

Cranioplasty with the Medpor porous polyethylene Flexblock implant

Technical note

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✓ The authors describe the use of a porous polyethylene Flexblock implant for cosmetic cranioplasty. The implant may be used to cover any small- or medium-sized (< 8 cm) cranial defect, offering similar cosmetic results to standard alloplast cranioplasty while decreasing operation time. The porous implant design permits ingrowth of soft tissue and bone to increase implant strength and decrease the risk of infection. The Flexblock alloplast has been utilized in 25 cases with excellent cosmetic results and no implant-related complications.

KEY WORDS • alloplast • cranioplasty • polyethylene • skull defect

DESIRABLE properties of alloplastic materials for closure of skull defects include rigid fixation and cosmetically acceptable edge-to-edge contact and contour. Many techniques using alloplastic and autogenous materials have been championed for this purpose, including autogenous bone grafts, silicone, porous hydroxyapatite, and various metals either alone or in association with methyl methacrylate.^{3,7,10,13,15}

Polyethylene is a highly inert material that has been used in the craniofacial skeleton, in some cases with follow-up periods of more than 30 years;¹² it has long been used as a standard reference material for biocompatibility testing.⁴ The Medpor Surgical Implant is composed of high-density polyethylene microspheres sintered to create a framework of interconnected pores. This porous character permits ingrowth of vascularity, bone, and soft tissue to reduce the incidence of infection while increasing the strength of the implant.^{1,13,14} This highly stable and flexible alloplast has been approved for use in humans and is available in rectangular blocks or preformed anatomical shapes for specific craniofacial applications. Although experience with Medpor in craniofacial repair has been reported elsewhere,^{1,11,15} we have found this to be a superior material for standard neurosurgical cranioplasty for small and medium-sized defects, which has prompted the present report in which we describe our initial experience and

implantation technique using the Medpor Flexblock implant.

Materials and Methods

The Medpor porous polyethylene Flexblock implant is designed with a smooth exterior surface and a series of conical projections on the undersurface (Fig. 1). The cost of the standard implant is directly comparable to a single-package methyl methacrylate cranioplasty kit.

Surgical Implant Technique

The Medpor surgical implant* may be used to cover any shape of cranial defect. It is fashioned as desired with Mayo scissors or a scalpel. To ensure an adequate fit, a pattern of the defect is drawn on a paper template, then transferred to the smooth surface of the implant. The implant may be cut slightly larger than the template with a pair of large Mayo scissors. The cones on the undersurface of the implant enable the block to be flexed to any desired contour (Fig. 2A and B). To fit the edge of the implant to the craniotomy edge without a deformity, the underside of the implant is feathered with a scalpel to enable "lapping" of the implant to the surrounding bone edge (Fig. 2C). Alternatively, a shelf

* Medpor Surgical Implant manufactured by Porex Surgical, College Park, Georgia.

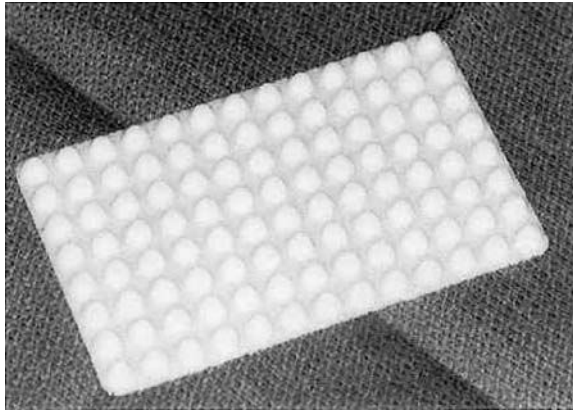


FIG. 1. The Medpor porous polyethylene Flexblock implant. The implant is designed with a smooth exterior surface and a series of conical projections on the undersurface, pictured here.

