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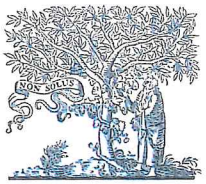

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Immediate and long-term results of unsintered hydroxyapatite and poly L-lactide composite sheets for orbital wall fracture reconstruction

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KEYWORDS
Orbital wall fracture;
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Long-term result

Summary *Introduction:* Bone defect reconstruction in orbital wall fractures with absorbable alloplastic such as the unsintered hydroxyapatite and poly L-lactide composite (u-HA/PLLA) system is gaining popularity. The u-HA/PLLA material has osteoconductive and osteosynthetic properties. However, quantitative, long-term outcome data after the use of u-HA/PLLA for orbital wall fractures are lacking.

Patients and Methods: We retrospectively analyzed 115 patients who underwent surgical repair of orbital wall fractures with a u-HA/PLLA sheet from 2011 to 2016. A chart review was performed, and the time-dependent changes at fracture sites were assessed by imaging. The immediate postoperative and the latest follow-up bony orbital volumes of the affected side were compared.

Results: Seventy patients were eligible for this study (mean age, 44.6 ± 22.1 years; 48 men and 22 women; mean follow-up period, 29.7 ± 12.8 months). Except for one case of hematoma, there were no postoperative wound complications. Of the 70 patients, 10 had postoperative diplopia and 2 had enophthalmos; these conditions were presumably caused by the extension and severity of the fracture. Satisfactory reduction in the entire orbital wall, without pathological changes, was demonstrated. There were no significant differences in the mean bony orbital volumes of the affected side immediately after surgery (24.774 ± 3.092 cm^3) and at the latest follow-up (24.749 ± 3.205 cm^3) ($p = 0.756$).

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Conclusion: The u-HA/PLLA sheet is useful for orbital wall fracture reconstruction because of its desirable handling characteristics, initial mechanical strength, long-term maintenance of structural stability, radiopacity, and few associated complications. Future randomized controlled trials need to be performed to compare u-HA/PLLA with other conventional materials.

Introduction

The orbit is the site of most facial fractures.[1] Owing to its important aesthetic and functional contribution to the facial skeleton, fractures to the orbit should be considered seriously.[2] Surgery for orbital wall fractures involves the release of the entrapped soft tissue and its appropriate repositioning inside the bony orbit. It also entails reconstruction of the normal wall to prevent any periorbital soft tissue from herniating into the maxillary or ethmoidal sinus.[2] In cases with bone defects, implants are used for reconstruction. The implant material for orbital wall reconstruction should be readily available, easy to mould, easy to anchor, biocompatible, noncarcinogenic, and strong.[3] To try and satisfy these criteria, the use of various materials has been attempted while the development of novel ones is ongoing.

Among the implant materials, absorbable alloplastic is currently gaining popularity. The unsintered hydroxyapatite and poly L-lactide composite (u-HA/PLLA) fixation plate system (OSTEOTRANS MX; Teijin Medical Technologies, Osaka, Japan) is one such material that has been developed to possess osteoconductive and osteosynthetic properties and its clinical usefulness has been demonstrated in several fields.[4-11]

However, to the best of our knowledge, the English-language literature lacks quantitative and long-term information on the effectiveness and the complications related to the use of u-HA/PLLA sheets in the reconstruction of orbital wall fractures.

The purposes of this study were to report our experiences with the clinical application of this osteosynthetic device in the treatment of orbital wall fractures and to objectively examine its safety and efficacy.

Patients and methods

Study subjects

Among the 231 patients with orbital wall fractures who underwent surgical repair at the Department of Plastic and Reconstructive Surgery, Ogaki Municipal Hospital, Gifu, Japan, from July 2011 to July 2016, the authors retrospectively reviewed 115 patients who were treated with the u-HA/PLLA sheet. The other patients were treated as follows: without artificial materials, 89 patients; with poly-L-lactic acid and poly-glycolic acid sheets, 20 patients; with silicon, 3 patients; with titanium, 3 patients; and with bone grafts, 1 patient. The exclusion criteria were failure to follow-up within 3 months after operation, incomplete documentation or images examinations, and eyeball injury.

