

## Porous Polyethylene Reconstruction of Orbital Floor and Roof Defects: Clinical and Radiological Evaluation

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### ABSTRACT

*Aim:* The aim of this study was to evaluate clinically and radiologically the use of high porous polyethylene (Medpor) for reconstruction of post-traumatic orbital roof and floor defects.

*Patients:* 37 patients had traumatic orbital wall defects were studied. Patients were classified into three groups. Group (A) included 22 patients had orbital floor defects. Group (B) included 10 patients had orbital roof defects. Group (C) included 5 patients had combined orbital roof and floor defects. All defects were reconstructed by medpor. Patients were followed by CT scan and by serial MRI.

*Results:* Near all presentations improved in the immediate postoperative period and maintained in the postoperative follow-up period. Neither extrusion nor infection was recorded in any case.

Enhancement was detected in the implants by MRI as early as one month post operative in 23 patients and 1.5 months postoperative in the remaining 14 patients.

*Conclusion:* Porous polyethylene was found to be flexible, strong, porous and is highly biocompatible. Its porosity enables vascular and bony ingrowth leading to tissue adhesion and a reduced risk of infection. The current study is the first one described in humans to detect vascular ingrowth into medpor orbital sheets utilizing Gadolinium enhanced MRI. Porous polyethylene sheets was shown to have very favorable results in orbital wall reconstruction.

### INTRODUCTION

Orbital floor fractures, alone or in conjunction with other facial skeletal damage, are the most commonly encountered midfacial fractures, second only to nasal ones [1].

Orbital floor fractures may cause severe aesthetic and functional deformities, and present with diplopia, infraorbital numbness, enophthalmos, displacement of the globe, restriction of ocular motility in the upward direction due to inferior rectus muscle entrapment and impaired facial appearance [2]. They have attained the name "blow-out fractures". Prompt therapy to restore the anatomic structure of the orbit and improve visual

function and orbital appearance is essential [3-6].

It should be taken into account that the management of orbital floor injuries is complicated not only by their technical difficulty per se, but also by the required extensive medical competencies, ranging from the maxillofacial to otolaryngological to neurosurgical to ophthalmic fields, and by the multitude of factors necessary to make a correct decision as to the proper timing of the repair [7].

Fractures of the orbital roof are rare traumatic lesions usually combined with more extensive craniofacial injuries after high energy impact, generally motor vehicle collisions. These fractures are rarely isolated and usually associated with injuries of the frontal sinuses. The orbital rims, the naso-orbital ethmoidal region, and other orbital wall fractures, such as Le Fort fractures [8,9].

Acute traumatic orbital encephalocele is a rare entity, with less than 25 cases reported. Early diagnosis and treatment of the orbital traumatic encephalocele is necessary in order to avoid the increase of the intra orbital pressure that might irreversibly damage the optic nerve. Repairing the orbital roof has to be performed in a rigid manner in order to avoid the transmission of the intracranial pressure variation to the orbit [10,11].

Defects of the orbital floor and roof should be reconstructed with either autografts or synthetic materials. One of the most commonly used autogenous graft is the autogenous calvaria split grafts [12]. There are two kinds of alloplastic implants for reconstruction of the orbital floor: Absorbable and non-absorbable. The absorbable materials that are in use are the polylactic acid, the polyglycolic acid implants and the polydioxanone sheets [13]. Nonabsorbable materials may be non-porous (plastic, metallic) or porous. The most commonly used

metallic material is the titanium mesh [14]. Porous, or “integrated” implants, such as porous polyethylene and hydroxyapatite [15], are the most commonly used materials for reconstruction of the orbital floor [16,17]. The use of calcium phosphate cement for reconstruction of calvarial defects and fracture repair of extremities and orbital floor fractures has been described [18].

There has been growing interest in the use of porous polyethylene (Medpor) sheets for orbital wall reconstruction in recent years [19]. Porous polyethylene is highly biocompatible, durable and remarkably stable alloplast. Polyethylene is a pure, noncomposite material. It is a pure polyethylene with specific pore size and manufacturing process. The material can be contoured, carved, adapted, and fixated to obtain strict three-dimensional structure. Polyethylene is not biodegradable. However, its high-density characteristics yield a high tensile strength and resistance to stress and fatigue. The porous architecture permits the incorporation of the surrounding soft tissue and bone into the implant, making migration and extrusion of the implant less likely. Also they are associated with decreased capsular contracture. In addition, once fibrovascular ingrowth is achieved in these implants, they offer the ability to resist infection and are associated with long term immobility [20].

