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Porous polyethylene implants in revision rhinoplasty: chances and risks*

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SUMMARY

Introduction: *High density Polyethylene (PE) is a chemically pure, porous plastic implant material that can perform supportive functions. The material has good tissue biocompatibility and permits ingrowth of connective tissue with related vascularization. The material is being used more frequently in nasal surgery. In this study we describe possibilities and limitations in the use of PE in rhino-surgery.*

Material and methods: *Thirty-two charts of patients with rhinoplasty and PE-implantation were reviewed. All patients were seen in our department again. A database was created which included the following parameters: date and exact area of implantation, shape and thickness of the implant, number of revisions, technique of prior rhinoplasties, complications and the patients´ satisfaction.*

Results: *Seventy-five percent of patients were revision rhinoplasties at the time of surgery. Seven out of thirty two (21%) patients developed a complication. In four cases, the complication was managed with total explantation; three patient's condition required partial explantation. The shortest implantation period was only 24 days and the longest lasting implant within the complication group was explanted 266 days after implantation. All these patients had undergone multiple rhinoplasties before, with heavy scar tissue and septal perforations. The most frequent complication (n=4) was a partially extruded implant without any signs of infection in the area of the anterior septum.*

Discussion: *Our descriptive study shows limitations in the use of PE for rhinoplasty. It seems crucial that the implant is completely covered with vital tissue, otherwise vascularization and healing is excluded. The implantation place should be vital and without any signs of infection. The covering tissue should not be too thin or scarred. An early infection of the open porous system prevents vascularization and healing and inevitably causes a rejection. The reason for the high complication rate (>20%) in this study lies in the specifications of the selected patient group at hand. All implantations were performed in seriously damaged scar tissue after multiple revision rhinoplasties. Due to the results of our evaluation we can recommend the use of PE:*

1. *in a vital, healthy implant site*
2. *with small material that can be embedded totally and without tension*
3. *in primary rhinoplasty or with only little scar tissue.*

Key words: polyethylene, porous, nasal implants, rhinoplasty, risks, limitations, extrusion, rejecton, revision, rhinosurgery

INTRODUCTION

Alloplastic materials have been used in surgical procedures since the 1930's [1,2]. In the beginning this was done without critical evaluation of their properties. Prior to the use of an implant, certain important key questions should be clarified:

1. Is the material dangerous for the tissue? Does it increase the danger of infection or does it interfere with wound healing?
2. Does it exhibit immunological reactions to blood or tissue?
3. Is it frequently rejected?
4. Does it form a capsule which reduces the usefulness?
5. Is the material permanent or absorbable?
6. Does the absorption involve tissue damage?
7. Can absorption or degradation of the material be controlled with adequate reliability?
8. Can the material be produced precisely enough to meet strict quality requirements and is it easy to work with the material?
9. Is the colour of the implant visible through the skin?

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High density Polyethylene (PE) or Medpor® (Porex Surgical, Newnan, GA, USA) is a chemically pure, porous plastic implant material which has supportive functions [3]. As has long been known, the material has good biocompatibility and permits ingrowth of connective tissue with related vascularization [4]. The material is also being used more and more frequently in nasal surgery, particularly as very specified implants become available for the bridge of the nose, the middle third, the septum and as replacements for the alar cartilages [5-7]. The material can be shaped after heating, can be cut, pierced with a needle and sutured. Further advantages that make PE especially safe and reliable are its stability under subsequent trauma and in the presence of long-lasting scar contraction forces [8]. These beneficial properties make porous polyethylene an interesting option not only for rhinoplasty but more generally for reconstructive procedures in the midface as well [9]. Recent publications in the literature appreciate porous polyethylene for the use in rhinoplasty. However, it is emphasized that care must be taken in augmentation procedures to avoid overcorrection which might promote extrusion of the material, especially when the skin is already under tension and the soft tissue envelope is damaged [10].

In this descriptive study we present possibilities and limitations in the use of PE in rhino-surgery based on our own clinical experiences. The study mainly focuses on specific complications in rare indications.

MATERIALS AND METHODS

Thirty-two charts of patients with rhinoplasty and PE-implantation were reviewed. The postoperative follow-up ranged from 169 days to 853 days (average: 380 days). The surgery was performed between 2004 and 2006 by the senior author using a closed approach (in contrast to an open rhinoplasty) at the Department of Otorhinolaryngology, Head and Neck Surgery, Grosshadern Medical Centre of the Ludwig-Maximilians-University, Munich, Germany. PE was only used in cases when autologous transplants (septal cartilage, concha cartilage, rib cartilage) were not available or if the patient refused the harvesting of rib cartilage. Photo documentation was performed in all patients at least two months prior and after surgery. All patients were treated peri and postoperativly with cefuroxime. The first three days antibiotics were applied intravenously 1.5g/three times a day and then orally 500mg/two times a day for another four days. The patients stayed in the hospital over all for seven days.

