Clinical Report

Feasibility of Single Folded Unsintered Hydroxyapatite Particles/Poly-L-Lactide Composite Sheet in Combined Orbital Floor and Medial Wall Fracture Reconstruction

Takahiro Kanno1,2, Masaaki Karino1,2, Aya Yoshino1,2, Takashi Koike1,3, Taichi Ide1,2, Hiroto Tatsumi1,4, Koji Tsunematsu1,5, Hideki Yoshimatsu1,2 and Joji Sekine1,2

1) Department of Oral and Maxillofacial Surgery, Shimane University Faculty of Medicine, Izumo, Japan
2) Maxillofacial Trauma Center, Shimane University Hospital, Izumo, Japan
3) Division of Oral and Maxillofacial Surgery, Hamada Medical Center, Hamada, Japan
4) Division of Oral and Maxillofacial Surgery, Oki Hospital, Oki, Japan
5) Division of Oral and Maxillofacial Surgery, Masuda Red Cross Hospital, Masuda, Japan

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Abstract: Combined orbital floor and medial wall defect fractures can be challenging to repair. The aim of this retrospective clinical study was to evaluate the feasibility of single folded uncalcined and unsintered hydroxyapatite (u-HA) particles and poly-L-lactide (PLLA; u-HA/PLLA) composite sheets with a tack fixation technique in computer-assisted combined orbital floor and medial wall complicated fracture reconstruction. This study included five patients (mean age, 27.2 years) with relatively large complex orbital floor and medial wall defects (three type III defects and two type IV defects). A single folded u-HA/PLLA sheet was fabricated and prepared with an average optimal orbital floor to mesial walls angle (OHMW-angle) of 130.84° ± 5.42; this was followed by adaption and stable fixation with tacks to the inferior orbital rim using computer-assisted and intraoperative navigation-assisted orbital reconstructive surgery. The clinical and radiological data were analyzed, and ophthalmologists diagnosed functional eye complications with a mean follow-up period of 9.1 months (range, 6 to 18 months). Although the postoperative computed tomography (CT) study revealed accurate three-dimensional (3D) orbital wall reconstruction, a slight OHMW-angle increase, to 133.68° ± 4.28, between the orbital floor and medial reconstructed walls was observed 1 month postoperatively compared with immediately postoperatively (p < .05), but no other angle changes were observed in the postoperative follow-up study (p > .05). There was full recovery of ophthalmological function and active eyeball mobility without enophthalmos or diplopia. Overall, computer-assisted single folded u-HA/PLLA sheets with a tack fixation technique provide stable and satisfactory ophthalmologic functional results for combined orbital floor and medial wall fracture reconstruction with no intraoperative or postoperative complications. Furthermore, this u-HA/PLLA composite sheet could be an optimal next-generation bioactive osteoconductive implant material for the reconstruction of relatively large orbital wall defects, which could be applied using computer-assisted surgery.

Key words: Orbital reconstruction, osteoconductive, u-HA/PLLA, orbital floor, medial wall

Introduction

Orbital fractures with orbital defects are common in oral and maxillofacial surgery because of the exposed position and thin bony walls of the midface area1,2. Approximately 40% of orbital fractures occur in combination with other midfacial fractures, including zygomatic complex fractures, Le Fort II and III fractures, naso-orbital-ethmoid fractures, and frontal bone/orbital roof fractures, although they may occur alone1,2. More than half inferior orbital wall medial fractures occur just medial to the junction between the infraorbital groove and inferior orbital fissure1,4. Although there is a range in the severity of orbital wall fractures, orbital reconstructive surgery for combined orbital floor and medial wall defect fractures remain challenging.

The goal of the initial surgery for these complex orbital wall fractures is to reconstruct the bony orbital volume while maintaining a harmonious balance with soft tissue. When treating combined orbital floor and medial wall defect fractures, the surgeon has two choices: the use of implant materials with multiple small pieces or the use of a single large implant5,6. When the fractured orbit is reconstructed using the former method, the orbit can be easily rebuilt. However, there is a possibility of implant

Correspondence to: Dr. Takahiro Kanno, Department of Oral and Maxillofacial Surgery, Shimane University Faculty of Medicine, Izumo, Shimane, 693-8501 Japan; Tel: +81-853-20-2301; Fax: +81-853-20-2299; E-mail: tkanno@med.shimane-u.ac.jp
buckling and displacement if the materials are not stably rigid with adaptations\(^3\). A third implant at the junction of the floor and medial wall implants may be necessary to avoid unstable restoration of bony fragments. Taken together, several surgeons have reconstructed these combined orbital floor and medial wall fractures concomitantly using multiple small pieces of implants\(^2\)-\(^9\).

