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Original Article

Differences between medpor monotherapy and a combination of titanium mesh with medpor in orbital fracture repair

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Abstract: Objective: Orbital implants primarily include autogenous bone, silica gel, hydroxyapatite (HA), Medpor, and titanium mesh, but are without uniform standards for which patients to choose an implant. This study was designed to investigate the dissimilarities in effects between titanium mesh combined with Medpor and Medpor monotherapy in orbital fractures. Methods: A total of 97 patients with orbital fractures were divided into a control group (n=45) and an observation group (n=42). The control group was treated with Medpor while the observation group received titanium mesh following Medpor. Results: The observation group had higher incidence of Grade 0 diplopia than the control group 6 months after operation (P<0.05) but lower grades I and II diplopia (P<0.05). Grade 0 dyskinesia occurred more frequently in the observation group other than in the control group 6 months after operation (P<0.05), but Grade I and II dyskinesia were on the contrary (P<0.05). It took less time for the observation group to have postoperative swelling and pain subside, together with lower AQP4 expression, by comparison with the control group (both P<0.05). The observation group showed higher incidence of enophthalmos and mild enophthalmos than the control group (P<0.05), while the case was on the opposite in terms of moderate and severe enophthalmos (P<0.05). The difference in incidences of postoperative complications between the two groups was not of statistical significance (P>0.05). Conclusion: The combination of titanium mesh with Medpor may result favorably, specially, reduce diplopia, downgrade dyskinesia, help shorten the time that it takes for swelling and pain to subside, lower AQP4 level in orbital fracture repair, and lead to less incidence of post-operation enophthalmos.

Keywords: Titanium mesh, medpor, orbital fracture, dyskinesia grading, AQP4, severity of enophthalmos, postoperative complications

Introduction

Orbital fracture is a type of craniomaxillofacial injury with high incidence, it can occur alone or in combination with other craniomaxillofacial fractures [1]. The orbital, which well protects the eyeball, can suffer fracture as a result of external force imposed on it or the bone around it [2]. In anthropotomy [3], the orbit is a cone-shaped bony cavity containing the eyeball of which the orbital apex is the peak, mainly composed of the maxilla, zygoma and ethmoid. The maxilla joins the zygoma and the palatine bones to form the floor. Medially, the orbital wall consists of the maxilla, the ethmoid, the sphenoid bone, and the lacrimal bone. This follows that the medial orbital wall is a complex anatomical structure, and thus results in a high fracture rate in the orbital floor and medial orbital wall. Clinically, orbital fractures are grouped into simple fractures and non-simple fractures [4]. The former means a fracture only at the orbital wall, leaving the orbital margin intact. The latter is an aggregate of combined orbital margin and orbital wall fractures. In recent years, orbital fractures are on the rise with the increase of trauma and traffic accidents. A data survey found that 3%-32% of facial trauma is accompanied by orbital fractures, which can cause enophthalmos, diplopia and eye dyskinesia, and affect the eye both aesthetically and visually [5]. Orbital floor frac-

Table 1. Comparison of clinical data

Clinical data		Observation group (n=44)	Control group (n=45)	χ^2/t	*P* value
Gender	Male	28 (66.67)	29 (64.44)	0.715	0.559
	Female	14 (33.33)	16 (35.56)		
Age (years old)		40.29 ± 4.51	41.14 ± 4.53	1.315	0.632
Time from surgery to trauma (weeks)		3.12 ± 0.69	3.15 ± 0.71	0.952	0.711
Fracture site	Lower orbital wall	13 (30.85)	14 (31.11)	0.773	0.735
	Medial orbital wall	20 (47.62)	21 (46.67)		
	Medial orbital wall with inferior orbital wall	9 (21.43)	10 (22.22)		
Intraocular pressure (mmHg)		18.58 ± 4.61	19.21 ± 4.65	1.121	0.558
Fracture grading	Type I	8 (19.05)	9 (20.00)	1.349	0.892
	Type II	12 (28.57)	13 (28.89)		
	Type III	16 (38.10)	15 (33.33)		
	Other	6 (14.29)	8 (17.78)		
Cause of fracture	Traffic accident	21 (50.00)	22 (48.89)	0.893	0.615
	Boxing injury	18 (42.86)	19 (42.22)		
	Explosive injury	3 (7.14)	4 (8.89)		