A database was created which included the following parameters: date and exact area of implantation, shape and thickness of the implant, number of revisions, technique of prior rhinoplasties, complications (i.e. implant displacement, extrusion of porous polyethylene implants, postoperative bleeding and infection of tissues surrounding the implants). Every patient was asked two months after surgery about the subjective result and if he/she would undergo this kind of surgery again if necessary.

RESULTS

The patients' mean age was 36 years with a range from 15 to 65 years. Eight were female (25%) and twentyfour were male (75%). More than 75% were revision cases at the time of surgery (Figure 1).

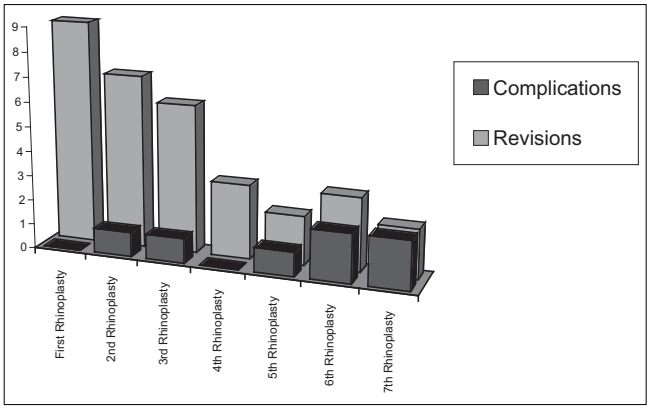

Figure 1. Number of complications depending on revision (n=32).

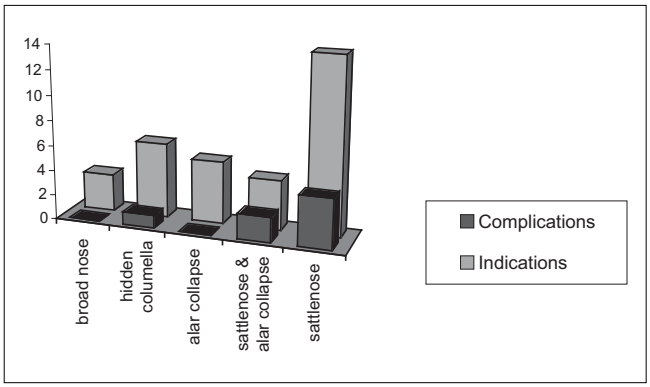

Figure 2. Indications and complications.

All patients in the primary rhinoplasty group suffered from a traumatic saddle nose deformity with hidden columella and missing septal cartilage. One of them had Wegener´s Granulomatosis, which had been clinically inactive for three years. Among the rest of the patients the spectrum of the aesthetic deformities ranged from saddle noses, to broad saddle noses and to hidden columella with or without alar collapse on both sides (Figure 2). In five cases a rhinoplasty with rib cartilage was performed with a disappointing outcome before.

Twentyeight columella struts, fifteen onlay-grafts for the nasal bridge, seven batten grafts and three shield grafts were implanted (Figure 3). All fifteen onlay grafts were fixed to a columella strut after heating (Figure 4), forming an L-shape (Figure 5). The thickness of the strut implants ranged from 0.25 mm to 2.0 mm, with 1.0 mm struts being the most common. All PE implants, especially the onlay grafts, were shaped by the surgeon with the knife for exact fitting (Figure 6).

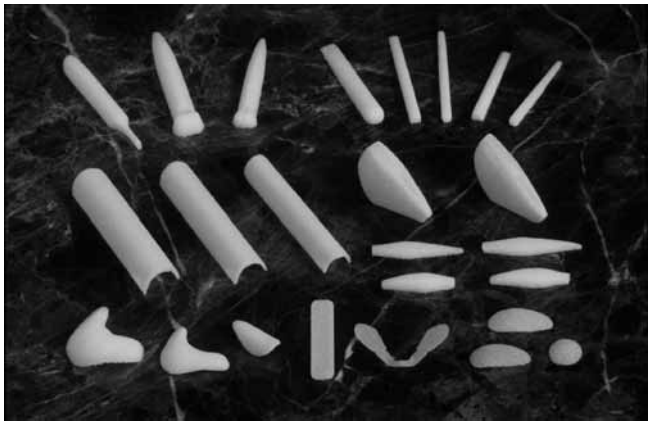

Figure 3. Different preformed shapes of MedPor Implants (picture courtesy of POREX Surgical Inc.).

