ORIGINAL ARTICLE

Complications Associated With Alloplastic Implants in Rhinoplasty

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Objective: To evaluate the incidence of infection and extrusion of porous high-density polyethylene (pHDPE) and expanded polytetrafluoroethylene (ePTFE) implants used in rhinoplasty at a high-volume, academic facial plastic surgery practice.

Methods: A total of 662 rhinoplasty procedures performed by 3 faculty surgeons from 1999 to 2008 were retrospectively reviewed. Patient demographics, medical comorbidities, operative details, and postoperative course findings were collected from patient records.

Results: The incidence of postoperative infection was 2.8% (19 of 662 patients). In each case of infection, alloplastic material had been used. Infections occurred in 1 in 5 rhinoplasty procedures in which pHDPE implants were used. In patients in whom ePTFE was used alone, the infection rate was 5.3%. Exposure developed in 12% of patients in whom an alloplast was used during surgery. Factors notably not associated with infection on bivariate analysis included sex, surgeon, purpose of procedure (functional vs cosmetic), current tobacco use, or history of cocaine use ($P > .05$ for all).

Conclusions: To our knowledge, this study represents the largest evaluation of the use of pHDPE implants in rhinoplasty to date. Our findings are in contrast to those of previous studies regarding the use of pHDPE in rhinoplasty and parallel to those regarding the use of ePTFE. Caution is strongly recommended when considering the use of pHDPE in rhinoplasty.

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While autologous tissue implants are the most desirable reconstructive materials for use in rhinoplasty, they are not always readily available, and the harvesting of such materials confers additional unwanted morbidity.[1] Porous high-density polyethylene (pHDPE) (Medpor; Porex Technologies) and expanded polytetrafluoroethylene (ePTFE) (Gore-Tex; W. L. Gore & Associates) are synthetic materials that have been advocated for use during rhinoplasty surgery.[2] Porous high-density polyethylene has been available since the 1980s, and its use remains controversial owing to concerns regarding infection and extrusion. Implants made of ePTFE are more widely accepted by rhinoplastic surgeons, but recent histologic studies have suggested that ePTFE may elicit greater foreign body reactions than previously suspected.[3] It also remains unknown whether complications are more common when ePTFE is used simultaneously with pHDPE. A recent meta-analysis of available alloplasts concluded that improved reporting of adverse outcomes is necessary before any firm conclusions can be made regarding safety and efficacy.[4] Our goal was to evaluate the incidence of infection and extrusion of pHDPE and ePTFE implants used for rhinoplasty in the setting of a high-volume, academic facial plastic surgery practice.

METHODS

The electronic medical records (EpicCare; Epic Systems Corp) of all patients who underwent a rhinoplasty and/or septorhinoplasty procedure at Oregon Health and Science University, Portland, from August 1999 to March 2008 were retrospectively reviewed. After institutional review board approval of the study design, cases were identified by querying the electronic billing system for rhinoplasty (*Current Procedural Terminology* codes 30400, 30410, 30420, 30430, 30435, 30450, 30460, and 30462) as well as for removal of nasal implants (*Current Procedural Terminology* code 30310). All clinical notes and operative records were reviewed to collect patient demographics, medical comorbidities, operative details, and postoperative course. The institutional review board deemed informed consent unnecessary for this retrospective study.

Table 1. Demographics and Medical Comorbidities

Demographics	Patients, No. (%)		
	All (N = 659)	Nonalloplast (n = 508)	Alloplast (n = 151)
Sex			
Male	307 (47)	258 (51)	49 (33)
Female	352 (53)	250 (49)	102 (67)
Medical comorbidities			
Diabetes	12 (2)	8 (2)	4 (3)
Smoking/tobacco use	36 (6)	30 (6)	6 (4)
Cocaine use	7 (1)	2 (<1)	5 (3)
Prior septorhinoplasty	145 (22)	73 (14)	72 (48)
Prior septoplasty	29 (4)	13 (3)	16 (11)
Preoperative septal perforation	37 (6)	21 (4)	16 (11)

A procedure was classified as primarily functional if nasal obstruction was the most important complaint on patient presentation, whereas the procedure was classified as primarily cosmetic if appearance was the most important concern. Postoperative infection was defined as visible redness, swelling, or purulent drainage involving the implant site and requiring antibiotics (without visible exposure of the implant). Postoperative exposure was defined as visible exposure of the implant with or without surrounding signs of infection. Abstracted data were organized using an Access database (Microsoft Inc).

