Original Investigation

Safety and Efficacy of Expanded Polytetrafluoroethylene Implants in the Surgical Management of Traumatic Nasal Deformity

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IMPORTANCE The ideal alloplastic implant for correction of traumatic nasal deformity has not been adequately examined.

OBJECTIVE To evaluate the safety profile and postoperative results of expanded polytetrafluoroethylene (ePTFE) implants used in functional nasal surgery (FNS) in the setting of traumatic nasal deformity.

DESIGN, SETTING, AND PARTICIPANTS We conducted a 13-year retrospective medical chart review for patients treated at a tertiary academic facial plastic and reconstructive surgery practice between July 1999 and July 2012. A total of 404 FNS procedures were performed by a single surgeon during this period, 255 to repair traumatic deformities, 35 of these involving ePTFE implants. Patient demographics, medical comorbidities, operative and technical considerations, functional and aesthetic results, complications, and postoperative course findings were collected from patient records. In addition, preoperative and postoperative photographic documents were examined.

EXPOSURES Functional nasal surgery.

MAIN OUTCOMES AND MEASURES Postoperative complications or presentations necessitating revision.

RESULTS A total of 404 patients (197 male, 207 female) underwent FNS. Of those, 255 procedures were to treat traumatic deformities. Forty patients altogether required the use of an ePTFE implant, 35 of those 40 deformities being associated with a traumatic injury. One of the 35 patients in the ePTFE-repaired traumatic deformities group experienced postoperative infection. This patient ultimately developed exposure after the infection failed to resolve with oral antibiotics, and the implant was removed. An additional patient in the ePTFE group required revision of the implant owing to contour irregularity and aesthetic concerns. No infections or other complications occurred among the 220 patients with traumatic deformity treated with autologous grafts. Analysis of other variables including sex, tobacco use, diabetes, immunosuppression, implant thickness, suture material, and prior septorhinoplasty were not associated with increased rate of infection ($P > .05$ for all).

CONCLUSIONS AND RELEVANCE In the setting of traumatic nasal deformities requiring FNS, ePTFE implants can be used at the level of the nasal dorsum, where soft tissue coverage is often adequate, with a low risk of complications.

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The use of functional nasal surgery (FNS) for the treatment of traumatic nasal deformity with associated nasal obstruction poses a complex reconstructive algorithm for the facial plastic surgeon. The underlying weakened, fibrotic, and distorted anatomy seen in this patient population often necessitates the use of grafts or implant materials. In many instances, there is a paucity of suitable septal cartilage owing to traumatic cartilaginous disruption or depletion from previous nasal surgery. Increased operative time, donor site morbidity, potential warping, and contour irregularities associated with harvesting cartilage from extranasal graft sites can be a deterrent to their use in selected circumstances. In this clinical setting, the use of alloplastic implants may be justified.

Several different alloplastic materials have been used in FNS, including silicone, expanded polytetrafluoroethylene (ePTFE), and porous high-density polyethylene (pHDPE). Prior to ePTFE gaining favor in the 1990s, various alloplastic materials were used for facial and nasal implants, including Supramid (S. Jackson Inc), Proplast (Vitek Inc), Silastic (Dow Corning Corporation), and Mersilene mesh (Ethicon Inc). However, many were associated with complications, including infection, migration, resorption, extrusion, or difficulty with removal.[1,2] Thus, many surgeons have been reluctant to use alloplasts in rhinoplasty.[1,3-8]

After establishing an exceptional, decades-long safety profile in the field of vascular surgery,[3,9,10] ePTFE implants began to be used in facial plastic surgery. The unique structural geometry of ePTFE consists of interwoven nodules and flexible fibrils of carbon polymers bound to fluorine,[3,9] which creates a microporous material limiting tissue ingrowth while maintaining form, allowing for easy removal if necessary.[11-13] These properties made its use desirable for facial and nasal surgery.