ture repair predominates in clinical therapy for orbital fractures, and it is an operation to perfect the facial appearance and visual function [6]. However, orbital floor fracture repair relies more on precise preoperative planning, meticulous operation and appropriate implant materials due to the special surgical site, rendering its outcome subject to varying factors. At present, orbital implant materials mainly contain autogenous bone, silica gel, HA, titanium mesh, and Medpor. Autologous bone grafting is acknowledged for great histocompatibility, high vascularization inclination, no immune rejection, and low incidence of complications such as infection and rejection after treatment. However, it has poor shaping ability and oly a small amount of bone available, which may expose the donor site to higher risks of diseases. HA is similar to human bone tissue in structure, with good biocompatibility and low incidence of immune rejection. HA is a brittle material with inadequate shaping capacity [7]. In order to make up for deficiencies in clinical materials, Medpor was first introduced to obtain good results in orbital fracture repair. Medpor is a new type of biomaterial with the characteristics of good histocompatibility, low infection rate, arbitrary shaping and free pruning, which can correct enophthalmos in various degrees. At the same time, Medpor has the advantages of easy shaping, low biocompatibility, easy fixation and low infection rate. It is suitable for the reconstruction of different orbital wall structures. However, there are few studies on its application in patients with orbital fractures [8].

In this study, patients with orbital fractures were taken as study subjects to explore the differences in repair effects of orbital fracture healing between the combination of titanium mesh and Medpor, and single application of Medpor; as reported below.

Materials and methods

Clinical data

A total of 97 patients confirmed to have orbital fractures from April 2018 to January 2019 were randomized into a control group (n=45) and an observation group (n=42). This study was started was approved by the Ethics Committee of Affiliated Hospital of Nanjing University of Chinese Medicine and was provided with informed consent from all subjects and their families, who had been informed of experimental trials. The two groups did not present any significant differences in clinical data (P>0.05), as shown in **Table 1**.

Inclusion and exclusion criteria

Inclusion criteria: (a) All patients were recruited in accordance with the diagnostic criteria of orbital fracture in The Practice of Ophthalmology

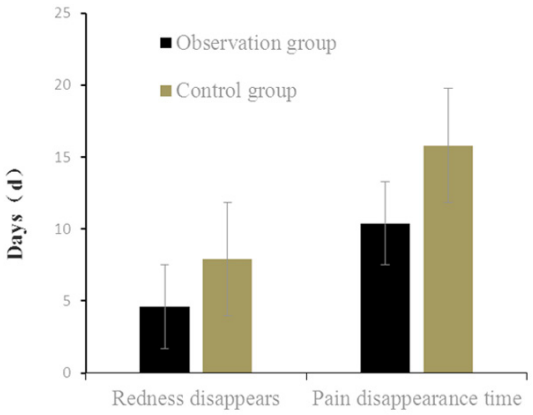

Figure 1. Comparison of time of swelling and pain. Note: We illustrated how long it took for swelling and pain to subside in the two groups post operation, and the observation group took less than the control group.

[9], and diagnosed by an orbital CT; (b) had a definite history of unilateral orbital fractures; (c) indications of tolerance to titanium mesh in combination with Medpor; and (d) clear consciousness and ability to communicate with doctors.

Exclusion criteria: (a) patients complicated with mental disorders, coagulation disorders or incomplete admission data; (b) patients complicated with cognitive dysfunction, malignant tumors or autoimmune diseases; (c) patients complicated with ophthalmorrhexis, or lens dislocation or subluxation; or (d) patients complicated with enlargement/displacement of extraocular muscles or ocular and visual nerve injury.

