

Expanded Polytetrafluoroethylene Implants in Rhinoplasty: Literature Review, Operative Techniques, and Outcome

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ABSTRACT

Gore-Tex, a form of expanded polytetrafluoroethylene (ePTFE), over the past 30 years has attracted much attention as an alloplast for use in rhinoplasty, both from advocates and opponents of its use. It has many desirable traits as an alloplast implant, but many surgeons harbor hesitation and reluctance for alloplast use in rhinoplasty based on historical data of previous nasal implants. Only when objective data from large series of patients with long-term follow-up become available will such skepticism be resolved. Large series of patients with Gore-Tex implant placement during rhinoplasty are beginning to emerge in the literature. The purpose of this article is twofold. The first is to provide the reader with an up-to-date review of the literature on the host response to polymer implants and, second, of the current indications and operative techniques for use and outcomes of Gore-Tex implants in rhinoplasty.

KEYWORDS: Gore-Tex, expanded polytetrafluoroethylene, rhinoplasty, nasal implants

An expanded polytetrafluoroethylene (ePTFE; Gore-Tex, W.L. Gore & Associates, Flagstaff, AZ) was originally developed in 1969 and first marketed in 1971. W.L. Gore is said to have shown a swatch of this material to a cardiovascular surgeon friend demonstrating its ability to retain water yet breathe, allowing smoke to pass through its porous framework.¹ Soon afterward, the first animal experiment as a vascular conduit implant was performed. This started a cascade of events leading to its introduction and increasing applications in general, cardiovascular, urogynecologic, fetal, and reconstructive surgery²⁻⁴ (Fig. 1).

BASIC CHEMICAL MAKEUP

ePTFE is a polymer of monomeric units of two carbon atoms doubly bonded (ethylene monomer) and each with two fluorine moieties, $(-\text{CF}_2=\text{CF}_2-)_n$. The PTFE polymer is extruded under pressure through a dye, creating a microporous framework consisting of PTFE nodules interconnected with PTFE fibrils.⁵ The resultant ePTFE relies on the extremely strong bond between carbon and fluorine for its nondegradable, biologically inert properties. There is no known enzyme in the body capable of cleaving carbon-fluorine bonds.⁶ In addition, the highly electronegative fluorine acts as a shield to lower the sur-

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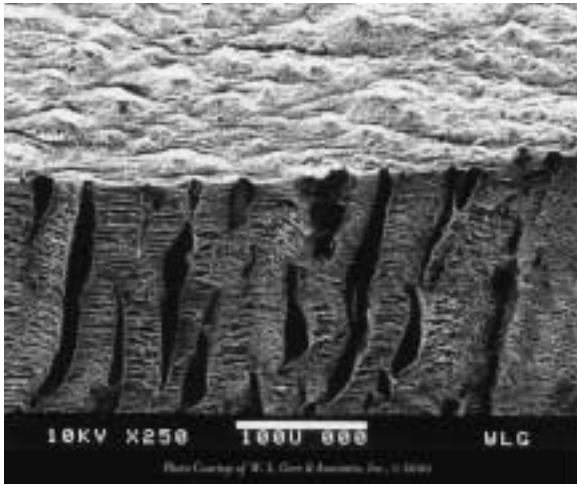


Figure 1 Scanning Electron Microscope (SEM) demonstration of the microstructure of the GORE subcutaneous augmentation material (SAM) that optimizes the balance between tissue ingrowth and revisability. GORE SAM is a trademark of W.L. Gore & Associates.

face energy of the polymer, resulting in its nonstick properties.¹ Because of its electronegative surface, it is impervious to blood and it is purported to be “non-thrombogenic.”⁴ The macromolecule can form long chains of repeating units with molecular weights ranging from 400,000 to 10,000,000 molecular units.¹ The woven pattern of fibrils in the nonreinforced sheets allows the implant material to stretch in any dimension as well as to compress in thickness.⁷ This is evident when the implants are grasped with forceps during placement, which leaves forceps imprints on the implant. ePTFE-reinforced sheets are commercially available that are reinforced with fluorinated ethylene propylene (FEP) to give added rigidity for better preimplantation shaping, shaving, and modification but still retain its softness.¹

The various products available for rhinoplasty are nonreinforced soft tissue augmentation (SAM) sheets in 1-, 2-, and 4-mm thicknesses; reinforced SAM sheets in 4.5- and 7.0-mm thicknesses; and preformed reinforced nasal implant in 2.2- and 3.4-mm thicknesses (Fig. 2).



