

# Applications of GORE-TEX Implants in Rhinoplasty Reexamined After 17 Years

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**Objective:** To determine the efficacy of GORE-TEX (W. L. Gore & Associates Inc, Flagstaff, Arizona) alloplast in rhinoplasty.

**Design:** A 17-year retrospective medical chart review at a teaching hospital, community hospital, and private facial cosmetic surgery center. A total of 521 patients (122 male and 399 female; age range, 13-70 years) were followed for 12 months to 17 years. All patients had undergone GORE-TEX implantation rhinoplasty (685 implants in 158 primary procedures and 508 secondary procedures) performed by 1 surgeon. Patient satisfaction, expressed with respect to desired cosmetic benefit and functional outcome, and physician assessment, based on aesthetic improvement, technical considerations, and complications, were evaluated. Results were assessed according to the follow-up notes in the medical chart reflecting patients' and surgeon's comments and full preoperative and postoperative photographic documentation.

**Results:** GORE-TEX alloplasts, 1 to 10 mm thick, implanted in the nasal dorsum (n=264), lateral nasal wall

(n=252), supratip dorsum (n=85), and premaxilla (n=84) showed excellent stability and tissue tolerance. Biological complications that required implant removal occurred in 1.9% of patients and included infection, soft tissue swelling, migration, and extrusion.

**Conclusions:** With the exception of the nasal tip, columella, or problems in which corrections would require rigidity of the grafted or implanted material, the GORE-TEX alloplast is a safe, inexpensive, and predictable alternative to autografts. In the present series, more than 95% of implants used were 1 to 4 mm thick. In the remaining 5%, 6 implants ranged from 8 to 10 mm thick, and we found them acceptable. It is our opinion that for both primary and secondary rhinoplasty with adequate endonasal and external soft tissue coverage, GORE-TEX should be strongly considered for major and minor corrections of the nasal wall and bridge in properly selected patients.

*Arch Facial Plast Surg.* 2008;10(4):224-231

**T**HE CHOICE OF AUGMENTATION material (grafts or implants) is one of many challenges confronting a rhinoplastic surgeon. There is a marked difference in the body response to grafts and to implants deserving our understanding and avoidance of interchangeable terms.<sup>1-3</sup> Authors who strictly adhere to the nomenclature reserve the term *grafts* for a tissue material. An autograft is a tissue transplanted from the same or a different site in the same individual, whereas a homograft is a transplant from another individual of the same species, and a tissue from a different species altogether is referred to as a xenograft or heterograft. A synthetic material that can be implanted (not grafted) is referred to as an implant or alloplast. Many articles<sup>4-16</sup> have been written on the topic of grafts and implants in rhinoplasty. There is no disagreement that the autologous cartilage is the most biologically acceptable augmentation material in rhinoplasty. Its shortcomings related to its esthetic ef-

fects, except when it is used around the nasal tip or columella, are also well known.

The main problem with cartilaginous grafts is warping. Large augmentation of the nasal dorsum can be achieved with costal cartilage autograft with minimal or no warping if it is carved from the central portion of the rib cartilage.<sup>17</sup> If thin grafts are required, costal cartilage is likely to produce more warping, and septal or conchal cartilage autografts are better for that purpose. Septal cartilage, especially in revision cases, may not be available, and auricular grafts, although meeting the thickness requirements, may not be sufficient in length for the nasal dorsum to provide a smooth contour, especially in thin-skinned individuals.

Inexorably, we encounter circumstances in which the use of an alloplast may present a practical and perhaps even superior solution from an esthetic standpoint.<sup>18-21</sup> A multitude of different alloplasts have been used in the past, including Silastic (AART Inc, Reno, Nevada), Proplast (Vitek, Houston, Texas), and Plasti-

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Pore (Porex Surgical Inc, Newnan, Georgia). Their use has been plagued by unacceptably high rates of migration, resorption, extrusion, or infection when applied in nasal reconstruction.<sup>22,23</sup> Others, such as Mersilene (Ethicon, Somerville, New Jersey) and Supramid (Ethicon), although stabilized by extensive tissue in-growth, have been shown to be very difficult to remove if necessary.

GORE-TEX (expanded polytetrafluoroethylene or ePTFE) (W. L. Gore & Associates Inc, Flagstaff, Arizona) is a polymer of carbon bound to fluorine formed into an inert weave of PTFE nodules and thin PTFE fibrils.<sup>24</sup> Its microporous nature allows in-growth of soft tissue into 10- to 30- $\mu$ m pores that provide adequate fixation of the implant yet allow its removal if necessary without disturbing surrounding tissues.<sup>23-28</sup> However, the controversy continues about the long-term efficacy of GORE-TEX because of the failure of other implant materials used in the nose in the past. In addition, there are occasional instances of inflammation associated with its use, leading to extrusion in neglected cases. These rare instances can easily be treated by removal of the implant without permanent sequelae.