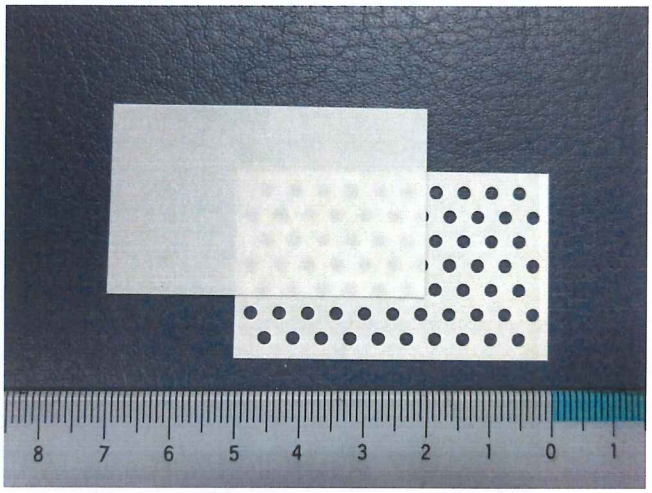

Figure 1 The smooth and porous mesh of the u-HA/PLLA sheet. The sheet is extremely thin and the porous mesh can be observed through the smooth sheet.

Indications for operation

At our hospital, the indications for operation were determined by the presence of symptoms and signs such as enophthalmos, diplopia, limited eyeball motility, and soft tissue displacement into the maxillary sinus on radiological workup. Although we usually use the sheet to reconstruct the orbital wall, we avoid its use in cases where the defect is very large and the sheet does not rest on the stable bone. In such cases, we use a titanium mesh.

Operative technique

All surgeries were performed under general anesthesia after a thorough physical and radiological examination. Restoration of the medial orbital wall was performed with the medial angle incision approach, whereas resection of the inferior orbital wall was routinely performed through the subciliary approach. After the incision, subperiosteal dissection was performed and the defect was exposed circumferentially. Dislocated bone fragments and orbital soft tissues were lifted out of the fracture site and repositioned. The u-HA/PLLA sheet was then designed, shaped with scissors to fit, and placed to bridge the defect. No part of the sheet was fixed to the wall. The thickness of the sheet used was 0.5 mm, and although the porous mesh type was used in our early experience, we switched to the smooth sheet type later on to avoid adhesions (Figure 1). Before wound closure, a forced duction test was performed to confirm that there was no residual soft tissue incarceration in the fracture site.