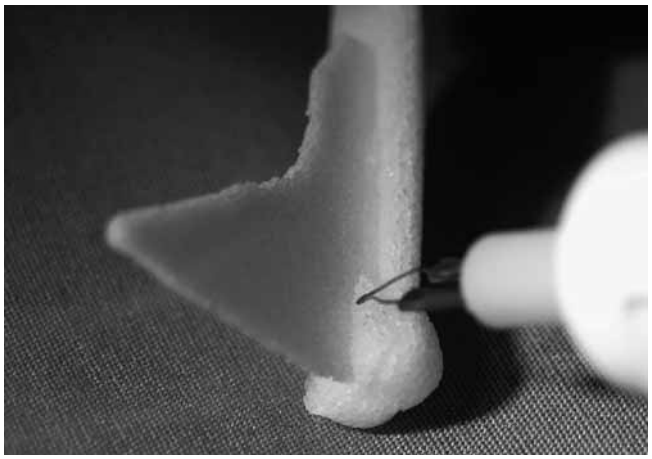

Figure 4. Punctate heat sealing of a dorsal and a septal PE implant using electrocautery.

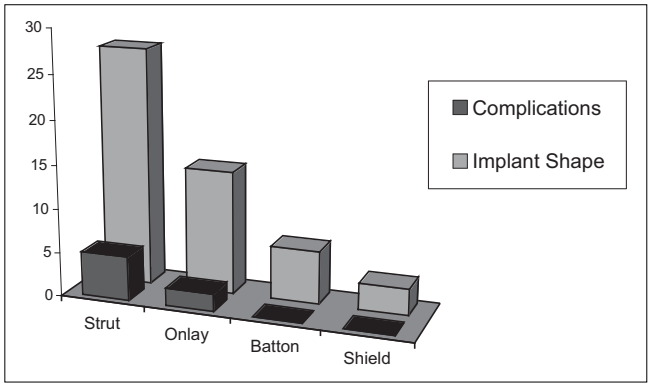

Figure 5. Shape of implanted grafts.

Seven out of thirtytwo patients developed complications. In four cases, explantation was necessary; in three cases partial explantation was mandatory. Within the complication group, the shortest implantation period was 24 days and the longest lasting implant was explanted 266 days after implantation. All

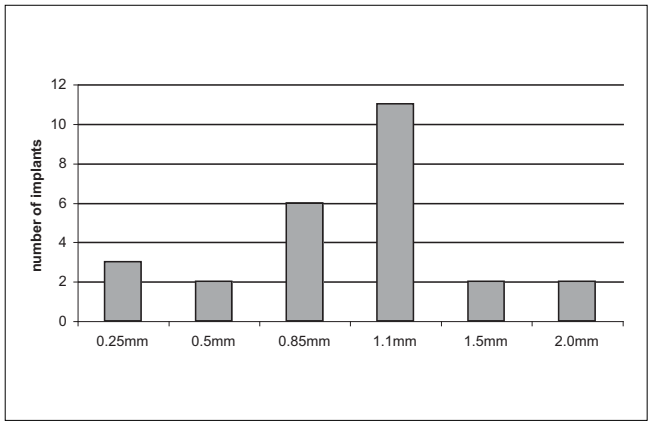

Figure 6. Thickness of implanted columella struts.

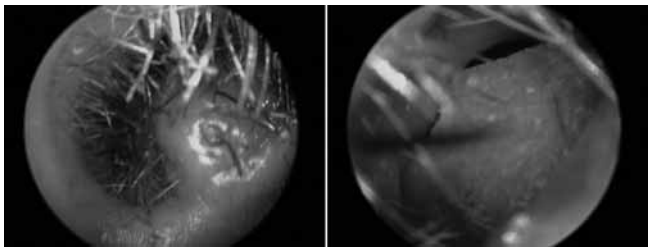

Figure 7. The nose, 174 days and 264 days after implantation. The columella strut is extruding in the old implantation scar.

these patients had undergone multiple rhinoplasties before leading to difficult implantation sites charcterized by scar tissue formation and septal perforations.