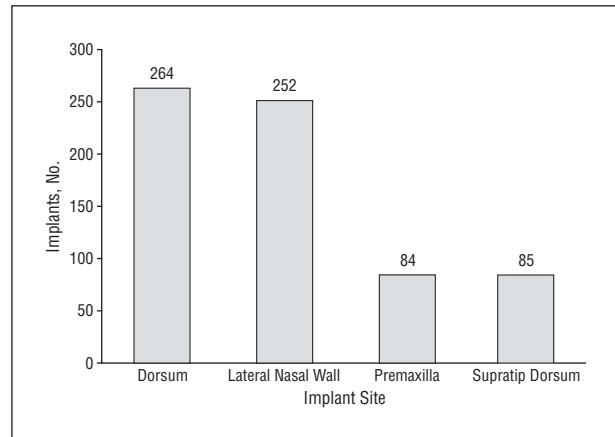
The proper review of reports on GORE-TEX as a nasal implant must include a number of factors. A review of the literature<sup>18-21,27,29-31</sup> suggests that many accompanying clinical circumstances contribute to its successful retention by the tissues. They include applied surgical methods, particular attention to the sterility and handling of the implant, and the choice of patients. Individuals receiving immunosuppressive therapy or with diabetes mellitus, septal perforation, or persistent chronic infection even in a remote site have to be counted in a special category because they are much less suitable for the placement of implants than the healthy general population.

Whether a wound becomes infected after surgery depends on a complex interaction between surgery-, patient-, wound-, and microbial-related factors.<sup>32,33</sup> Surgery-related factors include the applied surgical methods with particular attention to the sterility and handling of the implant.<sup>34</sup> Patient-related factors include diabetes mellitus, nutritional status, host immunity, use of steroids, or immunosuppressive drugs and age.

Diabetes mellitus is one risk factor in the host's ability to control the bacteria that inevitably settle into the wound during surgery. Dysfunctional healing occurs when there is not enough glucose, oxygen, or proteins supplied to the surgical site tissues.<sup>35</sup> Next, nutritional factors contribute to appropriate wound healing as well as the inflammation process. Poor nutrition results in impaired fibroblast proliferation, prolonging inflammation.<sup>32</sup>

Immunocompromised patients, or those receiving immunosuppressive agents, are at particular risk for developing infection following rhinoplastic surgery. Glucocorticoids inhibit leukocyte infiltration of inflamed tissues, interference with mediators of the inflammatory response, and suppression of humoral immune responses.<sup>36</sup> Finally, age-related changes in the immune system must also be considered, including atrophy of the thymus (the site of T-cell maturation), decreased ability to mount a delayed-type hypersensitivity response, and a generalized reduction of lymphocytic function.<sup>36</sup>

No matter what the circumstances, as with any implant, surgeons will either embrace or reject its use based



**Figure 1.** Distribution of implants; 24 of the 33 overall complications (73%) occurred in the dorsum, whereas 8 (24%) were observed in the lateral nasal wall and 1 was in the supratip.

on how well the material fares aesthetically, its ease of use, and, in particular, the frequency of complications such as extrusion, infection, and revision rates. That said, an implant's "success" in one surgical site is no guarantee of success in another site, and the thin skin-soft tissue envelope of the nose might well render this a "high-risk" area for implant materials.

For that reason, sharing long-term data and the reporting of extended clinical experiences with the use of GORE-TEX in rhinoplasty are invaluable to all rhinoplastic surgeons. With that as an impetus, we studied and present a 17-year experience with GORE-TEX implantation in rhinoplasty—to our knowledge, the longest such review in the literature.

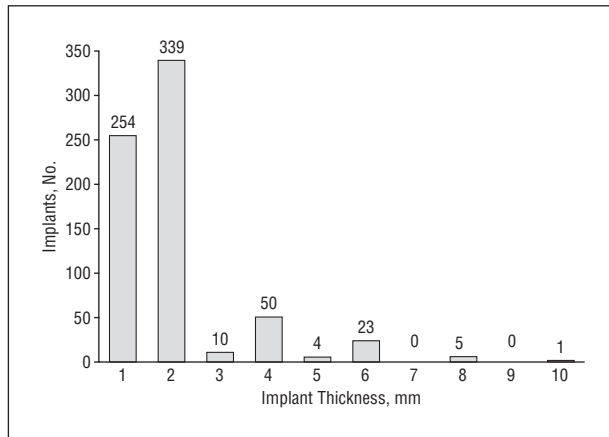
## METHODS

### SUBJECTS

A 17-year retrospective medical chart review of 521 consenting patients undergoing GORE-TEX implantation rhinoplasty was performed from December 1989 to January 2007 by the senior surgeon (K.C.) at a teaching hospital, community hospital, or in a private, accredited surgical facility. The participants included 122 males and 399 females (age range, 13-70 years), with a mean duration of follow-up of 71 months (median duration, 45 months; range, 12 months to 17 years).