Figure 2 SAM family of implants. GORE SAM is a trademark of W.L. Gore & Associates. (Courtesy of W.L. Gore & Associates.)

Inflammation

The life of the implant depends largely on the host inflammatory response to implant compatibility. After implantation, polymeric implants, due to their hydrophobic properties, immediately acquire a layer of host proteins. Albumin, immunoglobulin G, fibrinogen, fibronectin, vitronectin, and proteoglycans are among the proteins that predominantly adsorb readily to polymeric implants.⁸ This occurs by progressive denaturation, at times exposing potential epitopes for an immune response. Albumin appears to provide a protective coating to improve the polymer compatibility with the host by not attracting inflammatory cells. On the other hand, fibrinogen appears to elicit the greatest acute inflammatory response to implanted polymers.^{6,8} As a rule, host cells do not adhere directly to the surface of synthetic implanted materials. Extracellular proteins and proteoglycans form a substrate to which the cells attach. Interactions with cell membrane receptors furnish the linkage for cellular attachment to adsorbed extracellular matrix proteins on implant surfaces.⁶ The predominant cells that attach to the protein layer are the fibroblasts. The fibroblasts lay down immature collagen over the matrix on the implant and into the interstices of porous implant. This ingrowth of collagen fibers provides the framework for subsequent cellular adhesion.⁹

Another cell type involved in the inflammatory response is the macrophage. They are capable of engulfing and removing particles less than 20 μm in size but incapable of engulfing particles greater than 100 μm in size. The greatest likelihood of inflammatory reaction occurs when grafts fragment into particles ranging from 20 to 60 μm in size. Macrophages are able to engulf the particles of this size but are not able to clear them. This causes cell death with resultant release of intracellular cytokines and lysozymes, thereby producing a local inflammatory response.⁶ This local inflammatory response induces other macrophages to engulf the debris, which contains the undigested particle. These macrophages also die, propagating a chronic inflammatory response.⁹ A classic example of this cyclical inflammatory response is that of Proplast, a polytetrafluoroethylene carbon implant. Proplast had been used for malar, chin, nasal, and orbital floor implants with acceptable complication rates. When used as an interpositional disc implant in the temporomandibular joint, however, the results were catastrophic. Over time, the implant fractured into microfragments under the load of the temporomandibular joint. Moreover, the particulate fragments of Proplast elicited vigorous foreign body reactions and subsequent erosion of the joint and adjacent bone, with occasional perforation into the middle cranial fossa.¹⁰ In 1990, the Food and Drug Administration issued a safety warning against the use of the implant. Proplast is no longer manufactured in the United States.

Porosity and Infection Rate

The ePTFE polymer has pore sizes ranging of 10 to 30 μm , averaging 22 μm in diameter.³ Implants with pore sizes greater than 1 μm are capable of harboring bacteria.^{6,9} Macrophages necessary for host antimicrobial activity need pore sizes greater than 50 μm to infiltrate materials.⁹ The ideal infection-proof implant would have no pores (i.e., silicone) to prevent bacterial invasion or pores greater than 50 μm to allow tissue ingrowth and cellular antimicrobial activity. However, experimental studies examining infection rates in porous implants have shown unpredictable results. Merritt et al. showed increased infection rates with porous materials compared with dense ceramic when injected with *staphylococcus aureus* subcutaneously at the time of implant placement but decreased infection rates when injected 1 month later. However, both were statistically significant only at higher bacterial concentration of 10^5 . At lower concentrations, there was no statistical difference between the implant infection rates, and, at higher concentrations, the infection rates were close to 100% for both. The authors postulated that microorganisms may evade the host defense mechanisms if they enter the pores of the implant before tissue infiltration but that once the implant is established with host tissue the bacteria are less apt to establish infection.¹¹ In a similar study looking at the role of implant porosity on infection rates, Kiechel et al. were not able to demonstrate any statistical difference in behavior from solid controls.¹² However, in another study, Karlan et al. demonstrated statistically significant decrease in infection rate with fluorocarbon implants compared with silicone.¹³

