

Porous Polyethylene Implants for Nasal Reconstruction: Clinical and Histologic Studies

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Abstract. This paper describes a technique of using Medpor porous high-density polyethylene implants for nasal reconstruction and chin augmentation. This biocompatible material has been used successfully during the last decade for various applications in the reconstruction of the facial skeleton. Among its most frequent uses are repair of the orbital floor and reconstruction of the burned ear, which became standard methods at many centers. Relatively little experience is, at present, on hand concerning the use of porous polyethylene in reconstruction of the nasal framework. Twenty-three consecutive, difficult nasal reconstructions were performed using this method since 1996. Patients were followed up for from 1 to 3 years (mean, 2 years). The results were durable and stable over the time. Eight patients had saddle nose deformity and 15 had catastrophe noses, mostly referrals, previously operated on from one to four times. My aesthetic goals were correction of the depressed nasal dorsum, creation of an acceptable nasal dorsum in the thick and/or twisted noses, and tip elevation. For nasal applications Medpor is available as a strut or sheet. Its body, once implanted, becomes rapidly vascularized and both soft tissue ingrowth and collagen deposition occur. This was confirmed by the microscopic investigation of biopsies. One patient of Vietnamese origin had an aesthetically pleasing result, but her family refused to accept her westernized nose. This gave me a unique opportunity to study the whole Medpor implant 6 months after implantation. There were two complications, one small implant exposure and one low-virulent infection involving the nasal tip. Following revision and antibiotic treatment, both patients healed without sequel. All reconstructions were successful in restoring nasal aesthetics and function.

Four patients underwent chin augmentations with an uneventful clinical course.

Key words: Alloplast — Medpor — Implant — Rhinoplasty — Reconstruction

In nasal surgery, there is a frequent need for restoration or improvement of the nasal contour and respiratory function, requiring augmentation of the nasal structures. This may be necessary both in primary rhinoplasties and, more frequently, in secondary rhinoplasties or in posttraumatic reconstructions. Augmentation of the nasal bridge is probably as old as the history of rhinoplasty. Ivory and ceramics were historically used for dorsal grafts. An extensive review of the history of surgery for the correction of saddle nose was recently published by Lupo [1]. Most implants used in the past were eventually extruded, but some were occasionally retained for the lifetime.

In modern times autologous grafts for the nasal dorsum won general acceptance. Among them the primary choices are septal, conchal, and rib cartilage. Despite the general clinical success, each of them has its disadvantages. Septal cartilage is frequently defective or missing in secondary or posttraumatic noses. The obtainable volume may be insufficient, and preparation and suturing of the sandwich-graft cumbersome and time-consuming. Conchal cartilage is curved and has, in part, an irregular surface. Even morselized, it occasionally causes palpable and visible dorsal irregularities, because of its long-time "memory," and it may resorb. Rib cartilage harvesting has an unfavorable donor-site morbidity, carries the risk of pneumothorax, and leaves a conspicuous scar. It also prolongs the procedure and requires hospitalization and

Presented at the Joint Meeting of the Swedish and Italian Societies of Plastic Surgery, Ischia, Italy, June 3, 1999 Correspondence to Igor Niechajev, M.D., Lidingö–Clinic, Torsvägen 30, S-181 32 Lidingö, Sweden

general anesthesia. The natural curvature of the rib is a disadvantage and the frequent warpage may totally distort the result.

Because of the aforementioned drawbacks and in the search for simplicity, alloplastic grafts have also been used in the nasal dorsum with varying success. Soft Silastic, Gore-Tex, Proplast, and coralline hydroxyapatite grafts have sometimes yielded satisfactory long-term results [2–5]. Their advantages are that they can be factory preformed, and supplied sterile and are easy for instant use. Further, there is no donor-site morbidity, they are easy to place, and they usually produce a smooth straight nasal contour.

However, their disadvantages are rather numerous, and each of the alloplastic implants has its specific drawbacks. Silicone lacks potential for vascularization, promotes thick capsule formation, causes resorption of the underlying bone, and displays a tendency of the implant to shift or extrude over a long period of time [6]. Gore-Tex remains slippery, since there is no host tissue ingrowth, and carries increased risks of infection, seroma formation, and extrusion [7,8]. Hydroxyapatite is too hard really to resemble cartilage. Proplast seemed promising for some time [4] but eventually was withdrawn from the market because of the moderate antigenic reaction, susceptibility to infection, and late lamination [9–11].