All cases were categorized as either primary or revision rhinoplasties (including both secondary and multiple rhinoplasty). In total, 685 implants were inserted in 158 primary procedures (23.7%) and 508 revision procedures (76.2%) (666 total procedures). Implant site placement was recorded according to the aesthetic subunit, including the dorsum, lateral wall, supratip, or premaxilla. Most of the implants were placed in the dorsum (264 [38.5%]) and lateral wall (252 [36.8%]) (**Figure 1**). In patients who received implants to multiple sites, each implant was considered individually because every site offered a distinct potential for complication. The thickness of each alloplast was recorded and ranged from 1 to 10 mm (**Figure 2**). A total of 339 of the implants (49.5%) were 2 mm thick; 254 (37.1%) were 1 mm thick, and the remaining 92 (13.4%) ranged from 3 to 10 mm thick.

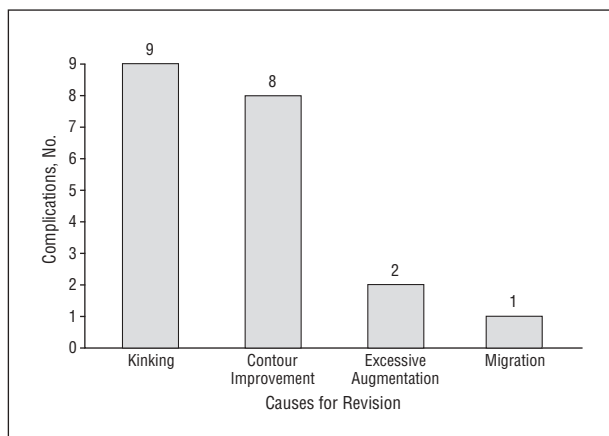
Outcome measures included patient satisfaction, expressed with respect to the desired cosmetic benefit and functional outcome, as well as a physician assessment that was based



**Figure 2.** Distribution of graft thickness; 14 of all 33 complications (42%) involved a 1-mm GORE-TEX (W. L. Gore & Associates Inc, Flagstaff, Arizona) implant, with 16 (48%) corresponding to 2-mm implants, 2 corresponding to 4-mm implants, and 1 to a 6-mm implant.



**Figure 3.** Vacuum antibiotic impregnation of the GORE-TEX (W. L. Gore & Associates Inc, Flagstaff, Arizona) implant. The arrow demonstrates the implant within the syringe.



**Figure 4.** Complications of surgical technique. Overall complication rate, 2.9%.

on aesthetic improvement, technical considerations, and complications. Results were assessed according to the follow-up notes in the medical chart reflecting patients' and the senior surgeon's comments and full preoperative and postoperative (at 1, 6, and 12 months) photographic documentation.

Complications were divided into 2 categories: those of surgical technique and those of a biological nature. Complica-

tions of surgical technique included kinking, migration, excessive or inadequate augmentation, and asymmetry that required a revision surgery to improve contouring. Complications of a biological nature included soft tissue reaction, infection, and extrusion.

## SURGICAL TECHNIQUE

All procedures were performed under local anesthesia, combined local and general anesthesia, or intravenous sedation. Intercartilaginous incisions were used to gain access to the nasal dorsum or lateral nasal wall in all but 2 cases in which an external approach (open rhinoplasty) was performed. For isolated defects of the lateral wall, a subcutaneous pocket was developed in that area only. A transfixion incision through the membranous septum was used to gain access to the premaxillary spine. Any concomitant surgery to the nasal tip was performed using the alar delivery technique that included both intercartilaginous and marginal rim incisions. Osteotomies and any nasal tip work, if required, were always performed before placement of the GORE-TEX alloplast.

