

## **Medpor implant in cranioorbitomaxillary reconstruction: institutional experience and a review of the literature**

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## ABSTRACT

Autologous materials remain the gold standard for complex skull base and craniofacial reconstruction, but they carry additional morbidity associated with the second harvest procedure and with prolonged operation time. These autologous materials also resorb in a way that is not predictable, rendering them less ideal in situations where cosmesis and function are of paramount importance to aid with primary healing of the intracranial wound. Medpor porous polyethylene implant is an alloplastic material with unique characteristics that make it an excellent alternative for cranioorbitomaxillary reconstruction. The porous nature of the implant permits the ingrowth of vascularized tissue eventually forming a highly stable complex resistant to infection and deformation. A total of 698 patients undergoing 719 procedures in which Medpor was implanted were reviewed. Two complications occurred that required removal of the implant. On the basis of our results, we believe that the Medpor implant is an excellent alternative to existing alloplastic materials with a low incidence of infection and excellent cosmetic and functional results.

**Keywords:** Medpor, alloplastic material, autogenous tissue, craniofacial reconstruction, skull base surgery, methylmethacrylate, silicone

Skull base surgery has evolved extensively over the last several decades with the advent of microsurgery and improved neuroimaging modalities, allowing the surgeon to perform radical en-bloc resections that were previously not thought impossible.

Unfortunately, skull base radical resections result in large cranio-orbitomaxillary defects that require complex reconstruction of the skull base for both functional and cosmetic purposes.<sup>4, 5, 16, 17</sup> It is important to eliminate the anatomical dead space that is produced after such a resection by creating an anatomical and functional seal between the intracranial and extracranial compartments.<sup>9, 10</sup> A watertight dural closure in this setting may be difficult if a dural graft is used or if there is a tenuous dural closure secondary to resection of the lesion.<sup>3, 4, 9, 10</sup> In these instances, a watertight reconstruction of the skull base is of paramount importance to promote primary healing of the intracranial compartment and to prevent secondary infection and formation of a fistulous cerebrospinal fluid tract. The use of well-vascularized tissue overlying the skull base defect promotes the most advantageous milieu for healing, especially in those instances where adjuvant radiation treatment is imminent.<sup>3, 4, 9, 10, 16, 17</sup>

Although our technical abilities now enable us to perform radical resections, cranial contour correction and repair of medium to large-sized cranioorbitomaxillary defects appears to be a relatively simple problem that has yet no clearly defined solution. Autogenous tissues are preferred for skull base and craniofacial reconstructions because they possess the optimal biocompatibility characteristics.<sup>2, 3, 4, 5, 6</sup> Autogenous grafts, however, require longer surgical time and greater expertise to ensure a successful outcome; in the absence of these, complications including donor site morbidity, difficulty with graft contouring, and prolonged operative times can result.<sup>2, 3, 4, 5, 6, 7, 9, 10, 13, 16, 17</sup>

These grafts also tend to resorb to varying and unpredictable degrees over time. These shortcomings associated with autogenous grafts have led to the development of synthetic frameworks to aid with immediate functional and aesthetic reconstruction after skull base surgery with the goal of minimizing complications. Unfortunately, implantation of inert substances has been demonstrated to promote capsule formation and an avascular interface between the host and graft; infections in these spaces are poorly tolerated and the alloplast eventually extrudes if not removed.<sup>2, 3, 4, 5, 9, 10</sup> Several alloplastic materials have been proposed and used as frameworks, including silicone, porous hydroxyapatite, titanium mesh, and methylmethacrylate.<sup>1, 9, 10, 11, 14</sup> Although these have proven successful in other anatomic regions, each of these materials has drawbacks that render them less than ideal for use in skull base reconstruction. Porous polyethylene, on the other hand, offers many benefits with fewer of the potential side effects affecting these other materials.

The Medpor porous polyethylene Flexblock implant (Porex Surgical, Inc., Newnan, GA) is a highly inert material made of pure medical grade high-density polyethylene microspheres sintered to create a framework of interconnected pores approximately 150  $\mu\text{m}$  in diameter. Medpor has been approved for use in humans since 1985; its long history means it has been used as a standard reference material for biocompatibility testing.<sup>2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17</sup> The porous nature of this material permits the ingrowth of blood vessels, bone, and soft tissue, thereby reducing the possibility of infection while increasing the tensile strength of the implant. The Medpor implant is flexible and can be easily contoured to accommodate a variety of medium-sized skull defects. Furthermore, if large areas of the skull base require reconstruction, a

customized implant can be created with the aid of high-resolution, three-dimensionally reconstructed computed tomography (CT) scans.<sup>2,3,9,10</sup> The implant is completely radiolucent on CT scans and produces no imaging artifact on magnetic resonance imaging scans, allowing for better management of those afflicted with malignant tumors that necessitate close monitoring.<sup>2,3,9,10</sup> Because of these advantages, we preferentially use Medpor for skull base (cranioorbitomaxillary) reconstruction. In this study, we build on a previous evaluation published in the neurosurgical literature and discuss our institutional experience with a total of 698 patients who have undergone cranioorbitomaxillary procedures.<sup>9,10</sup> In addition, we have reviewed the literature about the use of Medpor porous polyethylene in skull base and craniofacial procedures.