Methods

(1) Instruments and equipment. Titanium mesh (0.4 mm thick, optional specifications, Stryker Leibinger, Germany), titanium nails (5 mm long, Stryker Leibinger, Germany), Medpor (Porex, USA), Hertel exophthalmometer (6 6 VISION TECH Co., Ltd.) and Slit Lamp Microscope (TOPCON, Japan). (2) Preoperative examination. Upon admission, both groups received required examinations involving visual acuity, anterior segment/posterior segment, exophthalmos, diplopia and eye movement, to assess the eye state. Orbital CT was performed as a routine examination prior to operation, the scope and nature of the fracture were assessed, a picture of the extraocular muscles was made, and a detailed examination-based operative plan was created [10]. (3) Methods. All patients underwent general anesthesia, and the surgical sites were disinfected and draped after anesthesia took effect. An operative incision was made at the lower eyelid margin for patients with orbital floor fracture, an arc incision at the canthus for those with orbital wall fracture, an operative incision at canthus and descending edge for patients with lower orbital wall fracture. Following this, skin tissue was isolated along the incision to the orbital margin. Periosteal incision was made at the orbital margin for blunt separation to fully expose the fracture region. The tissue (especially extraocular muscle) is returned into the orbit, followed by integration and reduction of the collapsed bone, and accurate repair of bone defects. The control group was treated with Medpor (by methods the same as that of the observation group) whereas the observation group was treated with a combination of Medpor and titanium mesh. Medpor (the control group) and titanium mesh were trimmed into appropriate dimensions by the severity of enophthalmos, and scope and size of orbital wall defect. In the observation group, Medpor covered one end of titanium mesh and was fixed with black silk thread 1-0. The implant material was shaped in conformity with the appearance of the orbital wall defect, and implanted into the fracture region. Subsequently, titanium nails were applied for fixation. The procedures were shown in **Figure 1**.

Observation of binocular exophthalmos was made after the above steps (it is general to have 2 mm exophthalmos in the eye with orbital fracture than that of the healthy one), and with satisfactory observation results, a traction test was performed. For those without limited eye movement, periosteum and skin were sutured, and the operation was completed after conventional bandaging [11].

(4) After operation. Following postoperative inquiry, antibiotics were routinely given to prevent infection, coupled with hemostasis and corticosteroid intervention. Bandages were removed 3 days after surgery, and functional training was conducted for the eye muscles for 20 min minutes, 3 times per day. Both groups were followed up for 6 months post operation.

Observation indicators

(1) Diplopia. Before and 6 months after operation, a synoptophore was used for angle of stra-

Table 2. Comparison of diplopia [n (%)]

		Grade 0	Grade I	Grade II	Grade III
Observation group (n=42)	Before operation	10 (23.81)	25 (59.52)	7 (16.67)	0 (0.00)
	6 months after operation	19 (45.24)[a,b]	21 (50.00)[a,b]	2 (4.76)[a,b]	0 (0.00)
Control group (n=45)	Before operation	9 (20.00)	26 (57.78)	10 (22.22)	0 (0.00)
	6 months after operation	13 (28.89)[b]	25 (55.56)[b]	7 (15.56)[b]	0 (0.00)

Compared with the control group, [a]$P<0.05$; Compared with that before operation, [b]$P<0.05$.

Table 3. Comparison of dyskinesia [n (%)]

		Grade 0	Grade I	Grade II	Grade III
Observation group (n=42)	Before operation	8 (19.05)	22 (52.38)	12 (28.57)	0 (0.00)
	6 months after operation	17 (40.48)[a,b]	17 (40.48)[a,b]	8 (19.05)[a,b]	0 (0.00)
Control group (n=45)	Before operation	9 (20.00)	23 (51.11)	13 (28.89)	0 (0.00)
	6 months after operation	13 (28.89)[b]	20 (44.44)[b]	12 (26.67)[b]	0 (0.00)