Porous high-density polyethylene has a more than 20year history as a surgical implant in both animals and humans [12,13]. High-density porous polyethylene, available in sterile shapes as the Medpor Surgical Implant (Porex Surgical, 4715 Roosevelt Highway, College Park, GA 30349), has been used successfully during the last decade for the repair of defects in the orbital wall and skull and for reconstruction of the burned ear [13–16]. Relatively little experience is on hand at present concerning the use of porous polyethylene in reconstruction of the nasal framework [15–18].

The incentive for this study emerged upon encountering the aforementioned problems after several attempts, using autologous implants in severely twisted posttraumatic noses. Following the initial positive experience, the study was undertaken to investigate clinically the use of porous polyethylene implants in difficult rhinoplasties and for augmentation of the chin contour.

Animal data have demonstrated that Medpor biomaterial permits ingrowth of well-vascularized fibrous tissue within 4 weeks. Extensive bone ingrowth was observed at 6 weeks [11,13]. Biopsies from implants in humans have also demonstrated surrounding tissue proliferation [16]. Opportunity to obtain biopsies was stimulation to undertake simultaneously further microscopic investigation on Medpor behavior in human tissue and to study the host response to the polyethylene implant.

Patients and Methods

The Follow-up Study

Sixteen female and eleven male patients were operated on with Medpor implants from February 1996 to June 1998. Thus, the follow-up ranged from over 3 to 1 year (average, 2 years). Their ages ranged from 23 to 47 (mean, 30) years. Twenty-three of them underwent difficult rhinoplasties and four patients had chin augmentation. A Lidingö video-computer imaging system was used for preoperative analysis of the deformity and planning of the operation, with special regard given to the choice of the size of implant.

Fifteen rhinoplasty patients were so-called "catastrophe noses." Four of them had a history of a major trauma to the nose in car accidents and/or fist fights and 11 were iatrogenic. Thirteen patients were previously operated on elsewhere from one to four times (mean, 1.7) and three were previously operated on by the author. Eight patients had ethnic noses with saddle nose appearance. Two of them were previously operated on elsewhere. Medpor was used in these cases to correct saddle nose and sometimes to increase the nose tip projection. In three patients Medpor was, in addition to the main implant, used for auxiliary indications: as a 2- to 3-mm corn for the soft tissue fill in and as a narrow rod for the spreader graft.

Histology

A 24-year-old female (Case W.E.), previously operated in Iraq because of an injury to her nose in a car accident, underwent reconstruction in stages. A Medpor biopsy was obtained at stage II, 4.5 months after implantation. One patient of Vietnamese origin (Case A.L.) had an aesthetically pleasing result (Fig. 1), but her family refused to accept her westernized nose. This gave me a unique opportunity to study the whole nasal Medpor implant 6 months after implantation. Early in the series, the judgment concerning the size of the implant was erroneous in two patients. One nasal implant was too long and one was too wide in its distal part. Both were easily adjusted 10 and 17 months, respectively, after implantation and the removed parts were sent for microscopic investigation.

Altogether eight specimens from four patients were examined. The material was fixed in Zenker's solution for paraffin sections, which was subsequently stained with hematoxylin and eosin for a general overview and sometimes Masson trichrome for assessment of collagen fibers.

Physical Properties of Polyethylene

Medpor is manufactured from a liner high-density pure polyethylene that is sintered to create a somewhat flexible framework of interconnecting pores with a size in the range of 160–360 μ m (mean, 240 μ m) [14]. Polyethylene makes up slightly more than half of the total implant volume (54%) and the rest is pore volume. The interconnecting omnidirectional pore structure of the implants permits rapid ingrowth of vascularized tissue with collagen deposition that ultimately forms a highly stable complex resistant to infection, exposure, and deformation by the contractile forces of the surrounding tissues [13].



Fig. 1. Patient A.L., a 39-year-old woman of Vietnamese origin (A) underwent secondary rhinoplasty: excision of the dorsal scars after injections of liquid silicone and buildup of the dorsum with a Medpor implant. (B). Despite the aesthetically pleasing result, her family refused to accept her new westernized look.