Infiltration

Hanel et al. showed by light microscopy an ingrowth of mesenchymal cells into the internodal spaces from both sides of the vascular implant. Mature collagen was recognized in the interstices. Neocapillary formation was noted only at the outer surface of the implants.⁴ Fibroblasts were found within the interstices of the material, and collagen had penetrated into the anterior surface of the patch for a mean distance of 200 μm , demonstrating good healing within the 5-month period of the implant. A minimal inflammatory response was noted.¹⁴ Similarly, Maas et al., in an animal study, have examined the implant with the host tissue under routine light and scanning electron microscopy, demonstrating minimal inflammatory cell reactions that diminish and stabilize over time. This is in contrast to Mersilene, characterized by acute and chronic inflammatory response that does not diminish with time, and Proplast, which elicits an intense and ongoing inflammatory cell reaction that increases dramatically.¹⁵ Moreover, the porosity permits the ingrowth of tissue to stabilize and may help to prevent

micromovements of the implant, minimizing the chronic inflammatory response known to cause extrusion of the silicone nasal implants.

Carcinogenesis

Implant-associated carcinogenesis is an important consideration with nonbiodegradable implants, especially when the surgery is elective, as is the case with rhinoplasties, but it has not been reported with Gore-Tex in its over-30 years of clinical use. To date, metal fixation devices have been associated with 20 cases of malignancies, 1 from a head and neck region, with latencies ranging between 1 and 30 years. In addition, there has been a significantly increased risk of lymphatic and hematopoietic tumors in 1358 patients after total hip replacement. However, cancers in association with polymer implants appear to be rare, with Dacron vascular prostheses having been reported with five cases of sarcomas, with latency of 6 months to 5 years. In its over-30 years of clinical use, not one case of malignancy associated with ePTFE has been documented.¹⁰

GORE-TEX AND RHINOPLASTY

The first experimental study using ePTFE in facial aesthetic surgery was described by Neel in 1983.¹⁶ Gore-Tex cylinder materials were implanted in the perichondrial space and the subcutaneous tissues of the face and paraspinal region of New Zealand white rabbits. Histologic examination demonstrated minimal histiocytic and foreign body giant cell reactions in the surrounding tissues. It permitted tissue ingrowth yet it could be easily removed. The results were favorable and showed much promise. This study opened the door for Gore-Tex use in facial aesthetic surgery. Since then, applications in the field of plastic surgery have included reconstruction for facial paralysis¹⁷ and volume augmentation for the chin, malar area, nasal dorsum, nasolabial folds, lips, and eye defects,⁷ as well as for temporal deficiencies as a soft tissue filler.² For subcutaneous augmentation, a complication rate of less than 1% in a series of over 800 Gore-Tex implantations is documented.²

Rothstein and Jacobs¹⁸ reported a series of 11 patients with traumatic saddle nose deformities who underwent augmentative primary rhinoplasty with Gore-Tex implants. One-millimeter-thick soft tissue patches were rolled to "several layers," trimmed, sutured with 3-0 chromic gut sutures, and secured with stay sutures tied over a petroleum gauze bolster. Two patients developed erythema, which resolved with empiric 10-day intravenous cefazolin. There were no other incidences of inflammation, infection, skin necrosis, prosthesis migration, or extrusion. Patients were followed up for up to 4 years (Table 1).