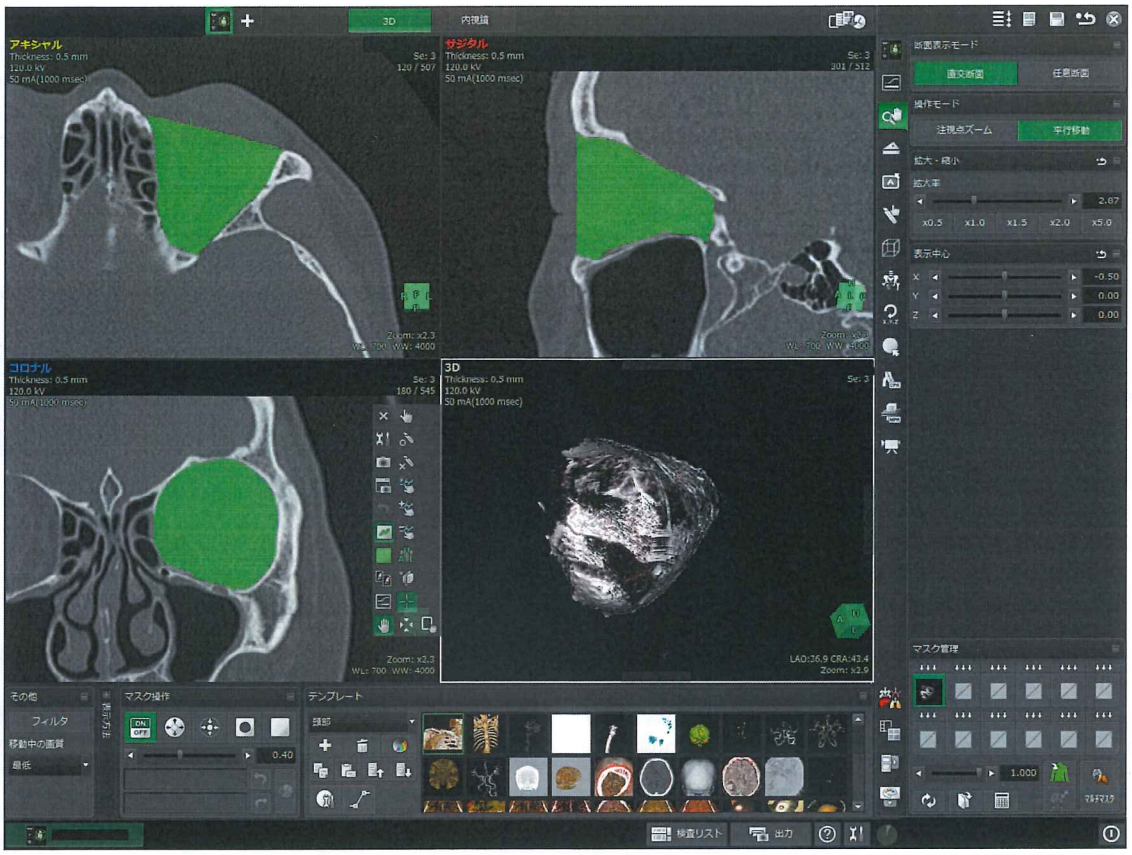

Figure 2 Screenshot from the analysis software after segmentation of the left orbit.

Variables assessed and recorded

This was a retrospective review, where we used the medical charts to obtain data on demographic characteristics, symptoms, cause of trauma, imaging analysis, time from trauma to surgery, postoperative complications (especially originating from the implanted materials), follow-up time, and follow-up findings. We assessed the fracture sites using computed tomography (CT). The patients underwent CT examinations before the operation, immediately after the operation, and afterwards in conjunction with a clinical examination. Follow-up visits were scheduled at 1 week, 1 month, 3 months, 6 months, 1 year, and yearly thereafter to check for complications. Enophthalmos of more than 2 mm relative to the opposite side was determined by a Hertel exophthalmometer (Oculus Inc., Wetzlar, Germany). Double vision in the primary position and within 30° of gaze that interfered with the patient's ordinary activities was subjectively defined as diplopia.

Imaging examinations and measurements

The CT examinations were performed using the Aquilion 16 CT scanner (Toshiba Medical Systems, Otawara, Japan) with 0.5-mm-thick contiguous slices. The bony orbital volume was measured using the Synapse Vincent three-dimensional image analysis device (Fujifilm Medical Systems, Tokyo, Japan). The bony orbital boundaries were traced manually using the mouse cursor in the axial, coronal, and sagittal planes, and the reconstruction of each slice was performed automatically using the system (Figure 2). This device can judge the boundary of the bone and soft tissue automatically to some extent, and this helped our manipulation.

Statistical analysis

The immediate postoperative and the latest follow-up bony orbital volumes of the affected side were compared with paired t-tests. In this comparison, the patients younger than 10 years were excluded, as the growth of the head might lead to misleading results. *P*-values corresponding to <0.05 were considered statistically significant. The statistical tests were performed using the SPSS 12.0 software package (SPSS Inc., Chicago, IL).

