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Orbital Soft Tissue Displacement After Blow-Out Fracture Repair Using Poly (L-Lactide-Co-Glycolide) Polymer Plates Based on Image Fusion Technique

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Purpose: To analyze the displacement of orbital soft tissue after blow-out fracture (BOF) repair with poly (L-lactide-co-glycolide) plates.

Materials and Methods: In this retrospective study, all patients who had undergone repair operations for orbital BOF from 2017 to 2021 were evaluated. Poly (L-lactide-co-glycolide) plates were used as repair materials. Preoperative and postoperative computed tomography images were integrated into the same coordinate system applying image fusion technique and were compared to determine the maximum displacement of orbital tissue after surgical repair.

Results: A total of 15 patients were included. Five were male, and 10 were female. Mean age was 33 ± 16 years. Median waiting period was 18 (12–23) days. Six cases were medial wall fractures, 5 were floor fractures, and 4 were combined fractures. Maxillo-ethmoidal strut was involved in 4. Mean defect area was 176.52 ± 108.48 mm^2. Median interval between postoperative imaging examinations was 292 (223–600) days. Mean orbital tissue displacement was 2.6 ± 1.8 mm. Using simple and multivariable linear regression analysis, the fracture defect area ($P = 0.001$) and maxillo-ethmoidal strut involvement ($P = 0.013$) were found to be significantly associated with orbital tissue displacement. Median orbital volume change was 0.804 (0.647–1.010) cm^3. Average proptosis variation was 1.2 ± 0.8 mm.

Conclusions: Poly (L-lactide-co-glycolide) plates were more suitable for orbital BOF with small defect size. Those with large defect or maxillo-ethmoidal strut involved might have greater tissue displacements due to decline of supporting strength of poly (L-lactide-co-glycolide) plates.

Key Words: bioresorbable implant, blow-out fracture, image fusion, PLGA

Orbital blow-out fracture (BOF) is one of the most common orbitopathy clinically, usually occurring as a result of traffic accidents or strikes from blunt instruments or fists. When detrimental external forces and compression impact on the globe or orbit, orbital pressure abruptly increases, oppressing orbital walls, and ultimately leading to fractures.[1] Orbital medial wall and floor are most likely to fracture as they are the most vulnerable parts of orbit, whereas in certain cases the maxillo-ethmoidal strut (inferomedial orbital strut) is also involved. Blow-out fracture is often accompanied by an increase in orbital volume, which is characterized by the displacement and herniation of orbital soft tissue to fracture defect, resulting in the sequela of enophthalmos.[2,3] The floor and medial wall of the orbit are thin in thickness and poor in bone mass, which makes orbit fracture reduction and fixation hard to achieve. To solve this problem, artificial repair materials are widely used clinically to repair the orbital defect, restore the orbital volume, and alleviate suffering from enophthalmos, limited eye movement, and diplopia.

The implant materials for BOF repair include autogenous or allogeneic bone tissue, synthetically derived products and natural materials. Poly (L-lactide-co-glycolide) polymer (PLGA) is a synthetic material made from the monomer of lactide and glycolide in a certain proportion, which can be absorbed by human body with desirable biocompatibility. It has been widely used as scaffold material for BOF repair.[4,5] However, the mechanical strength of PLGA will gradually fade over time, thus its support effects for orbital contents and how other factors influence it have always been the focus of academic attention.

As bioresorbable materials are radiolucent, invisible on computed tomography (CT) image, previous studies compared the orbital volumes immediately after the operations with the long-term results of orbital volumes to determine the support effects of bioresorbable materials. However, this conventional method of volume measuring is not convenient nor intuitive enough. In this study, based on image fusion technique, preoperative and postoperative CT images were integrated into the same coordinate system. The herniation of orbital soft tissue at the defective sites could be recognized directly and measured accurately according to the image fusion, contributing to further exploration of the outcome of orbital soft tissue displacement after surgical repair for BOF with PLGA and related influence factors.