Table 1 Review of the Literature

Author	Year	N	Age (mean)	Follow-up (mean)
Rothstein et al.	1989	11	18–41	6 wk–48 mo
Stoll et al.	1991	24	— ^a	12–24 mo
Owsley et al.	1994	106	— ^a	1–60 mo
Queen et al.	1995	12 ^b	18–52	6–24 mo
Conrad et al.	1996	189	15–70 (36.5)	3–72 mo (17.5 mo)
Mendelsohn	1998	30	— (35) ^a	18 mo to — ^a
Godin et al.	1999	309	— ^a	5–125 mo (40.4 mo)
Lohuis et al.	2001	67	— ^a	3–72 mo (17.9 mo)
Ham et al. ^c	2003	55	— ^a	1–60 mo

^aNot reported.

^bTwelve patients received Gore-Tex implants. 2 were lost to follow-up.

^cUnpublished data.

The second series, reported by Stoll, came out in 1991 with 24 patients followed for 1 to 2 years.¹⁹ Details on operative techniques and preparation are lacking other than two case reports, which are described. There were no reported complications of any type. It deserves mention that only a single layer of implant was used in every case, and the authors advised that further studies are required for multilayering of the implants.

It was not until 1994 that a large series of 106 patients over a 5-year period was reported by Owsley and Taylor.²⁰ Gore-Tex patches, 1 or 2 mm in thickness, “layered” and sutured together with resorbable suture material were used. For nasal dorsal Gore-Tex placement, Owsley first described using a traction suture for placement. A 2–0 Vicryl suture was secured to the cephalic end and the other end was sutured to a Keith needle. The Keith needle was then advanced along the dissected dorsum and through the overlying glabellar skin to pull the implant into place. Special mention was made to place the implants far enough cephalically to avoid a noticeable step-off. Both external and intranasal approaches were used, although in the small, localized defects the intranasal approaches were utilized using smooth forceps to place the implants into precise pockets. Three case reports are described, one in which “3 layers of 1- and 2-mm Gore-Tex” material are used. Aside from the case reports, no other mention of implant thickness is discussed. Perioperative prophylactic intravenous antibiotics and 7 days of postoperative oral antibiotics were given. The only complications reported are six cases of overaugmentation, four of which are revised in vivo, likely facilitated by use of resorbable suture material for layering, and two that were removed in toto. Upon removal, the implant was found to be intimately fixed by fibrous connective tissue without significant capsular formation. There was no mention of revisions or defects after removal of the implants in these two patients nor was the distinction of primary versus revision cases made (Table 2).

Queen and Palmer published a paper reporting 12 patients followed up for up to 2 years.²¹ They used the Gore-Tex implants as dorsal onlay in 11, shield grafts in 8, and 1 each of the lateral onlay graft, columellar strut, and total lower lateral cartilage reconstruction. Two were lost to follow-up, and the 10 available patients were satisfied with the results. Two patients are reported to have stated the “material was flexible” but made no reference to which implant and its location and whether there was any functional airway collapse. They did mention that one of the drawbacks of Gore-Tex is its softness and reasoned that this would preclude its use as a shield graft. There were no complications reported.

Conrad and Gillman published the next large series of patients in 1998⁵ of a 6-year experience with Gore-Tex use on 189 patients. This was the first paper to actively make the distinction of primary versus revision rhinoplasty, to report the thicknesses of each implant used, and to document vacuum impregnation with Bacitracin solution in addition to perioperative and postoperative antibiotics. The intercartilaginous incision was utilized for the nasal dorsal implants except for two cases, in which an external approach was chosen and the transfixion incision was used to gain access to the premaxillary spine. Tip surgery was via delivery technique. Gore-Tex placement was performed last, after osteotomies and tip work, if any. The edges of the implants were tapered with a scalpel or compressed with a needle driver. The implants were placed mainly on the nasal dorsum (34%) and the lateral nasal wall (20%) but also in the premaxilla and supratip with multiple sites in 34%. The thickness of implants used ranged from 1 mm (38%) and 2 mm (49%) to up to 8 mm. There were two cases of inflammation with persistent hyperemia and excessive induration on continued systemic antibiotics in which the implants were removed, and five infections requiring removal. Seven implants with kinking and contour irregularities in the 1st year of use required revisions along with two for excessive augmentation. After these incidences,