Complications surrounding ePTFE use in FNS have been uncommon, with infection being the most common complication, infrequently requiring removal of the implant.[6,9,14,15] Several histological studies have shown surrounding inflammation in the setting of explanted material but without a clinically meaningful association.[11,12,16] Traditionally, select patient populations such as those with diabetes or immunosuppression were deemed nonideal candidates for use of

PTFE owing to infection risk.[3,7,8,17] However, in the last few decades, several large clinical series have shown that ePTFE is a clinically safe, relatively inexpensive implant that provides a predictable alternative to autografts with long-term efficacy.[3,5,9,15,18,19] The aim of the present study was to describe the low complication profile of ePTFE in the surgical treatment of patients with traumatic nasal deformity.

Methods

The study design was evaluated and approved by the institutional review board at the University of North Carolina, which waived patient written informed consent. The electronic medical records of all patients who underwent FNS (septoplasty, rhinoplasty, nasal valve repair) at the University of North Carolina, Chapel Hill from July 1999 to July 2012 were retrospectively reviewed. All clinical and operative notes were reviewed, and patient demographics, medical comorbidities, and perioperative details collected.

The patients undergoing FNS were stratified by traumatic vs nontraumatic cause of the nasal deformity. Common traumatic causes included falls, sports injuries, assaults, and motor vehicle collisions. Patients were further stratified by the use of the ePTFE vs autologous material in reconstruction and whether they had undergone previous nasal surgery (Table).

Preoperative and postoperative photographs were routinely obtained and reviewed, with cosmetic and functional results taken from the medial record. The decision to use ePTFE was determined by the senior author (W.W.S.) based on the deformity, amount of septal cartilage available, and the patient's willingness to undergo harvest of costal or auricular cartilage. Those patients desiring to avoid undergoing harvest of autologous material outside of the nose and those with a paucity of septal cartilage were offered reconstruction with ePTFE; 40 patients overall underwent ePTFE reconstruction, 35 in the traumatic deformity group.

The surgeries were performed by or under the direct supervision of the senior author (W.W.S.). All patients underwent general anesthesia for the procedures. The external approach was used in all 35 traumatic deformity cases.

Table. Demographic and Clinical Characteristics of the Study Patients[a]

Characteristic	Total Patients (N = 404)	Implant Type Nonalloplast (n = 364)	ePTFE (n = 40)[b]	Infection (n = 1)	Contour Irregularity (n = 1)
Sex					
Male	197	181	16	1	1
Female	207	183	24	0	0
Age, mean, y	35.1	33.4	36.8	NA	NA
Deformity type					
Traumatic	255	220	35	1	1
Nontraumatic	149	144	5	0	0
Comorbidities					
Previous nasal surgery[c]	87	75	12	1	1
Tobacco use	76	68	8	1	1

[a] Unless otherwise noted, data are reported as number of patients.

[b] No spontaneous extrusions were seen.

[c] Of the 87 patients (44 male, 43 female) who had undergone previous nasal surgery, 61 had traumatic nasal deformity, and 26 had nontraumatic nasal deformity.

Figure 1. Male Patient With Preoperative Traumatic Deformity and Postoperative Results

A and C, Preoperative traumatic nasal deformity in a 17-year-old male patient. B and D, Postoperative photographs taken 10 months after primary functional nasal surgery and dorsal augmentation with expanded polytetrafluoroethylene.

Osteotomies, if required, were carried out before placement of the implant. New sterile gloves were applied before handling the implant material. Sterile 1- or 2-mm-thick ePTFE sheets were tailored to an appropriate shape, varying in size to fit the defect. If additional thickness was needed, the implants were stacked and layered with permanent suture fixation. Dorsal implants were held in place with a temporary transcutaneous horizontal mattress suture passed into the sub-SMAS (superficial musculoaponeurotic system) dissection plane, through the cephalic end of the implant and back out through the skin. The implant was then parachuted into position, and the suture was tied externally. Precise placement was confirmed by direct inspection. The absence of any surface irregularities or step-off deformities was confirmed prior to closure. Typically the caudal end of the implant was secured using a permanent suture to the underlying cartilaginous vault near the anterior septal angle. The incisions were meticulously closed followed by the application of paper tape and external nasal splints, which were left in place for approximately 1 week. Perioperative and postoperative antibiotics were used in all cases for 1 week.

