19</sup>

The operation was performed within 2 weeks of the injury using general anesthesia through a transconjunctival approach (**Figure 1**). Isolated defects of the medial wall were explored via a medial eyebrow approach. This approach is a modification of the Killian approach without extension onto the nasal skin. A 2-cm incision is performed below the medial aspect of the eyebrow. The supratrochlear and supraorbital arteries and nerves are carefully dissected and mobilized to the lateral border. By subperiosteal dissection, the trochlea is released and the medial wall of the orbit is exposed. If necessary, the anterior ethmoidal artery can then be clipped for better access. In cases with concomitant fractures of the frontal sinus or frontal skull, the bicoronal incision was used for exploration of the medial aspect.



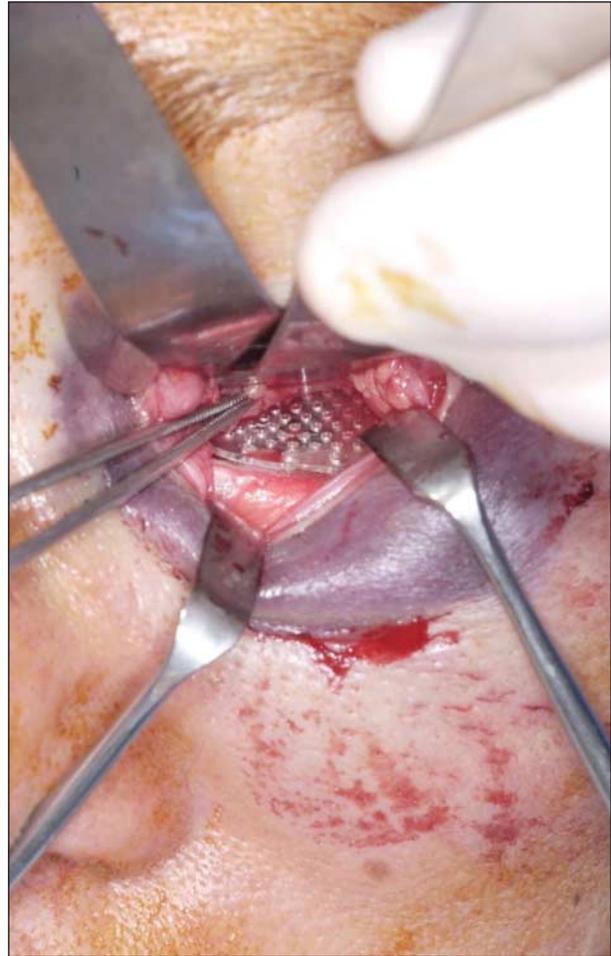
**Figure 2.** Poly lactide plate with a prebend template, before heating.



**Figure 3.** Poly lactide plate after heating in water.

The P(L/DL)LA 70/30 plates are available in 3 sizes: small, medium, and large. The plates used in this study had a 0.5-mm profile height and a maximum diameter of 24 mm (small), 30 mm (medium), and 35 mm (large). Templates were used to assess the size necessary and to define the contour of the implant (**Figure 2**). The plate was then placed on the template and heated in hot water, where it became malleable and adopted the prebent contour (**Figure 3**). If desired, it could then be trimmed to fit a specific defect and fixed with resorbable screws. After insertion of the plate (**Figure 4**), forced ductions were carefully monitored before wound closure. All the patients received prophylactic intravenous antibiotics intraoperatively and oral antibiotics for 5 to 7 days postoperatively.

Follow-up was routinely performed at 2, 6, and 12 weeks and at approximately 6 months postoperatively. Control CT was performed to check the outcome, as recommended and performed by several other researchers,<sup>18,19</sup> and to close the treatment case for the responsible accident insurance company approximately 1 year postoperatively. In these CT scans, a section thickness of 1 mm or less was used. For reasons related or unrelated to the orbital trauma, a second CT scan of the face was performed in some patients within 2 to 3 years after the operation. The section thickness of these investigations ranged from 0.75 to 2.0 mm. The medical records were reviewed, with special focus on enophthalmos, diplopia, clinical signs of foreign-body reactions, and other complications. A side difference of at least 2 mm, measured by Hertel exophthalmometry, was considered to be enophthalmos. Ocular motility was evaluated by assessing 8 fields of gaze. One investigator<sup>19</sup> analyzed the CT scans for accuracy of reconstruction, according to the scoring system of Ellis and Tan,<sup>18</sup> using se-