MATERIALS AND METHODS

Patients

This 4-year (2017–2021) retrospective study was conducted with approval from the Institutional Review Board of Shanghai Ninth People's Hospital (approval number SH9H-2020-T319-2), and adherent to the tenets of the Declaration of Helsinki. Requirement for written informed consent was waived due to the retrospective design of the study. Patients with unilateral BOFs of orbital floor and/or medial wall who underwent repair operations using PLGA polymer plates (RapidSorb, Synthes, Oberdorf, Switzerland) at the Ophthalmology Department of Shanghai Ninth People's Hospital were followed. Preoperative and at least 2 times of postoperative CT examinations, obtained within 1 month after operation and at least 4 months after operation, respectively, were performed for each patient. Patients with any previous surgical history for BOF on the same side or a second time of fracture or a second operation during follow-up were excluded.

Surgical Procedures

All patients received their surgical treatment for BOF under general anesthesia. The fractured orbital floor and medial wall were approached through an inferior transconjunctival incision. A transcaruncular incision was made when necessary for adequate exposure of medial wall. After retracting the orbital contents back into proper places, the defect edges appeared, and bone fragments were removed. By water-bath heating, PLGA plates were then trimmed, bent and molded into appropriate size and shape according to actual defect condition (Fig. 1). Under the shelter of malleable ribbon, PLGA plates were implanted into orbit and covered the defect completely, to rectify the orbital volume and ensure no residual entrapment. Eventually, absorbable screws or surgical glue were used to fasten the plates.

Data Acquisition and Measurements

Computed tomography scans for orbits were obtained on a 64-row multislice CT device (Philips Brilliance, Philips Medical Systems, Best, the Netherlands). All scan images were saved in the Digital Imaging and Communications in Medicine (DICOM) format and were analyzed with iPlan 3.0 (BrainLAB, Munich, Germany). The horizontal plane was set parallel to the Frankfort plane, while the midsagittal plane was constituted with 3 midpoints of foramen magnum, sella turcica, and crista galli. With the coordinate system adjusted, image data for each patient were unified into the same coordinate system using Image Fusion technique. Orbital wall defect area, orbital volume, and proptosis degree were measured and whether the maxillo-ethmoidal strut was involved or not was determined, respectively. Orbital wall defect area was defined as the product of the maximum extent of defect in coronal plane and that in horizontal plane (for medial wall fracture) and/or in sagittal plane (for floor fracture). The orbital volumetric measurement was performed and calculated automatically with the software "cavity tool," which is part of the 3-dimensional planning software iPlan. The orbital volume change was the discrepancy of orbital volumes shown on 2 postoperative CT images. Proptosis degree was the distance from the anterior vertex of globe to the straight line connecting the lateral orbit rim of 2 eyes. The maximum displacement of orbital soft tissue protruding from fracture defective orbital walls into the adjacent sinuses was determined by comparing 2 postoperative CT scans' fused image in coronal planes (Fig. 2). All measurements on CT were performed by one of the authors (Y.L.). Apart from that, enophthalmos degree before surgery was measured by one of the authors (W.S.) using Hertel exophthalmometer.

Data Analysis

Statistical analyses were conducted using Microsoft Excel, version 16 (Microsoft, Redmond, WA) and Statistical Package for Social Sciences (SPSS), version 26 (SPSS Inc, Chicago, IL). Data normality was assessed by Shapiro-Wilk test. Patient information and measured data were presented as mean ± SD when normally distributed or median (interquartile range) when nonnormally distributed. Potential variables that might exert an influence on the maximum displacement of orbital soft tissue were evaluated, respectively, using simple linear regression model, including sex, age, orbital volume on normal side, fracture site, defect area, whether the maxillo-ethmoidal strut was involved, degree of enophthalmos before surgery, waiting period and the interval between 2 postoperative CT scans. In line with the results of univariable analyses, variables with a P value < 0.1 were taken into account for the final predictive equation of the maximum displacement, using multivariable linear regression model by stepwise selection. Pearson correlation analysis was performed in normal distribution parameters and Spearman correlation analysis was performed in parameters with nonnormal distribution. A P value of < 0.05 was considered statistically significant.