The Fisher exact test was chosen for statistical analysis, given our small sample size and retrospectively collected data, and was performed using SPSS software, version 5 (IBM Corporation).

Results

During the 13-year period from July 1999 through July 2012, 404 patients (197 male, 207 female) underwent FNS. Of those, 255 procedures were to treat traumatic deformities. Forty patients altogether required the use of an ePTFE implant, 35 of those 40 deformities being associated with a traumatic injury (Table). The mean age of the patients undergoing ePTFE reconstruction was 36 years (age range, 17-65 years). Follow-up periods ranged from 1 to 47 months (mean follow-up, 9 months). Of the 35 ePTFE FNS reconstructions of traumatic nasal defects, 23 were primary reconstructions, and 12 were secondary (**Figure 1** and **Figure 2**).

The site of implant placement was at the nasal dorsum in all 35 cases; ePTFE was not used in any other sites. The thickness of the implants used ranged from 1 to 8 mm with 4 mm being the most common thickness (n=17; 43%) (**Figure** 3).

The immediate postoperative course was unremarkable in 33 of the 35 patients. One patient developed a postoperative infection, which appeared 10 weeks postoperatively following further trauma to the nose. This was treated with antibiotics but was refractory to medical management, and exposure occurred, necessitating operative removal of the implant and revision of the reconstruction 3 months after his initial surgery. In addition, 1 patient had an unsatisfactory contour irregularity, which was managed with implant removal and revision of the reconstruction 20 months after his initial surgery without the use of an implant. Excess scar tissue formation also appeared to play a role in the contour irregularity.

There were no factors identified with increased likelihood of infection. Variables including sex, tobacco use, diabetes, immunosuppression, implant thickness, suture material, and prior septorhinoplasty were analyzed ($P > .05$ for all). Both patients requiring removal had prior nasal surgery, and both were smokers who continued to smoke after their revision septorhinoplasties. There were 6 other smokers in the traumatic defect ePTFE reconstruction group who did well with their nasal implants. There were no perioperative infections noted.
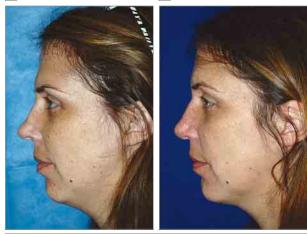
Discussion

Autologous cartilage grafts have long been considered the preferred grafting material for reconstruction in FNS. When there is adequate supply, cartilage grafts are considered the preferred material for reconstruction, since cartilage grafts are less likely to lead to infection or extrusion and are also generally considered to be more resistant and resilient should future nasal trauma occur.[2,20-22] Complications surrounding autolo-

Figure 2. Female Patient With Preoperative Traumatic Deformity and Postoperative Results

A   Preoperative oblique view

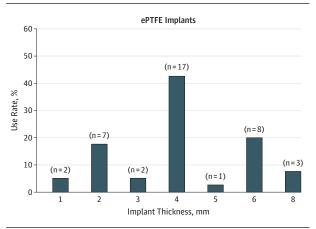B   Postoperative oblique view

C   Preoperative profile

D   Postoperative profile

A and C, Preoperative traumatic nasal deformity in a 36-year-old woman. B and D, Postoperative photographs taken 5 months after primary functional nasal surgery and dorsal augmentation with expanded polytetrafluoroethylene.

Figure 3. Expanded Polytetrafluoroethylene (ePTFE) Implant Thickness Comparison

The most commonly used ePTFE implant thickness was 4 mm for dorsal augmentation in functional nasal surgery for traumatic nasal deformity. No 7-mm thickness was used for any reconstruction.

gous grafts have been associated with surgical technique, graft contouring, recipient bed preparation, donor-site morbidities, and warping or migration of the cartilaginous graft itself.[23] Other considerations when choosing reconstructive materials include the patient's preference to avoid a second surgical site as well as the additional time, morbidity, and cost associated with harvesting and preparing the autologous graft.

