CLINICAL ARTICLE

J Korean Neurosurg Soc 38 : 96-101, 2005

Cranioplasty with the Porous Polyethylene Implant(Medpor) for Large Cranial Defect

Ki-Sun Hong, M.D., Shin-Hyuk Kang, M.D., Jang-Bo Lee, M.D.,
Yong-Gu Chung, M.D., Hoon-Kap Lee, M.D., Heung-Seob Chung, M.D.

Department of Neurosurgery, College of Medicine, Korea University, Seoul, Korea

Objective : This paper describes our experience and implant technique for cranioplasty of a large cranial defects using a porous polyethylene implant(Medpor) and compares the results with polymethylmethacrylate(PMMA).

Methods : Sixteen cranioplasties were performed using Medpor(n=10) and PMMA(n=6) implants between June 2003 and January 2005. The criterion for patient enrollment was a defect larger than 10cm in diameter. This study compared the operation times and complications.

Results : The operation times ranged from 105 to 250minutes(Mean 180° ±44minutes) in Medpor and from 185 to 460minutes (mean 128minutes) in PMMA. The absolute operation times were shorter using the Medpor implant and the differences were statistically significant(P=0.030). Satisfactory cosmetic results were obtained in all cases using the Medpor implant and with no implant-related complications. Bone ingrowth to the medpor implant was presumed to be the result on an increase in Houndsfield units of the implant, particularly at the marginal areas in the serial follow-up brain computed tomography images.

Conclusion : It is believed that the properties of a Medpor implant make this implant an good alternative to the existing methods of a cranial contour correction. However, a further follow-up study will be needed.

KEY WORDS : Medpor · Cranioplasty · Porous polyethylene implant · Large cranial defect.

Introduction

Since decompressive craniectomy has been used as a treatment modality to increased intracranial pressure[3,7,15,18], a cranioplasty had been needed to protect neural structures, retain cosmetics and improve brain function after a craniectomy[22].

The properties of ideal cranial reconstruction materials are the good cosmetic outcomes, shorter operation times, biocompatibility, strength, osteoconductive properties, lower cost and lower infection rate. Although various materials such as an autologous bone graft[24], polymethylmethacrylate(PMMA)[1,26] and hydroxyapatite cement[8,16] have been proposed for a cranial reconstruction but owing to the limitations in the properties of each material, an ideal material has not yet been identified, especially for treating large defects[2,11,14,17,19,21,23].

The porous polyethylene implant(Medpor) is composed of high-density polyethylene microspheres with a high porosity. The properties of this material are biocompatibility, osteoconductivity, and resistance to the infection. In addition, good cosmetic results and the simplification of the surgical procedure have been reported to be the advantages of using a Medpor implant for small and medium size cranial defects[2,25].

This paper describes our experience and implant technique using the Medpor implant for treating large cranial defects and compares the results with PMMA.

Materials and Methods

The criteria for patient enrollment

Sixteen patients, whom underwent cranioplasty using Medpor or PMMA between June 2003 and January 2005 were enrolled in this study. The inclusion criterion was a defect larger than 10cm in diameter and all surgical procedures was performed by a single surgeon. Ten patients underwent cranioplasty using

• Received : January 5, 2005 • Accepted : March 28, 2005
• Address for reprints : Shin-Hyuk Kang, M.D., Department of Neurosurgery, College of Medicine, Korea University, 126-1 Anam-dong 5-ga, Seongbuk-gu, Seoul 136-705, Korea Tel : +82-2-920-5391, Fax : +82-2-929-0629, E-mail : hermes23@medimail.co.kr