The most frequent complications (n=4) were partially extruded implants without any sign of local infection in the area of the anterior septum. Extrusion was localized exactly in the hemitransfixation scar (Figure 7). One patient showed a defect of the skin of the nasal dorsum right over the implant and another suffered from local swelling, reddening and secretion (without skin perforation). In these two cases, the implant was placed in scar tissue after revision rhinoplasty very near to the surface of the skin. Even after thorough skin care with antibiotic lotions and clindamycine orally the skin showed no signs of regeneration, therefore the implants were explanted after 52 and 132 days. In both cases, the implant was partially covered with vital connective tissue which fixed the implant in situ. For safety reasons both implants were removed completely and rib cartilage was implanted during the same operation to support the nasal dorsum. After explantation the skin healed in one case. In the second case another skin flap had to be performed to cover the skin defect (Figure 8).

One patient showed an infection with extrusion of the strut implant at the columella on day 40 after the implantation. The infected part of the columella strut implant was removed and the tip of the nose still showed enough projection after this par-

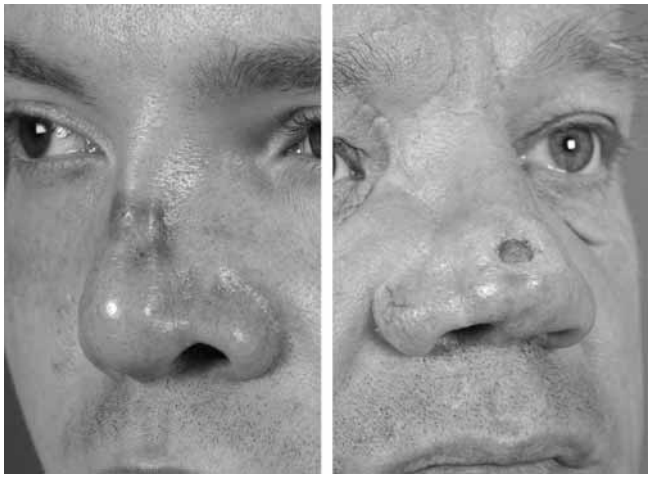

Figure 8. Left: Skin reddening and secretion 105 days after the implantation of an onlay graft. Right: Skin perforation with view of the underlying PE-implant 45 days after implantation.

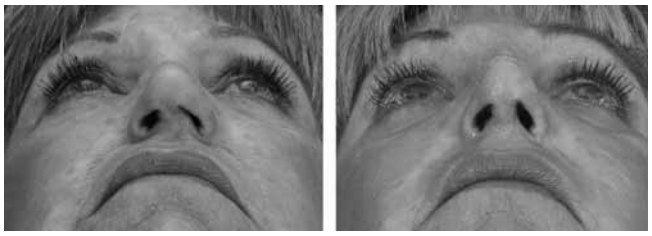

Figure 9. Aesthetically and functionally a fair result after augmentation of the columella with a strut (left preoperative) and after partial explantation of the infected strut (right postoperative).

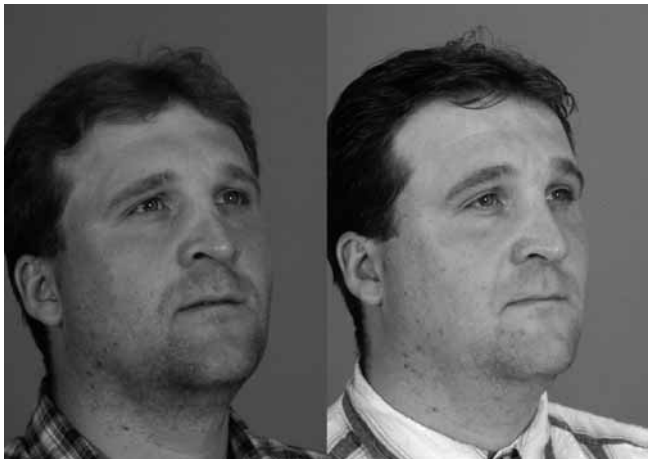

Figure 10. Aesthetically and functionally a fair result after augmentation of the columella with a strut (left preoperative) and after partial explantation of the infected strut (right postoperative).

tial removal with the rest of the implant left in place (Figure 9). In five cases no other materials were implanted after explantation of the PE-implants, neither alloplastic materials, nor autologous transplants. The functional and aesthetic outcome was satisfactory for the patients because of strong scar tissue formation sufficiently fixing the nose (Figure 10).