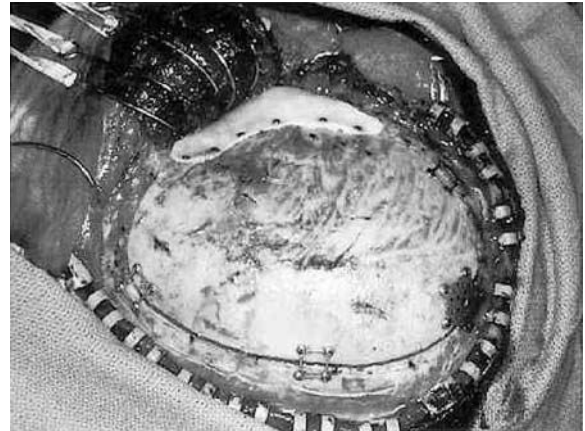


FIG. 3. Operative photograph of an illustrative case using the Medpor Flexblock implant to cover a standard temporal craniectomy defect. In this case, the implant was lapped to the surrounding bone edge and fastened with titanium miniscrews.

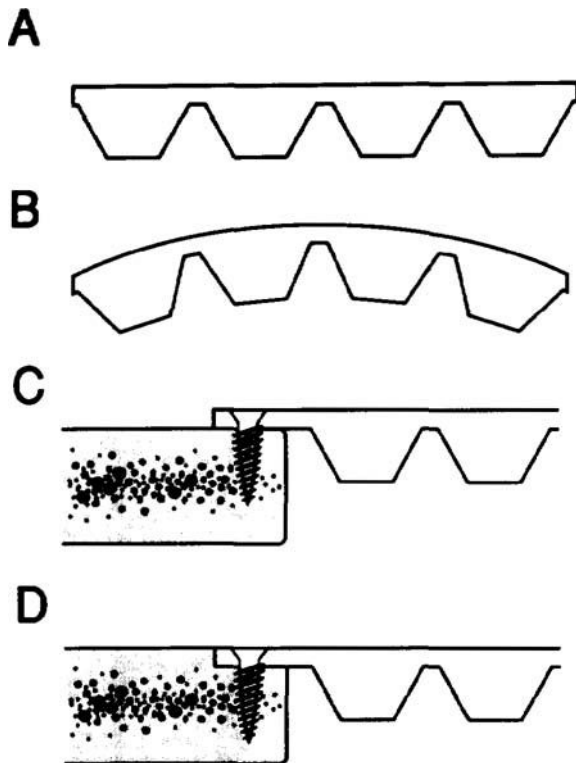


FIG. 2. Drawings demonstrating cross section of the implant (A) and the cones on the undersurface (B) that enable the implant to be flexed to the desired contour (B). To fashion the cranioplasty, the implant is cut in the desired shape (slightly larger than the defect to be closed) with a pair of Mayo scissors, and fastened in place with titanium miniscrew fixation. To facilitate an acceptable cosmetic result, the cones at the edge of the implant are shaved to allow the implant to be lapped to the surrounding bone edge (C). Alternatively, a shelf may be created at the edge of the craniotomy to seat the edge of the implant (D). The titanium screws may then be used to fasten the implant by directly screwing through the implant to the calvaria or the bone flap as shown here.

may be created at the edge of the craniotomy with a power burr to seat the edge of the implant into the surrounding bone (Fig. 2D). Fixation of the implant is performed by placing titanium screws directly through the implant into the bone (Fig. 3) or with the use of titanium miniplates together with the screws.

Although the implant is easy to bend without fracture, larger defects or sharp-contoured reconstructions may require additional molding, facilitated by heating the implant in warm normal saline. In such cases, the implant will retain its contour after cooling. For large defects (> 8 cm) requiring increased strength, custom-made thicker implants are available and are recommended; however, Medpor is designed to offer coverage of small- and medium-sized defects and is not intended for use in areas requiring load-bearing structural support. Specific sizes and shapes of thicker implants are available for individual applications, and may be custom-ordered on an individual basis depending upon defect shapes derived from three-dimensionally reconstructed computerized tomography (CT) images.

Microscopic Appearance and Histology of the Chronic Implant

The high-density polyethylene microspheres are sintered to create a porous framework (Fig. 4 left). With chronic implantation, this porous network enables the ingrowth of fibrous tissue (Fig. 4 right) and bone at the implant interface.