Technically, porous polyethylene sheets are easy to handle, strong but somewhat flexible, and offer the possibility of obtaining a precise three-dimensional shape for orbital defect reconstruction [21]. The orbital floor can be rebuilt using 0.85mm, 1.5-mm or 3-mm sheets, with good long-term success in a diversity of circumstances [14,22].

Fibrovascular tissue growth from adjacent orbital tissue into spherical porous polyethylene orbital implants is well established and has been demonstrated using several techniques (histopathologic findings [23,24] technetium isotope scanning [25], computed tomography [26] and magnetic resonance imaging [25-27]).

## PATIENTS AND METHODS

Over the past four years, in the Plastic Surgery Unit, El-Minia University and in Al Noor Specialist Hospital, Wholly Makkah, 37 patients had traumatic orbital wall defects were reconstructed with high porous polyethylene (medpor). They were clinically and radiologically evaluated. 22 patients had orbital floor defects (Group A), 10 patients had orbital roof defects (Group B), and 5 patients had both orbital roof and floor defects (Group C). 24 patients were males and 13 were females. Their age ranged between 12 and 66 years with a mean age of 32

years. In group (A) 15 patients had impure type of orbital wall fractures; the inferior orbital margin was fractured. 7 patients had pure type of orbital floor fractures; the inferior orbital margin was intact.

All patients had esthetic deformities and/or functional derangement. All patients in group (A) had limited ocular motility and diplopia in the upward direction of gaze. Enophthalmos was noted in 16 patients. Orbital dystopia (Hypoglobus) observed in 8 patients. Infraorbital numbness was complained from in 11 patients. Impaired facial appearance was evidenced in 9 patients. 5 patients in group (B) had exophthalmos that was pulsating in two of them. Associated frontal wall and/or sinus fractures was present in 6 Patients. CSF leak identified in 4 cases. Orbital encephalocele was radiologically detected in two cases. Associated supraorbital rim fracture was present in 4 cases and impaired facial appearance was evidenced in 5 patients. All patients in group C complained from enophthalmos, diplopia, CSF leak and impaired facial appearance (Table 1).

*Exclusion criteria:* Patients with very mild displacement that was not associated with any functional or esthetic deformities were managed conservatively and excluded from this study. Patients had orbital apex or superior orbital fissure syndrome were also excluded.

All patients were reconstructed within 15 days after trauma except for three patients (Two in group A and one patient in group C). They were reconstructed 23 days, 27 days, and 32 days post traumatic because of their bad general condition and associated cranial complications.

Orbital floor defects accessed through a mid-tarsal approach where the skin was incised in a midtarsal plane. This was followed by splitting the orbicularis oculi muscle along the incision line. The orbital septum was identified and was kept intact. The periorbita was then incised 2mm behind the inferior orbital margin. The orbital floor was explored till the posterior limit of the orbital defect. After performing reduction and fixation of the nearby fractured segments if they were fractured, the dimensions of the defect were determined. Medpor sheets in 0.5mm thickness were prepared in the required dimensions, put in hot sterile water, immersed in gentamycin solution, and utilized to obdurate the defect. The implants were either snugly fitted subperiosteally and the periosteum closed over the implant without any mean of fixation of the implant, or fixed by prolene stitches to the plates over the orbital ridge or to holes made

in the ridge itself.

All the orbital roof defects were managed transcranially either by raising a frontal osteoplastic flap or through an already present fractured frontal segment. A coronal approach was used in most of the cases. Patients had forehead extended wounds were accessed through these wounds. After the fractured walls of the frontal sinus have been dealt with, and after reducing the brain matter and repairing the dura or fixing dural patches, the orbital roof defects were identified and measured. Medpor sheets were then utilized in the same previously mentioned way and fixed by prolene stitches to holes made in the edges of the defect. The osteoplastic flaps were reset or the fractured frontal segments were fixed by plates. The scalp or the skin was then closed.

Patients were observed in the immediate postoperative period and were followed-up for one to two years with a mean follow-up period of one year. Patients were observed for improvement of their preoperative manifestations including the functional and the esthetic ones. They were observed for signs of inflammation or protrusion of the implant. They were observed for any long term relapse.

Patients were followed by CT scan immediately postoperative to detect the alignment of the fractured segments. MRI was done one month post operative, and it was repeated every 2 weeks till enhancement was detected which indicated vascular ingrowth.