**Figure 4.** Insertion of the poly lactide plate through a transconjunctival approach.

lected coronal sections of postoperative CT scans. A copy of the unaffected orbit was overlaid onto the reconstructed orbit. The stability after disintegration of the implant was assessed by analyzing the anterior, middle, and posterior parts of the defect (3 indicates ideal; 2, adequate; and 1, poor). For each reconstruction, the mean of the 3 analyses was obtained for further evaluation. For the analyses, results of the most recent clinical and radiologic examinations were used.

## RESULTS

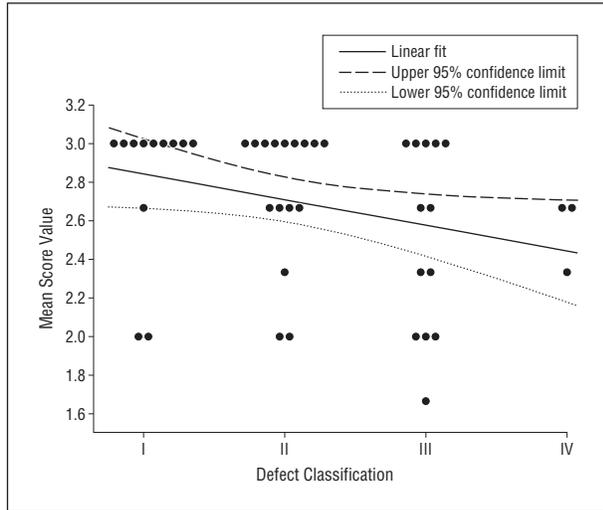
The 46 patients included in this study had a mean age of 40 years (age range, 14-87 years); 80% were male and 20% were female. Of 49 orbital wall fractures diagnosed, 47 needed surgical revision. The distribution of facial fractures and the size of the orbital defect (according to the classification of Jaquiéry et al<sup>19</sup>) are listed in **Table 2**. Plates were fixed with resorbable screws or tacks in none of the 14 patients with a class I defect, in 6 of the 16 with a class II defect, in 7 of the 13 with a class III defect, and in 2 of the 3 with a class IV defect.

The mean duration between the operation and the last CT scan was 18 months (range, 4-36 months). The mean duration between the operation and the last follow-up was 22 months (range, 5-39 months). In 17 patients, 2 CT scans of the face were performed within 3 years postoperatively

**Table 2. Distribution of 47 Orbital Fractures in 46 Patients**

Type of Fracture	Classification of Defect <sup>a</sup>				Total
	I (n=14)	II (n=17)	III (n=13)	IV (n=3)	
Blowout	9	12	5	1	27
Zygoma	4	3	7	2	16
LeFort	1	2	1	0	4

<sup>a</sup>For an explanation of the defect classifications, see Table 1.



**Figure 5.** Correlation of the size of the orbital defect (according to the classification of Jaquiéry et al<sup>19</sup>) with the mean score of the computed tomographic scan assessment (according to the scoring system of Ellis and Tan<sup>18</sup>).

(mean, 29 months; range, 25-36 months); in 24 patients at approximately 1 year postoperatively (mean, 13 months; range, 12-15 months). The remaining 5 patients had their radiologic control performed within the first year after the operation (mean, 7 months; range, 4-9 months). Regarding stability of the orbital reconstruction, optimal results were found in class I defects (score of 2.83 of 3). With enlargement of the defect, the repair became less accurate (scores of 2.51-2.75 of 3) (**Figure 5**). Of these patients with additional CT scans, 5 with a class I defect had a score of 3, six with a class II defect had a score of 2.78, four with a class III defect had a score of 2.33, and 2 with a class IV defect had a score of 2.67. Reasons for adequate or poor results were not sagging of the reconstructed area but misplacement of the plate. Eight patients had a score of 2.0 or less. In these cases, the plate was misplaced. Especially in defects involving the floor and the medial wall, the plate was not sufficiently supported by the cranial border of the medial wall defect but was placed into the ethmoid sinuses. In 6 of these 8 patients, the plates were fixed during the operation. Postoperative dislocation is, therefore, unlikely in these cases. Lateral wall defects in patients with central or lateral midfacial fractures did not account for any of the poor results. Clinical and radiologic findings at last follow-up are listed in **Table 3**. The prevalence of diplopia and restricted eye movement increased temporarily (in the first 2 weeks) after the operation. Diplopia was docu-