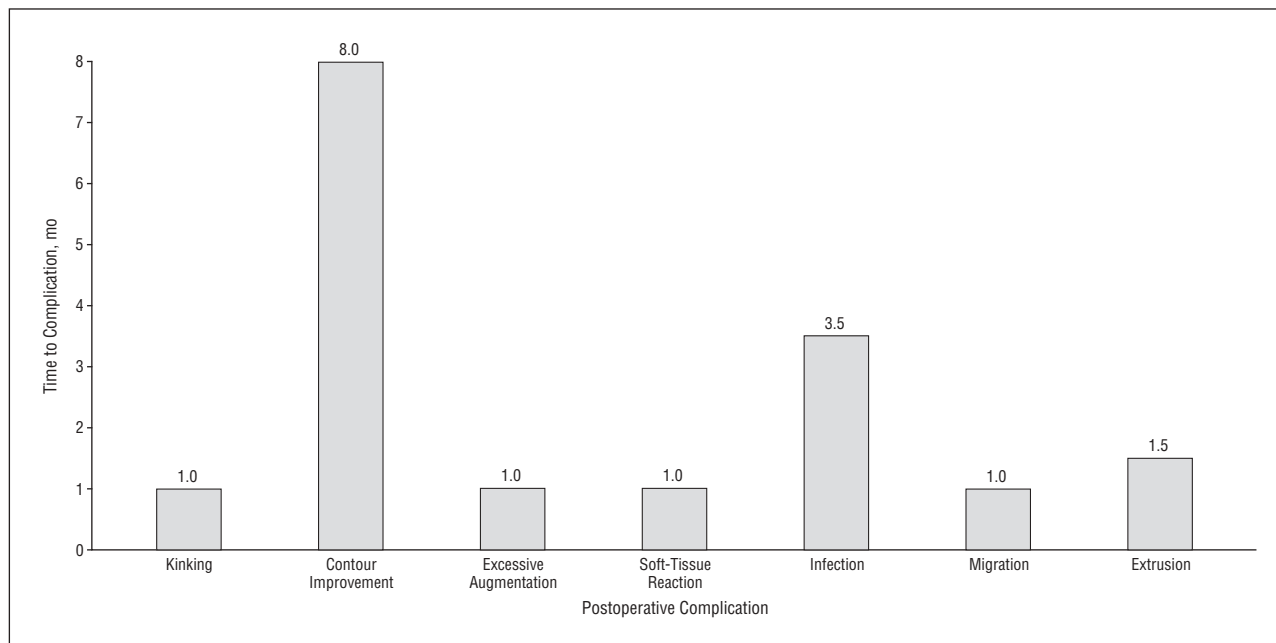
Sterile, 1- to 2-mm-thick GORE-TEX patches were tailored to an appropriate shape. Typically, patches up to 15 × 20 mm in size were used for the lateral nasal wall, and 10 × 40-mm patches were used for the nasal dorsum. The alloplasts were carefully vacuum-impregnated in a bacitracin solution (**Figure 3**). When thicker fillers were required, the patches were layered and sutured together using 4-0 chromic catgut. Margins of the implants were tapered by sculpting with a No. 11 scalpel. Special care was taken to touch the implant with instruments only and to avoid contact with secretions.

A 4-0 chromic traction suture was placed through the cephalic edge of the implant with the free end passed through a straight Keith needle, shielded by a specially designed passer (modified Freer elevator). This suture was then advanced through the subcutaneous pocket and withdrawn from the overlying skin so as to pull, rather than push, the alloplast into the desired position. All remaining suture above the level of the skin was removed at the time of surgery. The implant was inserted in this fashion deliberately in an effort to avoid any folding or bunching of the membrane, which can occur when pushed into position. Precise placement was needed to ensure a pleasing cosmetic result and to avoid any surface irregularities or step-off deformities. It was not deemed necessary to secure the patch position with placement of permanent sutures.

All incisions were carefully closed with 4-0 chromic catgut sutures. Adhesive tape and nasal splints were applied and left in place for 1 week. Nasal packing was used and removed within 16 hours, whenever indications existed. Plaster of paris was used whenever osteotomies were performed and was removed after 1 week. Perioperative and postoperative systemic antibiotics were routinely used.

## RESULTS

Overall, 33 of 685 GORE-TEX implants (4.8%) were associated with surgically or biologically related complications. Those related to biological phenomena always required removal of the implant. By contrast, complications related to surgical technique were treated by implant repositioning or sculpting, as well as occasional replacement. As demonstrated in **Figure 4**, the incidence of complications related to surgical technique was 2.9% (20 of 685 implants) and included kinking (9 implants), asymmetry requiring recontouring (8), excessive augmentation (2), and migration (1). The longest