MRI examination was done after general preparation and removal of all metallic parts e.g hair pins, coins and asked about metallic prosthesis, coils or implants or any other cause interfere with MRI. Imaging protocol includes: Axial T1WI (TR18/TE 400, FOV 25cm, Matrix 256, slice thickness 4mm, band width 4.8), coronal T2WI (TR 2500/TE 110, FOV 25 cm, Matrix 256, slice thickness 4mm, band width 10.8) and coronal STIR

(TR 3500/TE 37, FOV 25cm, Matrix 256, slice thickness 4mm, band width 6.9) and post Gad axial and coronal images.

## RESULTS

Intraoperatively, the medpor was found to be easily contoured, carved, adapted and fixed to the defects. It was found to be strong and flexible. Obtaining a precise three-dimensional shape of medpor for orbital defect reconstruction was done without difficulty (Figs. 1-3).

Immediately postoperative and after the mild oedema that has developed been subsided, the patient's ethetics and function have improved. In group (A), the enophthalmos, the diplopia, the ocular motility and the facial appearance have improved in all patients reconstructed within 15 days post traumatic (Figs. 4,5). Residual enophthalmos was present in these two patients who had delayed reconstruction. The infraorbital numpness persisted. In group (B), the exophthalmos, the CSF leak, and the facial appearance have improved in all patients. In group (C), the facial appearance, the diplopia, the enophthalmos and the CSF rhinorrhoea improved. Residual enophthalmos was present in this patient who had delayed reconstruction.

CT scan revealed adequate reduction and fixation with good alignment of the fractured segments. Enhancement was detected in the implants by MRI as early as one month post operative in 23 patients and 1.5 months postoperative in the remaining 14 patients. This indicated vascular ingrowth within the implant (Figs. 6-8).

This immediate postoperative results continued through the follow-up period. The numpness improved in a period ranged from 6-12 months postoperatively. Relapse of manifestations was not recorded in any case. Neither infection nor extrusion of the implant developed in any patient. All the results were stable in the follow-up period.

Table (1): List of presentations in the three groups.

Group (A)		Group (B)		Group (C)	
Presentation	Number	Presentation	Number	Presentation	Number
Pure type	7	Exophthalmos	5	Diplopia	5
Impure type	15	Impaired facial appearance	5	Enophthalmos	5
Diplopia	22	Associated frontal wall and/or sinus fracture	6	CSF leak	5
Limited upward mobility	22	Associated supraorbital rim fracture	4	Impaired facial appearance	5
Enophthalmos	16	Orbital encephalocele	2		
Hypoglobus	8	CSF leak	4		
Impaired facial appearance	9				
Infraorbital numpness	11				



Fig. (1): Medpor sheet.



Fig. (2): Medpor sheet reconstructing an orbital floor defect fixed by prolene stitches to an infraorbital plate.

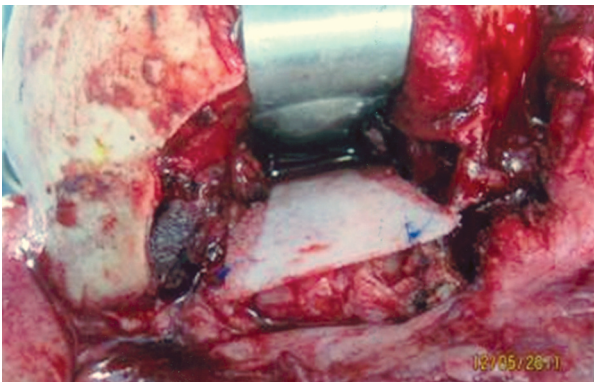


Fig. (3): Medpor sheet reconstructing an orbital roof defect fixed by prolene stitches to the edges of the defect. A malleable spatula reflects the frontal lobe of the brain upwards.



Fig. (4): Preoperative photo for one of Group (A) patients shows limited left ocular mobility in the upward direction as well as hypoglobus and enophthalmos.

Fig. (5): Immediate post operative photo for the same previous patient shows improvement of the ocular mobility and normalization of the level and position of the globe.

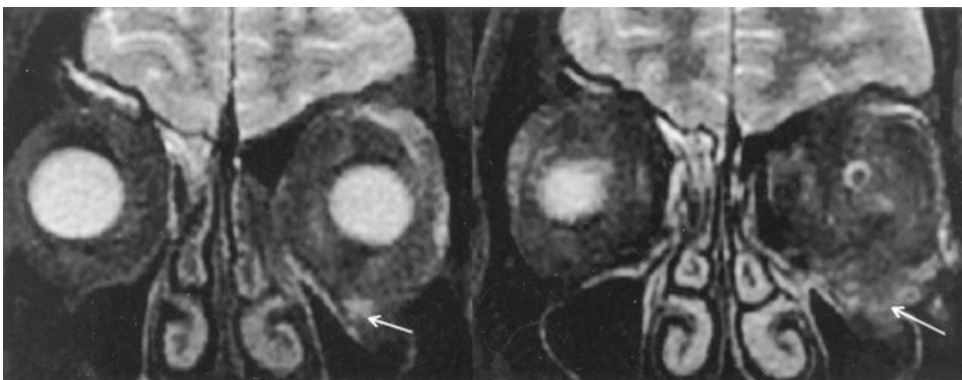


Fig. (6): A- One month post operative coronal pre Gad MRI image shows the implant within the left orbital floor (white arrow). B- Post Gad coronal MRI shows the enhanced orbital floor denoting vascular ingrowth (white arrow).