Results

The Medpor implant has been used in 25 cases requiring cranioplasty (Table 1). These included a variety of cranial defects of small to medium size, most commonly temporal craniectomy defects. Excellent cosmetic results were obtained in all cases, including three in which the implant was utilized to reconstruct the lat-

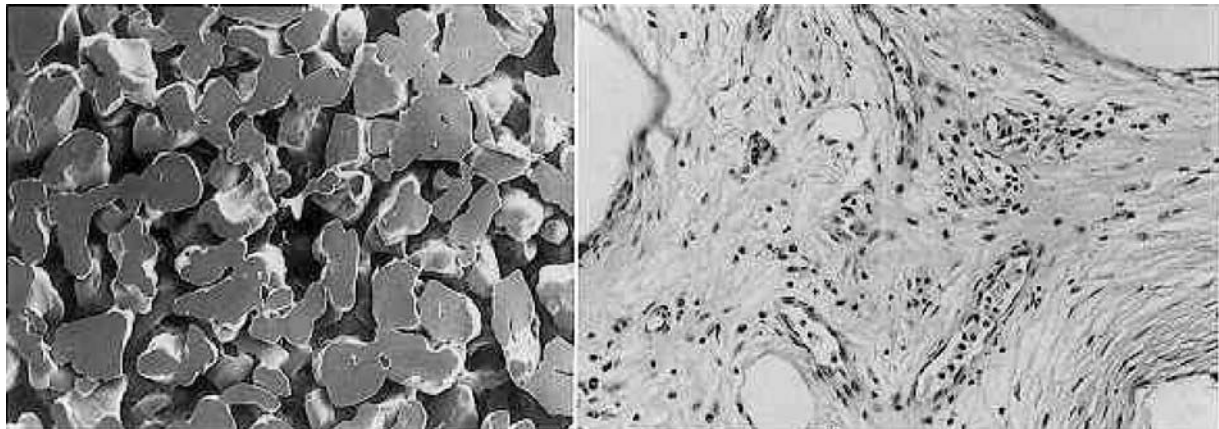


FIG. 4. *Left:* Scanning electron micrograph illustrating the porous nature of the implant. $\times 23$. *Right:* Histological section demonstrating neovascularization and fibrous tissue ingrowth into an implant after a 3-month period in a human craniofacial application. H & E, $\times 75$.

TABLE 1
Cranioplasty defect location and size in 25 cases

Location & Size*	No. of Cases
temporal	
small	11
medium	4
frontotemporal, medium	5
parietal	
small	1
medium	2
occipital, medium	1
suboccipital, medium	1

* Small: < 4 cm; medium: 4 to 8 cm.

eral orbital ridge. There were no implant-related complications; in two cases with use adjacent to an open sinus (frontal in both cases), no evidence of infection has been noted. Follow-up periods ranged from 6 to 15 months, with a median of 9.4 months. This cranioplasty material and technique appear to produce cosmetic results comparable to standard cranioplasty materials. In comparison to methyl methacrylate cranioplasty, operation time is shortened with the use of the Flexblock implant by avoiding obligatory "cure time" prior to closure.

Discussion

A variety of cranioplasty materials and implantation techniques have been reported in the literature.^{3,7,10,13,15} While autogenous materials for skull and craniofacial reconstruction possess optimum biocompatibility characteristics, complications arising from the donor site and increased operation time limit their widespread use. For these reasons alloplastic materials continue to be popular, the most widely used being methyl methacrylate alone or in combination with titanium or wire mesh.^{7,10} However, the use of methyl methacrylate may be associated with potential complications, including

an exothermic reaction produced during the curing process which may result in local tissue damage, release of a toxic monomer that has been implicated in local and systemic reactions, fracture of the brittle implant, and a significant rate of infection.^{3,9,10,13}