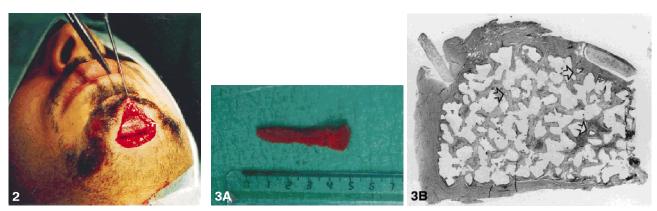


Fig. 2. Chin augmentation with porous polyethylene Medpor. The implant was divided into two halves, which, after introduction, were united in place by two nonresorbable 3:0 sutures. Fig. 3. The same patient as in Fig. 1. (A) Extracted Medpor implant. (B) Histologic cross section of the Medpor implant 6

months after implantation. Note the surrounding capsule of fibrotic tissue and the total ingrowth of the lamellar connective tissue into all available empty spaces. *Arrows* indicate larger blood vessels. H&E stain; original magnification, ×8.

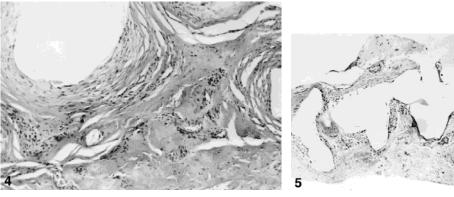


Fig. 4. The same specimen as in Figs. 3A and B. Beads of polyethylene are surrounded by fibrous connective tissue. Moderate lymphocytary infiltration indicates a slight inflammatory reaction. H&E stain; original magnification, $\times 25$.

Fig. 5. Case M.H. Medpor chip obtained by narrowing of the

dorsal strut in situ, by cutting it in the saggital plane 17 months after implantation. Maturation of the connective tissue. The inflammatory reaction subsided. H&E stain; original magnification, $\times 12$.

The firm nature of the material allows carving with a sharp instrument without collapsing the pore structure. Medpor is almost as hard as a cancellous bone at room temperature, but it has thermoplastic abilities. Submerged in hot (82–100°C) sterile saline for several minutes, Medpor implants can be bent to the desired shape, which becomes permanent after cooling. Warmed Medpor sheets can be cut with scissors and thicker implants easily shaped with a scalpel, bone cutter, or cutting burr.

Because of its white color, Medpor will not show through the overlying tissue. Its surface is rough, which makes its insertion a little cumbersome, but once manipulated into the desired position, it will stay there. This implant is insoluble in tissue fluid, has long-term structural stability, and does not resorb. Due to its highdensity characteristics, it has a high tensile strength, which resists stress and fatigue. When fixation of the Medpor implant is desired, stabilization can be accomplished with sutures, surgical wire, or rigid fixation screws.

Technical Considerations

The implants used in this study were prefabricated nasal onlay grafts and chin implants, supplied sterile by the factory. New talc-free surgical gloves were put on prior to handling implants, which was done mainly with instruments, avoiding contamination from the epidermis. Each implant was indeed individually customized by trimming and shaping in order to adjust them according to the preference of the surgeon for each individual patient's needs. It is important to feather the edges to obtain a smooth contour and eliminate any potentially visible borders of the implant. All carving was done on a specially made, sterile plastic carving block, in order to avoid contamination with lint and other particulate matter. Implants were soaked in a cloxacillin (Ekvacillin) solution prior to implantation. Adequate soft tissue dissection was carried out to ensure elimination of tension over the implant and, at the same time, to prevent implant migration. Vicryl rapide or chromic catgut was used for prolonged-duration strength at the soft tissue and mucosa closure. Sutures were made densely, in order to create a "water-tight" closure, preventing contamination of the implant with microorganisms from the nasal environment. Postoperatively patients were put on a 7-day course of oral antibiotic flucloxacillin (Heracillin, 750 mg twice a day).

Two patients underwent chin augmentation through the intraoral route, and two through the external route. The degree of arching in the chin implants was individually adjusted by manual bending, following a few-minute bath in the hot saline. Cooled and stiffened implants were divided in the middle. Prior to implantation, the implants were soaked in a basin with a sterile antibiotic solution as a prophylactic measure. The impervious plastic film (Op-Site) was used to isolate the incision and reduce the risk of contaminating the implant, as far as possible. Each half of the implant was slid individually into the subperiosteally dissected pocket. Both halves were united either with a pair of 3:0 nonresorbable multibraided sutures on a cutting needle (Fig. 2) or with an interlocking peg. The chin implant was additionally stabilized by suturing it to the adjacent tissues, using two sutures of the same type. The postoperative medication for the patients after chin augmentation was the same as that after nasal reconstruction.