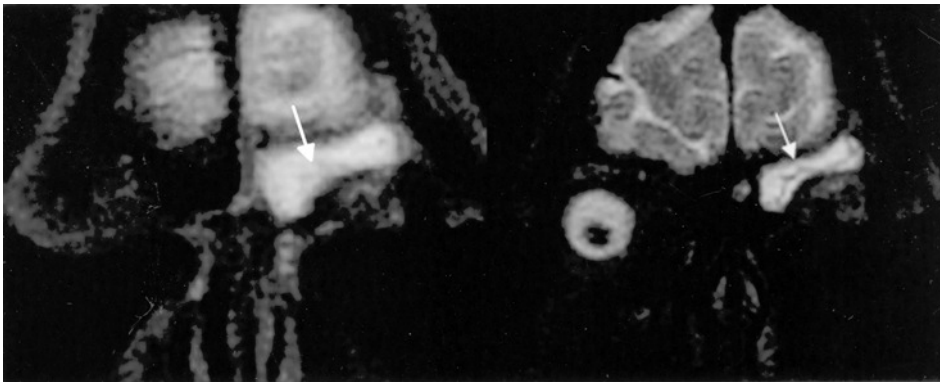


Fig. (7): A- One and half month post operative coronal pre Gad MRI images shows the implant at the left orbital roof (white arrow). B- Post Gad coronal MRI shows the enhanced implant and the traversing small vascular signal void denoting vascular ingrowth (white arrow).

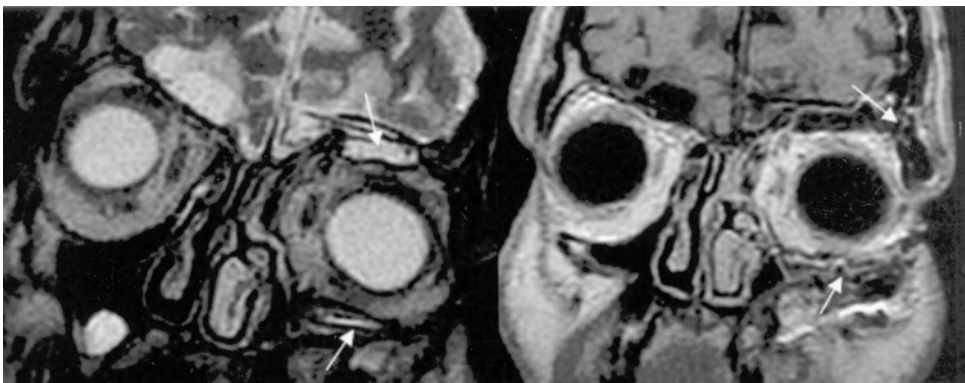


Fig. (8): A- One and half month post operative coronal pre Gad MRI images shows the implant at the roof and floor of the left orbit (white arrows). B- Post Gad coronal MRI shows multiple well defined serpiginous signal voids of the newly developed vessels at both orbital roof & floor denoting vascular ingrowth of the implant (white arrows).

## DISCUSSION

A wide variety of autogenous grafts and alloplastic materials are used for orbital wall fracture repair. Although bone graft is the most commonly used autogenous material in orbital reconstruction, it is not an ideal material because of donor-site morbidity, prolonged surgical time, unpredictable resorption, and difficulty in contouring the bone to fit complex defects of the internal orbital skeleton [19].

Many synthetic alloplastic materials have been used for orbital floor fracture repair. Among these, the most widely used include silicon rubber (silastic), polytetrafluoroethylene, polyamide mesh, titanium, polyglactin-910, gelatin film, and hydroxyapatite. However, silicone has been shown to cause resorption of underlying bone, encapsulation and migration [28]. Polyglactin-910 and gelatin film lack sufficient structural strength to provide adequate stability for a large orbital wall fracture. Titanium is a rigid malleable implant material, but the insertion of titanium mesh is sometimes not smooth because the cut edges of the plates can easily get caught in tissues [29]. Traditional hydroxyapatite sheets are very stiff, inconvenient to shape, and have been found to degrade in certain situations, although the recently developed hydroxyapatite cement appears to have great promise as a biologic material [30].

