Radiologic and Facial Morphologic Long-Term Results in Treatment of Orbital Floor Fracture With Flexible Absorbable Alloplastic Material

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Purpose: Although orbital floor fractures are frequently treated by the Ethisorb patch or polydioxanone foil, the utility of these treatments in extensive fractures remains controversial. The purpose of this study was to examine objectively the extent to which such flexible absorbable materials can restore orbital geometry in comminuted and defect fractures.

Materials and Methods: Twenty-one patients with isolated comminuted or defect fractures of the orbital floor (mean, 4.32 cm²) were recruited for this retrospective study. Using an infraorbital approach, 15 patients received an Ethisorb patch, whereas polydioxanone foil (0.25 mm) was used in the remaining cases. Follow-up examinations with cone-beam computed tomography and 3-dimensional facial scanning occurred on average 27.4 months postoperatively. Orbital heights and volumes were measured on the fracture side and compared with the unaffected side. Based on 3-dimensional facial scan data, the ocular bulb position was assessed in the sagittal and vertical directions. For all parameters, the difference between the left and right sides was calculated, which was statistically significant compared with the side difference of an age- and gender-matched control group using unpaired t test (P < .05).

Results: No statistically significant differences were observed in any variable between the surgical and control cohorts. A decreased diplopia rate of 38.14% was attained by the surgical intervention.

Conclusion: The reconstruction of moderate to extensive orbital floor fractures can be provided with polydioxanone foil or the Ethisorb patch without significant changes in orbital geometry.

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Depending on the defect size, a surgical approach may be necessary. Fissured defects often can be treated conservatively, whereas larger comminuted and defect fractures require surgical reconstruction of the orbital floor. This includes repositioning of the peribulbar fat tissue that is prolapsed into the maxillary sinus to provide unrestricted bulbus motility and a correct bulbus position adapted to the contralateral side. Although treatment of orbital floor fractures is a routine procedure in oral and maxillofacial surgery, there are no standardized guidelines as to which implant material should be applied for which indication.\(^6\)

There is a wide variety of implant materials and operator-dependent preferences on their use.\(^7\)–\(^12\) Preferably, implants consisting of titanium and porous polyethylene, poly-p-dioxanone (PDS) foils, and Ethisorb patches are used.\(^13\)–\(^16\) In addition, autogenous grafts from the external and internal tabula or from the iliac crest can be used.\(^17\)–\(^19\) These tissues lack immunogenicity and provide a potential restoration of the original form. However, transplant fixation is difficult and absorption is unpredictable.\(^14\) In contrast, titanium mesh plates provide adequate stability and the possibility of an exact adaptation to the contour of the fractured orbital floor. With the aid of computer-assisted design and manufacturing techniques, these mesh plates can be customized preoperatively to the individual orbit.\(^20\) Thus, the time required for surgery can be shortened considerably and the surgical procedure simplified. Currently, preformed titanium mesh plates are considered the first choice for large defects.\(^21\)

Orbital implants made of porous polyethylene (eg, Medpor, Stryker CMF, Newnan, Georgia) offer the advantage of a stable incorporation because of the surrounding ingrowing tissue.\(^22\)–\(^24\) Implants can be modified intraoperatively or sintered preoperatively with the help of Digital Imaging and Communications for Medicine (DICOM) datasets.\(^25\)

The use of PDS sheets is established and favored in defects up to 2.5 cm\(^2\).\(^26\)–\(^27\) The PDS foil (eg, Ethicon, Johnson & Johnson, Somerville, NJ) is an alloplastic,
elastic material that serves as a temporary closure of partial defects. The PDS is absorbed within 180 days and maintains a stability of approximately 50% after 5 weeks, with the developing scar tissue compensating for the gradual loss in stiffness of the foil. Foils are available in thicknesses of 0.15, 0.25, and 0.5 mm.25

Another flexible absorbable material is Ethisorb, which is recommended for the reconstruction of orbital floor defects up to 2 × 2 cm2.16,28 Ethisorb (eg, Ethicon, Johnson & Johnson) is a copolymer consisting of a fleece composed of polyglactin 910 and PDS, which is assembled by a thermoplastic process. Gradual absorption results owing to different absorption timelines (PDS absorbs within 180 days, whereas polyglactin 910 is absorbed after 45 to 60 days).29

The goal of therapy, regardless of the chosen material, is the best possible reconstruction of the orbital geometry and thus the bulbus position, whereby differences in the orbital volume to 20% can be tolerated bilaterally.21,30 The mean orbital volume for adults is about 26 cm³ and an increase in volume of 1 cm³ results in an enophthalmus of about 1 mm.31

The aim of this study was to examine objectively the extent to which orbital geometry can be restored using currently available flexible resorbable materials in comminuted and defect fractures.