Su and Harris\(^5\) reported that they repaired combined orbital walls with two or three overlapping nylon foil implants (thickness, 0.2–0.4 mm) through combined transcaruncular-transconjunctival incisions. Another similar technique, described by Choi et al.\(^7\) involved a technique relying on the use of two separate porous polyethylene channel implants (thickness, 2.3 mm) fixed to the orbital rim by titanium plates placed within the longitudinal channels. However, as this first approach, these multiple small pieces of implants are relatively thick and may cause postoperative hyperglobus\(^3,5,7\).

On the other hand, Cho and Davies\(^3\) reported a high revision rate (about 20%) in their study and discussed the difficulty of inserting a single large implant. Furthermore, the ideal shaping, modification, or anatomical positioning by spanning the wider bony defects with a single reconstructive implant may be technically challenging, requiring an experienced orbital trauma surgeon\(^1,3-5\). Taken together, as this second approach, single-implant repair, has been described by several authors\(^1,3,5,8\). Nunery et al.\(^9\) reported that they repaired combined orbital wall fractures with a single large nylon foil implant (thickness, 0.4 mm) using a transcaruncular-transconjunctival approach, similar to our surgical technique for type IV defects. Although their overall results were good, their short-term follow up (mean, 6.2 months) was not sufficient to support long-term stability of the inferomedial strut. The excessive bowing of non-rigid nylon foil implants at the inferomedial strut could lead to late enophthalmos\(^3,5,9\).

Several other authors described the use of rigid implants, such as porous polyethylene, polyethylene-embedded titanium mesh, preformed titanium sheet or titanium mesh implants\(^1,10,11\). Additionally, as we reported the utility of titanium mesh for reconstruction of the orbit\(^1\), especially in cases with complex fractures of the maxillo-zygomatic orbit, because of the surgical utility of simultaneous fixation of orbital rim fractures and orbital floor defects using anatomical titanium mesh plates\(^1,11,12\). However, these rigid and metal implants, as reliable titanium materials, are permanent, and usually cannot be removed when placed in the orbital floor because of bone and soft tissue scar ingrowth between the meshed structures\(^10,12\).

Super Fixsorb-MX® (Japanese trade name; also known as OSTEOTRANS-MX overseas; Takiron Co. Ltd., Japan), which is a composite of fine unsintered hydroxyapatite (u-HA) particles and carbonated ions combined with poly-L-lactide (PLLA; u-HA/PLLA), is a promising bioactive, osteoconductive, and completely resorbable osteosynthetic bone fixation and maxillofacial reconstructive material that has recently drawn attention for its long-term clinical stability in maxillofacial skeletal fixation and reconstruction\(^1,11,14\). The ground-breaking osteoconductive and bioactive properties of these composites allow them to fuse directly with bone. Thus, u-HA/PLLA composites are of interest as a candidate material for orbital wall reconstruction because of their advantageous physical properties, high levels of customizability and control, and sufficient stability to support the orbital content\(^1,13,14\). Furthermore, the tack fixation technique applied with thin u-HA/PLLA composite sheets in reconstructive surgery for large orbital wall fractures could be useful in combined orbital floor and medial wall defect fracture repair\(^1\).

Thus, this sheet was anatomically bent, based on computer-assisted 3-dimensional (3D) morphological customization preoperatively to conform to the natural bony contours of the orbit, as such human anatomically reported\(^3\) with reproducing the upward posteromedial slope of the floor, the anterior-to-posterior S shaped curvature, and the ordinally average angle of 120- to 130-degrees between the floor and medial walls (OHMW-angle; orbital floor to mesial walls angle).

Herein, we evaluate the single folded u-HA/PLLA composite sheet with a tack fixation technique for the repair of relatively large, complex orbital wall defect fractures by evaluating the postoperative outcomes, feasibility of computer-assisted and intraoperative navigation-assisted combined orbital floor and medial wall fracture reconstruction by further analyzing the stability of the reconstructed OHMW-angle as a radiographic stability index.

**Materials and Methods**

**Patients selection**

We designed a retrospective clinical study using samples of medical records from a series of patients with midface fractures and orbital wall defects requiring surgical reconstruction due to the presence of diplopia, restricted globe motility and eye mobility, or enophthalmos. Patients were treated at the Maxillofacial Trauma Center in the Department of Oral and Maxillofacial Surgery, Shimane University Hospital, Shimane, Japan, from September 2014 to December 2016.