Porous polyethylene, which is flexible, strong and porous, was developed in the early 1970s and has proven to be biocompatible. Its porosity enables vascular and bony ingrowth leading to tissue adhesion and a reduced risk of infection [31]. Studies using porous polyethylene sheets in orbital reconstruction have shown very favorable results in intermediate-term follow-up [14].

Porous high-density polyethylene is formed by sintering small particles of high-density polyethylene to create a strong firm material that can be molded using hot water. The basic structure of Medpor is a simple carbon chain that makes it the reference standard for an inert substance in assays of tissue reaction. Pore sizes range from 100 to 250 micrometer, with 50% being larger than 150 micrometer. This feature is important, because previous animal studies have shown that pore sizes greater than 100 micrometer encourage tissue ingrowth [32].

Many different sizes and shapes of medpor are available. Medpor comes in prefashioned models or can be tailored to a specific patient's needs based on stereolithographic reconstruction from a 3-D CT scan. Medpor is radiolucent on CT scans and MRI, causing no interference with postoperative imaging, although a new version with titanium mesh embedded in the Medpor is radioopaque with minimal scatter and is MRI safe [33].

Early studies of Medpor implants demonstrated fibroblast ingrowth that prevents capsule formation and infection. It promotes stabilization of the implant. Over long periods, bone eventually incorporates at the implant bone interface, providing additional stability [34,35]. De Potter and colleagues [26], demonstrated fibrovascular ingrowth in vivo in 10 patients who underwent orbital Medpor implantation after enucleation. They did serial MRI examinations that showed enhancement as early as 1.5 months postoperatively. Choi et al., [24] did enucleation in 40 rabbits and reconstructed the orbit with medpor. They assessed the fibrovascular ingrowth both histologically and by MRI. They found that there was a significant correlation between the enhanced area on MRI and the fibrovascularized area observed upon histological examination. They concluded that the Gadolinium (Gad) enhanced MRI is an excellent method for assessment of the fibrovascular ingrowth into medpor implant. In a human histopathologic study made on the anterior protruding edge of the medpor sheets used to reconstruct post traumatic orbital floor defects that needed trimming in 3 patients, Praveen et al., [31], recorded the first histologic description of fibrovascular ingrowth. Mavrikakis and colleagues [36] published a histologic examination of explanted lower eyelid Medpor spacers that showed microscopic vascular ingrowth, although growth vascularization was not observed.

The current study is the first one described in humans to detect vascular ingrowth into medpor orbital sheets utilizing Gadolinium enhanced MRI.

Medpor has been used for orbital reconstruction after enucleation, correction of lower eyelid retraction, and orbital fracture repair. Medpore has been extensively used for orbital roof, floor and medial wall fractures [32-43]. Medpor has been shown in experimental studies to support the load of the orbital contents, and bend, not break, with excess force. Estimations based on computed tomography scans of orbital volume after repair of unilateral orbital fractures with Medpor showed that orbital volume between the fractured and nonfractured sides are not significantly differ [44-46].

Disadvantages of porous polyethylene implants include adhesion of extraocular muscle or orbital fibroadipose tissue to the implant. If repeat surgery is necessary, the porous implant will have fused very tightly with the orbit. In addition, flammability of the porous polyethylene implant has been reported while using cautery [47].

The extrusion rate of porous polyethylene implants is low. In reviewing the literature, it has

been found that only one previously reported case of polyethylene implant extrusion [14]. Some authors have advocated screw fixation of porous polyethylene orbital implants [48]. However, in many cases, once intraorbital contents are allowed to fall back onto the sheet and the periosteum is closed at the orbital rim, which opposes the anterior migration of the implant, no further securing is necessary [49]. In a study made by Lin et al., 2007 [19], 21 implants were used. None of the implants were secured with screws or sutures, and no case of implant extrusion occurred. Extrusion was not recorded in any case in this study.

Infection is the most disastrous complication with the use of porous polyethylene implants in orbital wall reconstructions. Antibiotic prophylaxis, given either systemically or by direct soaking of the implant before implantation, remains controversial. Many authors have obtained good results by soaking the implants in antibiotic solutions before implantation [14-22]. Rubin et al. [50] reported a series of patients who received prophylactic antibiotics including systemic administration and direct soaking before implantation; only one patient required removal of the implant 1 week after surgery because of infection. Infection was not recorded in any case in this study.

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