Ethical policy

This was a retrospective, nonrandomized, interventional case series. Information on the efficacy and safety of the u-HA/PLLA sheet was provided to the patients, and written consent was obtained. Because of the retrospective nature of data collection, ethical committee approval was not required for this study.

Results

Seventy patients were eligible for this study, including 48 male and 22 female patients. The age range was 5–84 years,

with a mean of 44.6 ± 22.1 years. The postoperative follow-up period ranged from 3.3 to 52.3 months (mean, 29.7 ± 12.8 months). The main cause of exclusion was loss to follow-up. The most common cause of fractures was falls (27 cases, 38.6%), followed by traffic accidents (14 cases, 20.0%), sports (12 cases, 17.1%), and fist blows (10 cases, 14.3%). Concomitant maxillofacial fractures were present in 39 patients (55.7%). Before the operation, 31 patients had diplopia, 13 had infraorbital nerve hypaesthesia, and 9 had enophthalmos; 10 patients had more than one symptom. Some patients could not be evaluated adequately before the operation because they were uncooperative or unconscious or had facial swelling. Surgery for symptomatic diplopia or limited eye motility was performed in 31 patients (44.3%). The indication for surgery in the remaining 39 patients (55.7%) was enophthalmos or possible enophthalmos indicated by an apparent orbital wall defect. The delay between the accident and the surgery ranged from 0 to 37 days (mean, 7.3 ± 5.1 days).

In the immediate postoperative period, hematoma was observed in one patient and was treated by a Penrose drain. Except for this single complication, there were no postoperative wound complications (including infections or extrusions of the implant and foreign body reactions) during the follow-up period. The preoperative symptoms improved postoperatively in all patients. However, at their latest follow-up visits, seven patients (10.0%) had postoperative diplopia in the extreme gaze, two (2.9 %) had enophthalmos, and three (4.3 %) had infraorbital nerve disturbance. These sequelae can be assumed to be not due to the implant itself or time-dependent changes in the implant, but due to the extension and severity of the fracture that causes unrecoverable tissue damage and the undercorrection of the orbital wall reconstruction, such as in combined facial fractures.

In three patients, both orbits were included in the analysis; therefore, the number of evaluated orbits was 72. As fracture sites, 23 orbits (31.9%) had solo orbital floor fractures, 18 (25.0%) had solo medial wall fractures, and 31 (43.1%) had orbital floor and medial wall combination fractures. All the implanted materials were visualized, and satisfactory reduction in the orbital wall and restoration of the original anatomic position were demonstrated with CT during the follow-up period (Figures 3 and 4). In all cases, a gradual decrease in the density of the implant was observed on CT images, eventually reaching a density nearly same as that of the bone. However, none of the implants were totally resorbed. Follow-up CT images demonstrated that the u-HA/PLLA sheet firmly maintained its fit to the contour of the orbital wall without deviation, herniation of soft tissue into the maxillary sinus, broad or round sagging effects, or any other changes surrounding it.

The mean bony orbital volumes of the affected side were 24.774 ± 3.092 cm^3 (range, 19.732–35.533) immediately after surgery and 24.749 ± 3.205 cm^3 (range, 19.404–36.381) at the latest follow-up (one patient's orbit was excluded owing to age). There were no significant differences in bony orbital volume immediately after surgery and at the latest follow-up ($p = 0.756$). Even in the patients with enophthalmos at the latest follow-up, the enophthalmos did not depend on the postoperative bony orbital volume change. The orbital wall reconstruction did not seem to result in any pathologic change in bony orbital volume.