The Institutional Review Board of the hospital approved this retrospective study (Number #2056), which was performed in accordance with the Declaration of Helsinki. The unlinked anonymity of all patient data was ensured by the President of Shimane University Faculty of Medicine.

Inclusion criteria for study enrollment were 1) the presence of fresh orbital fractures (within 2 weeks) with combined orbital floor and medial wall defect fractures; 2) surgical treatment with computer-assisted and intraoperative navigation assistance, such as combined orbital floor and medial wall defect fracture repairs using samples of medical records from a series of patients with midface fractures and orbital wall defects requiring surgical reconstruction due to the presence of diplopia, restricted globe motility and eye mobility, or enophthalmos. Patients were treated at the Maxillofacial Trauma Center in the Department of Oral and Maxillofacial Surgery, Shimane University Hospital, Shimane, Japan, from September 2014 to December 2016.
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Table 1. Descriptions of computer-assisted single folded u-HA/PLLA sheets with the tack fixation technique for combined orbital floor and medial wall fracture reconstructions in five patients.

<table>
<thead>
<tr>
<th>No.</th>
<th>Age</th>
<th>Sex</th>
<th>Maxillofacial Fractures</th>
<th>Defected Orbital Walls</th>
<th>Defect Category</th>
<th>Reconstructed Size</th>
<th>Surgical Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>64</td>
<td>F</td>
<td>nasoorbitoethmoidal (NOE) fracture</td>
<td>Orbital floor + medial wall</td>
<td>III</td>
<td>20×25 + 20×28 mm</td>
<td>Subtarsal</td>
</tr>
<tr>
<td>2</td>
<td>17</td>
<td>M</td>
<td>nasoorbitoethmoidal (NOE) fracture</td>
<td>Orbital floor + medial wall</td>
<td>III</td>
<td>16×23 + 17×27 mm</td>
<td>Subtarsal</td>
</tr>
<tr>
<td>3</td>
<td>27</td>
<td>M</td>
<td>nasoorbitoethmoidal (NOE) fracture</td>
<td>Orbital floor + medial wall</td>
<td>III</td>
<td>26×20 + 27×16 mm</td>
<td>Subtarsal</td>
</tr>
<tr>
<td>4</td>
<td>12</td>
<td>M</td>
<td>nasoorbitoethmoidal (NOE) fracture</td>
<td>Orbital floor + medial wall</td>
<td>IV</td>
<td>28×22 + 26×20 mm</td>
<td>Combined transcaruncular-transconjunctival</td>
</tr>
<tr>
<td>5</td>
<td>16</td>
<td>M</td>
<td>nasoorbitoethmoidal (NOE) fracture</td>
<td>Orbital floor + medial wall</td>
<td>IV</td>
<td>18×30 + 18×30 mm</td>
<td>Combined transcaruncular-transconjunctival</td>
</tr>
</tbody>
</table>

Table 2. OHMW-angle changes between orbital floor and medial reconstructed walls expressed as the mean ± standard deviation in five patients.

<table>
<thead>
<tr>
<th></th>
<th>Postop 1 day</th>
<th>Postop 1 month</th>
<th>Postop 3 months</th>
<th>Postop 6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>130.84°± 5.42</td>
<td>133.68°± 4.28</td>
<td>134.46°± 4.11</td>
<td>134.2°± 4.77</td>
</tr>
</tbody>
</table>

Figure 1. A single folded u-HA/PLLA sheet fabricated, shaped, and prepared using computer-assisted three-dimensional (3D) morphological individual customization. A: The original preoperative 3D-model image was evaluated overlapping the mirrored 3D-model image for 3D morphological individual customization of u-HA/PLLA sheets. B: Using the stereolithographic model and testing paper, we designed the u-HA/PLLA sheet implant to mirror the shape of the intact opposite orbit. It was designed to precisely cover the bony defect and support the orbital globe. C: The u-HA/PLLA sheet was shaped and prepared using the stereolithographic model and testing paper.

A single folded u-HA/PLLA composite sheet with tack fixation, and complete medical records available for evaluation by the authors; and 3) availability of preoperative and postoperative computed tomography (CT) radiographs with follow up of more than 6 months, as well as follow-up examinations by ophthalmologists at 1 week, 1 month, 3 months, 6 months, and more than 6 months after surgery. We excluded patients who did not meet the inclusion criteria above (e.g., treated with another orbital reconstruction material or technique) and patients who did not regularly attend follow-up evaluations up to 6 months.