mented in 6 patients at 3 months postoperatively but normalized in 5 patients at 6 to 9 months. One patient with a size IV defect had persistent diplopia in upper gaze and abduction at last follow-up. Mild enophthalmos (side difference of 2 mm) was seen in 2 patients postoperatively at 1 year. None of the patients showed any clinical foreign-body reactions. There was no evidence of infection. One patient experienced an operative-related complication. He developed an ectropion, which was successfully corrected by the ophthalmologists in the first postoperative year. The final CT showed bone healing along the plate in 30 patients (**Figure 6**) and scar formation in 16 patients.

#### COMMENT

The best method to assess the outcome and accuracy of the orbital reconstruction, volume measurements of the internal orbit. This is, however, a complicated and extremely time-consuming method. We, therefore, used a qualitative method introduced by Ellis and Tan,<sup>18</sup> which since has been used by other researchers as well.<sup>19</sup>

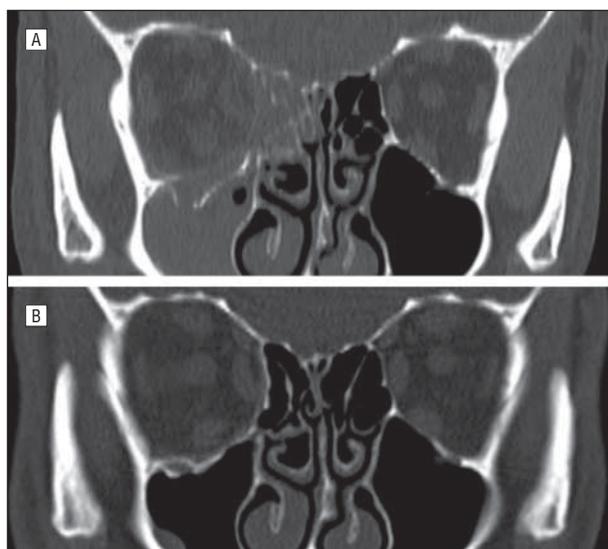
In the assessment of the reconstruction, we found a clear correlation of the score with the size of the orbital defect. In small defects, the outcome was close to ideal, whereas in class III and IV defects, the scores were only 2.51 and 2.56, respectively. This is in accordance with the findings described by Jaquiéry and his team,<sup>19</sup> who used the same method of assessment. A review of 72 patients who had been treated with different implants showed a score of 3 in patients in class I, 2.73 in class II, 2.37 in class III, 3 in 1 patient in class IV, and 2.22 in class V. In this study, reconstructions with a score of 2.0 or less were associated with misplacement of the implant rather than with any sagging effect. The assessment of the additional CT scans performed within 2 to 3 years postoperatively showed results comparable with the rest of the group. This would also corroborate the opinion that the surgical skills and the presence of anatomical landmarks are crucial factors in optimal reconstruction rather than insufficient support of the plate due to degradation. Whether there is an indication for this implant in the reconstruction of large defects (classes IV and V) cannot be answered because only 3 patients had sustained class IV defects.

Isolated medial wall defects were found in 5 patients (each with a class II defect). The accuracy of these reconstructions was very good and received a mean score of 2.8 (**Figure 7**). This is in contrast with the findings of Ellis and Tan,<sup>18</sup> where medial wall defects were associated with