**Materials and Methods**

The study sample included primarily patients with midfacial fractures involving the orbital floor who underwent surgery from 2006 through 2008 in the authors’ facility (n = 236); of these, patients with isolated orbital floor fractures (n = 97) were selected. Within this group, 64 patients sustained comminuted and defect fractures (fracture area, >1 cm²) that were treated with resorbable flexible implants. The present investigation consisted of 21 patients (7 women and 14 men; age range, 21 to 53 yr; mean age, 43.14 yr). The mean fracture area of the 11 defect and 10 comminuted fractures was 4.32 cm² (maximum, 5.76 cm²);
In all cases, orbital floor exploration was performed using an infraorbital approach. In 15 patients an Ethisorb patch was used for orbital floor repair, whereas 6 orbital floors were stabilized using PDS foil (0.25 mm). Follow-up examinations were conducted at 27.4 months on average (range, 17 to 41 mo). In addition to a clinical examination consisting of finger perimetry for the evaluation of diplopia, cone-beam computed tomography (Galileos, Sirona, Bensheim, Germany) and optical 3-dimensional (3D) facial scanning (FaceSCAN3D, 3D-Shape GmbH, Erlangen, Germany) were performed.

Subsequently, the DICOM datasets generated by cone-beam computed tomography were used to determine the orbital volume. Using iPlan CMF 3.0 software (BrainLAB, Feldkirchen, Germany), all 42 orbits were segmented by manually outlining the orbital borders in each section plane using the mouse cursor (Fig 1). To simplify the segmentation procedure, the program also permits a gray-scale-based interpolation of up to 8 layers. From the acquired data, the software automatically calculated a 3D image of the segmented orbits, which directly appeared in the plan content of iPlan, and the object volume (cubic centimeters; Fig 2). To verify the correct orbital reconstruction in the vertical dimension, orbital height was measured at 2 representative cuts with this software. For this purpose, the authors developed a defined algorithm. 1) The orbital longitudinal axis was set parallel to the median sagittal plane from the dorsal end of the orbit in the axial cut to the infraorbital margin in the sagittal cut. 2) The first orbital height (OH1) was calculated by measuring the perpendicular line from the center of the longitudinal axis to the orbital roof. A second perpendicular line from the orbital floor to the orbital roof (OH2) was designed and surveyed 5 mm laterally to OH1 with the aid of a trajectory and distance tool (Fig 3). Identical measurements were made in an age- and gender-matched control group (C1) in which cone-beam computed tomography was performed for indications other than fractures of the facial skeleton.

In addition, objective data for bulb position were provided by optical facial scanning. The incidence of an ex-/enophthalmus compared with the unaffected side was evaluated. This meant that the globe position

FIGURE 3. Measurements of the orbital height according to a defined algorithm at 2 positions.

FIGURE 4. A, B. Verification of the ocular bulb position in the sagittal plane to identify ex- or enophthalmus by determining the supraorbitale-pupil-infraorbitale angle.

FIGURE 5. A-C, Determination of the angle from the plane, consisting of the pupil on the measured side, the pupil on the contralateral side, and the tragus, to the line connecting the tragus and infraorbitale using facial scan datasets for the evaluation of the vertical bulbus position. (Figure 5 continued on next page.)

in the sagittal orientation was controlled. For this purpose, the facial scan datasets were imported into a commercially available orthognathic planning software (Onyxceph\textsuperscript{TM} 3.1.55, Image Instruments, Chemnitz, Germany), and on the surgical and nonsurgical sides, the supraorbitale-pupil-infraorbitale (SPI) angle was defined and automatically measured by the software (Fig 4A, B). Further, using the facial scan data, the bulbus elevation or depression could be verified by exactly determining the vertical bulbus position. In addition, an angle was constructed from the plane, consisting of the pupil on the measured side, the pupil on the contralateral side, and the tragus, to the line connecting the tragus and infraorbitale (PPTI; Fig 5A-C). This angle was determined in a similar fashion on the surgical and nonsurgical sides. This analysis of bulbus position also was conducted in an age- and gender-matched reference group (C2) acquired from the 3D facial scan database.