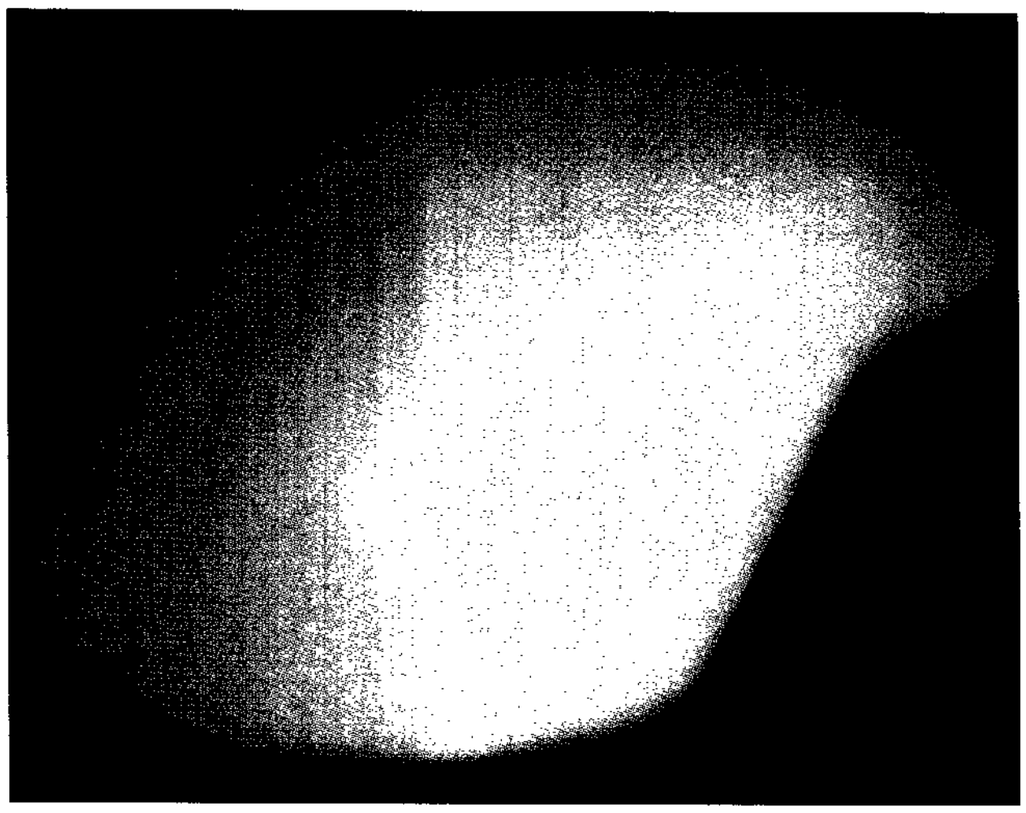

Fig. 1. The MEDPOR Cranial Hemisphere. This implant approximates the contour of a half cranium.

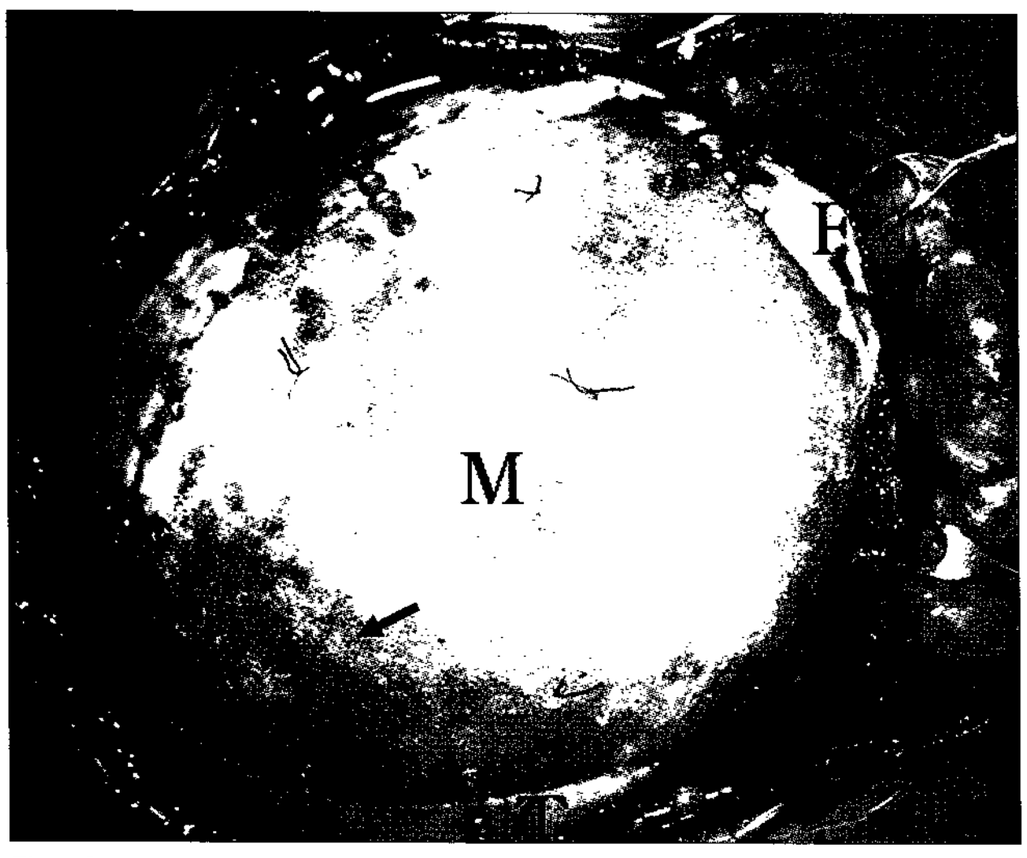

Fig. 2. Photograph showing the fixation of the Medpor(M) to a bony defect with miniplates. To facilitate ingrowth of bone and soft tissue, the contact plane of implant and bone requires close adhesion. Because of the porous properties, the implant is soaked in blood(arrow). F(frontal), P(parietal), T(temporal), O(occipital).