Compared with the control group, [a]$P<0.05$; Compared with that before operation, [b]$P<0.05$.

bismus examination of the fractured eyes in different directions: upper, lower, left, right, upper left, lower left, upper right and lower right, in both groups. The severity of diplopia was assessed with scores being as follows: Grade 0: no diplopia; Grade I: periorbital diplopia; Grade II: No diplopia in primary gaze or while reading, but diplopia in other directions; Grade III: diplopia in primary gaze or while reading [12]. (2) Dyskinesia grading. Both groups underwent forced traction test, Hirschberg Test and eyeball's active movement before and 6 months after operation. Dyskinesia was graded as follows. Grade 0: move well without limitations; Grade I: able to move, but with limitations on movements in one or more directions; Grade III: obviously limited movements, but eyeballs are not fixed; Grade IV: fixed eyeball, unable to move [13]. (3) Presence of swelling & pain, and AQP4 level. Time when swelling and pain subsided in the two groups was recorded. Peripheral venous blood (fasting) was taken from both groups before and 6 months after operation, and centrifugated to determine AQP4 level by enzyme-linked immunosorbent assay [14, 15]. (4) Severity of enophthalmos. Protopsis was measured in both groups before and 6 months after the operation, and compared to identify the severity of enophthalmos based on differences. Mild: 2-4 mm of difference; Moderate: 4-6 mm difference; Severe: difference >6 mm [16, 17]. (5) Incidence of postoperative complications. The incidences of postoperative infection, implant rejection, translocation, irreversible vision decline and nerve paralysis were recorded in the two groups.

Statistical analysis

SPSS 18.0 was used to process the data. χ^2 test was used for counting data, which were expressed as n (%). All data were normally distributed. *t* test was used for measuring data, which was expressed as ($\bar{x} \pm s$). The data were of statistical significance at $P<0.05$.

Results

Comparison of diplopia

The two groups did not differ significantly in the incidence of diplopia before operation (P>0.05), as well as in the incidence of Grade III diplopia before and 6 months after operation (P>0.05). Grade 0 diplopia had a higher incidence in the observation group than in the control group 6 months post operation (P<0.05), whereas the incidences of Grades I and II diplopia were on the contrary (P<0.05), as shown in **Table 2**.

Comparison of dyskinesia

The two groups showed no significant difference in dyskinesia grades before operation (P>0.05), nor Grade III dyskinesia before and after operation (P>0.05). Six months after operation, Grade 0 dyskinesia occurred more frequently in the observation group than in the control group (P<0.05), whereas the incidence of Grades I and II dyskinesia was the opposite (P<0.05), as shown in **Table 3**.

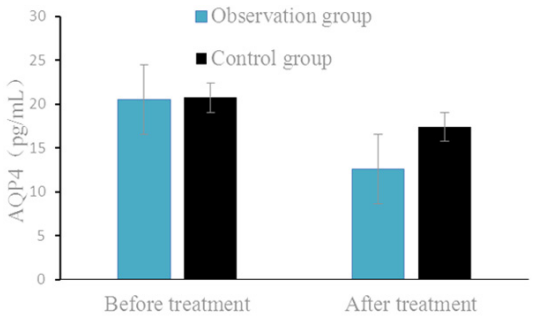

Figure 2. Comparison of AQP4 levels. Note: on the left is AQP4 level before operation while on the right is AQP4 level post operation.

Comparison of the subsidence of swelling and pain and AQP4 level

The observation group had swelling and pain subside earlier than compared with the controls (P<0.05), and the two did not differ from each other in AQP4 level before operation (P>0.05). AQP4 level in the observation group was lower than that in the control group 6 months after operation (P<0.05), as shown in **Figure 2**.

Comparison of severity of enophthalmos

The preoperative incidence of enophthalmos exhibited no statistically significant difference between the two groups (P>0.05). The incidences of enophthalmos and mild enophthalmos in the observation group were higher than those in the control group (P<0.05), while those of moderate and severe enophthalmos were lower in the observation group (P<0.05), as shown in **Table 4**.