Results

Clinical Observations

Twenty-three difficult rhinoplasties and four chin augmentations were performed using the porous polyethylene implants described above. Each of these patients has been followed since surgery; the maximum postoperative follow-up time was 3 years. All reconstructions undertaken produced an aesthetically pleasing nose, owing in large part to the successfully restored straight contour of the nasal bridge. Prefabricated Medpor struts were used in all cases on the nasal dorsum. I found it necessary always to slim the distal end, and sometimes also the proximal end, of the implant. In one case (L.G.) a second, narrower implant was used as a columellar strut for nasal tip projection. In several other cases the double conchal "pea-pod" graft of Hoefflin [19] was utilized for this purpose. It is safer not to use Medpor in the mobile parts of the nose.

Augmented chins were firm and felt bony-like on external palpation. The thermoplastic abilities of Medpor were particularly useful for adjustment of the chin implants. Also, the straight nasal dorsum implants could be modulated into a slightly concave shape when desired. Medpor corns were used in one case for smoothing of the contour between the lateral edge of the chin implant and the lower jaw and in another as a fill in the root of the nose. They have been also working well, producing durable augmentation of the soft tissues.

An interesting and important observation was that, after 4 to 10 months in the human body, the Medpor implants were as hard as at the time of insertion. After 17 months the implant retained its structure but was softer and could be sliced more easily with the scalpel.

The side of one implant became exposed in an area measuring 3×4 mm in the valve area of the nose vestibulum 3 months after implantation. There was no visible inflammatory reaction. Under the coverage of antibiotics the mucosa was mobilized and resutured. Healing and the further course were uneventful. Another patient with saddle nose deformity developed intermittent and recurring redness in the tip area 4 months after the operation. The distal third of the implant (1.5 cm) was removed, the pocket was flushed with cloxacillin, and the patient was put on oral clindamycin. The culture showed growth of *Staphylococcus aureus*. She recovered quickly and has had no new remission during the past 12 months.

Besides the 2 aforementioned manageable complica-

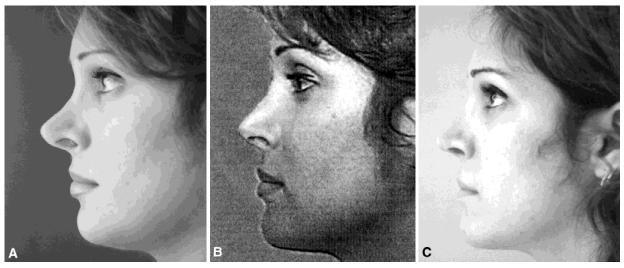


Fig. 6. Case E.K. (A) Catastrophic nose maiming this otherwise good-looking 24-year-old student. (B) Planing of the procedure with the video-computer imaging system. (C) Two and a half years

after extensive reconstruction aided by a Medpor implant augmenting the nasal dorsum.

tions, the other 25 patients healed as planned. There was no implant extrusion, migration, rotation, or postoperative infection. The healing was uneventful and without any detectable inflammatory reaction. The resultant nasal reconstructions and augmentations were stable throughout the observation period.

Histologic Observations

Microscopic findings were similar in all specimens, showing ingrowth of the dermal-like tissue, which occupied all available space. This tissue was highly viable, rich in collagen, elastic fibers, and fibrocytes, and well vascularized (Figs. 3 and 4). Lymphocytes were sparsely dispersed, indicating the presence of only a mild inflammatory reaction. Multinucleated giant cells were occasionally seen in close apposition to the polyethylene surface. There were a few in the specimens 4.5 and 6 months after implantation and they appeared even more seldom in the older specimens obtained 10 and 17 months after implantation (Fig. 5). This was interpreted as a sign that the host-foreign body interaction was on the low-intensity level. Implants were anchored to the surrounding tissues through the capsule, produced by the host and consisting of several layers of fibrotic tissue. More detailed histologic analysis of human porous polyethylene implants will be the subject of a forthcoming paper.

Case Reports

Clinical applications of Medpor are exemplified by the treatment summaries of several patients in this series.

Case 1 (E.K.). A 24-year-old woman was operated on with primary rhinoplasty at the age of 16. The operation was performed in Teheran by the surgeon, a former friend

of the family. She presented to me with a twisted nose, deviating 10° to the right and with a Pinocchio tip turning to the left. The bony dorsum and alar cartilages were overresected. Further, she had cartilage bosing in the tip and retraction of the left alar margin and the columella. Her nasal tip was pinched, causing mechanical obstruction of the air passage. Following surgical correction of these iatrogenic deformities, her nasal dorsum was brought into balance with the Medpor graft (Fig. 6).