Study data were analyzed using Stata version 9.0 (StataCorp). Descriptive statistics were tabulated, and measures of association were calculated using χ^2 analysis and risk ratios. Variables found to be statistically associated with the outcomes of infection or exposure were included in multivariate analyses using logistic regression. $P < .05$ was considered statistically significant for all analyses.

RESULTS

Three faculty surgeons performed 662 rhinoplasty procedures on 659 patients during the study period. Patient demographics and associated medical comorbidities are listed in **Table 1**. The average age of all patients was 43 years (age range, 7-90 years), and the average age of patients who received an alloplastic implant was 46 years (age range, 7-86 years). The medical factors that might affect healing, such as tobacco use at the time of surgery, prior use of cocaine, and a history of diabetes mellitus, are also listed in Table 1. A total of 58.3% of the patients who received an alloplast during surgery had previously undergone either a septoplasty or a rhinoplasty procedure.

The intraoperative maneuvers used during the rhinoplasty procedures are listed in **Table 2**. Per standard practice, all patients received an intravenous dose of an antistaphylococcal antibiotic immediately before the procedure, followed by a week of oral antibiotics. Most rhinoplasties were performed primarily for functional concerns (86.0%), and 63.0% of all patients underwent an endonasal rhinoplasty. However, in those patients who received an alloplast, an endonasal approach was used only 46.0% of the time. A septoplasty was performed concurrently in 90.8% of cases and endoscopic sinus surgery in 9.7%. Other intraoperative maneuvers, such as cephalic trim, osteotomies, and alar batten grafts, were performed with similar frequency whether or not a synthetic material was used.

Alloplastic materials were used in 151 cases (22.8%) (**Table 3**). Approximately 85.0% of the cases in this cohort were functional, and 54.0% were performed via an endonasal approach. In 99 cases (15.0%), ePTFE was used, whereas pHDPE was implanted in 76 cases (11.5%). Simultaneous use of ePTFE and pHDPE occurred in 24 cases (3.6%). When used, ePTFE was only implanted as a sheet to augment the nasal dorsum. In contrast, pHDPE was used as a columellar strut in 40 cases (6.0%), as an alar batten implant in 14 cases (2.1%), and as both a columellar strut and an alar batten in 2 cases (0.3%). The implants were routinely handled in a "no touch" fashion. Fresh gloves were put on when the implants were prepared. The pHDPE and ePTFE implants were then handled only with unused instruments, not the gloved hands. In 2 cases in which pHDPE was used, the implant was first soaked in povidone-iodine (Betadine). The pHDPE was used as a columellar strut in both of these cases, and there were no infections or extrusions in either case.

Factors that led to the increased use of an alloplast are listed below (RR indicates relative risk).

Variable	RR (95% CI)
History of cocaine use	3.23 (1.98-5.28)
Prior rhinoplasty	3.23 (2.48-4.20)
Prior septoplasty	2.72 (2.08-3.54)
Open approach	2.15 (1.62-2.86)
Septal perforation	2.02 (1.36-3.01)

A history of cocaine use (7 cases) was significantly associated with implant use. In 6 of the 7 cases with prior cocaine use, a preoperative septal perforation existed with a saddle-nose deformity in which ePTFE was used to augment the nasal dorsum. Prior nasal surgery, including previous rhinoplasty or septoplasty, was positively associated with the use of a synthetic material during the procedure. These are expected findings given that native septal cartilage, the most desirable autologous grafting material, is often deficient in revision nasal surgery.