For all ascertained parameters (orbital volume, OH\textsubscript{1}, OH\textsubscript{2}, SPI, PPTI), the differences between the left and right sides were calculated in the experimental group and the corresponding control groups (C1, C2). The calculated differences between the right and left sides for the experimental and C1/C2 groups were compared statistically using an unpaired $t$ test. The effects were considered significant if the $P$ values did not exceed the 5% level. All statistical computations were performed using SPSS 14 for Windows (SPSS, Inc, Chicago, IL).
Results

For the orbital volume, there were no significant differences between the side differences in the experimental and control groups (Fig 6). The confidence interval indicated that the side differences of the surgical group resembled the level of the age- and gender-matched healthy control group (Table 1).

The side difference between the surgical and control groups for reconstruction of the vertical orbit dimension showed no significant difference for OH$_1$ or OH$_2$ (Table 2, Fig 7A, B). Therefore, the performed orbital floor reconstructions did not seem to result in any pathologic change in orbital height.

An examination of the mean differences between the measured SPI angles, which suggested a possible ex-/enophthalmus, showed no significant differences (Table 3). Stabilization of the orbital floor by the Ethisorb patch or PDS foil did not seem to have any influence on sagittal eye bulb alignment. Likewise, there was no significant difference when comparing the PPTI angles of the 2 groups as a control parameter for bulbus elevation or depression (Table 4). Thus, a significant difference between the surgical versus the healthy reference group could not be established for any of the examined parameters (Table 4).

For the crucial issue of the development of double vision, a decrease in the incidence of diplopia from 57.14% preoperatively to 19% postoperatively was determined (Table 5). In fact, the diplopia rate decreased by 50% using the PDS foil compared with 75% using the Ethisorb patch. Cases of persisting diplopia after the surgical procedures appeared only in connection with extreme globe positions.

On balance, by reconstructing the orbital floor with Ethisorb or PDS, the orbital volume and height and the bulbus position could be restored sufficiently and without substantial differences from the contralateral side.

Discussion

Recently, moderate to extensive orbital floor fractures have been preferably treated with 3D mesh plates because of their reconstruction potential in 3 dimensions and, hence, the original anatomic structure of the orbital floor. As such, the orbital geometry can be reconstructed exactly, and functional and esthetic impairments can be minimized significantly. Conversely, flexible materials such as the PDS foil or Ethisorb cannot be adapted fully a priori to the complex contour of the orbital floor. According to previous studies, these materials

### Table 1. COMPARISON OF ORBITAL VOLUME BETWEEN THE SURGERY AND CONTROL GROUPS

<table>
<thead>
<tr>
<th>Group</th>
<th>OV$_r$ (cm$^3$)</th>
<th>OV$_l$ (cm$^3$)</th>
<th>Difference (OVl-OVR) (cm$^3$)</th>
<th>t Test</th>
<th>P Value</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery</td>
<td>27.51 ± 4.10</td>
<td>27.67 ± 3.55</td>
<td>0.16</td>
<td>.522</td>
<td>−1.14 to 2.08</td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>26.18 ± 2.82</td>
<td>25.87 ± 2.77</td>
<td>0.31</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: Data are presented as mean ± standard deviation.

Abbreviations: CI, confidence interval; OV$_l$, left orbital volume; OV$_r$, right orbital volume.


### Table 2. COMPARISON OF ORBITAL HEIGHT BETWEEN THE SURGERY AND CONTROL GROUPS

<table>
<thead>
<tr>
<th>Group</th>
<th>OH$_l$ (mm)</th>
<th>OH$_r$ (mm)</th>
<th>Difference (mm)</th>
<th>t Test</th>
<th>P Value</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>OH$_1$</td>
<td>30.75 ± 5.61</td>
<td>31.62 ± 3.17</td>
<td>0.87</td>
<td>.590</td>
<td>−2.37 to 4.08</td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>29.82 ± 3.40</td>
<td>29.83 ± 2.08</td>
<td>0.01</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OH$_2$</td>
<td>33.39 ± 4.96</td>
<td>34.24 ± 2.71</td>
<td>0.85</td>
<td>.442</td>
<td>−1.74 to 3.86</td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>33.13 ± 3.01</td>
<td>32.92 ± 2.62</td>
<td>0.21</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: Data are presented as mean ± standard deviation.