Case 2 (M.H.). This young male has been a patient of mine since 1989. During adolescence his life became adventurous and he had a history of several nasal injuries in a car crash and fist fights. At the first consultation he presented with a severely twisted and depressed nose and also suffered because of airway obstruction. Primary septorhinoplasty with nasal dorsum reconstruction with conchal cartilage corrected the breathing problems, but the patient was dissatisfied because the nasal bridge was uneven. In the second operation the conchal cartilage graft was replaced by rib cartilage, but again, the cosmesis was unsatisfactory due to warping of the graft. The patient was age 28 at the time of the third and final reconstruction attempt with Medpor (Fig. 7). After 10 months his implant pressed distally on the nasal tip. It was trimmed about 4 mm. He remained stable during the 2 years.

Case 3 (L.G.). A 38-year-old woman born in Brazil was operated on 8 years ago by the chairman of the Plastic Surgery Department at one of our major university hospitals. The objective of refinement of her Negroid nose was not achieved. It was unclear how many of her present aberrations were overlooked at the primary surgery or if they occurred because of the surgery. Extensive secondary rhinoplasty included considerable defatting of the tip and supratip areas, reduction of the alae,



Fig. 7. Case M.H. (A) At the age of 22, before his first rhinoplasty. (B) At the age of 31, 2 years following his third rhinoplasty, employing a Medpor implant for reconstruction of the nasal bridge.

Fig. 8. Case L.G. (A) Catastrophic nose 8 years after primary "rhinoplasty" at St. Elsewhere Hospital. (B) Two years following reconstruction aided by a surgically created L-shaped Medpor graft.

elevation of the left nasal wing, and lowering and opening of the columella–lip angle. Contour reconstruction was carried out using two Medpor implants, one as an onlay on the nasal dorsum and the second, narrower, as a columellar strut for the nose tip projection (Fig. 8). Both grafts were united with nonresorbable sutures, creating a L-shaped frame.

Case 4 (R.G.). A man of Iranian origin, age 26 at the time of reconstruction, underwent rhinoplasty in 1988 and a secondary rhinoplasty in 1995, both with the opensky technique, carried out by a colleague in another city. Probably due to too-rough work with a file on the lateral cartilage area, his nose looked grotesque, with massive scar tissue buildup in the supratip area (Fig. 9). The bony nasal dorsum and caudal septum were overresected and the right ala was retracted. Reconstruction was done with the aid of a Medpor nasal graft measuring 45, 5, and 3–4 mm in length, width, and height, respectively. Also, the patient's other iatrogenic deformities were corrected.

Discussion

Reconstruction of the congenitally severely twisted nose and posttraumatic or iatrogenic nose deformity poses a serious challenge even for the experienced rhinoplastic surgeon. Numerous techniques, using autologous and alloplastic materials for reconstruction or correction of the nasal dorsum, have been tried in the past, with varying degrees of success [1]. None was fully satisfactory.

The use of alloplastic implants in nasal surgery always was and still is highly controversial. It is a little bit like swearing in the church. At present, it is generally agreed that solid smooth-surfaced implants should not be used in rhinoplastic surgery, because they fail to become united with the surrounding tissues. Medpor porous polyethylene can be compared with other porous materials: coralline hydroxyapatite and Proplast II and its unique combination of properties give it clear advantage over the other porous alloplasts.

Levet et al. [8] reported a positive experience with coralline hydroxyapatite for nasal augmentation. Hy-

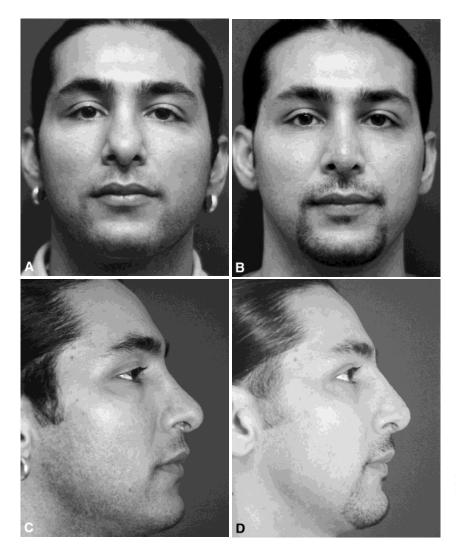


Fig. 9. Case R.G. (**A**, **C**) Grotesque-looking nose following two surgeries. (**B**, **D**) One and a half years after reconstruction involving a Medpor implant.

droxyapatite had generated significant interest because its composition is similar to that of human bone and because of bone ingrowth. Hydroxyapatite, however, can be difficult to use and therefore it never won wider popularity in nasal reconstruction. It is very hard, overly brittle, abrasive, and difficult to carve. Medpor, having similar surrounding tissue acceptance, has several advantages compared with hydroxyapatite: it has thermoplastic abilities and can be easily bent or carved, pieces of Medpor can be sutured or screwed together, and its surface is less rough.