During the study period, 41 patients with midface fractures and orbital wall defects were treated with orbital reconstruction at our Maxillofacial Trauma Center. Of these, five patients (all Japanese) met the inclusion criteria and were analyzed in this study, although four more patients, not included in this study, are currently undergoing postoperative follow up within 6 months after treatment with the same surgical technique.

Patient profiles are summarized in Table 1. Briefly, the study sample was composed of four male patients and one female patient aged from 12 to 64 years (mean age, 27.2 years).

**u-HA/PLLA composite system preparation**

The bone fixation tacks and sheets were both commercially available composites of u-HA/PLLA (Super Fixsorb-MX; Takiron Co. Ltd., Osaka, Japan). The tacks were 4 or 5 mm long with a very low screw-head profile (0.1 mm above the plate) and had 2-mm threads with a backstitch shape. The u-HA/PLLA sheets had a 0.5 mm thick panel. A single u-HA/PLLA sheet was fabricated, shaped, and prepared with folding, achieving an optimal angle between the orbital floor and medial walls based on computer-assisted 3-dimensional (3D) morphological customization (Fig. 1). The final intraoperative navigation was confirmed prior to
insertion based on the actual orbital surgical reconstruction fields.

**Classification of orbital wall defects**

For patient profiles, orbital wall defect sizes were classified according to the modified system described by Dubois et al.\(^{(1)}\), which was based on the simplified two-dimensional fracture model originally described by Jaquiéry et al.\(^{(1)}\).

The treated complex of the combined orbital floor and medial wall defect fractures were all nasoorbitoethmoidal (NOE) fractures. Three patients had relatively large and highly complex category III defects, and the other two patients had even more complex category IV defects (Table 1).

**Surgical procedure**

All surgeries were performed by experienced maxillofacial trauma surgeons with a single surgical team (chief Maxillofacial Trauma surgeon TKa, Maxillofacial Trauma Center, Shimane University Hospital, Izumo, Shimane, Japan). Surgeries were performed under general anesthesia within 2 weeks after the injuries. An intraoperative navigation system (BrainLab, Feldkirchen, Germany) was used to determine the extent of orbital wall defects and confirm the accurate placement and adaptation of the u-HA/PLLA sheet implant for combined orbital floor and medial wall defect fracture reconstruction. A sub-tarsal approach was used for three cases, and a combined transcaruncular-transconjunctival (retroseptal) approach was used to access the orbit in the other two cases (Table 1). Intraoperatively, a single u-HA/PLLA sheet, which was fabricated, shaped, and prepared with folding, achieving an optimal angle between the orbital floor and medial walls using computer-assisted 3-dimentional (3D) morphological customization, was inserted and anatomically spanned both the orbital floor and medial walls (Fig. 1). Accurate placement of the single folded u-HA/PLLA sheet with shape modification to span the anatomical defects was confirmed using intraoperative navigation (Fig. 2). After drilling, a facilitator and hammer were used to manually tap two tacks into the sheet and infraorbital rim for sheet stabilization as described previously.\(^1\)

Postoperative CT scans were performed within 24 h after surgery. An intravenous antibiotic (1.0 g cefazolin sodium/12 h) was administered upon hospital admission and continued until the third postoperative day.

**Radiographic evaluation (OHMW-angle; orbital floor to mesial walls angle)**

Postoperative CT radiographic evaluations were performed to assess the accuracy of three-dimensional (3D) orbital reconstruction and orbital fracture healing at 1 day and 1, 3, and 6 months postoperatively. The postoperative OHMW-angle changes of the folded single u-HA/PLLA sheet implant between the orbital floor and medial reconstructed walls were assessed using ImageJ software (National Institutes of Health, Bethesda, MD, USA) at 1 day and 1, 3, and 6 months postoperatively (Fig. 3). Briefly, the coronal CT views of anatomically the most similar phasic slice at each postoperative follow up were chosen for OHMW-angle assessment (Fig. 4). The measured values of the OHMW-angle changes between the orbital floor and medial reconstructed walls were expressed as the mean ± standard deviation. To assess reliability, the same investigator repeated the procedure 2 weeks later.

**Clinical evaluations**

Clinical data regarding any abnormal postoperative events were collected from the medical records of evaluations performed pre-, intra-, and postoperatively. All patients underwent routine pre- and postoperative ophthalmological examinations by an ophthalmologist at the Department of Ophthalmology, Shimane University Hospital.