RESULTS

Thirty-three patients who had undergone surgical repair with PLGA plates for orbital BOF from 2017 to 2021 were retrospected. A total of 15 patients (5 men and 10 women) were ultimately included in this study. Clinical characteristics are displayed in Supplemental Table 1 (Supplemental Digital Content 1, http://links.lww.com/SCS/E371). Herniation of orbital contents was found in all patients after surgical repair. The mean postoperative maximum displacement of orbital soft tissue was 2.6 ± 1.8 mm. The herniating soft tissue in all cases were displacing in the direction towards paranasal sinuses. The fractured orbital volumes were increasing gradually, and the median orbital volume change was 0.804 (0.647–1.010) cm^3. The average proptosis variation was 1.2 ± 0.8 mm.

On the basis of the results of univariable analysis, variables with a P value of < 0.1 were re-evaluated for further multivariable analysis. The associations identified between clinical characteristics of patients and the maximum displacement are summarized in Supplemental Table 2 (Supplemental Digital Content 1, http://links.lww.com/SCS/E371). According to the final equation, there were 2 related predictors that played a pivotal part in the displacement of orbital soft tissue. The postoperative maximum displacement presented significant positive correlation with orbital wall defect area and whether maxillo-ethmoidal strut was involved.

The multivariable linear regression equation was as follows (whether maxillo-ethmoidal strut was involved, STRUT).

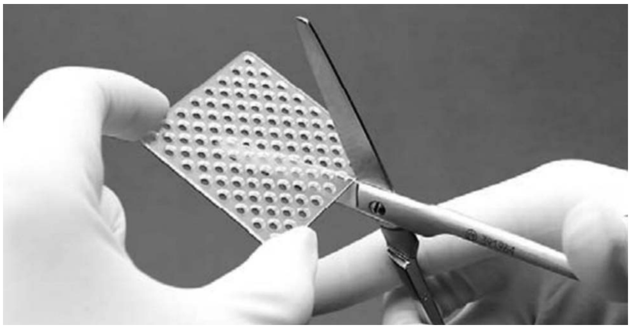

FIGURE 1. The resorbable 85:15 poly (L-lactide-co-glycolide) implant. It can be trimmed and bent into an ideal size and shape with dedicated scissors after water-bath heating.

Maximum displacement (mm) = 0.136 + 0.11 defect area (mm^2) + 1.834 STRUT.

If maxillo-ethmoidal strut was involved, STRUT = 1, otherwise strut = 0.

The R^2 value of this model was 0.697, with no multicollinearity. On the basis of the confirmed multivariable linear regression model, STRUT, of which the absolute value of regression coefficient was bigger, made a greater impact on the maximum displacement than defect area.

To investigate the effect that the maximum displacement might have on proptosis variation and orbital volume change, leading to the risk of residual enophthalmos, Pearson correlation analysis, and Spearman correlation analyses among the maximum displacement, proptosis variation, and orbital volume change were performed by rule (orbital volume change data did not accord with normal distribution, whereas the others did). The results did not indicate any statistically significant correlation between any 2 of them.

DISCUSSION

Orbital BOF are caused by a steep rise in orbital pressure due to traumatic blunt forces or compression on the globe or orbit, which may eventually result in enophthalmos, eyeball movement restrictions, diplopia, and even more severe complications, such as infraorbital nerves involvement and vision impairment.[3,6] Repair operations for BOF should be performed when displacement of the globe causes malformation, such as enophthalmos, or function impairment, such as diplopia, and when obvious entrapment or incarceration of extraocular muscles and/or orbital tissue are observed on CT.[6–8] Ideal repair materials require satisfactory biocompatibility, supporting strength and stability, and can be completely absorbed within an ideal period of time. Traditional repair materials for orbit are mainly composed of artificial materials that cannot be absorbed or degrade, therefore the long-term retaining of a foreign body results in an increased probability of complications such as infection and hemorrhage.[9] Along with the rapid development of tissue engineering, bioresorbable materials have become a hotspot and have been applied widely in clinic.[4]

