Clinical Report

Applicability of an Unsintered Hydroxyapatite Particles/Poly-L-Lactide Composite Sheet with Tack Fixation for Orbital Fracture Reconstruction

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(Received for publication, May 11, 2016)

Abstract: The aim of this retrospective clinical study was to evaluate the applicability of newly developed uncalkined and unsintered hydroxyapatite (u-HA) particles and poly-L-lactide (PLLA; u-HA/PLLA) composite sheets with tack fixation for navigation-assisted orbital fracture reconstruction. Osteosynthetic bone fixation and reconstruction systems made from u-HA/PLLA composites have recently drawn attention for effective application in maxillofacial bone surgery because of their osteoconductive properties and bioresorbability. One limitation of these systems in the clinical setting, however, is the complicated drill hole tapping that is required for screw fixation. Herein, we report the feasible application of a u-HA/PLLA sheet with tack fixation for intraoperative navigation-assisted orbital wall reconstruction; this approach may be suitable for fragile and anatomically complicated periorbital-maxillofacial bony regions. The study included 9 patients (mean age, 46.6 years) with moderate and medium complexity to large and high complexity orbital wall defects (3 type II defects and 6 type III). The mean follow-up period was 8.9 months (range, 6 to 18 months). Overall, the application of the u-HA/PLLA sheet with tack fixation gave excellent stability for orbital wall reconstruction at the infraorbital rim, and produced satisfactory ophthalmologic functional results with no intraoperative or postoperative complications. This material may be an optimal bioactive, osteoconductive, and bioresorbable bone alternative for orbital wall reconstruction with fewer complications in patients with orbital fractures.

Key words: Bioactive, Orbital reconstruction, Osteoconductive, Tack fixation, u-HA/PLLA

Introduction

Orbital fractures with orbital defects are some of the most common facial fractures encountered by oral and maxillofacial surgeons because of the exposed position and thin bony walls of the midface area1,2). Almost 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 also occur alone1,2). Complications caused by failed primary reconstruction of posttraumatic orbital deformities include diplopia, enophthalmos, restricted eyeball mobility, disturbed sensory innervation, reduced globe motility, and altered visual acuity related to increased orbital volume1,2,3). The primary goal of reconstructing the internal orbital cavity is to restore the pre-injury anatomy and volume of hard tissue, and to free incarcerated or prolapsed orbital tissue from the fracture, by spanning the bony defects with reconstructive implant material and restoring the maxillofacial-orbital skeleton with open reduction and internal fixation of fractures1,3).

Super Fixsorb-MX® (Japanese trade name; also known as OSTEOTRANS-MX overseas; Takiron Co. Ltd.,Osaka, Japan) is a promising bioactive, osteoconductive, and totally resorbable osteosynthetic bone fixation device that has recently drawn attention for its long-term clinical stability in maxillofacial skeletal fixation and reconstruction4,5). The device material, which is a composite of fine unsintered hydroxyapatite (u-HA) particles and carbonated ions combined with poly-L-lactide (PLLA; u-HA/PLLA), has a mechanical strength approximating that of human cortical bone and is suitable for clinical applications involving the maxillofacial bony regions, including maxillofacial trauma repair and orthognathic and reconstructive surgery4,5). The groundbreaking osteoconductive and bioactive properties of these composites allow them to fuse directly with bone. Furthermore, because they are bioactive and biodegradable, u-HA/PLLA composites have the potential to stimulate total bone replacement...
with mechanically rigid and stable strength, even for thin sheets and plates. Thus, u-HA/PLLA composites are of great 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.

However, as is true of all implant materials for orbital wall reconstruction, stable fixation is required to prevent migration, which can lead to infections, fibrosis, and scarring. Severe complications may require secondary surgery or result in diplopia or even blindness. With the exceptions of bioglass and the recent preliminary application of fibrin-glue adhesive, orbital implant materials generally must be stably fixed to the surrounding periorbital tissues, mostly to the buttressing periorbital bone, for spanning of the orbital defect with sufficient longevity and minimal complications. In this respect, one limitation of current bioresorbable implants, including u-HA/PLLA composites, is the need for repeated tapping to prepare drill holes before screw insertion. This can create technical difficulties in fragile and anatomically complicated periorbital maxillofacial bony regions, especially in cases with additional associated midfacial and periorbital bone fractures. In order to overcome this drawback, tack fixation systems have been developed for the application of thin u-HA/PLLA composite sheets in reconstructive surgery for large orbital wall fractures.

Herein, we report the feasible preliminary application of this newly developed tack fixation system for intraoperative navigation-aided orbital wall reconstruction using bioresorbable, osteoconductive, and bioactive u-HA/PLLA composite implant materials in patients with orbital defect fracture.