Table 2 Review of the Literature: Results

Author	n	Primary	Revision	Inflammation	Infection	Overaugmentation	Removal	Implant Revision
Rothstein et al.	11	11	0	2 ^a	0	0	0	0
Stoll et al.	24	— ^b	— ^b	0	0	0	0	0
Owsley et al.	106	— ^b	— ^b	0	0	6	2 ^c	4 ^d
Queen et al.	12 ^e	— ^b	— ^b	0	0	0	0	0
Conrad et al.	211 ^f	52	159 ^g	2 ^h	5 ⁱ	2	7 ^j	9 ^k
Mendelsohn	30	— ^b	— ^b	1 ^l	3 ^m	2 ⁿ	3	2
Godin et al.	309	162	147	0	10 ^o	2 ^p	11	1
Lohuis et al.	66	19	47	0	0	1 ^q	1	0
Ham et al. ^r	55	— ^s	— ^s	0	0	0	0	0

^aTwo cases with erythema over the implant site, treated with 10 days of IV cefazolin empirically with improvement.

^bNot specified.

^cTwo implants were removed entirely for overaugmentation.

^dFour implants reduced in vivo intranasally.

^e12 patients received Gore-Tex implants; two were lost to follow-up.

^f189 patients with 211 procedures and 256 separate implants.

^gOf the 159 revision cases, 76% were minor and 24% major.

^hPersistent hyperemia with excessive induration but no exudate on systemic antibiotics.

ⁱPathogen not specified.

^jTwo with inflammation and five infected implants.

^kFour revisions for kinking, three for contour improvement. These seven performed within the 1st year of this series. Technique since then modified to "pull" technique using traction suture. Two revisions done for excessive augmentation.

^lOne straw-colored fluid collection, negative for culture not responding to antibiotics requiring graft removal.

^mAll three infected with *S. aureas*, one in combination with *Streptococcus pyogenes*. One resolved with antibiotic therapy. Two implants removed.

ⁿTwo cases of "excess scarring" with "persistent swelling" which required graft and scar revision.

^oAll 10 implants removed. Primary 1.2% versus revision 5.4% ($p < 0.02$). Three of 10 (30%) patients requiring implant removal for infection had septal perforation. One culture positive for *Pseudomonas aeruginosa* in Godin's 6-year review article.

^pOne removed, one revised.

^qOne implant removed secondary to overaugmentation and replaced with auricular cartilage.

^rUnpublished data.

^sCurrently under review.

a temporary 4–0 chromic catgut traction suture was used for traction placement to correct the problems with bunching that occurred when pushed into position. Gore-Tex implants ranging from 1 to 8 mm in thickness were placed in 189 patients. The initial implant revision rate was 4.7% (9 of 189 patients) but was reduced to 1.1% (2 of 189 patients) after the change in insertion technique. The total infection was 1.9% (5 of 256 implants, or 2.6% for 5 of 189 patients). The total complication rate (infection + inflammation requiring removal) was 2.7% (7 of 256 implants, or 3.7% for 7 of 189 patients). However, when broken down into primary and revisions, the complication rates were 1.9% (1 of 52 primary rhinoplasties) and 3.8% (6 of 159 revision rhinoplasties). The authors concluded that, with the exception of the nasal tip and columella or in which the graft or implant rigidity would be required, Gore-Tex implant is an excellent alternative to autografts or even preferable to autografts for localized depression of the lateral wall and deformities of the nasal dorsum or for use as a premaxillary plumping graft.