A 10-year retrospective study demonstrated the safety and effectiveness of bioresorbable materials in orbital fracture surgical repair.[10] Seen et al[11] also proved that bioresorbable materials have comparative safety and effectiveness in isolated BOF. Ramesh et al[5] reported in a systematic review that bioresorbable materials are suitable for isolated fractures of medial wall or floor, and an appropriate criteria of patients is vital for BOF repair when using bioresorbable materials.

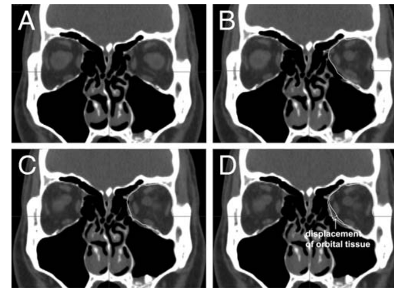

FIGURE 2. Image fusion for the measurement of the maximum displacement of orbital tissue on coronal planes. (A) The image of preoperative CT. An obvious protrusion of orbital tissue was spotted at the fracture site. (B) The image of the first postoperative CT. The shape of orbital tissue was outlined. (C) The image of the second postoperative CT. The shape of orbital tissue was outlined. (D) Boundaries from 2 postoperative CT merged in the same coordinate system by Image Fusion. The maximum displacement of orbital tissue was measured. CT indicates computed tomography.

Manifold forms of bioresorbable materials are in use, and the monomers mainly consist of glycolide, lactide, P-dioxanone, and caprolactone.[5] Materials can be synthesized from one or more of them in different concentrations or proportions. The superiority of bioresorbable implants are shown in that most patients recovered well and they eliminate the need for implant removal. In addition, they are mostly thinner than traditional titanium plates, easier to be adapted. Also, these materials will not restrict the physiological growth of orbit, and since they are radiolucent, they do not interfere with image formation. Their disadvantage mainly lies in the relative lack of strength and toughness, and possibility of inflammation and edema at surgical sites.[12] Poly (l-lactide-co-glycolide) plates were used as the repair material in this study, synthetized by monomers of lactic acid and glycolic acid in a proportion of 85:15, as known as resorbable 85:15 PLGA implants. It is generally considered that the wound healing period is 3 months after initial injury, when cicatrization is almost done, so an ideal material is expected to maintain its tensile strength for at least 3 months. Poly (l-lactide-co-glycolide) plate maintains 95% of mechanical strength 4 weeks after operation, 85% of strength at 8 weeks, and is resorbed within 12 months. It reduces the possibility of complications, and improves the strength compared with previous bioresorbable materials. Also, this malleable material is convenient for bending and pruning, so as to be tailored for each individual. It is an ideal material for orbital fracture repair, whose disadvantages are similar to other types of bioresorbable materials. However, as the bioresorbable materials deform and degrade, persistent support for orbital contents cannot be guaranteed over the long haul.[13] Moreover, seldom has any study reported the role of bioresorbable implants in precluding a large displacement of orbital tissue.

In this study, the maximum displacement of soft tissue and its influence factors were elucidated to provide an explicit answer to the puzzle that who are the most suitable patients in the use of this kind of bioresorbable plates. During follow-up of BOF patients, along with implant degradation, obvious herniation of orbital soft tissue was found in every patient. Previous study generally measured the change of orbital volume to illustrate how far the soft tissue had protruded, which was elusive and not intuitive enough. Therefore, we directly measured the farthest distance of the boundary of tissue herniating from the defect area, namely the maximum displacement of soft tissue on postoperative CT images. The displacement of soft tissue was identified to be instrumental in prediction of the orbit volume change and enophthalmos.[14,15] The more the maximum displacement of orbital soft tissue is, the larger the orbital volume gets. Furthermore, several studies confirmed that the increment of the orbital volume could predict the degree of enophthalmos at the late stage.[13,16,17] It is of great value to make a thorough inquiry into the outcome of orbital tissue's location and its influence factors, which is conducive for estimating the efficiency of surgical treatment, and providing more evidence for indications of using PLGA polymer plates in orbital repair.