the Medpor implant and six patients were carried out using PMMA. The operation time and number of complications were compared.

Medpor implant

The Medpor implants were manufactured to several designs. The MEDPOR Cranial Hemispheres(Fig. 1) is one of several types, and it is indicated for large cranial defects. The implants shape approximates the contour of a half cranium. They have a 4mm thickness and are available in left and right versions. The cranial hemisphere type was used for large cranial defects.

Surgical implant technique

The Medpor implants may be used to cover any cranial defect shapes. In order to ensure an adequate fit, the defect pattern was drawn on cellophane paper with a pen, and transferred to the surface of the implant. The implant may be cut to a slightly larger size than the bony defect with a ronger or a high-speed drill. In order to obtain the desired contour, the implant was soaked in boiling normal saline and the contour was corrected by bending. In order to facilitate acceptable cosmetic results, the underside of the edge was shaved to allow the implant to overlap the surrounding bony edge. Fixation of the implant was performed by placing titanium screws directly through the implant into the bone or with the use of a titanium miniplate together with the screws(Fig. 2).

Statistical analysis

The independent T test was used to compare the defect sizes, operation times and severities of adhesion of the different groups. The Pearson correlation test was used to analyze the of correlations between severity of adhesion, defect size and operation time. All statistical analyses were performed using a commercial program from the Statistical Program Social Science (SPSS®)(Version 11.5).

Results

Patients analysis

All the patients were male except for one patient in the each groups and all patients had been operated hemicraniectomy at frontotemporopatietal area. In the Medpor group, the cranial defects were the result of a prior trauma(n=8) and severe brain swelling after tumor surgery(n=2). In the PMMA group, trauma (n=4), tumor(n=1) and intracerebral hemorrhage(n=1) were the causes(Table 1).

The correlations between size and operation time, and between severity of adhesion and operation time were not statistically significant(P=0.993 and 0.430, respectively). Therefore, severity of adhesion, the defect size and the operation time were independent variables.

The mean age of the patients in the two groups were 33±10years in the Medpor group and 40±6years in the PMMA group. In all cases, the defect sizes were larger than 10cm. The mean area of the defects was 116.5±29cm^2 in the Medpor group and 109±7cm^2 in the PMMA group, and this difference was not statistically significant(P=0.561). The severities of adhesion were similar and there was no statistical significance (P=0.890)(Table 2).

Operation time

The operation times ranged from 165 to 250minutes(Mean 180±44minutes) in the Medpor group and from 185 to 460 minutes(mean 285±128minutes) in the PMMA group. The

Table 1. Patients characteristics

NO of Patient	Age(yrs) /Sex	Cause	Size(cm)	Area(cm^2)	Op time (mins)	Follow-up (mos)	Complication	Adhesion
Medpor								
1	25/M	Trauma	16×10	160	210	8	None	Moderate
2	35/M	Tumor(Meningioma)	11×10	110	165	7	None	Mild
3	29/M	Trauma	10×12	120	170	7	None	Mild
4	51/M	Trauma	9.7×14.5	140	190	8	None	Moderate
5	49/M	Trauma	10.5×7	73.5	120	2	None	Mild
6	62/M	Trauma	13×9	117	180	5	None	Mild
7	26/M	Trauma	14×9.6	134	105	4	None	Severe
8	24/M	Trauma	15×11.5	126	230	3	None	Severe
9	24/M	Trauma	15×11	125	250	4	None	Severe
10	13/F	Tumor	10×6	60	180	6	None	Moderate
PMMA								
11	52/M	Trauma	10×10	100	185	12	None	Mild
12	57/M	Tumor	10×12	120	189	2	None	Mild
13	23/M	Trauma	11×9.5	104	440	13	None	Severe
14	38/M	ICH	13×8.5	110	460	11	Infection	Severe
15	36/M	Trauma	10×10.5	105	240	6	None	Moderate
16	39/F	Trauma	10.5×11	115	200	8	None	Mild

yr s : years, M : male, F : female, ICH : intracerebral hemorrhage, OP : operation, mins : minutes, mos : months, PMMA : polymethylmetha crylate