Mendelsohn and Dunlop reported a series of 30 rhinoplasty cases using Gore-Tex out of 310 consecutive rhinoplasties with minimal 18-month follow-up.²² There was one implant removed that was associated with inflammation manifesting as a collection of straw-colored

fluid, negative for cultures, and not responding to antibiotics. Three implants became infected, one that resolved with antibiotics, the other two requiring removal. All three were positive for *S. aureas* on culture, one in combination with *Streptococcus pyogenes*. All cases that required removal were multilayered grafts. It is postulated that the larger grafts are more disruptive to the blood supply and possibly lead to impaired response to infection. The authors also noted "persistent swelling" attributed to scarring and "reactive capsule" requiring two revisions for overaugmentation and suggested that surgeons consider slightly undercorrecting to allow for these changes (Table 3).

The latest series came from Lohuis et al. in 2001 consisting of 66 patients over 3 to 72 months; 19 were primary and 47 were revisions.²³ Implants were used exclusively on the dorsum via the external approach. The pocket was nearly the exact size as the implant. The implant was handled in a "no-touch" manner using new gloves and instruments in a clean field. The implants were soaked in Gentamycin solution and the pocket was irrigated with the same solution prior to placement. In one patient, the implant was replaced with auricular perichondrium and cartilage due to excessive augmentation. Otherwise, there were no complications. They postulated that possible reasons for this low complication rate are

Table 3 Review of the Literature: Prophylactic Antibiotic Usage

Author	Preoperative	Perioperative	Implant Impregnation	Postoperative (Oral)
Rothstein et al.	— ^a	Ampicillin, oxacillin	— ^a	Ampicillin, dicloxacillin; 10-day course
Stoll et al.	— ^a	— ^a	— ^a	— ^a
Owsley et al.	— ^a	Yes	No	7-day course
Queen et al.	— ^a	— ^a	— ^a	— ^a
Conrad et al.	— ^a	Yes	Bacitracin ^b	Yes
Mendelsohn	— ^a	Cephalosporin, ampicillin	— ^a	Amoxicillin, ampicillin; 5-day course
Godin et al.	Cephalosporin ^c	Cefazolin, clindamycin ^d	Lincomycin ^e	Cephalosporin; 7-day course ^c
Lohuis et al.	— ^a	Flucloxacillin ^f	Gentamycin ^g	— ^a
Ham et al. ^h	No	Cefazolin	No	Cephalosporin; 5-day course

^aNot specified.

^bVacuum impregnated with a bacitracin solution in a 20-cc syringe.

^cCephalosporin administration 2 days prior to surgery and 7-day course postoperatively reported in Waldman's "Preliminary Report," the first of the three articles. The postoperative oral antistaphylococcal antibiotics such as cephadrine or cephalexin given for 7 days are also mentioned in the second article.

^dIn the second article, intravenous cephalosporin used, with clindamycin as an alternate for patients who are allergic.

^eImplant is soaked in saline containing a broad-spectrum antibiotic such as lincomycin.

^fOne hour prior to starting.

^gImplant soaked in solution and pocket irrigated with same solution.

^hUnpublished data.

twofold: the external approach versus the intercartilaginous to minimize exposure of the implant to intranasal flora and the relatively short follow-up, as other alloplasts are known to extrude after a long period of time, even more than 10 years.