## **Clinical Material and Methods**

### *Patients*

A retrospective review of medical charts of all patients who underwent vascular, skull base, and epilepsy procedures by the senior author (W.T.C) between January 1996 and December 2006 was performed to identify patients who received the Medpor porous polyethylene implants in cranioplasty and skull base reconstruction.

### *Surgical Procedure*

Once the resection has been completed, the reconstruction of the skull base procedure proceeds. The size of the defect must be determined by the surgeon and then the Medpor surgical implant can be molded to fit. The pattern of the defect is drawn on a paper template and transferred to the smooth surface of the implant. The implant generally has

a smooth exterior surface and a series of conical projections on the undersurface. Mayo scissors and a scalpel are used to fashion the implant to the desired shape and size. To ensure an adequate fit, the implant is cut larger than the template to allow for molding. The implant material is available in various shapes and sizes to allow for optimal molding to fit.<sup>2, 3, 9, 10, 16, 17</sup> To fit the edge of the implant without deformity, the underside of the implant is feathered with a scalpel to prevent any irregularity and to obtain a smooth contour at the bony edges. A high-speed drill may also be used to create a shelf at the edges of the bone to allow the implant to seat without deformity. Great care must be taken while using the drill to ensure that debris does not clog the pores of the implant. If a larger cranial defect requires additional molding, the Medpor implant may be placed in a warm saline bath to facilitate the process. The implant retains its contour after cooling. In all cases, fixation of the implant is performed either by placing titanium screws directly through the implant into the bone or with the use of titanium plates along with screws (Figure 1). Once the implant has been placed, the overlying galea is sutured to create a watertight closure and the overlying subcutaneous tissue is subsequently sutured. Optimum conditions for success of the implant include using as thin an implant as possible to optimize vascular ingrowth and to ensure that no excess pressure is exerted on the overlying skin.

## Results

The Medpor porous polyethylene implant was used in 698 patients who underwent 719 procedures that resulted in craniorbitomaxillary defects necessitating reconstruction.

Twenty-one patients underwent bilateral surgeries via different approaches; Medpor was

used at different locations in these patients accounting for the discrepancy among patients and implants used. The implant was most commonly used after a craniotomy for aneurysm clipping (65.5%) skull base tumor resection (34%), and cranioplasty (0.5%). The most common approaches used were the orbitozygomatic, pterional, and subtemporal (Table 1). Each of these operative approaches extends to involve the orbitomaxillary spaces necessitating proper reconstruction to allow for appropriate wound healing and cosmesis. The mean follow-up period for these patients was 6.3 years (range 8 months to 11.8 years). Two postoperative infections were noted in our series: In one case, a postoperative wound infection and purulent discharge was noted with associated signs and symptoms of meningitis two months after resection of a large left petrous intracranial schwannoma. Reexploration confirmed a postoperative abscess cavity that extended into the Medpor implant and required removal of the implant. The other postoperative infection involved a custom-made Medpor implant for a large craniectomy defect placed after a decompressive craniectomy secondary to trauma. The skin overlying the implant was thin and atrophic and became exposed and secondarily caused infection. Prompt removal of the implant was necessary. This patient required further surgery after implant removal to correct his craniectomy defect. On follow-up review, all other patients had satisfactory cosmetic and functional outcomes as judged by the senior author.

### **Case Illustration**

A 64-year-old man was brought to the University of Utah Emergency department for a gunshot wound to the head. Upon examination, he was lethargic but able to answer questions and state his full name and the date. After stabilization by the trauma team he

underwent CT imaging of his head, which showed evidence of severe penetrating trauma with a metallic fragment lodged in the right inferior frontal lobe with associated subdural and subarachnoid blood. Point of entry appeared to be directly in the sagittal midline between the orbits. Severe comminution was present in the frontal bone and ethmoid air cells, ethmoidalis, medial orbital walls bilaterally, and right lateral orbital wall superior to the zygomatic arch. A CT angiography study was also performed to rule out any vascular injury or pseudoaneurysm formation, and it was negative for any of the above findings.

The patient was taken to the operating room for debridement and repair of his intracranial defects, as well as to remove any loose bone fragments that had the potential to encroach upon the globes and cause optic nerve injury. Intraoperatively, the regions involved as described above were comminuted and unable to be salvaged (Figure 2A,B). The bullet fragment was removed and the overlying dura was repaired but a large defect involving the frontal, ethmoid, and orbital bones remained.