Comparison of incidence of postoperative complications

The observation group and the control group were followed up for 6 months after operation for the incidence of infection, implant rejection, translocation, irreversible vision decline and nerve paralysis; all of which did not differentiate significanlty between the two groups (P>0.05), as shown in **Figure 3**.

Discussion

Orbital fracture, an important component of maxillofacial fracture, can be classified into compound fracture and blowout fracture [18]. An external force on the orbital Iliac bone will act along the shape of the bone and thus cause fracture, translocation or collapse of the force point and the surrounding structures; including along brittle bone or the joints of Iliac bones, which suffer most. Fracture will affect other surrounding tissues and result in deformity, restricted eye movement, limitation of mouth opening, all of which are harmful to health and life [19].

Recent application of titanium mesh combined with Medpor has been well established in orbital fracture repair with good outcomes. In this study, the observation group showed higher incidence of Grade 0 diplopia (P<0.05) but lower incidences of Grade I and II diplopia (P<0.05) than the control group 6 months after operation. The observation group had Grade 0 dyskinesia with higher incidence (P<0.05) but Grade I and Grade II with lower incidence by a comparison with the control group 6 months after operation (P<0.05). This indicated the combined treatment application might reduce the incidence of diplopia and dyskinesia in orbital fracture repair, which could contribute to recovery of patients. The operation brought favorable outcomes to patients with orbital fractures, including releasing incarcerated extraocular muscles, helping recover the orbital anatomical structure, supplementing the orbital volume loss, and maximizing facial appearance and visual function [14]. Wall fracture is a specially-located condition, and not all patients need surgical treatment. Extraocular muscle incarceration is shown via preoperative CT examination to give a picture of the severity of the fracture. It is preferred to perform the surgery 2-4 weeks after severe fracture, which can lessen the organization and atrophy caused by soft tissue ischemia and contribute to the recovery of the facial appearance and vision. In this study, the effects of different implant materials on orbital fracture repair were analyzed and compared [20]. High density porous polyethylene (Medpor) is a high molecular material. It was first proposed in 1960 and ratified for clinical use by the United States Food and Drug Administration (FDA) in 1984. It has been widely used in therapies of ophthalmology, stomatology and other diseases. Medpor prevails over traditional implants for the following [21]: (1) It has porous structures with pores between every two structures, providing three-dimen-

Table 4. Comparison of severity of enophthalmos [n (%)]

		None	Mild	Moderate	Severe
Observation group (n=42)	Before operation	0 (0.00)	21 (50.00)	9 (21.43)	12 (28.57)
	6 months after operation	23 (54.76)[a,b]	15 (35.71)[a,b]	4 (9.52)[a,b]	0 (0.00)[a,b]
Control group (n=45)	Before operation	0 (0.00)	22 (48.89)	10 (22.22)	13 (28.89)
	6 months after operation	14 (31.11)	20 (44.44)[b]	8 (40.00)[b]	3 (6.67)[b]

Compared with the control group, [a]$P<0.05$; Compared with that before operation, [b]$P<0.05$.

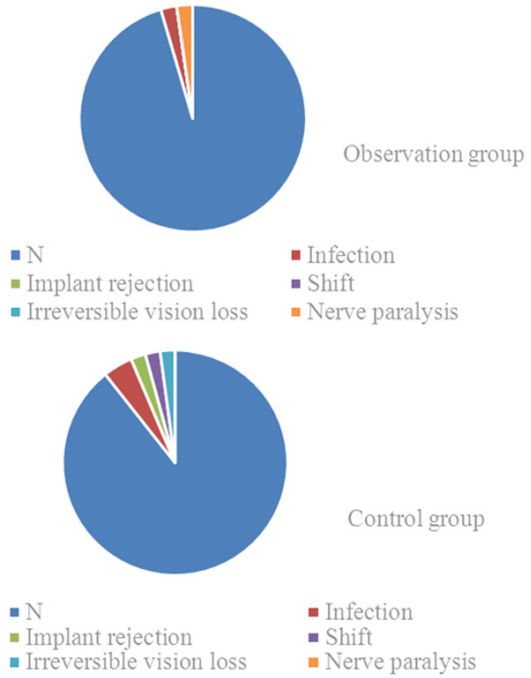

Figure 3. Comparison of incidence of complications.