In our series, 220 patients with traumatic nasal deformity underwent FNS without the use of ePTFE. They were found to have sufficient autologous material for reconstruction of structural deficiencies and contour irregularities at the time of their surgery.[2,3,15,20] Not a single case of infection occurred in this group. Autologous materials remain the preferred graft material for the vast majority of defects and deficiencies encountered in FNS. However, surgeons must always consider the donor site morbidity, graft warping, possible graft visibility, resorption, and availability when choosing between autologous grafts and alloplastic materials.[22,24,25]

The use of alloplastic implant material has gained acceptance in facial plastic and reconstructive surgery. The advantages of alloplastic materials include the abundant supply, structural integrity, and pliability when designing and creating a custom-made implant. This translates into increased efficiency, decreased operative times, and avoidance of a donor site.[3,19,26] Within our series, the amount of dorsal augmentation needed was determined at the time of surgery (Figure 3). An advantage of using ePTFE is the ability to customize the alloplast to the patient's exact deformity at the time of the surgery by adding and removing stacked grafts until appropriate augmentation has been achieved.

Peled et al[6] performed a meta-analysis on the most commonly used alloplastic implants from 1966 to September 2005 and concluded that the low complication rates associated with alloplastic materials supports their substitution in place of autologous materials. In addition, they found ePTFE to have a superior safety profile to that of pHDPE or silicone.[6]

The most common complications associated with alloplastic implants are related to infection, migration, and contour irregularities[3,9]; in our series, infection and contour irregularities were the only 2 complications encountered. Godin et al[15,18] reviewed their experience at 6 and 10 years with a total of 309 cases and found infection rates of 2.2% and 3.2%, respectively. They noted that 30% of their patients with postoperative complications had preexisting septal perforations. Based on this finding, they recommended against the use of ePTFE in patients with preexisting septal perforation. Conrad at al[3] reported on 521 patients with 685 implants over 17 years and noted only a 1.9% incidence of infection. They described a 2.9% surgical complication rate related to migration, buckling, or contour irregularity.[3] Comparable incidences of complications have been noted between ePTFE and autologous grafting materials.[22,25]

Recently, 2 large series have been reported highlighting the results of ePTFE use in rhinoplasty. Dong et al[26] described over 1700 primary rhinoplasty patients in China who underwent

augmentation with ePTFE with a 1% infection rate and 3% malposition complication rate. Yap et al[19] reviewed the clinical records of 1054 patients who underwent augmentation rhinoplasty (95.6% primary) using ePTFE implants with only a 0.38% incidence of infection and 1.89% incidence of contour deformity or migration. The low incidences of complications reinforces the safety and effectiveness of ePTFE in a large clinical series related to primary rhinoplasty.

The impetus to our study was to explore the efficacy and safety of ePTFE in the setting of traumatic nasal deformity. Conrad et al[9] in 1998 reported that 24% of their revision patient population (38 patients) underwent "major revision," meaning that the patients had traumatic injury or required extensive revision. "Minor revision" was used to describe their revision procedures with minimal reconstructive demands. The six patients with complications in their study were not noted to have undergone major revision surgery. In 2008, Conrad et al[3] reported that 76.2% of their patients were revision cases, but complications were not grouped based on primary vs secondary rhinoplasty. In contrast, several authors have stratified their infection and contour irregularities by primary vs secondary (revision) rhinoplasty, showing increased likelihood of complications in secondary cases.[5,15,19,26] Jin et al,[27] in a multicenter study, showed a complication rate of 4.6% in their secondary cases compared with 1.9% in their primary surgeries with a mean follow-up period of 18 months.