The largest series is a 10-year experience with 309 patients from Godin et al., published in 1999.²⁴ This paper is a follow-up of two previous papers, the original by Waldman in 1991²⁵ and Godin et al. in 1995, which at that time was a 6-year experience.²⁶ The cumulative patient data on the most recent paper only will be reviewed here, but the information in previous papers on preparation and operative techniques not mentioned in the current paper was assumed to be unchanged. This is the first paper to report a series utilizing the preformed dorsal implants reinforced with FEP. The external approach was utilized for two reasons according to the authors, one to place the incision as far away from the implant as possible by avoiding the intercartilaginous incision and to avoid introducing the implant intranasally. The maximal thickness of the implants used was 10 mm. One implant was removed due to excessive augmentation, at 5 months without further need for re-augmentation, and another implant, also for excessive augmentation, was revised and replaced into the dorsum. There was a significant difference ($p < 0.02$) in infection rates requiring implant removal between the 2 of 162 patients with primary rhinoplasty (1.2%) versus 8 of 147 revisions (5.4%). It is noteworthy that the complications (infection) have slightly risen, from 2.2 to 3.2%, with longer follow-up. Interestingly, one infection in the 6-year-experience paper had *Pseudomonas aeruginosa*-positive cultures. Other cultures were not specified. Grafts have required removal as long as 3 years after placement. The average postoperative duration to time of complication for the 10 pa-

tients was 16 months. Of these 10 patients, 3 had septal perforations, which were rare in the overall practice. The authors regard septal perforations as contraindications to Gore-Tex implant placement. The 299 patients (96.8%) with implants, which were not infected, were pleased with the results. A separate sterile table was used for preparing the implant, gloves were changed, and fresh instruments were used. The implant was fashioned into a boat shape, with the tapered point over the anterior septal angle. Specific mention is given for adequate cephalic dissection. Because the Gore-Tex resorption has never been observed, overcorrection of the defect is not necessary. When layering they are sutured with 5-0 polypropylene mattress sutures on a noncutting needle. Beveling is done with a #10 blade. The length is measured using a cotton-tipped applicator placed into the dissected dorsum. The implant is soaked in antibiotic solution and placed using a bayonet, making sure to remove any rolling of the edges. The caudal end is sutured to the anterior septal angle and tucked under the cephalic edges of the lower lateral cartilage. Tip modifications are performed prior to implant placement (Table 4).

Seven hundred sixty-nine rhinoplasties with Gore-Tex implantation are documented in the literature dating from 1989 to the present. There have been 18 infections and 2 cases of inflammation not responding to antibiotics that required removal. This gives us 20 of 769 procedures for an inflammation/infection-requiring-removal rate of 2.6%. However, when the numbers are broken down to primary versus revision for the three papers that made the distinction, we have 1.3% (3 of 233) for primary rhinoplasty and 4.3% (14 of 325) for revision rhinoplasty. The total combined for these three papers is 3.0% (17 of 558), which is in line with the cumulative rate of 2.6%.

Table 4 Review of the Literature: Implant Type, Thickness, and Layers Used

Author	Implant	Thickness/No. of Layers Used
Rothstein et al.	1-mm-thick soft tissue patch	Several layers of rolled sheets sutured with 3-0 chromic
Stoll et al.	— ^a	Single layer only
Owsley et al.	1- to 2-mm-thick soft tissue patches	"Layers" sutured together with resorbable suture ^b
Queen et al.	— ^a	— ^a
Conrad et al.	1- to 2-mm-thick soft tissue patches	1 mm thick in 38%, 2 mm thick in 49% "Up to 8 mm in some patients" Varying size from 10 × 30 mm for lateral nasal wall to 10 × 60 mm for the nasal dorsum.
Mendelsohn	2-mm soft tissue patch ^b	Double and triple layered ^b
Godin et al.	1, 2, and 4 mm SAM 4.5- and 7.0-mm reinforced SAM 2.2- and 3.4-mm preformed reinforced nasal implant	289 cases using SAM 28 cases using reinforced SAM 2 cases using preformed reinforced nasal implant Maximal thickness 10 mm
Lohuis et al.	1, 2, and 4 mm SAM	—
Ham et al. ^c	1 and 2 mm SAM	Maximal thickness 4 mm

^aNot reported.^bCase report using a three-layered implant mentioned in the article.^cUnpublished data.