sional space for tissue growth; (2) It has good histocompatibility and will not cause cytotoxicity and tissue rejection after implantation; (3) It good for anti-infection and has good permeability; (4) It has great vascularization capacity (the average pore diameter is 150-300um) to satisfy capillary growth [22]; and (5) Despite being hard in texture, it can be cut in accordance with clinical needs, hence good shaping [19]. Although it has these advantages and favorable outcomes in the repair of orbital wall fractures, Medpor has certain limitations in clinical use; such as difficulty in fixing it during the perioperative period. Poor fixation is prone to causing a rise in the incidence of postoperative complications, and what's worse, visual deterioration and downgraded outcomes [7].

In recent years, titanium mesh has been developed and started to be used in the clinic as material science moves forward unceasingly in China. It is an inert metal material with high elasticity, great mechanical strength and strong processing and shaping performance. Clinically, titanium mesh is applied with its surface being covered by a dense oxide film, which brings high biocompatibility and is helpful to reduce postoperative recurrence [23]. Material studies show that [24] titanium mesh has the following advantages in patients with orbital wall fracture: (1) It has good biocompatibility and its implantation will never result in rejection; (2) It has special structures providing space for tissue growth; (3) It has small density and is 0.5 mm thick, so that it can be trimmed freely according to clinical and patients' needs; (4) It has high strength, enabling use in large-area defect repair; (5) Fixation with titanium nails after implantation may lead to lower incidence of postoperative complications and avoid material displacement [6]; and (6) It can be visualized via CT and MRI, without participation in postoperative evaluation, generating favorable prognosis. In this study, the observation group had higher incidence of enophthalmos and mild enophthalmos ($P<0.05$) but lower incidence of moderate and severe enophthalmos than the controls ($P<0.05$). This suggested that the combination of titanium mesh with Medpor could reduce the incidence of enophthalmos after operation and bring about good therapeutic effect.

AQP4, or aquaporin, is a protein located on cell membranes, which can control the entry and exit of water in cells. AQP4 has been reported as a major member of a group of erythrocyte membrane proteins, making red blood cells expand and contract rapidly to adapt to changes in permeability. It also exists in other tissues and allows water molecules, but not small molecules and ions, to pass through. A large number of studies show that [25] AQP4 is highly expressed in patients with orbital wall fracture, mainly in supraoptic nucleus and paraventricu-

lar nucleus. It can enhance the water permeability of cell membranes and accelerate liquid flux, thus causing changes in cell membrane structure and increasing the incidence of edema after fracture. Clinically, combination treatment is ideal for orbital fracture repair as it may give full play to the advantages of titanium mesh and Medpor to shorten the edema and pain time, and to reduce the incidence of postoperative edema. The combination treatment is characterized by high safety, no effect on the incidence of postoperative complications, and is conducive to elevate the treatment tolerance and compliance [11]. In this study, swelling and pain subsided in less time in the observation group compared with the control group ($P< 0.05$). AQP4 level was lower in the observation group than that in the control group 6 months after operation ($P<0.05$). Differences in the incidence of complications in the two groups was not of statistical significance ($P>0.05$). These findings suggested the safety of the combination application treatment in orbital fracture repair and with shortened recovery.

To sum up, the combination application in orbital fracture repair can alleviate diplopia, downgrade dyskinesia, help shorten the time spent with swelling and pain, and bring down AQP4 levels. Moreover, it neither leads to frequent enophthalmos, nor raises the incidence of complications. Thus, it is worth popularizing and applying.

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Disclosure of conflict of interest

None.

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