Other sources of complications including exposure and extrusion have been linked to specific implantation subsites. Several authors have cited the tip and columella as nonideal for ePTFE placement owing to minimal soft tissue coverage.[3,5,9,19,26,28] In our series, the implants were used solely at the level of the nasal dorsum with no evidence of spontaneous exposure or extrusion. The functional aspects of all procedures were preferentially corrected with autologous material, and the aesthetic dorsal irregularities were corrected with alloplastic material in those patients for whom it was deemed appropriate based on the deformity, amount of septal cartilage available, and the patient's willingness to undergo harvest of costal or auricular cartilage. Similarly, in an effort to avoid the use of ePTFE in the nasal tip, autologous material was prioritized to nasal tip grafting prior to its use in the dorsum. Others have described techniques aimed at decreasing risk of infections, such as using intraoperative vacuum-mixed antibiotic-impregnated implants or soaking the ePTFE in an antibiotic solution prior to placement.[3,9,19,26,29] However, no formal controlled trials have been published.

In the setting of infection or extrusion of alloplasts, the surgeon must consider reconstructive timing, materials, and approaches. Some authors have looked at the timing of reconstruction, and most authors use autologous cartilage or cadaveric costal cartilage for immediate reconstruction after alloplast complications necessitating removal.[28,30,31]

Most surgeons would agree that patients presenting for surgery 6 weeks after their initial trauma are similar to the majority of patients presenting for FNS. However, our retrospective study was designed to evaluate the safety and efficacy of ePTFE reconstruction techniques in patients with nasal injuries. Our series demonstrates the use of ePTFE for reconstruction of the nasal dorsum in the setting of traumatic injury as a safe alternative to autologous material: of 35 ePTFE reconstruction procedures for traumatic deformity, only 2 complications occurred, 1 infection (3% rate) and 1 contour irregularity (3% rate). This falls within the accepted range reported in many other series.[3,5,9,14,15,18,26,28] Our series serves as a unique review of patients with traumatic nasal deformity as the primary indication for surgery compared with these previously published series. Our population consisted of 35 individuals who underwent major surgery, as defined by Conrad et al,[9] with 33% of our group (n=12) falling into the most complex category: posttraumatic deformity requiring revision surgery. In our series, both complications (1 infection and 1 contour irregularity) were seen in traumatic revision cases as well. In addition, both patients with complications were smokers. Of the 35 cases of traumatic ePTFE reconstruction, 6 patients smoked, and 2 of those 6 had complications. However, this did not reach statistical significance as an adverse factore, likely owing to the small sample size.

In the present series, we documented the incidences of contour irregularities and dorsal deviation among the ePTFE-reconstructed traumatic deformity cases, and only 1 patient of 35 required revision from the dorsal deformity. The incidences of other complications such as septal deviation, nasal valve collapse, alar retraction, or other tip deformities including overprojection or overrotation were not evaluated because these regions were outside the site of ePTFE augmentation.

We also annotated the complications in relation to the nasal dorsum. Despite the possible effects that trauma may have had on the natural barriers to infection, including disruption of the skin–soft-tissue envelope and the nasal mucosa, we found that patients with traumatic nasal deformities could be treated and categorized in a similar fashion to patients with nontraumatic deformities presenting for functional or cosmetic rhinoplasty.

Limitations of our study include the retrospective nature of the review, limited duration of follow-up in some instances, and the small sample size. Direct controls were not evaluated, although there was a large portion of our patients with traumatic deformity (86%) who did not undergo ePTFE implantation. These patients underwent autologous grafts and could serve as the counterpart to those patients who underwent augmentation with ePTFE when evaluating complications and infections. The numbers were disproportionate between these 2 groups, limiting meaningful statistical analysis.

Conclusions

The use of ePTFE implants in FNS for traumatic nasal deformity demonstrated a low risk of complications: 1 infection and 1 contour irregularity in 35 patients. Larger-scale studies directed toward the use of ePTFE implants in a similar population are still necessary. Based on our findings as well as those of other authors, ePTFE is an excellent alternative or adjunct to autologous materials for reconstruction of the nasal dorsum where exposure to the nasal cavity is unlikely and soft-tissue coverage is adequate.

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