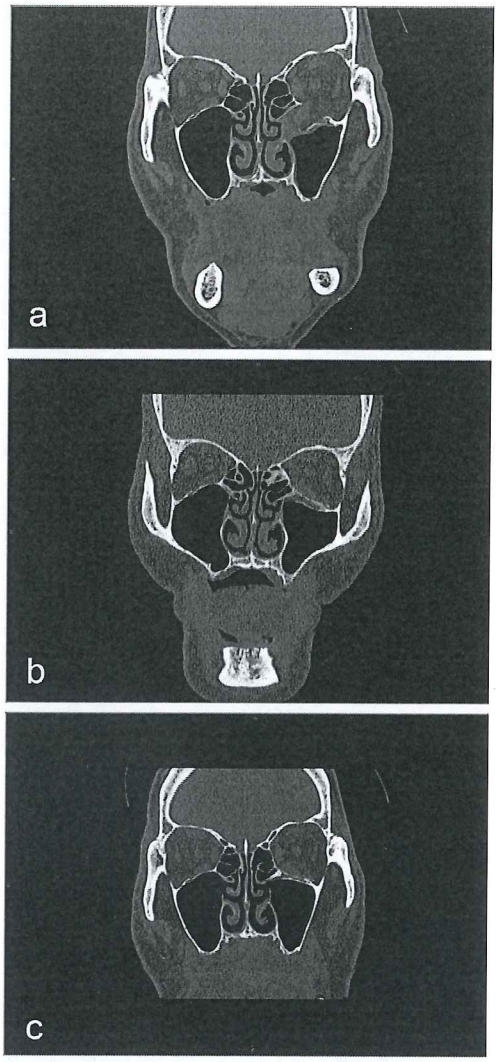

Figure 3 Coronal computed tomography findings in a 63-year man with orbital wall fracture caused by a fall. a, Preoperatively, the left orbital floor fracture and soft tissue herniation with a bony defect is seen. b, Two-months after the operation, the left orbital floor was reconstructed with the u-HA/PLLA sheet. c, Fifty-one months after the operation, satisfactory reduction and fixation was maintained.

Discussion

The u-HA/PLLA fixation system consists of a fine particle composite of bioactive and bioresorbable u-HA and carbonated ion, combined with PLLA that has been reinforced using a forging process involving a unique compression molding and machining treatment.[4,12] The u-HA/PLLA sheet is 40% u-HA by weight. Commercially available u-HA/PLLA sheets include the porous mesh type and nonporous sheet type and are 25–50 mm in length, and 0.5–0.7 mm in thickness. The sheet can be cut with scissors, and its shape can be adjusted to match the defect easily. Although the sheet is more brittle than titanium, it can be bent in the same way owing to the elastic property of u-HA/PLLA.[5]

These composites have greater mechanical strength than any other previously used bioactive materials, with an initial bending strength of 270 MPa (greater than that of the