Computed tomography is the gold standard for diagnosis of BOF.[18] An innovative strategy for measurement and evaluation, image data fusion technique, was introduced in this study. Forepassed studies usually amalgamated images data acquired in the same period but from different modalities into one coordinate system. For example, preoperative CT-magnetic resonance fusion images, aimed at orbital neoplasms, were used to guide the operation procedures and improve the effect of computer-assisted navigation-guided operations.[19] While in other studies concerning postoperative CT measurements, image data of different periods were usually measured separately, instead of being merged.[20] It may cause the measurement process to be affected by a variety of interference factors and magnify the error. In the current study, images of the same modality (ie, CT) from different periods were integrated into the same coordinate system, and image superimposition made it more intuitive and convenient to observe and measure the position change of orbital tissue, providing quantitative indexes for research. Meanwhile, this strategy reduced the possible error when measuring in different coordinate systems to a certain extent, so that the postoperative follow-up data were more authentic and reliable.

Through simple linear regression and stepwise multivariable linear regression, the maximum displacement of orbital soft tissue was confirmed to be positively correlated with whether the maxillo-ethmoidal strut was involved and the orbital wall defect area. Maxillo-ethmoidal strut is a crucial supporting structure located at inferomedial part of orbit, serving to maintain the position of intraorbital contents and the original shape of orbit. In a systematic review, an opinion was raised that resorbable implants could only help BOF that did not involve maxillo-ethmoidal strut to recover better.[5] The current study further justified that when maxillo-ethmoidal strut was wrecked, the supporting strength of bone wall was diminished, making it hard to attain a satisfying repairing effect. Even if the repair operations were performed, a high risk of large displacement would be cautionary. Moreover, the current study also illustrated that the larger the defect size was, the further the displacement might be. That is to say, bioresorbable materials rely on a relatively intact structure of orbit to separate the intraorbital fat and extraocular muscles from sticking out into adjacent sinuses. Subsequently, PLGA plates are more suitable for BOF where the defect size is small and without maxillo-ethmoidal strut involvement. Conversely, for BOF that has a large defect area or involves maxillo-ethmoidal strut, due to deficiency in osteogenic induction, PLGA plates degrade before fibrous cicatricial tissue is formed, and the consequential weakness in supporting strength of PLGA plates may result in a higher risk of tissue displacement.

Some limitations were acknowledged in this study. Owing to the retrospective design, the validity cannot hold a candle to prospective studies, more cases should be further collected to achieve more valid verdict. In addition, numerous patients were not closely followed up, so a great deal of data were lost unfortunately. Eight out of 15 patients included were followed up for no more than 1 year, and the duration might be insufficient for the implants to be fully absorbed. Current data could not demonstrate that the extent of displacement represented the orbital volume change or the risk of enophthalmos, suspected to be due to the limited sample size. A correlation at moderate degree was found between the maximum displacement and proptosis variation, the maximum displacement and orbital volume change, and a weak correlation between proptosis variation and orbital volume was found, but none was statistically significant. Nonetheless, the role of the orbital tissue displacement in reflecting the increment of orbital volume and proptosis variation was elucidated in previous study.[14,15] Besides, image fusion is a novel strategy, and the measurement procedure is subjective, hence there might be human error probability and it remains an obstacle to popularize and standardize the technique.