Table 2. Statistic analysis of the variables showing that the difference in operation time and severity of adhesion between the two groups are not statistically significant(P=0.556, and P=0.890, respectively). The difference of operation time is statistically significant(P=0.030)

	Area(cm^2)	Severity of adhesion	Op time(mins)
Medpor(Mean)	116±29.9	1.9±0.87	180±44
PMMA(Mean)	109±7.5	1.8±0.98	285±128
P-value	0.561	0.890	0.030

yrs : years, mins: minutes, PMMA : polymethylmethacrylate, OP : operation
Severity of adhesion : 1-mild, 2-moderate, 3-severe

absolute time was shorter in the Medpor group and this difference was statistically significant(P=0.030)(Table 2).

Ingrowth of the bone to medpor implant

The pathology of the bone ingrowth was not confirmed because the implant was not removed. In the serial follow-up computed tomography(CT) images of patient 1, taken 5 and 8months after surgery, soft tissue and bone ingrowth could not be confirmed. However, the follow-up CT images showed an increase in the Houndsfield(HF) units of the implant, particularly at the marginal areas(Fig. 3).

Cosmetic result

Satisfactory cosmetic results were obtained in the Medpor group(Fig. 4, 5).

Complication

In the Medpor group, there were no implant-related complications, migration or construct failure. Especially, the patient 6 had been complicated case, because he had performed twice cranioplasties with PMMA and twice revision operations owing to infection. But third trial was successful with Medpor, without infection. However, in the PMMA group, an infection developed in one case and the implant was removed.

Discussion

A variety of cranioplasty materials and implantation techniques have been reported in the literatures[10,19,21,25].

While autogenous material for a skull reconstruction possesses optimum biocompatibility characteristics, their widespread use has been limited by complications arising from the donor site, increased operation time, a late deformation and graft resorption[2]. In addition, the bone flaps removed from the cranium of patients has an inherent risk of being absorbed after implantation[13,24].

For these reasons alloplastic materials such as PMMA, hydroxyapatite cement continue to be popular. One of the most widely used alloplastic materials is PMMA. However, the use of PMMA can have many complications, including an exothermic reaction produced during the curing process which might result in local tissue damage, the 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 (13.3%)[13,14,19,21].

Hydroxyapatite has advantages such as biocompatibility, osteoconductivity, which makes it more for the repair of bone defects compared with other commercially available products[8,16].