As for excessive augmentation requiring additional procedures for revision or removal, the rate is 2.6% (20 of 769). Moreover, some patients did not require re-augmentation to correct deformities after implant removal in its entirety, and they were satisfied with the outcome.^{20,24} Mendelsohn and Dunlop attributed this in part to scar formation that was apparent on gross intraoperative inspection during implant revisions and suggested slightly undercorrecting to allow for these changes.²²

Along with the series, a case report of Gore-Tex extrusion from the nasal dorsum was found in the literature. The patient has a history of multiple nasal reconstructions and 18 months after the last surgery presented with an infected papule on the nasal dorsum and a visible implant. The Gore-Tex was removed and the wound healed completely in 2 months. The author concluded that multiple factors contributed to the extrusion: the history of multiple surgeries with scarring, the thickness of the Gore-Tex implant, and infection exacerbated by impaired vascular and lymphatic pathways. Cultures, however, were positive only for a nonpathogenic staphylococcus epidermidis.²⁷ Caution is raised by Schoenrock and Chernoff from their experience of Gore-Tex use in over 800 subcutaneous implantations for facial reconstruction. Their observation is that approximation of Gore-Tex to the dermis of the skin creates risks for potential exposure and infections or extrusion.² This may explain the extrusion in the previous patient and the probable increased risk with revisions due to the loss of fascial planes secondary to scar formation and possible dissection to the dermis (Table 5).

In the experience of the senior author in this practice, 55 patients have undergone rhinoplasty via trans-

Table 5 Review of the Literature: Implanted Sites in Rhinoplasty

Site	Author
Dorsum	Conrad, Godin, Lohuis, Mendelsohn, Stoll, Rothstein, Queen, Ham
Lateral nasal sidewall	Conrad, Owsley
Premaxilla	Conrad, Godin
Supratip	Conrad
Tip/shield	Owsley (soft tissue triangle), Queen (8 shield grafts, 1 columellar strut, 1 total LLC reconstruction)
Radix	Johnson ²⁸

columellar incision approach with Gore-Tex implant over the last 6 years, all for nasal dorsal augmentation (unpublished data). SAM sheets of 1-mm, 2-mm, and up to 4-mm thicknesses have been used. The implant is prepared with new gloves and new instruments. The implants are not vacuum impregnated nor are they prepared with antibiotic washes. The nasal dorsal skin is marked to indicate the appropriate size of the implant with both ends tapered to a point. The implant is placed over the marking for an imprint and trimmed. Subsequent layers are cut smaller to allow the outermost layer to drape over for better contouring, and a mattress suture is placed with a 6-0 Prolene in the midline to allow further tapering of the edges as needed. For placement, a 22-gauge spinal needle is introduced percutaneously through the inferior margin of the glabella and out underneath the elevated dorsal soft tissue envelop. A 6-0 Prolene is placed through the cephalic end of the implant. Both ends of the suture are then inserted into the spinal needle and



Figure 3 (A, C) Preoperative. (B, D) Postoperative.

out the other end. The implant is inserted under direct visualization using Cushing's forceps, and traction is applied simultaneously with the stay suture, which is then taped to the forehead to secure the implant. The stay suture is removed after 4 days. Wetting the suture ends facilitates simultaneous insertion of both ends into the needle. The caudal end of the implant is then trimmed and sutured down to the anterior septal angle. No implants have been noted to be malpositioned. No patient had septal perforations. There have been no incidences of graft infection or overaugmentation (Fig. 3).

CONCLUSION

There remains a natural hesitation and reluctance by surgeons to use alloplast material in rhinoplasty based on historical data of previous implants. Several implants

have received much enthusiasm initially only to reveal discouraging results years later. Gore-Tex, as an implant, has demonstrated favorable results in its over-12 years of use in rhinoplasty and provides an alternative when the morbidity associated with the donor site is undesirable and when autogenous grafts are insufficient or less than ideal. Although the infection rates of Gore-Tex are much higher than the rate of 0.1% for autogenous grafts, Gore-Tex may have a role in carefully selected patients. Only with time will the long-term results be revealed.

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