Four months later, the patient returned to undergo repair of the defects. The Medpor cranioplasty implant was modeled from the stereotactic imaging of postoperative defects. The patient was placed under general endotracheal intubation and was sterilely prepped and draped in the usual fashion. His previous incision was marked out, injected with lidocaine and epinephrine, and then opened with a No. 10 blade. Circumferential dissection of the cranial wound was performed until the orbital rims were appreciated. The bony margins were cleared from any overlying soft tissue, and a high-speed drill was used to smooth out any sharp ridges along the existing bony margin. The custom Medpor



implant was soaked in a bacitracin solution and then fitted to the defect. Any irregular margins were smoothed by the high-speed drill, and a shelf was created to allow for appropriate seating of the implant. The implant was then affixed with 4-mm screws and irrigated with bacitracin solution, and the overlying galea was reapproximated. Postoperatively, cosmesis and function were restored and postoperative imaging demonstrated appropriate cranial contours (Figure 2C).

### Discussion

It is of paramount importance to restore both function and cosmesis in complex skull base resections to promote the healing process and to prevent complications. Well-vascularized tissue and obliteration of anatomical dead space secondary to removal of the lesion promote primary healing and prevention of perioperative and future complications.<sup>9, 10, 16, 17, 11, 12</sup> Autogenous materials have long been touted as the optimal graft materials for complex skull base and craniofacial reconstructions because of their biocompatibility profile. Problems with donor site morbidity, increased surgical complexity, increased operative time, difficulty shaping the graft, and disappointing late results with warpage or resorption, however, have led to the desire to find synthetic alternatives.<sup>1-17</sup>

Initial attempts at the use of alloplastic materials involved materials such as methylmethacrylate, titanium mesh, silicone products, and hydroxyapatite. The most widely used alloplast is methylmethacrylate, a highly thermoplastic material.<sup>2, 3, 6, 10, 11, 14</sup> This material can be problematic because of identified complications. It has been shown that cold-cured methylmethacrylate contributes to tissue damage, an exothermic reaction

results in a high curing temperature, and release of a toxic monomer that has been the cause of both local and systemic reactions.<sup>16, 17</sup> Other disadvantages to the use of methylmethacrylate include fracture of the brittle implant, bone resorption around the implant, loosening of the implant, and infection.<sup>16, 17</sup> To add strength and stability to the implant, a technique of molding the methylmethacrylate over a titanium wire framework has been used, but this framework can produce significant artifact in postoperative imaging.<sup>2, 3, 7, 16, 17</sup>

Silicone, a popular material for maxillofacial procedures because of its plasticity, was initially thought to be suitable for cranioorbitomaxillary defects adjacent to the sinuses.<sup>15</sup> After some use with these implants it was deemed less suitable for cranial applications. Solid silicone implants do not become integrated into the surrounding tissue and also create a thick avascular capsule that lends itself to infection more readily. There is also some evidence that points to bone resorption under the implant, and, in animal studies, it has been shown to be associated with prolonged local fluid accumulation.<sup>1, 5, 15</sup>

Another alloplastic material has been proposed for use in closing these defects. Porous hydroxyapatite was initially thought to be an excellent alloplastic material for craniofacial applications because of its similarity in composition to human bone and the degree of bone ingrowth into the implant.<sup>16, 17</sup> Unfortunately, in the clinical setting, the porous hydroxyapatite implants may be brittle and difficult to use and contour. This implant also has an unpredictable degree of resorption after implantation.<sup>2, 3, 6, 9, 10, 16, 17</sup>

Medpor porous polyethylene implant possesses a combination of properties that make it superior to other available alloplastic materials. The implant is easy to mold and

is strong yet flexible. The unique porous architecture of the implant enables tissue fluid to circulate throughout the implant facilitating rapid vascularization with accompanying soft tissue ingrowth. Over time, it permits the incorporation of bone at the implant-bone interface that anchors the implant.<sup>2, 3, 5, 8, 9, 10, 13</sup> High-density porous polyethylene has a consistently benign response in patients.<sup>2, 3, 5, 8, 9, 10, 13</sup> Furthermore, it can provide an improved cosmetic and functional outcome for patients (Figure 2).

