• Clinical Research •

Analysis of the effect of repair materials for orbital blowout fracture on complications

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Abstract

• AIM: To investigate the effect of repair materials for orbital blowout fractures on the occurrence of postoperative complications.

• METHODS: The clinical data and follow-up data of 54 subjects with orbital blowout fractures were retrospectively analyzed. The study was divided into three groups according to the used repair materials: titanium mesh (16 cases), Medpor (12 cases), and Medpor titanium mesh (26 cases). All test data were analyzed using the SPSS version 23.0 statistical software. The mean age and duration of disease between the groups were compared through one-way analysis of variance. The Chi-square (χ^2) test was used to compare the number of males and females, different fracture types, and different surgical approaches among groups. The χ^2 test was used to compare the frequencies for complications in each group.

• RESULTS: The baseline characteristics of age and gender in each group were matched (F=1.763, P=0.172; χ^2=0.026, P=0.987). In addition, there was no difference in the type of fracture and surgical approach (χ^2=0.460, P=0.977; χ^2=0.691, P=0.952), or the incidence of complications (χ^2=0.081, P=0.960) between the three groups.

• CONCLUSION: Although there is no difference in effect of various repair materials on the incidence of complications, the effect of repair materials on postoperative complications of orbital blowout fractures should not be ignored.

• KEYWORDS: orbital blowout fracture; repair materials; postoperative complications

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INTRODUCTION

With the rapid development of social and economic undertakings, an increasing number of cases of orbital fractures are caused by industrial production and traffic accidents[1]. Orbital blowout fracture refers to the application of an external force on the orbit, causing the pressure to suddenly increase or the external force to pass along the orbital margin to the orbital wall. Consequently, the thinner orbital bone wall bursts under the action of the force[2]. Orbital blowout fractures may result in enophthalmos, diplopia, eye movement disorders, decreased vision, and infraorbital nerve sensory disorders. Surgical treatment is required when orbital soft tissue is incarcerated by fracture slices, and associated clinical symptoms appear. The main treatment method for recovery or improvement of clinical symptoms involves surgical removal of bone fragments, release of incarcerated or herniated orbital soft tissues into the paranasal sinus, and use of repair materials to cover the bone wall of the defect. Depending on the surgical timing and approach, repair materials, and the experience of the surgeon, residual elevation or depression limitation, diplopia, and eye movement disorder may remain following surgery. Moreover, incision scarring, infraorbital nerve sensory disorder, lower eyelid retraction, implant infection, and other complications may occur[3-5]. Among them, the effect of repair materials on long-term postoperative efficacy is particularly prominent. The aim of this study was to investigate the effect of orbital fracture repair materials (*i.e.*, titanium mesh, Medpor, and Medpor titanium mesh) on the occurrence of postoperative complications.

SUBJECTS AND METHODS

Ethical Approval The retrospective study was approved by the Ethics Committee of the Affiliated Eye Hospital of Nanchang University. All subjects provided written informed consent prior to surgery.

Subjects This was a retrospective analysis of the clinical data of subjects with orbital fractures admitted to the Affiliated Eye Hospital of Nanchang University (Nanchang, China) between July 2012 and July 2017. Inclusion criteria were as follows:

Table 1 Comparison of the baseline characteristics of the population, fracture status, and surgical approach in the three groups

Groups	No. of cases	Age (y, mean±SD)	Gender (male/female)	Duration of illness (d, mean±SD)	Fracture condition (lower wall/inner wall/inner and lower wall combined)	Surgical approach (skin/ conjunctival/skin combined conjunctiva)
Medpor	12	36.58±14.20	8/4	22.50±31.70	2/4/6	1/5/6
Titanium mesh	16	37.06±12.78	11/5	25.38±34.05	3/4/9	2/5/9
Medpor titanium mesh	26	38.54±12.36	18/8	33.15±57.52	4/9/13	4/8/14
F/χ^2	-	1.763	0.026	65.366	0.460	0.691
P	-	0.172	0.987	0.000	0.977	0.952

all subjects who were operated by a single surgeon, and those with complete clinical data and a follow-up period ≥6mo. Exclusion criteria are as follows: subjects with orbital margin fracture and eyeball rupture, and those aged <18y. A total of 54 eyes (21 right eyes and 33 left eyes) of 54 subjects (41 males and 13 females) were included in the study. The subjects were aged 18-61y (average age: 37.67±12.69y). In terms of the cause of injury, 25, 12, 10, and 9 cases were attributed to car accidents, falls, boxing smashing, and other accidents. The interval from injury to surgery ranged from 5 to 307d (average: 28.48±46.03d); the follow-up period after surgery ranged from 6 to 28mo. The selected cases were divided into three groups according to repair materials: titanium mesh (Synthes GmbH, Switzerland), Medpor (Porex Surgical Inc., USA), and Medpor titanium mesh (Stryker Leibinger GmbH & Co. KG, Germany). The baseline characteristics of the population, fracture status, and surgical approach were matched for the three groups of subjects (Table 1).