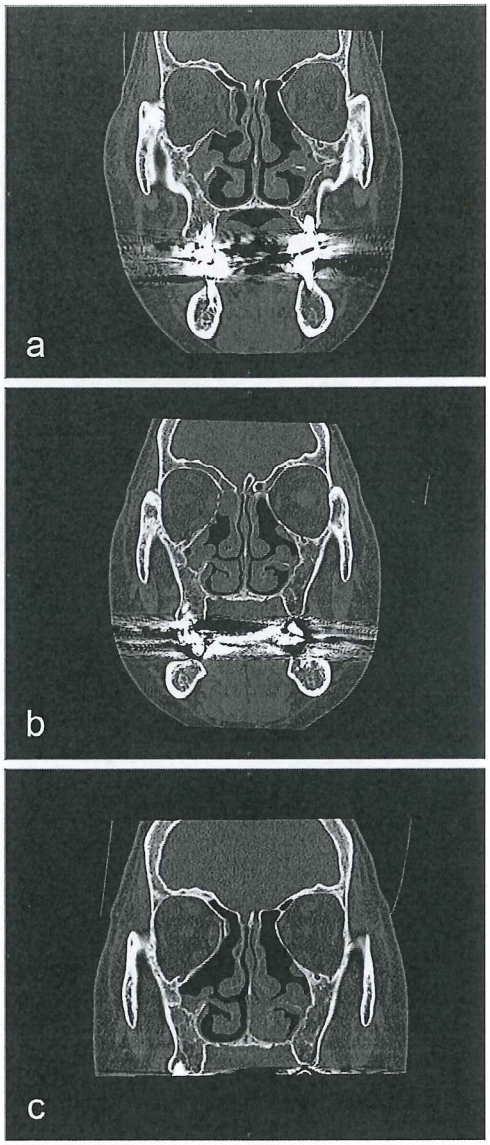

Figure 4 Coronal computed tomography findings in a 62-year woman with orbital wall fracture caused by a fall. a, Preoperatively, the right orbital floor and medial wall fracture and soft tissue herniation with a bony are seen. b, Immediately after the operation, the orbital floor and medial wall were satisfactorily reduced with the u-HA/PLLA sheet. c, Forty-seven months after the operation, the curve and the location of the implant were satisfactory.

cortical bone), a modulus of 12 GPa (almost equivalent to that of the cortical bone), and an impact strength of 166 kJ/m^2 (about twice the value of polycarbonate).[5,8] In addition, these devices retained a bending strength equal to that of the human cortical bone for 25 weeks in vivo.[4,13] There are some clinical reports that indicate no significant difference in the postoperative time-course stability between the u-HA/PLLA plate system and conventional titanium plate systems.[6,7] Similar to the results in these reports, the sheet in our study was able to maintain the bony orbital volume during the follow-up period.

U-HA/PLLA has been reported to have good biocompatibility and osteoconductivity.[14] This leads to good bone-bonding capability, and animal experiments have demonstrated direct bonding between the u-HA/PLLA and the bone without interposition of nonmineralized tissue.[13,14]

The complete process of bioresorption and bone replacement of the u-HA/PLLA implants was documented by Shikinami et al.[12] They elucidated how biodegradation of the u-HA/PLLA was accompanied by the following processes: gradual loss of strength; resorption of PLLA, which was degraded to a low-molecular-weight compound; and release of unbound u-HA debris and deposition of calcium phosphates, which affected osteoconduction.[12] As a result, the mechanical strength of the u-HA/PLLA implant was almost lost after 2.5 years, the PLLA matrix was completely absent after 4.5–5.0 years, and almost all u-HA particles were replaced with the natural bone after 5.5 years, with no significant foreign-body reaction or inflammation.[12] The inclusion of long-term u-HA/PLLA residual material into the regenerating bone after it had been used for facial fracture fixation was demonstrated by bone biopsy.[8] Although it is unclear how the sheet changed during the follow-up period in our cases, it may well have been replaced by the normal bone according to the reports.

The u-HA/PLLA sheet is radiopaque, and the device can be observed clearly on radiographic images without metallic artifacts.[9] This is a major advantage that enables the evaluation of device positions on radiographs at postoperative follow-up.[9] In fact, all the sheets used in our cases could clearly be observed on CT scans postoperatively and until the final follow-up.

However, several possible disadvantages remain. First, the possible postoperative complications following the use of u-HA/PLLA are not yet known. To the best of our knowledge, only two previous studies in other fields reported postoperative wound complications. Landes et al reported that 2/29 patients had foreign-body reactions near the plate, and Hayashi et al reported that 1/17 patients had foreign-body reactions and 1/17 patients has bone excesses, all of which occurred more than 6 months after the operation.[4,8] Numerous other reports documented no postoperative wound infections or foreign-body granulomas.[5–7,9–11]

In all these studies, the implanted u-HA/PLLA plate was surrounded with viable tissue.[4–11] However, in our case, the sheets were implanted in the fractured orbit, which is usually connected to the nasal cavity or paranasal sinuses. This is an important risk factor for infection or other postoperative complications. Nevertheless, none of our patients exhibited any sign of infection or inflammatory reactions in the follow-up period. We believe that the plate's biocompatibility and amenability to host-tissue ingrowth avoids complications. Postoperative hematoma occurred in one patient, and its relation to the use of the sheet was unclear.