**Figure 5.** Postoperative time to surgical and biological complications.

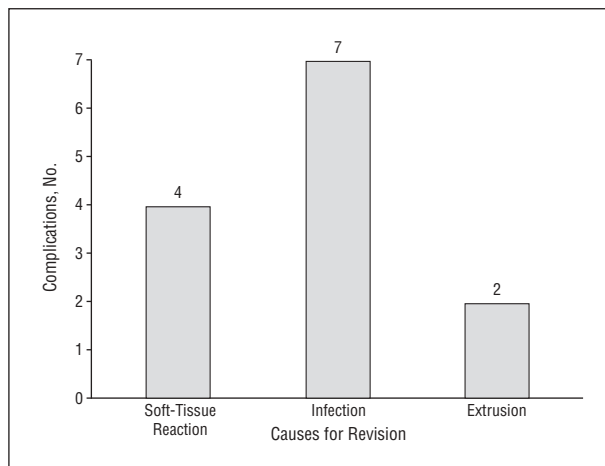
time for a complication related to surgical technique (asymmetry requiring contour improvement) to become apparent was 12 months (mean time required, 8 months) (**Figure 5**).

The incidence of biologically related complications was 1.9% (13 of 685 implants) and included soft tissue reaction (4 implants), infection (7), and extrusion (2) (**Figure 6**). There were no cases of implant resorption or volume loss. The longest time that elapsed between the GORE-TEX implantation and the occurrence of biological complications (infection, extrusion, soft-tissue reaction) was 6 months (mean, 2 months) (Figure 5).

Of the 33 overall complications, 24 (73%) occurred in the dorsum, whereas 8 (24%) were observed in the lateral nasal wall and 1 was observed in the supratip. 14 (42%) of all complications involved a 1-mm GORE-TEX implant, with 16 (48%) corresponding to 2-mm implants, 2 corresponding to 4-mm implants, and 1 to a 6-mm implant. The 94.8% of patients who did not experience any complication were pleased with both their cosmetic and functional outcomes (**Figures 7, 8, 9, 10, and 11**). Similarly, despite requiring a revision procedure, the 20 patients (2.9%) who required surgical revision were also pleased with their final result. None of our patients reported any concerns with regard to an abnormal feel of the alloplast. Of 13 patients (1.9%) who experienced biological complications with subsequent implant removal, 11 had replacement with a cartilage autograft, which resulted in no functional consequence or notable compromise. Two patients chose to seek treatment elsewhere.

#### COMMENT

GORE-TEX is an exceptional augmentation material for implantation in rhinoplasty. In our 17-year experience, we have observed it to be a superior soft tissue filler when-