Surgical Methods All subjects underwent general anesthesia. Following routine skin disinfection, the appropriate surgical approach was selected according to the condition of the fracture (*i.e.*, conjunctival approach for small fractures and skin approach for larger fractures). Lower eyelid lashes approach may be used for fracture of the inferior wall with larger area. The skin was incised 2 mm below the lower eyelid lashes, and the orbicularis oculi muscle was incised under the skin. Then orbicularis muscle was separated from the orbital septum to the lower orbital margin, and the orbital septum and periosteum were cut at the lower orbital margin. Finally, the periosteum tissue was separated to expose the fracture defect area and margin of the inferior wall. Caution should be exercised to protect the infraorbital nerve and inferior oblique muscles. The bone fragments were removed, and the muscle or soft tissue incarcerated or herniated into the paranasal sinus was released and retracted. According to the size and shape of the fracture defect area, a suitable repair material was cut to cover the defect area and fix the repair material. Different fixation methods may be selected according to different repair materials. Medpor may be fixed with biological adhesive, while titanium mesh may be fixed with titanium at the lower rim of the orbit. For small medial wall fractures, the lacrimal caruncle conjunctival approach is feasible as follows: incision of the lacrimal conjunctiva, careful separation of the fascia avoiding damage to the lacrimal and medial canthal ligament, incision of the periosteum at the crista lacrimalis posterior, separation deep in the periosteal space, exposure of the fracture edge, removal of the bone fragments, and release of soft tissue incarceration. Caution should be exercised to avoid damage to the anterior and posterior ethmoidal arteries. For combined fractures of the inferior or medial walls, it is feasible to use the lower fornix conjunctiva coupled with the lacrimal caruncle conjunctival approach, or the inferior eyelid margin skin coupled with the lacrimal caruncle conjunctival approach. When the fracture area is deep in the orbit, caution should be exercised to avoid damage to the optic nerve and ophthalmic arteries/veins during separation and implantation of the repair materials. After fixation of the repair material, a passive tension test was performed to ensure the absence of soft tissue incarceration, and the incision was closed layer by layer. The operated eye was coated with gatifloxacin ointment and pressure bandaged. On postoperative day 2, the bandage was removed, and the subject was trained in the four directions of upward, downward, left, and right eye movements.

Indicators of Clinical Detection and Evaluation of The Effect The duration of illness indicated the time from the injury to the start of surgery. Preoperative observation was performed, and data for the eyelids, vision, enophthalmos, diplopia, eye movement disorders, and subgingival nerve sensory disorders were recorded. The eyelids and the anterior segment of the eye were observed through a slit lamp. The Hertel exophthalmometer was used to detect differences in eyeballs on the affected side of the subject. A difference >2 mm was considered enophthalmos. Ocular diplopia and movement disorders were detected using synoptophore. According to the standard proposed by Findl *et al*[6], diplopia is divided into the following levels: level 0, no diplopia; level 1, diplopia in one direction of the peripheral field of view (>15°); level 2, no diplopia at the front or in the reading position (<15°), diplopia in more than one direction; and level 3, diplopia is present at the front and in the reading position (<15°). According to Nagy *et al*[7], eye movement is divided into the following levels: level 0, eye movement is not limited; level 1, slightly

Table 2 Complications at 6mo after surgery in the three repair material groups

Groups	No. of cases	Enophthalmos	Diplopia	Eye movement disorder	Skin scarring	Nerve sensory disorder	Lower eyelid retraction	Implant infection	Total complications
Medpor group	12	0	1	0	0	0	1	0	2
Titanium mesh group	16	1	0	0	1	1	0	0	3
Medpor titanium mesh group	26	0	0	1	1	1	0	1	4

restricted movement in one or more directions; level 2, limited movement in one or more directions; level 3, unable to reach the center line while moving in one or more directions. The preoperative and postoperative levels of diplopia and movement disorders were compared, and there were four conditions: cure, improvement, invariability, and aggravation. The postoperative zero level of diplopia and movement disorders means that diplopia and movement disorders was cured. When the postoperative level was lower than, equal to, or higher than the preoperative level, it was defined as improvement, invariability or aggravation. Suborbital neurosensory disorders were assessed by swab touching the innervation area and asking the subject to report subjective sensation. The subjects were reexamined 1wk, and 1, 3, and 6mo following surgery to observe the enophthalmos, vision, eye movement, diplopia, and infraorbital nerve sensation of the eyes. Timely reexamination using orbital computed tomography was performed to understand the position of the implant and the condition of the extraocular muscle. All subjects were followed up to assess long-term postoperative outcomes.