Twentyseven out of thirtytwo patients were satisfied with the aesthetic and functional result. Five patients expected a better aesthetic outcome, but intended not to undergo an additional nasal surgery. Four patients still suffered from nasal obstruction after the operation. In contrast, all six patients with a nasal valve stenosis who got a nasal alar batten graft were improved significantly from the functional point of view.
Table 1 lists each shape and site of all grafts with and without complications. It also provides the exact explantation time, cause and location of explantation.

DISCUSSION

Alloplasty in nasal surgery must currently be evaluated in comparison to autogenous grafts, since these continue to be regarded as the most suitable replacement materials [11]. Septal cartilage, for example, is stable, is absorbed only slightly (if at all) and has probably the best biocompatibility. Moreover, from a practical standpoint, it can be processed well, and is thus ideal for use in spreader grafts, onlay grafts for the bridge of the nose, and columella struts [12,13]. In case of surgical revisions, however, septal cartilage is often not available in adequate amounts and crushed cartilage has a much higher rate of absorption. Concha cartilage is especially suitable where smaller amounts of soft and/or slightly curved cartilage are required.
Autogenous costal cartilage is easily acquired in larger quantities and exhibits few problems during the healing process [14]. However, its acquisition is accompanied by certain risks and complications at the point of harvesting such as the danger of pneumothorax, deformities of the costal arches, and visible scarring [15,16]. Therefore the search for alloplastic materials in surgical procedures began in the 1930's and at first this was done with little critical evaluation of their biological and functional properties. Porous polyethylene turned out to have good tissue biocompatibility and permits ingrowth of connective tissue with related vascularization [17,18]. Ozdemir et al. succeeded experimentally and clinically in creating pre-fabricated, vascularized tissue flaps into which PE alloplastic material was integrated. After initial healing, these grafts were covered with a layer of thin, full skin grafts [19]. This represents a new alternative for treating combined skeletal and soft tissue defects, especially in the case of patients for whom donor tissue is available only in limited amounts. Presumably this method can be developed even further. These composite flaps demonstrate that vascularization in the porous system of PE after healing is sufficient to allow free full thickness skin flaps to grow on it. This principle has already been realized in the use of porous polyethylene for ear reconstruction [20].

The material is also being used more and more frequently in nasal surgery [7]. Our retrospective evaluation shows limitations

Table 1. Extract from the database: Age, prior rhinoplasties, implant site, shape and size and complication of every graft.

Age	Revisions	Implantsite	Shape of PE	PE size	Complication - Portion	on day:
28	0	Columella	Columella strut	0.25mm		
20	0	Columella	Columella strut	1.1mm		
35	0	nasal dorsum+Columella	L-Shape (strut+onlay)	1.5mm		
15	0	nasal dorsum+Columella	L-Shape (strut+onlay)	1.1mm		
49	0	nasal dorsum+Columella	L-Shape (strut+onlay)	1,1mm		
22	0	nasal dorsum+Columella	L-Shape (strut+onlay)	0,85mm		
40	0	Columella	Columella strut	1.1mm		
18	0	nasal dorsum+Columella+tip	L-Shape (strut+onlay), shield			
30	0	Columella	Columella strut	1.1mm		
23	1	Columella	Columella strut	2mm		
35	1	Columella	Columella strut	0.85mm		
31	1	Columella	Columella strut	0.85mm	partial extrusion - columella	230
65	1	nasal dorsum+Columella	L-Shape (strut+onlay)	1.1mm		
15	1	Columella	Columella strut	1mm		
18	1	nasal dorsum+Columella	Columella strut	0.5mm		
55	1	nasal dorsum+Columella+alar	2 Columella struts, batten	1.1mm		
15	2	nasal dorsum+Columella	L-Shape (strut+onlay)	2mm		
42	2	nasal dorsum+Columella+alar	L-Shape (strut+onlay), batten	0.5mm	partial extrusion - columella	118
59	2	nasal dorsum	L-Shape (strut+onlay)	1.1mm		
36	2	nasal dorsum+alar	2 battens			
33	2	Columella+right alar	batten, shield			
40	2	nasal dorsum+alar	batten			
34	3	nasal dorsum	L-Shape (strut+onlay)			
44	3	nasal tip+right alar	batten, shield	1.1mm		
48	3	Columella	Columella strut	0.25mm		
31	4	nasal dorsum+Columella	L-Shape (strut+onlay)	0.85mm		
55	4	nasal dorsum+Columella	L-Shape (strut+onlay)	1.1mm	skin defect - nasal dorsum	52
49	5	Columella	Columella strut	0.25mm	partial extrusion - columella	266
24	5	nasal dorsum+Columella	L-Shape (strut+onlay)	1.1mm	skin defect - nasal dorsum	132
21	5	Columella	Columella strut	1.1mm		
64	6	nasal dorsum+Columella	L-Shape (strut+onlay)	0.85mm	partial extrusion - columella	40
44	6	nasal dorsum+Columella	L-Shape (strut+onlay)	1.5mm	total extrusion - columella	24