To summarize, prudent assessments for BOF patients should be made before operations, and surgical indications should be under strict control. Poly (l-lactide-co-glycolide) polymer plates can obtain better repairing effects in BOF with relatively small defect area. For patients with a large orbital defect area or with maxillo-ethmoidal strut involved, PLGA plates are not recommended. The severity of BOF should be cautiously evaluated consulting preoperation CT scans, to supply guidance in choosing surgical manipulations and appropriate implants, and improve the operation outcomes.

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Morphological Changes in Total and Inferior Part of Maxillary Sinus After Le Fort I Osteotomy, as Determined by Cone-Beam Computed Tomography

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Abstract: To investigate morphological changes of the total and inferior part of the maxillary sinus following Le Fort I osteotomy. 21 skeletal class II and 49 skeletal III patients who underwent orthognathic surgery were enrolled in this retrospective study. Cone-beam computed tomography taken before (T1) and 6 to 24 months after (T2) orthognathic surgery were imported into Mimics 20.0 software to analyze morphological changes of the total and inferior part of the maxillary sinus. Volume of the whole maxillary sinus was significantly reduced after surgery ($P \leq 0.008$), while the volume of the inferior part of the maxillary sinus was significantly greater than before surgery ($P \leq 0.004$). Maxillary sinus floor moved occlusally after Le Fort I osteotomy. Movement in the pitch direction of the posterior maxilla affected the state of the maxillary sinus mucosa after orthognathic surgery. Le Fort I osteotomy exerts a significant impact on the morphology of the total and inferior part of the maxillary sinus.

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Key Words: CBCT, Le Fort I osteotomy, maxillary sinus

Orthognathic surgery (OS) combined with orthodontic therapies are a routine treatment procedure for patients with dentofacial deformities. OS results in improved esthetic appearance, neat dentition, and better masticatory function.[1–3] Le Fort I osteotomy is the main orthognathic surgical method used to move the maxillary segment in 3 dimensions (D) to obtain a harmonious positional relationship of the maxilla relative to the overall craniofacial bone.[4,5] Although Le Fort I osteotomy improves the patient's facial contour, it may affect the normal anatomy near the surgical field.

Le Fort I osteotomy traverses the maxillary sinus (MS) cavity and may therefore affect the morphology of the MS.[6–9] According to previous reports, the reduction of maxillary sinus volume (MSV) and maxillary sinus mucosal (MSM) thickening represent clear and significant outcomes of Le Fort I surgery.[10,11] However, previous articles have mostly focused on the morphological changes of MS after the advancement of the maxilla rather than the use of Le Fort I segment osteotomy to regress the anterior maxilla. Moreover, only a very limited number of studies have investigated the influence of the direction of maxilla movement on the morphological structure of MS.[7]

The morphology of the inferior part of the maxillary sinus (IMS) is the anatomically and clinically important structure that can be related to many clinical practices, such as tooth extraction, orthodontic tooth movement, and MS floor augmentation.[12–14] Le Fort I osteotomy may have a major impact on the morphology of the IMS.[15] Meanwhile, changes in the morphology and airflow of MS may lead to remodeling of the sinus floor. Despite these considerations, very few studies have focused on morphological alterations in the IMS before and after Le Fort I surgery.

Therefore, the aim of this study was to evaluate the effect of the different direction in the maxilla movement on morphological changes of MS and IMS for both skeletal class II and III malocclusion before and after Le Fort I osteotomy.

MATERIALS AND METHODS

Patients

This retrospective study was approved by the Peking University School of Stomatology (Approval number: PKUSSIRB-202059185). The study population included patients with skeletal class II and III malocclusion who were admitted to the Department of Oral and Maxillofacial Surgery in Peking University School and Hospital of Stomatology between January 2017 and December 2019. The inclusion criteria were as follows: skeletal class II or III patients, completion of preoperative orthodontics, Le Fort I or Le Fort I segment osteotomy applied for the first time, and imaging involving cone-beam computed tomography (CBCT) 1 week before (T1) and at least 6 months (T2) after surgery. Each participant provided informed consent to participate in this study.