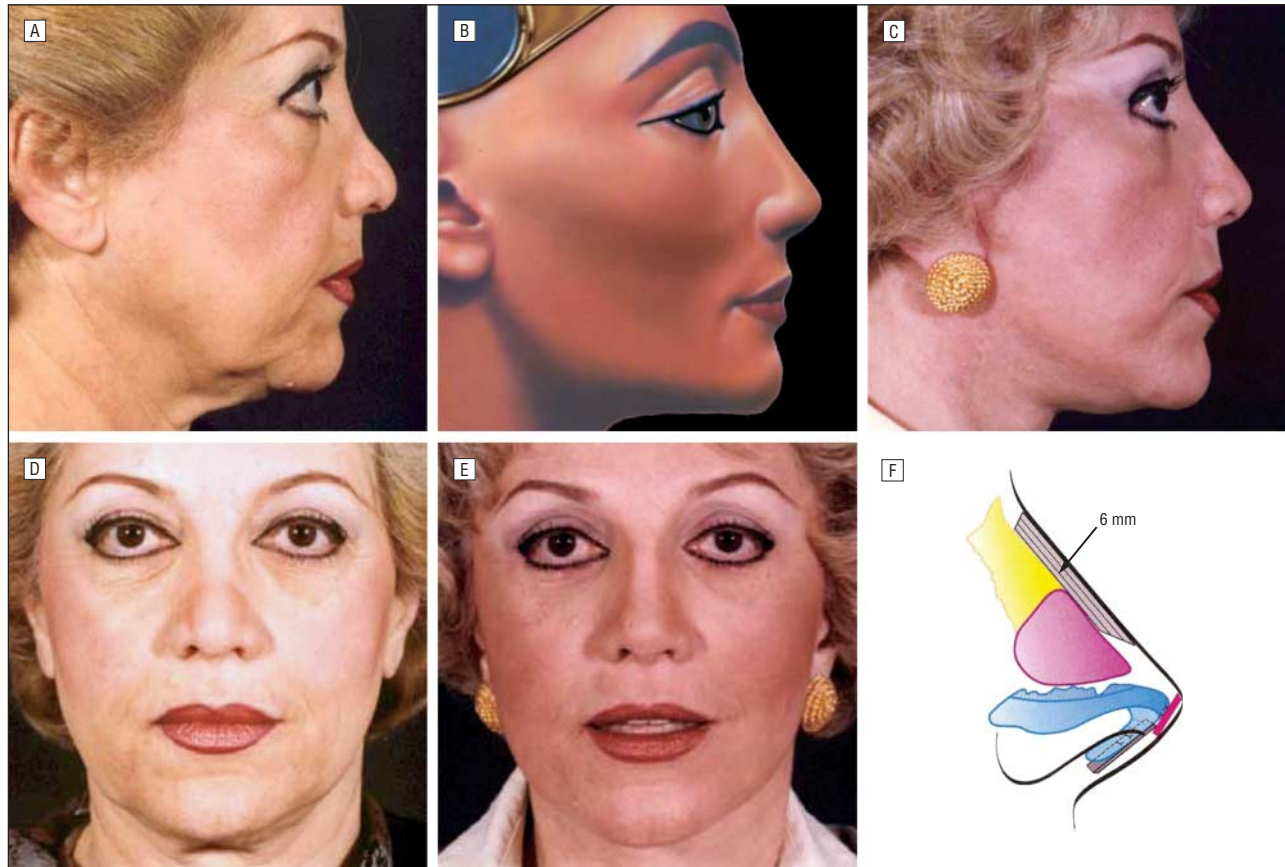


**Figure 6.** Complications of biological nature. Overall complication rate, 1.9%.

ever rigidity is not required. The existence of a very small biological complication rate (inflammation or infection, extrusion), which hopefully can further be reduced with improved surgical techniques, better patient selection, and successful treatment of complications once discovered, makes it a good option in nasal correction.

In our series, 20 of 685 implants (2.9%) required some kind of intervention or revision for issues relating to surgical technique, such as folding of the implant, asymmetry, or excess augmentation. There is no reason to think that these rates would be any different if another alloplast or autograft was used, and, for that matter, most surgeons who use cartilage onlay grafts would consider a 2.9% revision rate to be more than acceptable.<sup>37</sup>

Comparatively, biological complications (as opposed to surgical complications) occurred in 1.9% of the implants reviewed for this study. This corresponds to other reports in the literature, wherein reported infection rates



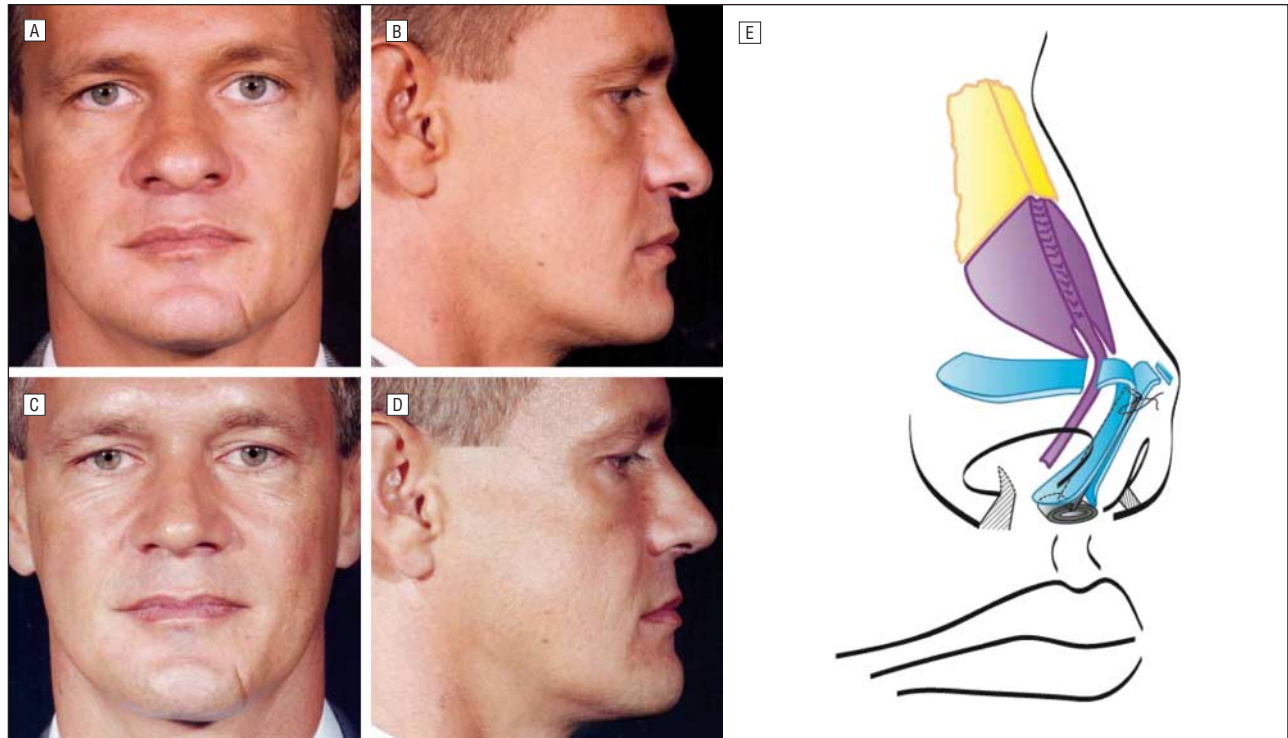
**Figure 7.** A 59-year-old patient desired to have a nasal profile like Egyptian Queen Nefertiti, after 3 unsuccessful rhinoplasties. A, Preoperative lateral view; B, profile of Nefertiti (illustration by Harald Konopatzki, Heidelberg, Germany, adapted with permission); C, postoperative (158-month follow-up) lateral view; D, preoperative frontal view; E, postoperative frontal view; F, lateral schematic of the dorsal GORE-TEX (W. L. Gore & Associates Inc, Flagstaff, Arizona) implant, 6 mm in thickness. The implant was precisely sculpted to obtain a smooth, continuous, and permanent augmentation, a result that is very difficult to achieve without GORE-TEX. Nasal illustration by Aleksandra Conrad, MSc, PEng, AOCAD, PSC, used with permission.