The average follow-up period for this cohort was 12.1 months (range, 0-74.0 months). During this period, 19 of 662 patients (2.8%) developed a postoperative infection. In each case of infection, a pHDPE or an ePTFE implant had been used. No postoperative infection devel-

Table 2. Rhinoplasty Operative Details

Variable	Patients, No. (%)		
	All (N = 662)	Nonalloplast (n = 511)	Alloplast (n = 151)
Goal of procedure			
Functional	569 (86)	441 (86)	128 (85)
Cosmetic	25 (4)	20 (4)	5 (3)
Functional and cosmetic	65 (10)	48 (9)	17 (11)
Not noted	3 (<1)	2 (<1)	1 (<1)
Surgical approach			
Endonasal	418 (63)	349 (68)	69 (46)
Open	244 (37)	162 (32)	82 (54)
Concurrent procedures			
Septoplasty	601 (91)	472 (92)	129 (85)
Sinus surgery	64 (10)	59 (12)	5 (3)
Turbinoplasty	97 (15)	85 (17)	12 (8)
Intraoperative maneuvers			
Osteotomies	395 (60)	320 (63)	75 (50)
Dome division	61 (9)	48 (9)	13 (9)
Dome suturing	63 (10)	40 (8)	23 (15)
Cephalic trim	138 (21)	113 (22)	25 (17)
Shield graft	41 (6)	26 (5)	15 (10)
Butterfly graft	402 (61)	317 (62)	85 (56)
Alar batten graft	42 (6)	31 (6)	11 (7)
Spreader graft	74 (11)	68 (13)	6 (4)

oped in any of the 511 procedures performed without implants. Of the 151 cases in which an synthetic material of any kind was used, 19 (12.6%) developed an infection. Of the 52 rhinoplasties in which pHDPE implants were used, 10 implants became infected, for an infection rate of 19.2%. In those cases in which pHDPE was used solely as a columellar strut, the infection rate increased to 21.8%. No infections occurred when pHPDE was used solely as an alar batten implant. Of the 75 patients in whom ePTFE was used alone, only 4 developed an infection, yielding an ePTFE-specific infection rate of 5.3%. Of the 24 patients in whom pHPDE and ePTFE were used simultaneously, 5 (20.8%) developed an infection.

As might be expected, most of the infected implants also eventually became exposed and vice-versa. Overall, 18 of the 151 patients (11.9%) with implants developed exposure. The highest exposure rate (23.4%) was seen when pHDPE columellar struts were used. When only pHDPE alar battens were used, 1 of 10 implants (10.0%) was exposed, although the implant was not infected in this case. The lowest exposure rate was seen when ePTFE was used alone (2 of 75 cases [2.7%]).

As shown below, a number of factors were shown to be associated with postoperative infection on bivariate analysis.

Variable	RR (95% CI)
Alloplast (any type)	29.09 (6.80-124.50)
pHDPE columellar strut	21.24 (8.37-53.88)
Prior septoplasty	6.91 (2.77-17.21)
Diabetes mellitus	6.34 (1.65-24.45)
Prior rhinoplasty	5.01 (2.05-12.21)
ePTFE dorsal onlay	4.11 (1.70-9.97)

Use of an alloplast of any kind was associated with an RR of infection of 29.09. Using pHDPE as a columellar strut increased the RR of infection by 21.24, whereas onlay ePTFE implants increased the RR of infection by 4.11.

Table 3. Alloplastic Implants Used During Rhinoplasty[a]

Variable	No. (%)
Alloplast material	
pHDPE or ePTFE	151 (22.8)
pHDPE only	52 (7.8)
ePTFE only	75 (11.5)
pHDPE and ePTFE	24 (3.6)
pHDPE implant	
Columellar strut only	40 (6.0)
Columellar strut and ePTFE	22 (3.3)
Batten graft only	14 (2.1)
Strut and batten graft only	2 (0.3)
ePTFE Implant	
Dorsal onlay only	75 (11.3)
Dorsal onlay and pHDPE	99 (15.0)

Abbreviations: ePTFE, expanded polytetrafluoroethylene; pHDPE, porous high-density polyethylene.
[a] A total of 662 rhinoplasty procedures were performed.

Other factors significantly associated with postoperative infection included prior septoplasty, prior rhinoplasty, and history of diabetes mellitus. Factors that were notably not associated with infection on bivariate analysis included sex, surgeon, purpose of procedure (functional vs cosmetic), current tobacco use, or history of cocaine use ($P > .05$ for all).

COMMENT

The main argument against using alloplastic materials in rhinoplasty is the concern for postoperative infection.[5] In this study, we reviewed the use of 2 synthetic materials during rhinoplasty at an academic facial plastic surgery practice. Our data indicate that both pHDPE and

ePTFE confer an increased risk of infection. This risk remains significant, even after other potentially confounding factors, including revision surgical status and medical comorbidities, are controlled for.