Statistical Analysis All test data were analyzed using the SPSS version 23.0 statistical software. The age and duration of disease in each group were expressed as mean±SD, and the mean of such data between groups was compared through one-way analysis of variance. The Chi-square test was used to compare the number of males and females, different fracture types, and different surgical approaches among groups. The Chi-square test was used to compare the frequencies (*i.e.*, complications) in each group. A $P<0.05$ denoted statistical significance.

RESULTS

In the titanium mesh group, there were 16 cases. At 1mo following surgery, two subjects continued to have diplopia (both improved: level 3 to 2), which were caused by paralytic strabismus, two subjects had eye movement disorder with elevation limitation (both improved: level 3 to 2), one subject had obvious residual skin scarring, and one subject had infraorbital nerve sensory disorder. At 3mo following surgery, enophthalmos, diplopia (improved: level 2 to 1), and eye movement disorder (one improved: level 2 to 1) were present in three subjects (one per condition).

In the Medpor group, there were 12 cases. One month following surgery, three subjects continued to have diplopia, which were caused by paralytic strabismus too; the conditions of two subjects improved compared with the preoperative condition, while that of one subject remained unchanged. Of the three subjects, one had residual eye movement disorder with external turn limitation (though improved: level 2 to 1), while another subject had lower eyelid retraction. At 3mo after surgery, there were two subjects with diplopia (one improved: level 2 to 1, one unchanged); symptoms disappeared in subject with eye movement disorder.

In the Medpor titanium mesh group, there were 26 cases. At 1mo following surgery, four subjects had residual diplopia (all improved: level 3 to 2), which also were caused by paralytic strabismus, two subjects had eye movement disorder with elevation limitation (both improved: level 3 to 2), one subject had skin scarring, and one subject had infraorbital nerve sensory disorder. At 3mo after surgery, two subjects had diplopia (both improved: level 2 to 1), one subject had eye movement disorder (one improved: level 2 to 1), and one subject had implant displacement. We performed HE pathological staining on the surrounding tissues of the implant and found that there were neutrophils and multinucleated giant cells infiltrating in the tissues.

At 6mo after surgery, some complications had resolved, whereas others persisted. Table 2 shows the incidence of complications at the 6-month follow-up ($\chi^2=0.081$, $P=0.960$).

DISCUSSION

Common complications after surgery for the repair of orbital blowout fractures include the following: diplopia, enophthalmos, eye movement disorders, infraorbital nerve sensory disorders, skin scarring, lower eyelid retraction, scleral exposure, conjunctival granuloma, and implant infection. The main factors affecting the occurrence of complications are the timing of surgery, surgical techniques, surgical approach, and repair materials[8]. Regarding the timing of the operation, in the first week of the orbital fracture, the soft tissue in the orbit is in the stage of inflammatory edema. During this period, the soft tissue in the incarceration may be aggravated by edema and extraocular muscle damage. If surgery is performed 4wk after fracture, the incarcerated or scooped soft tissue may undergo ischemic necrosis or fibrosis, which is not conducive to intraoperative and postoperative recovery. Therefore, surgery should be performed within 2-3wk after the fracture. Owing to subjects' personal reasons, there were cases in the three groups with disease duration >3mo. This may increase the

incidence of complications, such as postoperative diplopia and eye movement disorder. The difference in duration of illness in the three groups of this study was statistically significant (F=65.366, P=0.000), which would affect the accuracy of the final conclusion. The proficiency and experience of the surgeon in relation to the surgical techniques were also evident in the effects of surgical outcomes and postoperative complications[9]. During the operation, injury to important nerve vessels, incomplete release of incarcerated soft tissue, or negligence in the pruning, placement, and fixation of the repair materials may to lead to a series of postoperative complications. All operations in this study were performed by a single surgeon to avoid interference with the results of the different surgical techniques between groups.