Polyethylene is a highly inert material that exhibits a consistently benign clinical response and has been proven stable over many years of use in humans. Medpor is a form of high-density polyethylene that contains a system of interconnecting pores of approximately 150 μm in diameter.¹⁵ This porous architecture enables the ingrowth of vascularity and soft tissue within a period of 3 to 4 weeks to form a stable interface that anchors the implant.^{1,2,5} Over longer periods, it permits the incorporation of bone at the implant-bone interface.^{1,5,14} Maas, *et al.*,⁶ compared various porous materials (Proplast, Silastic, Supramid, and Medpor) for facial bone augmentation in dogs, and found the greatest implant stability with Medpor. Moreover, Merritt, *et al.*,⁸ demonstrated that, after healing, dense ceramic implants were more susceptible to infection than porous polyethylene; they suggested that the vascular ingrowth may protect the implant from infection. In this regard, in a recent series reported by Romano, *et al.*,¹¹ the implant was used in 140 cases of open facial fractures with no infectious complications. Similarly, in an orbital blow-out fracture model in rabbits, ingrowth of vascularized soft tissue occurred with Medpor implanted adjacent to the contaminated maxillary sinus, eventually resulting in normal mucosal covering of the implant. In contrast, Proplast implants in the same model produced only fibrous reaction that failed to develop vascular, bone, or mucosal ingrowth.¹

In the present series of patients, the implant has been used for coverage of small- and medium-sized (< 8 cm) cranial defects in various locations. This experience suggests that the Medpor Flexblock implant offers a safe, cosmetically equivalent alternative to standard methyl methacrylate cranioplasty while ease of im-

plantation shortens operation time. It is not designed to function as a structural support material; as such it is recommended only for nonload-bearing small and medium-sized defects, and may in fact prove to be particularly useful for implantation adjacent to nasal sinuses in skull base and craniofacial reconstruction.^{1,11}

One potential liability with the use of Medpor for cranioplasty is that the ingrowth of soft tissue may render secondary removal difficult in cases that demand later reoperation, although as yet we have no experience with this.

Disclosure

The authors have entered into no consultation agreement with the manufacturer, and no outside funding or materials were provided for this work.

References

1. Dougherty W, Wellisz T: The natural history of alloplastic implants in orbital floor reconstruction: an animal model. **J Craniofac Surg** 5:26-32, 1994
2. Eppley BL, Sadove AM: Effects of material porosity on implant bonding strength in a craniofacial model. **J Craniofac Surg** 1:191-195, 1991
3. Futrel JW, Edgerton MT: Use of methyl methacrylate in reconstructive craniofacial surgery, in Converse JM, McCarthy JG, Wood-Smith D (eds): **Symposium on Diagnosis and Treatment of Craniofacial Anomalies**. St Louis: CV Mosby, 1979, pp 194-202
4. Homsy CA: Bio-compatibility in selection of materials for implantation. **J Biomed Mater Res** 4:341-356, 1970
5. Klawitter JJ, Bagwell JG, Weinstein AM, et al: An evaluation of bone growth into porous high density polyethylene. **J Biomed Mater Res** 10:311-323, 1976
6. Maas CS, Merwin GE, Wilson J, et al: Comparison of biomaterials for facial bone augmentation. **Arch Otolaryngol Head Neck Surg** 116:551-556, 1990
7. Malis LI: Titanium mesh and acrylic cranioplasty. **Neurosurgery** 25:351-355, 1989
8. Merritt K, Shafer J, Brown SA: Implant site infection rates with porous and dense materials. **J Biomed Mater Res** 13:101-108, 1979
9. Ousterhout DK, Baker S, Zlotolow I: Methylmethacrylate onlay implants in the treatment of forehead deformities secondary to craniosynostosis. **J Maxillofac Surg** 8:228-233, 1980
10. Rish BL, Dillon JD, Meirowsky AM, et al: Cranioplasty: a review of 1030 cases of penetrating head injury. **Neurosurgery** 4:381-385, 1979
11. Romano JJ, Iliff NT, Manson PN: Use of Medpor porous polyethylene implants in 140 patients with facial fractures. **J Craniofac Surg** 4:142-147, 1993
12. Rubin LR: Polyethylene as a bone and cartilage substitute: a 32-year retrospective, in Rubin LR (ed): **Biomaterials in Plastic Surgery**. St Louis: CV Mosby, 1983, pp 474-492
13. Schulz RC: Reconstruction of facial deformities with alloplastic materials. **Ann Plast Surg** 7:434-446, 1981
14. Spector M, Flemming WR, Kreutner A: Bone growth into porous high-density polyethylene. **J Biomed Mater Res** 10:595-603, 1976
15. Wellisz T, Dougherty W, Gross J: Craniofacial applications for the Medpor porous polyethylene Flexblock implant. **J Craniofac Surg** 3:101-107, 1992

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