**Statistical analysis**

Mean values for postoperative OHMW-angle changes in the
folded single u-HA/PLLA sheet were analyzed using StatView5 software (SAS Institute, Cary, NC, USA). A paired t-test was used to assess changes at 1 day and 1, 3, and 6 months postoperatively. The reliability and error analysis was also performed with acceptance using a paired t-test at the 5% significance level.

**Results**

The orbital wall reconstructive surgeries, together with the open reduction and internal fixation of midfacial fractures, reestablished the midfacial skeleton and restored the pre-injury anatomy of the hard tissue, freeing all incarcerated or prolapsed orbital tissue from the defects. None of the patients experienced intraoperative complications.

In all patients, postoperative CT radiographic evaluations revealed anatomically correct reduction of the orbital contents, with full bony suspension spanning the combined defects in the or-
bital floor and medial walls (Fig. 4). The average reconstruction OHMW-angle between the orbital floor and medial walls using a folded single u-HA/PLLA sheet was 130.84° ± 5.42 at 1 day after surgery; this angle reflected a statistically significant increase of 133.68° ± 4.28 at 1 month after surgery (a paired t-test; p < .05) (Table 2). The further postoperative follow-up CTs showed changes of 134.46° ± 4.11 at 3 months after surgery and of 134.2° ± 4.77 at 6 months after surgery (a paired t-test; p > .05), but these changes were not statistically significant (Table 2). Thus, the OHMW-angle of the reconstructed folded single u-HA/PLLA sheet showed the greatest change during the first month following orbital floor and medial wall reconstruction; these changes did not affect the ophthalmologic clinical characteristics of the patients. Moreover, bone healing was good around and beneath the u-HA/PLLA sheet, with bony (possibly regenerated osteoconduction) radio-opaque tissues at 6-months postoperatively, and there was no CT evidence of complications, such as nonunion, mobility, resorption of the orbital wall bony segments, or migration with breakage or loosening in any patients.

The results were also regularly both clinically and radiographically evaluated based on CT as described above. Each patient was examined by ophthalmologists before and after the surgical procedure; visual acuity improved after the acute phase of trauma and surgery in all cases, and there was no record of complete or partial vision loss in any of the study subjects. All patients presented with preoperative diplopia, which resolved after surgery in all cases (Fig. 3). No patients complained of visual problems, and no further treatment was required by 6 months after surgery. Preoperative enophthalmos (asymmetry with more than a 2-mm difference), which was observed based on Hertel exophthalmometry in all five patients, was also resolved 1 month after surgery. Postoperative slight eyelid ectropion was found in two patients after surgery using a subtemporal approach, within a small degree, but the condition resolved spontaneously without further treatment. Clinical follow-up revealed no surgical site infections (e.g., sinusitis) or clinical signs of persistent inflammation due to foreign-body reactions. No patients complained of surgical site problems at the final postoperative checkup, which occurred after a mean follow-up period of 9.1 months (range, 6 to 18 months), and no patients in this study required secondary surgical procedures.

**Discussion**

In this report, u-HA/PLLA composite effectively could meet all the ideal characteristics of an orbital implant material^{1,2,4,10-14}. Briefly, in defining the ideal characteristics of an orbital implant material, many surgeons prefer materials that 1) allow conformation to an anatomical shape, 2) are radiopaque, and 3) remain stable over time. This is because, as discussed in this report, larger and more complicated orbital fractures (types III and IV) with "combined orbital floor and medial wall fractures" are highly complex with regard to anatomy, surgical technique, and ophthalmology and require special consideration of both contour and biocompatibility^{10-14,16}. In this respect, a single u-HA/PLLA sheet was then fabricated, shaped, and prepared by folding, achieving an optimal angle between the orbital floor and medial walls using computer-assisted 3D morphological individual customization. Further support of the final intraoperative navigation revealed anatomically correct reduction of the orbital contents with full bony suspension spanning the combined defects in the orbital floor and medial walls following insertion of the single folded u-HA/PLLA sheet via a subtemporal approach or a combined transcaruncular-transconjunctival approach without any difficulties. At 1 month after surgery, the reconstructed OHMW-angle showed a slight increase, which may be due to ophthalmologic functional pressure, weight, or stabilization by the surrounding orbital bony ledges. We also observed the stability of the bony union to the native orbital skeletons with regeneration, and minimal functional and cosmetic complications^{1,13,14}. Additionally, tack fixation could limit unstable positions in the single folded u-HA/PLLA composite sheet under ophthalmologic functional pressure and weight, providing a non-fragile and anatomically complicated periorbital maxillofacial bony region without the risk of unexpected orbital wall breakage, which would worsen the orbital wall defect and lead to screw loosening^{13}. However, follow up is crucial until 1 month after surgery after combined orbital floor and medial wall fracture reconstruction, and OHMW-angular or positional changes should be monitored until 3 months after surgery.