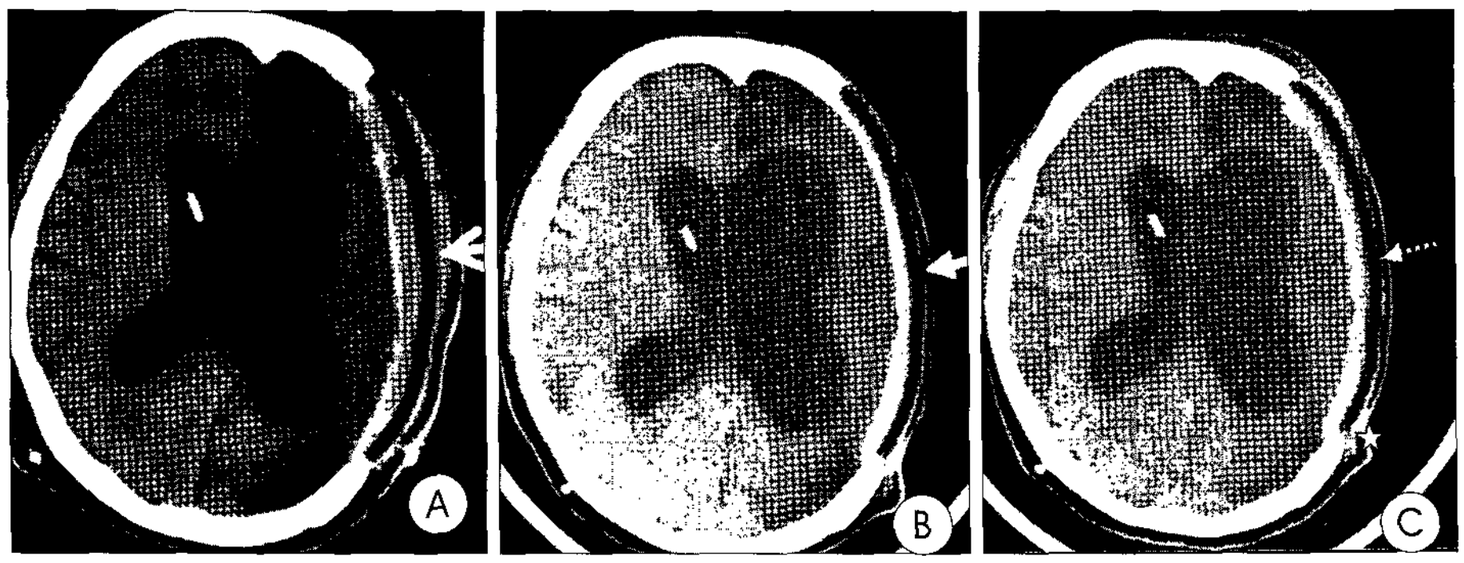

Fig. 3. A : Computed tomography(CT) images of patient 1, taken 7days after surgery, show a Medpor implant of a low density(open arrow). The Hounsfield(HF) units of the implant are −105 at the center area and −20 at marginal area(arrow) B : In the CT images of the same patient, taken 5months after surgery, the HF units are −21(arrow) and −2, respectively. C : The last follow up CT images taken 8months after surgery show an overall increased density of the implant, and the HF units are −20 at center area(dotted arrow) and 18 at the marginal area(star). Therefore, it is presumed that this serial increase in the HF units as indirect evidence of the ingrowth of vascularity, soft tissue and bone from the bony edge area.