**Figure 8.** A 24-year-old patient with right lateral asymmetry following unsuccessful rhinoplasty. She was unwilling to undergo extensive reconstruction. A, Preoperative frontal view; B, postoperative (102-month follow-up) frontal view; C, dorsal schematic of the right lateral GORE-TEX (W. L. Gore & Associates Inc, Flagstaff, Arizona) implant, 2 mm in thickness, overlying the right upper lateral cartilage. Good aesthetic correction with subjective improvement of the right nasal airway is shown. Nasal illustration by Aleksandra Conrad, MSc, PEng, AOCAD, PSC, used with permission.

with the use of GORE-TEX in the nose are consistently quite low. Owsley and Taylor<sup>38</sup> experienced no complications in 106 patients. Godin et al<sup>21</sup> reported a 2.2% infection rate in their 6-year retrospective and a 3.2% infection rate in their 10-year retrospective series. Finally, in our previously published 6-year review<sup>20</sup> of the use of GORE-TEX in rhinoplasty, we reported a 2.7% inci-

dence rate of biological complications—a slightly higher rate than that seen in the current study. In this report, based on a large series of cases, with a 17-year experience, we documented that any extrusions or inflammatory reactions requiring implant removal occurred within 1 year of implantation. This further reinforces the claim to long-term stability of the implant.



**Figure 9.** A 37-year-old patient with premaxillary implant. A, Preoperative frontal view; B, preoperative lateral view; C, postoperative (84-month follow-up) frontal view; D, postoperative lateral view; E, frontal schematic of the premaxillary GORE-TEX (W. L. Gore & Associates Inc, Flagstaff, Arizona) implant. Improvement of the nasal tip projection and support was combined with a Medpore (Porex Surgical, Newnan, Georgia) columellar strut based on a 4-mm-thick GORE-TEX footing. Nasal illustration by Aleksandra Conrad, MSc, PEng, AOCAD, PSC, used with permission.

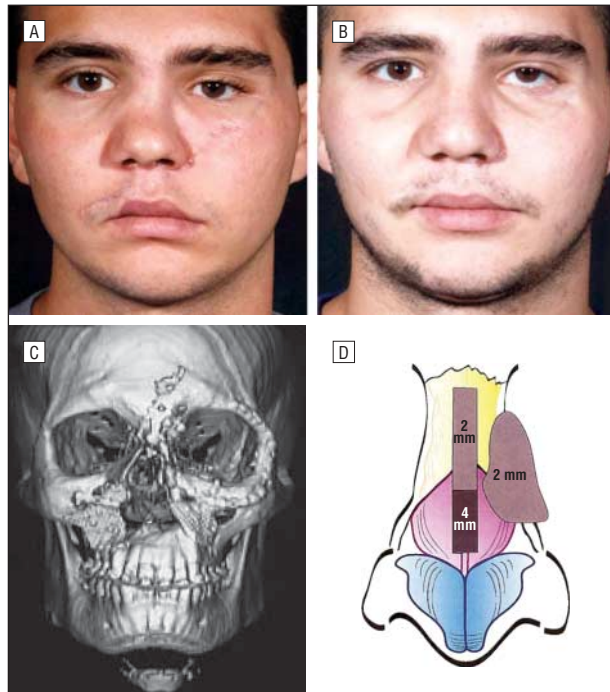


**Figure 10.** A 30-year-old patient with a history of Wegner granuloma on immunosuppressive medication. A 10-mm-thick dorsal implant was inserted in 2 stages 10 months apart via an open rhinoplasty. A, Preoperative frontal view; B, preoperative lateral view; C, preoperative basal view; D, postoperative (39-month follow-up) frontal view; E, postoperative lateral view; F, postoperative basal view; G, frontal schematic of the dorsal GORE-TEX (W. L. Gore & Associates Inc, Flagstaff, Arizona) implant. Nasal illustration by Aleksandra Conrad, MSc, PEng, AOCAD, PSC, used with permission.