Abbreviations: CI, confidence interval; OH$_l$, orbital height measured on a perpendicular line from the center of the longitudinal axis to the orbital roof; OH$_2$, orbital height measured on a perpendicular line from the orbital floor to the orbital roof and 5 mm lateral of OH$_l$; OH$_r$, left orbital height; OH$_r$, right orbital height.

should be used for defects no larger than 2 x 2 cm because of their semiflexibility and a further loss of stability caused by biodegradation after incorporation. In such cases, osseous support is obligatory. Nonetheless, excellent long-term results can be achieved for smaller defects. Jank et al. observed diplopia 15 to 24 months after reconstruction of the orbital floor with PDS foil and Ethisorb in 4% and 3% of cases, respectively, and enophthalmus in only 1% of patients.

As the present results suggest, in accord with the current literature, it is apparently possible to adequately treat larger defects (≤ 9 cm²) with flexible absorbable materials. This means that the orbital geometry can be reconstructed properly (ie, with side differences corresponding to a healthy control group) using Ethisorb patches and PDS foil. These findings apply to the bulbus position resulting from orbital floor reconstruction. In most cases, the patients’ crucial criterion for treatment success should be the disappearance or at least alleviation of preoperative diplopia after orbital floor reconstruction. The authors observed a 38.14% decrease of double vision in the present retrospective study. Only 19% of the present patients treated with the PDS foil or Ethisorb complained of postoperative diplopia, although a diplopia rate of 10% to 30% has been found after orbital floor reconstruction with titanium mesh plates. Thus, the postoperative diplopia rate is at least at the same level as for titanium meshes. Furthermore, the positioning and intraoperative adaptation of these meshes occasionally can be very difficult, leading relatively often to a malposition of the ocular bulb, especially when using nonpreformed meshes.

An exact reconstruction of the orbital geometry is always essential irrespective of the chosen implant material to achieve a satisfying final result. In this regard, the operative skills and experience with the particular implant material are significant for the surgical outcome.

In conclusion, the reconstruction of moderate to extensive comminuted and defect fractures, which warrant osseous support for the implanted material, can be provided with a PDS foil or an Ethisorb patch without significant changes in orbital volume, orbital height, or ocular bulb position. A functional improvement of fracture-associated diplopia can be achieved in most patients, although a com-
be a helpful tool in this context. The described evaluation algorithm may
be accomplished in all cases. Admittedly, in cases of total or subtotal
loss of the orbital floor, prefabribrated titanium mesh plates remain the material of choice to ensure the safe support of the orbital content. The authors recognize that further studies with larger samples, including all types of orbital floor repair, are necessary to advance knowledge in this area. The described evaluation algorithm may be a helpful tool in this context.

References


Table 4. COMPARISON OF VERTICAL BULBUS POSITION BETWEEN THE SURGERY AND CONTROL GROUPS BY PPTI ANGLE

<table>
<thead>
<tr>
<th>Group</th>
<th>Right PPTI (°)</th>
<th>Left PPTI (°)</th>
<th>Difference (°)</th>
<th>t Test</th>
<th>P Value</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery</td>
<td>151.96 ± 11.36</td>
<td>151.60 ± 14.29</td>
<td>-0.36</td>
<td></td>
<td>.928</td>
<td>-7.29 to 7.94</td>
</tr>
<tr>
<td>Control</td>
<td>154.50 ± 9.03</td>
<td>153.81 ± 6.36</td>
<td>-0.69</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: Data are presented as mean ± standard deviation.
Abbreviations: CI, confidence interval; PPTI, angle of the plane (pupil on the measured side, pupil on the contralateral side, and the tragus) to the line connecting the tragus and the infraorbitale.


Table 5. DIPLOPIA INCIDENCE PREOPERATIVELY VERSUS POSTOPERATIVELY

<table>
<thead>
<tr>
<th>Polidioxanone foil 0.25 mm</th>
<th>Preoperative Diplopia</th>
<th>Postoperative Diplopia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>4</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Ethisorb</td>
<td>8</td>
<td>7</td>
</tr>
</tbody>
</table>