Compared to other conventional alloplastic materials, wound complication rates such as infection or foreign body reactions after orbital wall reconstruction might be lower with the u-HA/PLLA sheet.[15–18] However, because of varying experimental conditions, a direct comparison between studies is difficult.

In addition to postoperative wound complications, some sequelae did persist at the latest follow-up visit despite successful surgery. Some were caused by the unrecoverable damage to the tissue at the time of injury, whereas others were caused by the extension and severity of the fracture,

thus causing undercorrection of the orbital wall. Several authors have reported similar sequelae in cases involving other materials, and our results agree with these reports.[3,19]

Postoperative changes in the bony orbital volume after reconstruction with an absorbable plate may also be a problem.[1,15,16] Theoretically, the role of absorbable alloplastic plates is to provide temporary support of orbital content, thereby allowing fibrous granulation tissue to develop as the plate degrades.[15,16,20] This protects orbital contents against herniation forces during the initial stage of healing.[20] In the case of conventional absorbable alloplastic materials, the developed fibrotic scar is not stiff and stable enough to provide adequate support to the weight of the eyeball.[15-17] There have been some reports of sagging of orbital floors reconstructed by absorbable materials in the paranasal sinus on postoperative CT scans.[15-17] Therefore, absorbable materials are considered to carry a risk of reherniation and late enophthalmos.[1] Many factors such as fat atrophy, loss of ligament support, and scar contracture may lead to late enophthalmos; however, enlargement of the bony orbital volume is the major mechanism.[3] In our study, there were no significant differences between the bony orbital volumes of the affected side immediately after surgery and at the latest follow-up. This indicates that the reconstructed orbital wall is strong enough to support the orbital contents and that there was little movement of the implant over a long period.

There are two possible reasons for the sustained maintenance of the reconstructed orbital wall after long periods. One reason is that the u-HA/PLLA sheet is not absorbed, and the other reason is that it has been replaced with something firm. The absorbable property of u-HA/PLLA and its replacement with firm natural bone has been demonstrated in animal and clinical studies.[8,12] However, Shikinami et al pointed out that the bioactivity, bioresorbability, and osteoconductive behavior of u-HA/PLLA are dependent upon the implantation site.[12] As mentioned above, in the fractured orbit, some part of the sheet can be exposed to the nasal cavity or paranasal sinus, and as the fractured orbital wall is not flat and the sheets are placed to bridge the defect, the contact surface between the sheet and the bone or periosteum is small. Furthermore, even the modest contacting bone or periosteum is usually damaged by injury. Therefore, in the fractured orbit, the complete resorption of the sheet and total replacement with natural bone may take more time or not fully occur.

However, setting aside the question of bone replacement, the most significant finding is that all the sheets used in our study provided successful structural support of the eyeball without abnormal movement or complications during the follow-up period. The finding that structural support was maintained after 25 weeks (the point at which the u-HA/PLLA is no longer equal in bending strength to the human cortical bone[13]) is particularly noteworthy.

Although we attempted to minimize bias when analyzing complications and sequelae by excluding patients who were lost to follow-up within 3 months, had incomplete documentation or imaging examinations, and had eyeball injuries, certain limitations to our study should be considered. The main limitations are its retrospective, nonmatched, and nonrandomized nature; its small sample size; and the relatively short follow-up period. The authors recognize that further studies are necessary to advance our knowledge of this technique.

Conclusion

Our results demonstrated the excellent safety and effectiveness of the u-HA/PLLA sheet in the reconstruction of orbital wall fractures. The sheet is a useful device because of its desirable handling characteristics, initial mechanical strength, long-term maintenance of structural stability, radiopacity, and few complications. Most of these characteristics are the result of its biocompatibility and osteoconductivity. As bioresorption and total bone replacement was not confirmed, further observational studies need to be performed. Future randomized controlled trials need to be performed to compare u-HA/PLLA with other conventional materials.

Conflict of interest statement

None.

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