Studies to examine the benefits of various alloplastic materials in wound healing have shown that the material is very successful for this function. Dougherty and Wellisz<sup>5</sup> designed a rabbit animal model to simulate orbital blowout fracture in humans. Standard 8-mm defects were made in bilateral maxillary sinuses including both bone and mucosa. Two implants were used, silicone and Medpor. Both implant types were placed in the soft tissue defects exposing one surface of the implant to the open sinus. At the end of the study period, the Medpor implants were shown to be affixed to the bone and soft tissues and demonstrated mature mucosa overlying open sinus. The silicone implants, however, produced an avascular fibrous capsule and did not become incorporated to the surrounding bone or soft tissue and had a high percentage of associated infections. It is believed that the porous architecture of the Medpor implant contributed to the success of the implant in these animal models. Romano et al.<sup>13</sup> reported the use of the Medpor implant in 140 patients with facial fractures. Although these authors reported the use of Medpor in facial bone reconstruction was controversial, none of their patients had adverse effects from the Medpor implant.

Cenzi et al.<sup>2</sup> retrospectively reviewed the clinical outcome of patients in whom 285 Medpor grafts were used for craniofacial reconstruction. They found that the

location of the implant (i.e., nose, maxillae, and ear) affected the risk of implant failure, and syndromic patients who had prior operations also had a higher risk of implant failure. Overall, few complications were reported within their series, but several patients had persistent pain, paresthesia, implant exposure, infection, and subsequent graft removal.

Sevin et al.<sup>15</sup> reported the use of 52 Medpor implants for craniofacial reconstruction in 31 patients over a four-year period. They reported 9 complications with the implant in which each complication was associated with thin atrophic or scarred overlying skin and subsequent exposure and infection of the implant. The authors recommended appropriate patient selection and avoidance of any region that requires the implant to be covered by only a mantle of thin or scarred tissue. Instead, they advised that the implant should be placed under a thick tissue coverage, such as muscle, fascia, or a thick layer of subcutaneous tissue.

In our series of 698 patients, two were found to have infection associated with the implant, but all patients achieved both a satisfactory functional and cosmetic outcome. A complication rate of less than one percent is satisfactory and acceptable in the use of the Medpor implant as compared with other alloplastic materials available. In fact, our institutional complication rate is lower than that reported in other series.<sup>2</sup> The Medpor implant was used in small- and medium-sized defects, and larger defects were fitted with custom-made implants. In our experience, the properties of Medpor make this material an excellent alternative to the other methods of skull base and craniofacial reconstruction. The implant is easy to use and flexible and produces adequate cosmetic and functional results. Appropriate patient selection and avoidance of thin, atrophic, or scarred tissues should be avoided to prevent implant failure.

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Figure 1. Use of Medpor for reconstruction after subtemporal approach for resection of a skull base tumor.

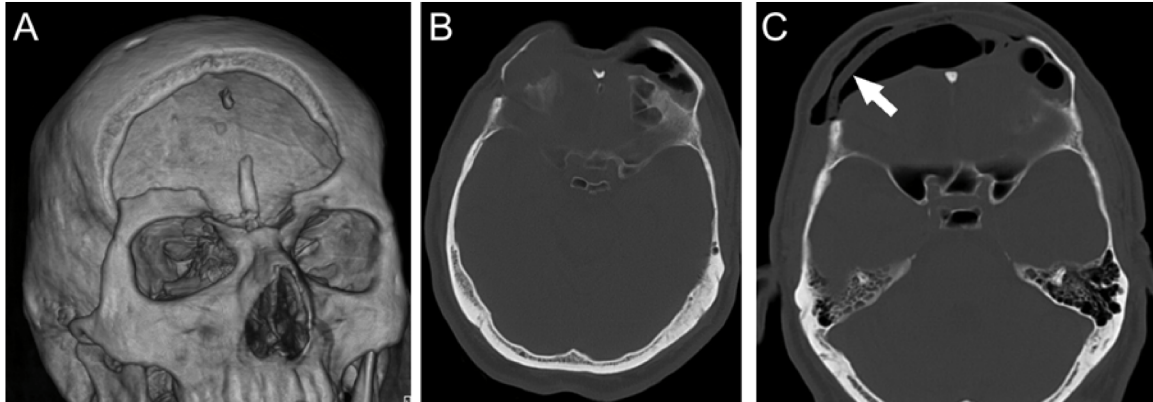


Figure 2: A. Stereotactic three-dimensional reconstruction of the cranial defect after the initial surgery demonstrating the large defect involving the frontal ethmoid and orbital bones. B. Axial CT image of bone windows demonstrating the cranial defect. C. Postoperative axial CT image of bone windows demonstrating the Medpor implant with smooth margins (arrow).

Table 1. Approaches and number of cases necessitating Medpor reconstruction of the cranioorbitomaxillary spaces.

Indication	Cranioorbitomaxillary approaches used	Number of cases	Percentage
Aneurysm (anterior and posterior circulation)	Pterional Orbitozygomatic	449	65.5%
Skull base tumor	Orbitozygomatic Subtemporal	246	34%
Cranioplasty	Approach appropriate for the defect	3	0.5%