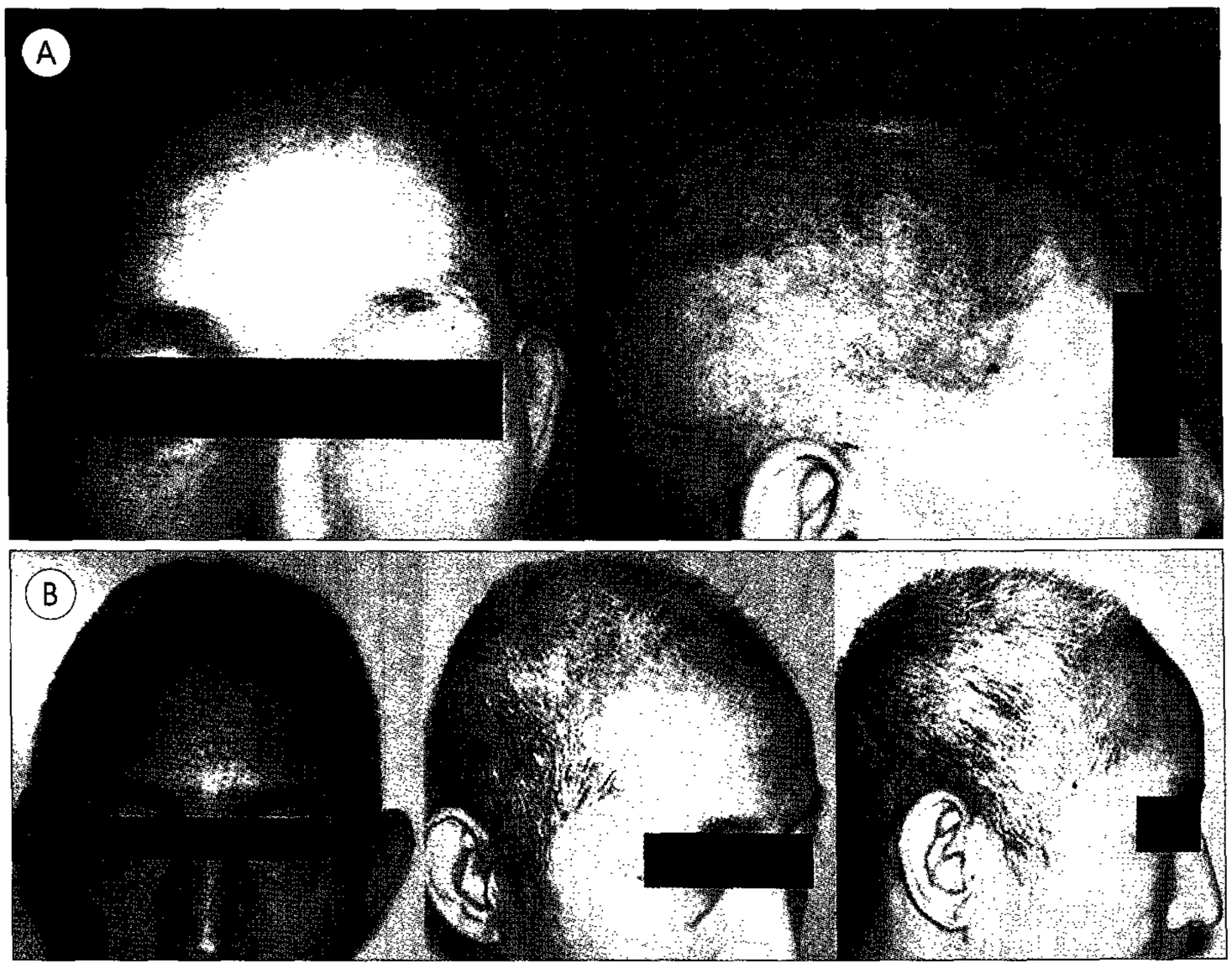

Fig. 4. Preoperative(A) and postoperative(B) photographies of patient 4 who had a large cranial defect at the right hemisphere show good cosmetic result.

However hydroxyapatite is fragile and for the settlement of the paste, the surgical site needs to be clear of blood and be dry for at least 4hours. Therefore, the correction of contour deformities and the achievement of good cosmetic results are quite difficult[11,16]. Given these disadvantages, computer-designed prefabricated hydroxyapatite materials such as Ceratite or reinforced hydroxyapatite with a titanium mesh are promising, particularly for large cranial defects but these quite expensive[11]. In addition, a high infection rate have been reported (22.2~22.4%)[5,13].

Polyethylene is a highly inert material that exhibits a consistently benign clinical response and has been demonstrated to be stable after many years of use in humans, in some cases with a follow-up period of more than 30years[25]. Medpor is a form of high-density polyethylene that contains a system of interconnecting pores of approximately 150㎛ in diameter. 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 anchor the implant[4,6,9]. Although in most instances there is several millimeters of bone growth into the implant, the ingrowth forms a stable interface with a high tensile strength that anchors the implant[4,6,23]. This study could not verify the ingrowth of bone and soft tissue on the imaging study. However, the follow-up CT images showed an increase in the HF units of the implant, particularly at the marginal areas. Therefore, this finding was considered to be indirect evidence for the ingrowth of vascularity, soft tissue and bone from bony edge area. Actually, some authors demonstrated neovascularization and fibrous tissue ingrowth into an implant pathologically after a 3-months period in human craniofacial applications[4].

The ingrowth of vascularity might protect the implant from infection. In this regard, in a recent report, the implants were used in 140cases of an open facial fractures with no infection complications[20]. In addition, there were no infection in the Medpor group but one case in the PMMA group in this study.

In our experience, the correction of contour deformities and the achievement good cosmetic results are easy because the Medpors are manufactured uniform customized implants and the Medpor Cranial Hemispheres shape approximates the contour of a half cranium. The correction of the implant contour according to the patient's original contour can also be achieved simply by heating with boiling water and then bending. However, PMMA requires time for dissolution, molding

and setting in order to for fit into original contour, and correction of implant is impossible once it hardens. The specific sizes and shapes of the Medpor implants are also available for complex bony defects, and may be customordered on an individual basis depending upon the defect shapes derived from the three-dimensionally reconstructed computerized tomography images, even though these are more expensive.