Proplast II, a Teflon–aluminum oxide composite, is very different from Medpor. It collapses under pressure and thus does not provide desirable structural stability. Pores in Proplast are not totally interconnecting and ingrowth of the surrounding tissue is slower and less complete. Lack of reliable stabilization, late fragmentation, and occasional anigenicity have also been problems.

The nasal dorsum is constantly exposed to pressure and trauma, and in previously operated patients its blood supply is already compromised. Daniel [7] emphasized that subcutaneous insertion of any alloplastic material acts as a barrier preventing vascularization of the skin, except from the periphery. He felt that it was the main reason for the disastrous outcome in secondary cases. The present histologic investigations confirm good vascularization of the porous polyethylene (Fig. 3). During extraction of this whole implant, I noticed how well it was ingrown in the subcutaneous tissue, and after sharp dissection bleedings occurred. This explains why in this series good results were achieved in the difficult secondary cases, without any detrimental impact on the cutaneous circulation during the observation period.

Previous histologic studies on Medpor were done mostly on animals [11,12,14,20], but also on the external ear in humans [21]. They showed soft tissue ingrowth, vascularization with mature blood vessels, and lamellar collagen deposition within the pores of the implant. The present histologic investigation confirmed reliability of the porous polyethylene implants also for nasal applications. Ingrowth of the well-vascularized connective tissue, with a minimal foreign-body reaction, gradually decreasing over time, demonstrated at the 4.5-, 6-, 10-, and 17-month intervals after implantation indicates excellent biocompatibility and the probability of indefinite stability of the polyethylene implants used for reconstruction of the nasal dorsum.

My experience from working with this material underlines how important it is to determine the appropriate size of the Medpor implant. The nose, particularly when previously operated on, has very little tolerance for both under- and overcorrection. After the initial postoperative edema subsides, mistakes will inevitably show through the relatively thin, sensitive-to-pressure nasal skin and subcutis envelope.

Augmentation of the nasal dorsum has a higher complication rate than implants placed in locations with thicker soft tissue coverage [13]. Because of the large surface area of porous implants, there is increased risk of infection. It is most important, therefore, that the highest level of aseptic care and antibiotic coverage be used when handling and preparing polyethylene implants. The complications in this series of predominantly difficult rhinoplasties, one implant exposure and one infection, were manageable, they did not destroy the final result, and their frequency should be considered as an acceptable level.

This report on 23 difficult rhinoplasties and 4 chin augmentations, positively solved with the help of Medpor implants, has a middle-range follow-up time averaging 2 years. Vascularization of Medpor was also confirmed by the present study. This allows for optimism regarding the permanent acceptance of Medpor implants in the nose. However, it will be interesting to continue to observe the tolerance of Medpor implants in the nose over even longer periods of time. The reported results are in concordance with the recently published clinical series of Türegun et al. [17] and Romo et al. [18]. It was felt worthwhile to publish them because of the complexity of the actual clinical problems and the history of unsuccessful surgical attempts to correct them by conventional surgical approaches.

It is significant that, in this short series, 18 of 23 cases (78%) were secondary rhinoplasties or had been operated on previously three or four times. In such intricate, sometimes desperate, clinical situations, porous polyethylene implants, owing to their ability to be proliferated with viable, well-vascularized tissue, were found to be a useful tool for restoration of the nasal form and function. Therefore Medpor seems at present to be the best alloplastic material for nasal reconstructive and aesthetic surgery, when dorsal augmentation and/or straightening is desired. However, Medpor should not be considered an all-season solution for every difficult rhinoplasty. It is rather an adjuvant providing a stable nasal frame, around which an advanced and skillful nasal surgery is per-formed.

Acknowledgments. The author is grateful to Dr. Erik Borglund, Medilab, and photographer Ingeborg May, Department of Pathology, Karolinska Institutet, Stockholm, for fruitful discussions and expert assistance with microscopic photography.

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