Materials and Methods

Patients

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

The Institutional Review Board of the hospital approved this retrospective study (number 2056), which was conducted 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 old) with orbital wall defects, including pure blowout fractures as well as impure blowout fractures occurring in association with zygomatic complex fractures, Le Fort type fractures, and naso-orbital-ethmoid fractures; 2) surgical treatment with orbital wall reconstruction using a u-HA/PLLA composite sheet with tack fixation and complete medical records available for evaluation by the authors; 3) the availability of preoperative and postoperative computed tomography (CT) radiographs; and 4) regular clinical follow-up for more than 6 months according to our clinical and radiographic records, as well as follow-up examinations by ophthalmologists at 1 week, 1 month, 3 months, 6 months, and more than 6 months after surgery, at minimum. We excluded patients who did not meet all the inclusion criteria above (e.g., treated by another orbital reconstruction materials) and patients who did not regularly attend follow-up evaluation up to 6 months.

u-HA/PLLA composite tack fixation systems

The bone fixation tacks and sheets were both commercially available composites of u-HA/PLLA (Super Fixsorb-MX; Takiron Co. Ltd., Osaka, Japan), and indicated for whole maxillofacial bone fixation. The tacks were 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 (Fig. 1A). The u-HA/PLLA sheets were 0.5 mm thick panel. After drilling, a facilitator and hammer were used to tap the tacks into the sheet and periorbital bone (Fig. 1B).

Classification of orbital wall defects

For patient profiles, orbital wall defect sizes were classified according to the modified system described by Dubois et al., which was based on the simplified two-dimensional fracture model originally described by Jaquiéry et al. Additional and/or associated maxillofacial fractures and the cause of trauma were also recorded.

Surgical procedure

All surgeries were performed by experienced maxillofacial
trauma surgeons based on a single surgical team (chief maxillofacial trauma surgeon TKa, Maxillofacial Trauma Center, Shimane University Hospital, Izumo, Shimane, Japan). Surgeries were performed within 2 weeks after the injuries, under general anesthesia. An intraoperative navigation system (BrainLab, Feldkirchen, Germany) was routinely used to determine the extent of orbital wall defects and to confirm accurate placement of the u-HA/PLLA sheet implant for reconstruction (Fig. 1C). A retroseptal transconjunctival approach without lateral canthotomy was used to access the orbit in 6 cases of orbital floor reconstruction, and a subtarsal approach was used for the other 3 cases, which involved more complex defects of the orbital floor and medial walls as well as reduction and fixation of associated periorbital fractures (Table 1). Accurate placement of the u-HA/PLLA sheet implant and modification of the sheet to correctly span the anatomical defect were confirmed using the intraoperative navigation system for precise adjustment (Fig. 2A). After drilling, a facilitator and hammer were used to manually tap two 5-mm tacks into the sheet and infraorbital rim. Postoperative CT scans were performed within 24 h after surgery.

An intravenous antibiotic (1.0 g cepezolin sodium/12 h) was administered on hospital admission and continued until the third postoperative day.

**Clinical evaluations**

Clinical data regarding any abnormal postoperative events were collected from the medical records of patient evaluations carried out pre-, intra-, and postoperatively. All patients underwent routine pre- and postoperative ophthalmological examinations at the Department of Ophthalmology, Shimane University Hospital. Postoperative CT radiographic evaluations were performed to assess orbital fracture healing and the accuracy of the orbital reconstruction and u-HA/PLLA sheet implant position at 1 day and 1, 3 and 6 months postoperatively.

**Results**

During the 1.5-year study period, 26 patients with midface fractures with orbital wall defects were treated with orbital reconstruction at our Maxillofacial Trauma Center. Of these, 9 patients, all Japanese, met the inclusion criteria and were analyzed for this study.

Patient profiles are summarized in Table 1. Briefly, the study sample was composed of 5 male patients and 4 female patients, with ages ranging from 17 to 74 years (mean age, 46.6 years).
Numerous studies have reported orbital fracture repair with a variety of implant materials that offer various advantages and disadvantages. However, in defining the ideal characteristics of an orbital implant, many surgeons prefer materials that 1) allow conformation to anatomical shape, 2) are radiopaque, and 3)
remained stable over time, especially for the reconstruction of relatively large bony walls. In cases of linear fractures or relatively small defects (categories I and II), successful outcomes are predictable with a wide variety of flexible implant materials, such as membranes.\textsuperscript{3,8,10} Larger and more complicated orbital fractures (types III and IV) are highly complex with regard to anatomy, surgical technique, and ophthalmology, and require special consideration of both contour and biocompatibility.\textsuperscript{9-12}\textsuperscript{9,12} In this regard, u-HA/PLLA composites are one of the most promising orbital reconstruction implant materials, as they fulfill all three clinical requirements listed above.\textsuperscript{4,5,10} These materials are particularly suitable for application as an internal reconstructive bone fixation device in the anatomically complex maxillofacial skeletal region, not only because of their mechanical properties (such as their thinness and their mechanical and bending strength, which approaches that of maxillofacial cortical bone) but also because of their osteoconductivity and bioresorbability.\textsuperscript{4,5,10} Together, these characteristics make u-HA/LLPA composites highly advantageous for bone healing and allow easy shaping and adjustment to three-dimensional morphology. With the use of appropriate surgical techniques, we believe that these composites may supersede conventional metal materials, such as titanium mesh or sheet plates as well as other commercially available bioresorbable materials, such as PLLA and PLLA/PGA sheets, panels, or mesh for surgical reconstruction of midfacial fractures with repair of large orbital wall defects.\textsuperscript{4,5,12,13\textsuperscript{4,5,12,13}}