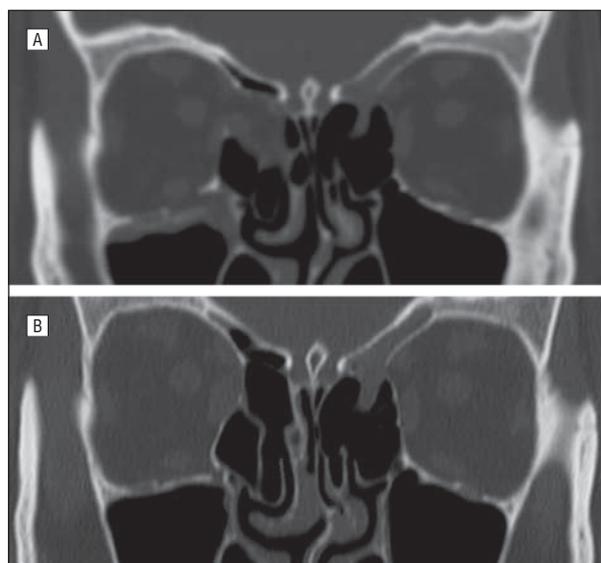
**Table 3. Postoperative Findings at Last Follow-up in 46 Patients**

Finding	Classification of Defect <sup>a</sup>			
	I (n=14)	II (n=16)	III (n=13)	IV (n=3)
Clinical				
Diplopia	0	(1 Transient)	(2 Transient)	1 In upper gaze and abduction (2 transient)
Enophthalmos (Hertel test)	0	1 (2-mm Difference)	0	1 (2-mm Difference)
Foreign-body reaction				
Complications	1 (Entropion)	0	0	0

<sup>a</sup>For an explanation of the defect classifications, see Table 1.



**Figure 6.** Class II orbital wall defect. A, Postoperative computed tomographic scan showing the plate in situ. B, Computed tomographic scan at 1-year follow-up showing bone healing along the implant.



**Figure 7.** Isolated medial wall defect (class II). A, Preoperative computed tomographic scan showing herniation of the medial rectus muscle into the ethmoid sinuses. B, Computed tomographic scan at 1-year follow-up showing bone healing along the implant.

the poorest reconstructions. They suggested that for better exposure of the posterior aspect of the defect, a coronal approach or endoscope visualization and manipulation could improve the results. With use of the medial eyebrow approach, as performed at the University Hospital of Bern, the posterior aspects could be sufficiently explored. In the present group, the worst results were found in situations where the fracture involved the orbital floor and a large part of the medial wall. We believe that in these cases, a combined approach, such as transconjunctival/medial eyebrow or transconjunctival/transcaruncular, would yield better results. Combined approaches should be considered as soon as the situation does not permit a sufficient overview of the whole defect.

In this study, the degree of diplopia and the restriction of eye movement in 1 patient remained unchanged at 1-year follow-up. Preoperative CT of this patient showed soft tissue and muscle entrapment in the floor area. Postoperative control CT confirmed good repositioning of the incarcerated tissue and optimal placement of the implant. Nevertheless, eye movement did not improve. We, therefore, assume that injuries to the muscles are responsible for this limitation.

Clinical complications occurred in 3 patients. This rate is comparable with the incidence of complications found

in other studies.<sup>6,19,30</sup> Misplacement of the implant was the cause of enophthalmos in 1 patient. The second patient with enophthalmos had sustained a severe globe injury and class I defect of the orbital floor, which had been adequately revised. In the process, the globe began to shrink (phthisis bulbi) and finally had to be removed. One patient required surgical correction of a postoperative ectropion. This rate is similar or slightly lower than that described in the literature.<sup>40-42</sup> No clinical symptoms of this inflammatory reaction were recorded in this study. To our knowledge, there are no studies showing any clinical symptoms of foreign-body reaction with the use of a P(L/DL)LA plate.

In a pilot study by Al-Sukhun et al,<sup>38</sup> a group of 13 patients with orbital floor defects was treated using the same P(L/DL)LA 70/30 plate. The latest clinical and radiologic follow-up was performed 36 weeks postoperatively. These researchers found that the inferior orbital walls did ossify during follow-up and that bone healing seemed to occur along the bone fragments. To achieve optimal reconstruction of the orbit, surgeons at the University Hospital of Bern routinely place the loose bone fragments underneath the implant. However, when looking at the results, the functional outcome did not depend on the presence or ab-

sence of bone in the floor area but on the correct 3-dimensional reconstruction.

In conclusion, bioresorbable P(L/DL)LA 70/30 implants can be recommended for the reconstruction of small (class I and II) and middle-sized (class III) defects. The implant is safe and user-friendly and provides sufficient support in the reconstructed area. It, therefore, could obviate the need for bone grafts and nonresorbable alloplastic materials in many cases.

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