The surgical approach for orbital fractures mainly includes the following: the lower eyelid skin approach, inferior conjunctival approach, and lacrimal caruncle conjunctival approach[10]. For fractures involving the lateral or supraorbital wall, it is necessary to combine the external skin with the skin under the eyebrow approach. The skin approach may fully expose the surgical field of view; however, it is prone to skin scarring and affects appearance. The conjunctival approach is less invasive and thus, less prone to scarring. However, the limited exposure of the surgical field affects the operation[11]. For the inferior and medial walls of the fracture, the lower conjunctival approach or the lacrimal caruncle conjunctival approach may be used. In the case of a combination of internal and inferior wall fractures, the lower conjunctiva combined with the lacrimal internal conjunctival approach or the lower eyelid skin combined with the lacrimal internal conjunctival approach should be selected. In short, it is necessary to select the appropriate surgical approach based on the specific conditions of the fracture, aiming for the best possible cosmetic outcome. In this study, an analysis using the Chi-squared test was performed on the different surgical approaches used between groups. There was no statistically significant difference observed in the choice of surgical approach between the groups (χ^2=0.691, P=0.952).

Orbital fracture repair materials include autologous bone, allogeneic bone[12], and heterogeneous materials. Autologous bone exhibits good tissue compatibility; however, it has the disadvantage of limited source and the risk of damaging the anatomical function of the donor site[13]. Allogeneic bone is of sufficient origin, but is associated with a risk of immune rejection and disease transmission. Heterogeneous materials mainly include absorbable polymer compounds, high-density porous polyethylene (Medpor), titanium mesh, and Medpor titanium mesh. Absorbable materials are mainly used for the repair of orbital fractures in children. Medpor is capable of good biocompatibility and rapid vascularization of human tissue after implantation with a multi-aperture structure[14]. However, it is difficult to evaluate the accuracy of the implantation site because this material is not radiopaque[15]. Medpor is typically selected for the repair of smaller fractures of the medial and inferior walls of the orbital bone. In this study, one case of lower eyelid retraction occurred in the Medpor group. This may be attributed to the pulling effect of the repair material wrapped by the surrounding tissue on the lower eyelid tissue. Titanium mesh can be radiopaque, it is easily shapeable, and exhibits high mechanical strength. For the repair of large-area wall defects, we usually select preformed titanium mesh. This material can better restore the anatomy of the defective area of the orbital wall. However, the titanium mesh is thin and cannot complement the traumatic atrophy of the orbital tissue. On the other hand, its mesh is large, and the soft tissue in the orbit can partially leak out of the mesh, which further increases the loss of tissue in the orbit. This may explain the development of enophthalmos in one subject in the titanium mesh group 3mo after surgery. Medpor Titan is a titanium mesh embedded in Medpor that combines the advantages of both materials. it is radiopaque. Moreover, It can fill the orbital volume, which can avoid the occurrence of postoperative enophthalmos[16]. In cases with a small defective area, we select the Medpor titanium mesh for the repair of the bone defect. However, in this study, one subject in the Medpor Titanium mesh group developed clinical manifestations of implant displacement and infection 3mo after surgery. This is consistent with previous reports in the literature[17-18]. We performed pathological examination and bacterial culture on the surrounding tissues of the implants. The results showed that neutrophils and multinucleated giant cells had infiltrated the tissues, and revealed the presence of *Staphylococcus epidermidis* infection (a low-toxicity bacterium) in the focal area. Studies had suggested that in addition to these inflammatory cells, the presence of fibrous vascular tissue around the implant helps to reduce implant displacement[19]. Bacterial culture results showed: *Staphylococcus epidermidis* infection. This is a common organism of conjunctival flora[20]. There are numerous reasons for the displacement and infection of the implant (*e.g.*, presence of bacteria during the operation, or immune rejection induced through stimulation of the tissue by the foreign body)[21]. In addition, the ability of different repair materials to resist microbial colonization is also a factor affecting the occurrence of postoperative infection. For example, recent studies have found that Silicone orbital implants can resist microbial colonization better than porous polyethylene implants[20].

Collectively, the results of the present study showed that different repair materials for orbital blowout fractures exert similar effects on the long-term occurrence of postoperative complications. However, this study is a retrospective study

with a small sample size, and these factors have an impact on the credibility of the research conclusions. Improvements in the surgical techniques, timing of surgery, and selection of the most appropriate surgical approach are essential to reduce the incidence of complications. The development of new repair materials with good biocompatibility, high mechanical strength, and plasticity is warranted to improve the repair of orbital wall fractures.

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