u-HA/PLLA composites are one of the most promising orbital reconstruction implant materials for combined orbital floor and medial wall fractures of type III and IV defects as they fulfill all three clinical requirements listed above, easy to adjust with skeletal well fit and, properly and stably fixed with tacks, as reported here^{1,14}. Together, u-HA/LLPA composites are advantageous for bone healing and allow for easy shaping and adjustment of the 3D morphology, in addition to their osteoconductivity, bioreabsorbability, and long-term stability^{1,13,14}. However, as complete resorption can take over 5 years, this gradual progress should be followed regularly by CT during bone healing^{14,17}. We believe that these composites may be more useful than conventional metal materials, such as titanium mesh or sheet plates, as well as other commercially available bioreabsorbable materials^{7,10}, such as PLLA and PLLA/PGA sheets, panels, or mesh, for the surgical reconstruction of midfacial fractures and the repair of large orbital wall defects, as described here. We used CT radiography to confirm orbital floor healing during the late postoperative period in all patients; the reconstructed sheets could be observed because the u-HA particles render them radiopaque, another advantage of this type of material. CT radiography
confirmed that the sheets spanned the entire fracture site at various stages of healing in all patients; this is indicative of the promotion of bone regeneration by this osteoconductive bioactive material, which represents another major advantage\textsuperscript{1,12-14}.

Computer-assisted surgery (CAS) can improve outcomes in complicated maxillofacial trauma surgeries\textsuperscript{1,11,16,18}. The use of 3D CT imaging reconstruction and virtual planning provides accurate and individualized assessment for the restoration of orbital walls, orbital volume, and orbital fractures with bony defects as reported here\textsuperscript{1,11,16,18}. Proper implant sizing and shaping is critical to the success of this technique. Given the relatively large surface area of the implant, the rigidity of the material, and the close proximity of the implant to vital orbital structures, seemingly small deviations in contour and shape can result in significant complications\textsuperscript{1,11,16,18}. Therefore, we recommend the use of computer-assisted 3D morphological customization, even for the single folded u-HA/PLLA composite sheet, as well as the use of preoperative CT scan measurements to determine the appropriate dimensions of the implant. Additionally, 3D intraoperative final positioning of the implant on stable ledges of bone is critical, as no implant (no matter how well designed or shaped) will function properly if not placed in an anatomically correct position\textsuperscript{1,11,16,18,19}.

A patient-specific titanium mesh orbital wall reconstruction system, based on such CAS, is the most commonly used implant material for complicated orbital reconstructions\textsuperscript{10,11,15,20}, such as the combined orbital floor and medial wall defect fractures described here, with feasibility shown in some limited case series reports; however, other modern materials, such as the u-HA/PLLA composites, may be optimal materials as they are patient-specific and anatomically modified bioactive orbital implants. These materials can be combined with current CAS techniques. Another advantage of CAS and the surgical navigation system is the possibility of checking implant fit both preoperatively and intraoperatively in an accurate digital environment\textsuperscript{18-20}. This digital planning is not material-specific: the only prerequisite is that the material is sufficiently rigid and the digitally formed shape is coherent with the actual shape of the implant, even after manipulation.

The retrospective design, non-randomized patient selection, and relatively short, mid-term follow up together with the 2-dimensional reconstructed material evaluation index using OHMW-angle were weaknesses of this study, necessitating further clinical and 3-dimensional evaluation, together with long-term studies to establish an evidence-based protocol for surgical reconstructive treatment using computer-assisted and intraoperative navigation-assisted large orbital floor and medial wall defect fracture reconstruction using a single folded u-HA/PLLA composite sheet with a tack fixation technique.

In conclusion, this retrospective clinical study showed that computer-assisted single folded u-HA/PLLA sheets with a tack fixation technique provide stable and satisfactory ophthalmologic functional results for complex combined orbital floor and medial wall fracture reconstruction with no intraoperative or postoperative complications.

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**Conflict of Interest**

The authors have declared that no COI exists in this research.

**References**