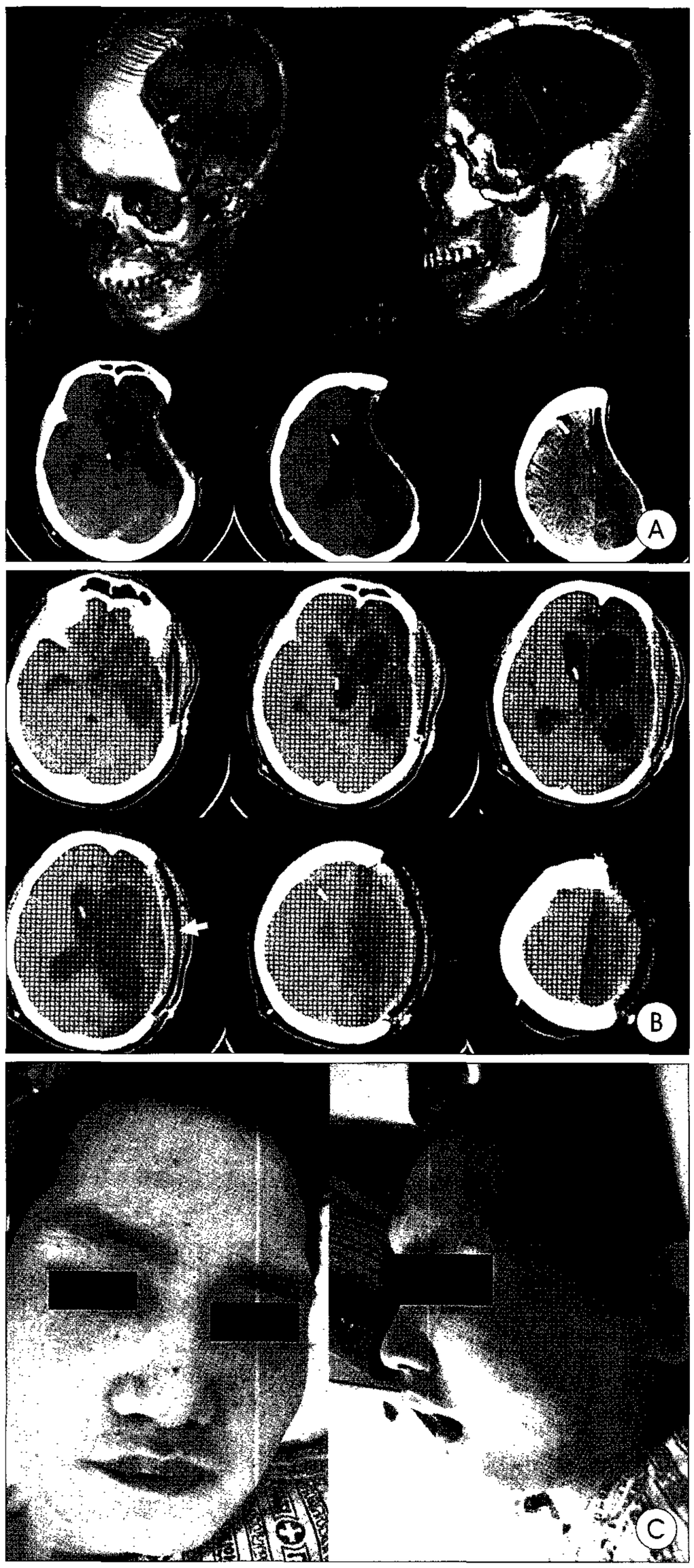

Fig. 5. Patient 1. A : Preoperative 3-dimensional reconstruction Computed tomography(CT) scan and pre-enhance CT scan show a large cranial defect at the left hemisphere approximately 16×10cm size. B : The postoperative CT scan that was taken 7 days after from the cranioplasty shows a very low density Medpor implant(arrow) and a good contour correction. C : Photographies of the patient that was taken 5months after the cranioplasty shows a good contour correction.

These characteristics make the surgical procedure simpler than with other canioplasty materials. The simplicity of implantation shortens the operation time. In this study, a comparison of the operation time with a cranioplasty using PMMA showed that the absolute operation time was shorter in the cranioplasty using the medpor implant, and the difference was statistically significant.

Prior reports on the cranioplasty using porous polyethylene implants were confined to small and medium sized cranial defects using Medpor FLEXBLOCK®. However, there are no reports using Medpor for large cranial defects. Some authors recommended the use of Medpor FLEXBLOCK® be confined to small and medium size defects because of it is not designed to function as a structural support material[2]. Other authors have recommended a thicker customized Medpor implant (Medpor Cranial Hemispheres) for larger cranial defects[25]. Therefore, a long term follow-up and a larger clinical study on the strength of Medpor implant as a shield of vital neural structure was not taken yet, we think that more follow-up periods are needed for confirmation of safety of medpor for large cranial defects.

Conclusion

A cranioplasty with Medpor was performed in ten patients, who had a large cranial bone defect after a decompressive craniectomy. The properties of the Medpor design make this implant an excellent alternative to the existing methods of cranial contour correction. The implant material is easy to use, strong yet somewhat flexible, and remarkably stable. However, a long-term follow-up and large series study on the suitability of using a Medpor implant for treating large cranial defects will be needed.