There may be, however, certain populations in whom it is reasonable to expect a higher than normal biological complication rate and who would therefore merit caution or even avoidance of an alloplast altogether. Patient-related factors including diabetes mellitus, poor nutritional status, compromised host immunity, use of steroids or immunosuppressive drugs, and advanced age may all con-

fer additional risk, and so, in such circumstances, autologous tissue is preferred.

In our series published in 1998,<sup>20</sup> we asked “Is GORE-TEX the ideal alloplast for use in nasal augmentation?”, to which we added that “what remains to be answered at this point is only the test of time.” Many an alloplastic implant material has indeed failed the test of



**Figure 11.** A 23-year-old patient with multiple traumatic facial fractures. Nasal symmetry and function was restored by septal correction and overlay GORE-TEX (W. L. Gore & Associates Inc, Flagstaff, Arizona) implant to the left lateral nasal wall and dorsum. A, Preoperative frontal view; B, postoperative (116-month follow-up) frontal view; C, a 3-dimensional radiograph showing multiple facial fractures corrected by plating, making nasal osteotomies impossible; D, dorsal schematic of the dorsal (4 mm thick) and left lateral (2 mm thick) GORE-TEX implants. Nasal illustration by Aleksandra Conrad, MSc, PEng, AOCAD, PSC, used with permission.

time, but after 17 years, we feel that GORE-TEX has met our expectations when used with appropriate technical precision in properly selected rhinoplasty patients. Although attempted, it has been very difficult to track every patient postoperatively for 17 years to reinforce the statistical low rate of biological complications. We were able to contact 240 patients who had been lost to regular follow-up after 1 year. In all the patients who were contacted, no surprising details were found to undermine the reliability of our complication rates. In the 10-year experience of Godin et al,<sup>19</sup> reports of biological nasal GORE-TEX complications were not observed past 44 months after surgery. Our observations have indicated such complications occur only within the first 12 months. All our patients were followed for a minimum of 12 months (mean duration of follow-up, 71 months). During the span of this study, the senior surgeon had not changed his practice address; his name and e-mail address have been available on his Web site for easy patient access. Furthermore, all the patients included had been instructed preoperatively about the nature of the surgical technique used and the need to report all possible complications to avoid permanent deformity. It is reasonable to assume, therefore, that the accumulated data provided herein, especially pertaining to the incidence of biologically related complications, such as extrusion, although not absolute, are very likely correct.

The unlimited supply and natural feel of the GORE-TEX implant and excellent blending with the nasal con-

tour, together with minimal operating time required, outweigh the disadvantage of occasional complications, all of which can be treated successfully as long as they are not neglected. Based on the physical properties of the implant material (microporosity) and a favorable 17-year experience as outlined herein, we feel that GORE-TEX is an excellent material for implantation in rhinoplasty and worthy of consideration as an alternative to autologous tissue in selected patients.

Accepted for Publication: January 7, 2008.

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Author Contributions: Study concept and design: Conrad and Torgerson. Acquisition of data: Conrad and Torgerson. Analysis and interpretation of data: Conrad, Torgerson, and Gillman. Drafting of the manuscript: Conrad, Torgerson, and Gillman. Critical revision of the manuscript for important intellectual content: Conrad, Torgerson, and Gillman. Statistical analysis: Torgerson and Gillman. Obtained funding: Conrad. Administrative, technical, and material support: Conrad. Study supervision: Conrad and Gillman.

Financial Disclosure: None reported.

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#### Announcement

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#### Correction

**Error in Manufacturer Information.** In the Original Article by Conrad et al titled “Applications of GORE-TEX Implants in Rhinoplasty Reexamined After 17 Years,” published in the July/August issue of the *Archives* (2008; 10[4]:224-231), Porex Surgical Inc was incorrectly referenced on pages 224-225 as a listed manufacturer of the product Plasti-Pore. Porex Surgical Inc has never produced a material called Plasti-Pore, and Plasti-Pore is, to the best of our knowledge, currently commercially unavailable.