The high infection rate for pHDPE seen in this study stands in contrast to existing reports describing much lower infection rates.[6-10] Wellisz[6] was the first (to our knowledge) to report using pHPDE for nasal reconstruction. There were 2 infections in his series of 27 patients, both involving columellar struts. Türegün et al[7] reported 0 infections in 36 patients, with an average of 14 months of follow-up. The largest study published to date involved 187 patients who were followed up for 26 months.[8] In that cohort, there were only 5 infections (2.6%), all involving alar battens. None of the 168 columellar struts became infected.

It may be tempting to explain the current study results as the isolated findings of a single institution. However, 3 separate surgeons were included in this review, each with fellowship training and substantial rhinoplasty experience. All patients received both intraoperative and postoperative antibiotics to cover common nasal flora, although rarely were the implants soaked in an antibiotic or antiseptic solution. In the 2 cases in which the pHDPE was soaked in povidone-iodine, no infections or extrusions occurred. It is possible that soaking the pHDPE implants in povidone-iodine or a similar solution may prevent infection or extrusion, although this does not seem to be necessary for ePTFE implants.

Given the large number of revision procedures, this patient cohort does represent a "high-risk" population; however, these factors were controlled for with logistic regression, and the risk of infection persisted. Also, no infections were seen in the 511 rhinoplasties that were performed without synthetic material. The fact that pHDPE has never been fully embraced by rhinoplastic surgeons suggests that actual clinical results may be less stellar than those reported in the published literature. Publication bias is a well-documented phenomenon in which clinicians are less likely to present negative or nonflattering results.[11] This bias may be particularly problematic in the field of surgery, in which clinicians are reluctant to be associated with a negative outcome.[12]

In contradistinction to pHDPE, there is a large body of evidence describing the use of ePTFE in rhinoplasty.[13-15] The low infection rate for ePTFE seen in our study mirrors that of earlier reports. The largest study by Godin et al[13] reviewed 309 cases and found an infection rate of 3.2% at an average of 40 months of follow-up. This finding validated 2 earlier studies by separate groups showing 0% and 2.6% infection rates in 106 and 189 patients, respectively.[14,15] There are also numerous studies showing low infection rates when ePTFE is used in hernia repair and as a vascular patch.[16,17]

In our patient cohort, most infections occurred when pHDPE was used as a columellar strut. In these cases, the implant serves as a buttress to support the mass of the nasal tip.[18] The skin and mucosa covering the implant in this region are thin, and their vascularity may be compromised, especially in revision cases. Also, this region of the nose is mobile and subject to repetitive trauma. It is not unreasonable to think that these factors together would place any synthetic columellar implant at high risk for infection and/or extrusion. In contrast, alar battens and dorsal onlay implants are covered by thicker skin and are not subject to the same load-bearing demands. One senior author of this study (T.D.W.) suggests that an important factor in lowering infection risk for pHDPE columellar struts is to ensure that the implant is completely surrounded by soft tissue and under no tension.

Although synthetic materials increase the risk of infection, the decision to use an implant must be considered on a situational basis. In certain "catastrophe noses" that have undergone multiple prior operations, adequate autologous tissue may not be available or their harvest may be impractical such that a defined infection rate may be acceptable to the patient and the surgeon. In other cases, such as primary cosmetic rhinoplasty, even a very low infection rate may be intolerable to the patient and the surgeon alike.

This study has several important limitations that must be taken into account. As a retrospective review, the analysis is limited to the data that were available in the medical records. Also, it is possible that the rate of infection may be underestimated, as some patients may have developed an infection and presented elsewhere for care. Furthermore, the data set did not include information regarding the timing of the infection; therefore, it remains unknown whether the risk of infection diminishes over time.

In conclusion, the use of pHDPE and ePTFE implants in rhinoplasty is associated with an increased risk of postoperative infection. This risk remains significant after demographic factors, medical comorbidities, and revision surgical status are controlled for. Our findings are in contrast to those of previously published studies regarding the use of pHDPE in the nose and parallel those regarding the use of ePTFE. Caution is recommended when using pHDPE in rhinoplasty, especially as a columellar strut, although there may be situations in which the increased risk is acceptable.

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