With regard to bioresorbability, reinforced fabricated PLLA is hydrophobic and degrades slowly; a thin PLLA film provides an interface with invading water molecules, allowing homogeneous hydrolysis and steady degradation of the PLLA matrix in u-HA/PLLA composite materials.\textsuperscript{12,13}\textsuperscript{12,13} The resulting release of small amounts of PLLA debris has not been shown to provoke adverse tissue responses in experimental or clinical studies.\textsuperscript{4,5,12,13,14}\textsuperscript{4,5,12,13,14} Thus, u-HA/PLLA has the advantage of preventing foreign-body reactions because of its moderate and stable hydrolysis. The sheet and tack fixation system examined in this study has demonstrated stable degradation without foreign body reactions in vivo.\textsuperscript{4,5,12,13,14,16}\textsuperscript{4,5,12,13,14,16} However, as complete resorption is a lengthy process occurring over 5 years or more, its gradual progress must be followed regularly by CT during bone healing.\textsuperscript{6}\textsuperscript{6} We here used CT radiography to confirm orbital floor healing in 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 demonstrated spanning of the fracture site by the reconstructed sheet at various stages of healing in all patients, indicating the promotion of bone regeneration by this osteoconductive bioactive material, as reported previously.\textsuperscript{6}\textsuperscript{6}

Furthermore, the newly developed tack fixation system functioned well to stably fix the u-HA/PLLA composite sheet to fragile and anatomically complicated periorbital maxillofacial bony regions without the risk of unexpected orbital wall breakage, which would worsen the orbital wall defect and cause screw loosening. The new system eliminates the need for technically complicated tapping procedures before screw insertion, which had previously been reported as a drawback of fixation using bioresorbable implant materials for maxillofacial surgery.\textsuperscript{9,10,13}\textsuperscript{9,10,13} Altogether, u-HA/PLLA composite sheets with tack fixation have substantial clinical advantages and potential for broader applications in maxillofacial fracture repair surgery, such as more complex, complicated, or comminuted periorbital and midfacial fractures or bone regenerative surgical sites.\textsuperscript{4-7}\textsuperscript{4-7}

Computer-assisted surgery (CAS) could greatly improve outcomes in these types of complicated fracture surgeries.\textsuperscript{16-19}\textsuperscript{16-19} The use of three-dimensional CT imaging reconstruction and virtual planning offers accurate and individualized assessment for the restoration of orbital walls, orbital volume, and orbital fractures with bony defects.\textsuperscript{16-19}\textsuperscript{16-19} One of the greatest advantages of CAS and especially surgical navigation systems is the possibility of checking implant fit both preoperatively and intraoperatively in an accurate digital environment.\textsuperscript{19}\textsuperscript{19} This digital planning is not material-specific: the only prerequisite is that the material be sufficiently rigid that the digitally formed shape is coherent with the actual shape of the implant, even after manipulation.\textsuperscript{18,20}\textsuperscript{18,20}

A patient-specific titanium mesh orbital wall reconstruction system has been clinically shown to meet this prerequisite\textsuperscript{18,20}\textsuperscript{18,20} and is currently the most commonly used implant material for complicated orbital reconstructions, with feasibility shown in some limited case series reports;\textsuperscript{17-19}\textsuperscript{17-19} however, other modern materials, such as the u-HA/PLLA composites described here, may in the near future become the best material and more frequently implemented as patient-specific, anatomically modified bioactive orbital implants, with the combined application of current CAS techniques.

The retrospective design and non-randomized patient selection were weaknesses of this study. Further clinical studies using contemporary CAS techniques, such as intraoperative surgical navigation, should be performed to establish an evidence-based protocol for surgical reconstructive treatment of orbital fracture using the u-HA/PLLA composite sheet with tack fixation.

In conclusion, this retrospective clinical study showed that the u-HA/PLLA composite sheet with application of a newly developed tack fixation system is an optimal next-generation bioactive implant material for the reconstruction of relatively large orbital wall defects, with minimal complications.

**Conflict of Interest**

The authors have declared that no COI exists.

**References**