References

1. Blum KS, Schneider SJ, Rosenthal AD : Methyl methacrylate cranioplasty in children : Long-term result. **Pediatr Neurosurg 26** : 33-35, 1997
2. Couldwell WT, Chen TC, Weiss MH, Takanori F, Willam D : Cranioplasty with the Medpor porous polyethylene Flexblock implant. **J Neurosurg** : 483-486, 1994
3. Cushing H : The establishment of cerebral hernia as a decompressive measure for inaccessible brain tumor : with bone defect in temporal and occipital regions. **Surg Gynecol Obstet 1** : 297-314, 1905
4. Dougherty W, Wellisz T : The natural history of alloplastic implants in orbital floor reconstruction : an animal model. **J Craniofac Surg 5** : 26-32, 1994
5. Durham SR, McComb JG, Levy ML : Correction of large (>25cm²) cranial defects with "reinforced" hydroxyapatite cement : technique and complications. **Neurosurgery 52** : 842-845, 2003
6. Eppley BL, Sadove AM : Effects of material porosity on implant bonding strength in a craniofacial model. **J Craniofac Surg 1** : 191-202, 1979
7. Gaab MR, Rittierodt M, Lorenz M, Heissler HE : Traumatic brain

swelling and operative decompression : a prospective investigation. **Acta Neurochir Suppl 51** : 326-328, 1990
8. Holmes RE : Bone regeneration within a coralline hydroxyapatite implant. **Plast Reconstr Surg 63** : 626-633, 1979
9. Klawitter JJ, Bagwell JG, Weinstein AM, Sauer BW : An evaluation of bone growth into porous high density polyethylene. **J Biomed Mater Res 10** : 311-323, 1976
10. Malis LI : Titanium mesh and acrylic cranioplasty. **Neurosurgery 25** : 351-355, 1989
11. Maniker A, Cantrell S, Vaicys C : Failure of hydroxyapatite cement to set in repair of a cranial defect : case report. **Neurosurgery 43** : 953-954, 1998
12. Miyaka H, Ohta T, Tanaka H : A new technique for cranioplasty with L-shaped titanium plates and combination ceremic implants composed of hydroxyapatite and tricalcium phosphate(Ceratite). **Neurosurgery 46** : 414-418, 2000
13. Moreira-Gonzalez A, Jackson IT, Miyawaki T, Barakat K, DiNick V : Clinical outcome in cranioplasty : critical review in long-term follow-up. **J Craniofac Surg 14** : 144-153, 2003
14. Ousterhout DK, Baker S, Zolotolow I : Methylmethacrylate onlay implants in the treatment of forehead deformities secondary to craniosynostosis. **J Maxillofac Surg 8** : 228-233, 1980
15. Polin RS, Shaffrey ME, Bogaev CA, Tisdale N, Germanson T, Bocchicchio B, et al : Decompressive bifrontal craniectomy in the treatment of severe refractory posttraumatic cerebral edema. **Neurosurgery 41** : 81-94, 1997
16. Pompili A, Caroli F, Carpanese L, Caterio M, Raus L, Sestili G : Cranioplasty performed with a new osteoconductive osteoinducing hydroxyapatite-derived material. **J Neurosurg 89** : 236-242, 1998
17. Prolo DJ, Oklund SA : The use of bone grafts and alloplasic materials in cranioplasty. **Clin Orthop 268** : 270-278, 1991
18. Ransohoff J, Benjamin MV, Gage EL Jr, Epstein F : F Hemicraniectomy in the management of acute subdural hematoma. **J Neurosurg 34** : 70-76, 1971
19. Rish BL, Dillon JD, Meirowsky AM, Caveness WF, Mohr JP, Kistler JP, et al : Cranioplasty : a review of 1030 cases of penetrating head injury. **Neurosurgery 4** : 381-385, 1979
20. Romano JJ, Iliff NT, Manson PN : Use of Medpor porous polyethylene implants in 140patients with facial fractures. **J Craniofac Surg 4** : 142-147, 1993
21. Schulz RC : Reconstruction of facial deformities with alloplastic materials. **Ann Plast Surg 7** : 434-446, 1981
22. Segal DH, Oppenheim JS, Murovic JA : Neurological recovery after cranioplasty. **Neurosurgery 34** : 729-731, 1994
23. Spector M, Flemming WR, Kreutner A : Bone growth into porous high-density polyethylene. **J Biomed Master Res 10** : 595-603, 1976
24. Vanaclocha V, Bazan A, Saiz-Sapena N, Palmoa V, Idoate M : Use of frozen cranial vault bone allograft in the repair of extensive cranial bone defect. **Acta Neurochir (Wien) 139** : 653-660, 1997
25. Wellisz T, Dougherty W, Gross J : Craniofacial applications for the Medpor porous polyethylene flexblock implant. **J Craniofac Surg 3** : 101-107, 1992
26. Yanai A : Resin sealant : A new method of methyl methacrylate cranioplasty-Technical note. **J Neurosurg 75** : 328-330, 1991