in the use of PE for rhinoplasty. It seems one of the most important points to cover the implant completely in the patient´s body with vital tissue, otherwise vascularization and healing is not possible. The implantation site has to be vital and without any signs of infection. The covering tissue should not be too thin or scarred. An early infection of the open porous system prevents healing and inevitably causes a rejection.
Only one patient suffered from an infection with rejection of the implant disregarding several weeks of systemic and local antibiotics. Therefore, we assume that this patient was prone with a secondary infection after implantation caused by wound healing. An early infection with strong tissue reaction or rejection has never been observed. In contrast to the use of PE for ear reconstruction the nasal implants were not drowned in antibiotics before implantation. Our observations with regard to the absence of infections show that this procedure is adequate.

Angiogenesis and ingrowth of tissue in PE always originate from the border of the implant. That is why the PE implant should be totally covered by vital and vascularized tissue. Skin can not grow directly on PE, because nutrition is impossible before vascularization of the porous system. If the skin covering the implant is too thin or devascularized it comes to a necrosis of the tissue - even of vital, healthy skin. In two cases this led to a skin necrosis. We hypothesize that the implant was not completely vascularized and linked to the host. Both implants had to be removed and were exchanged with rib cartilage or concha cartilage. In one case the skin lesion healed without any complications after this manouvre. In the other case a skin flap was used.

Should partial extrusion of a PE implant occur after weeks or months, partial resection of the implant can be carried out. It is mandatory to extend the resection to areas of the implant where connective tissue infiltration into the pores is recognizable. The partial removal is technically easy, and the remainder of the implant can be left in situ; in contrast to silastic, for example. After removal of the implant there is often scar tis-

sue, which exerts supportive function leading to a sufficient aesthetic outcome.

The patients presented in this study appeared to have no real alternative to an alloplastic implant. Eight patients were operated with PE after an inadequate result with rib cartilage. The commonly observed complication rate with rib cartilage is about 16% [21], which is only a little less than the complication rate in our study (which is 22%).

Most rhino-surgeons prefer the open approach when dealing with implants such as PE [22]. The open technique provides a better overview on the implantation site [23], but the implants augment the tension at the columella suture and thus increase the risk of inappropriate scars [24]. Moreover the vascularization of the nasal tip is decreased by the columella incision and the healing and acceptance of the implant is more in danger. These disadvantages can be avoided with the closed technique, but the perfect fit of the implant with a closed approach demands a very experienced rhino-surgeon, because of the lack of overview.

CONCLUSION

The rather high complication rate (22%) in this study refers to the evaluated patient group. All implantations were performed in seriously damaged scar tissue after multiple revision rhinoplasties.

Many studies have shown that PE implants have their place in nasal surgery, after appropriate indication and choice of the surgical technique. However, the use of alloplastic materials in rhinoplasty should be done by experienced surgeons. After our evaluation we can recommend the use of PE in revision rhinoplasty:

- if the host provides a vital implant site;
- if the implant is not too large and can be embedded completely without tension in a vital envelope;
- if only little scar tissue formation has occurred at the implantation site.
- When implanting in scar tissue it is important to consider that even small implants can cause strong tension on the implant site.

The surgical approach - closed or open - should depend on the experience of the surgeon. The use of alloplastic materials in rhinoplasty should however be reserved for special indications. Current research aims at the analysis of the interactions between the alloplastic implant and its host site to derive improved biomaterial implant solutions by preconditioning or tissue engineering. Our working group focuses on the ingrowths and angiogenesis of the surrounding tissue in vivo and in vitro. First unpublished data show healthy cells with stable, differentiated matrix inside the pores of the polyethylene. A prospective study of the inter-relation of tissue qualitiy and extrusion/acceptance of the implant would be desirable. Because of our experience with the implantation of PE in severe damaged tissue we would currently draw back from such a study in humans.

If possible the autogenous transplant should always be preferred. On the other hand surgeons who accept only human tissue grafts as replacements run the risk of overlooking the drawbacks and risks of these grafts.

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