Clin. Otolaryngol. 2001, **26**, 214–217

Augmentation of the nasal dorsum using Gore-Tex®: intermediate results of a retrospective analysis of experience in 66 patients

P.J.F.M. LOHUIS,* S.J. WATTS* & H.D. VUYK†

**European Acadamy of Facial Plastic Surgery and †Department of Otolaryngology, Facial Plastic and Reconstructive Surgery, Gooi Noord Hospital, Blaricum, the Netherlands*

Accepted for publication 6 December 2000

LOHUIS P.J.F.M., WATTS S.J. & VUYK H.D.
(2001) *Clin. Otolaryngol.* **26**, 214–217

Augmentation of the nasal dorsum using Gore-Tex®: intermediate results of a retrospective analysis of experience in 66 patients

Out of the numerous implant materials that have been used for augmentation of the nasal dorsum, autogenous cartilage is considered to be the optimal grafting material due to its versatility and long-term survival. However, in the case of extensive augmentation often an alternative grafting material is needed. Homologous cartilage seems an attractive option, but is not commonly used because of the fear of disease transmission, the long-term unpredictability and the possibility of warping. Alloplastic grafts have offered varying degrees of success in rhinoplasty, but have resulted in significant complications as well. Lately, expanded polytetrafluorethylene (Gore-Tex®) has proven to be a promising synthetic material in nasal dorsal augmentation. However, convincing long-term success compared to autogenous cartilage grafts is still lacking and numbers are insufficient. This paper consists of a prelimary report about the use of Gore-Tex® soft-tissue patches in nasal dorsal augmentation in 66 patients over a 6-year period, which forms the largest European series so far. No complications were observed in either primary (29%) or revision rhinoplasties (71%).

Keywords *nasal dorsal augmentation* *alloplast* *polytetrafluoroethylene*

In augmentation of the nasal dorsum, even the most experienced surgeons differ in their approach and choice of materials, highlighting the many options that are available. Most would, however, concur that autogenous cartilage is the material of choice in most of the cases. It is manipulated with ease while its resilience lends good support to the reconstruction. In addition, infection and resorption of autogenous cartilage grafts in the nose are extremely rare.[1,2] At times, autogenous material is not the automatic choice. The quantity or quality of septal cartilage may be limited due to previous surgery or problems might be expected regarding the irregularity or unpredictability of auricular and costal grafts.[3]

Correspondence: H.D. Vuyk, Department of Otolaryngology, Facial Plastic and Reconstructive Surgery, Gooi Noord Hospital, Rijksstraat 1, 1261 AN Blaricum, the Netherlands.

In the quest for an adequate substitute, several alternative materials have been used with varying degrees of success. Homologous cartilage seems an attractive option but is not commonly used, because of fear of disease transmission, long-term unpredictability and the possibility of warping.[4–6] In terms of volume consistency, xenografts are probably even more unpredictable than homografts.[7] Out of the several synthetic materials that have been used as allografts in nasal dorsal augmentation, silicone and Mersilene (polyethylene terephthalate) have been documented rather well.[8] Most of the silicone dorsal implants have been used in oriental patients.[9] Because silicone is not porous, tissue ingrowth does not occur, which increases the risk of infection and eventual extrusion as a result of dead space between graft and tissues.[10,11] Mersilene is stable and easily shaped providing a natural feel. It has been used in the nasal dorsum with reasonable success by a selected group of rhinoplasty surgeons who reported infection rates of up to 4%, necessitating removal in 2%.[12,13] Unfortunately,

extensive fibroblast ingrowth makes it extremely difficult to remove should the occasion arise.

A promising alloplast in rhinoplastic surgery seems to be Gore-Tex® (polytetrafluoroethylene). Animal studies have shown it to be highly biocompatible.[14,15] The success of Gore-Tex® as an allograft is already well documented in other areas of the human body, in particular in vascular surgery.[16] Since the early 1990s it has been increasingly used for nasal dorsal augmentation as well. Subsequently, several studies have reported this nasal implant material to be well tolerated.[17–21] The most comprehensive study derives from Godin *et al.*,[22] who reported a multicentred, retrospective study of 309 patients all receiving Gore-Tex® implants to augment the nasal dorsum with a follow-up ranging from 5 months to 10 years and a mean of 44 months. Ten (3.2%) of the 309 grafts became infected and were removed, mostly in patients undergoing revision rhinoplasty and/or concomitant septal perforation closure.

Although many initial reports within the literature have been optimistic, scepticism prevails about the use of Gore-Tex® as a nasal implant, based mainly on complications such as infection and extrusion that have occurred with other 'promising' implants in the past. Therefore, careful evaluation and reporting of intermediate and long-term results with alloplasts in rhinoplastic surgery has become imperative. With this study we would like to contribute our experience to the few published series on the use of Gore-Tex® in nasal dorsal augmentation.

Patients and methods

From 1999 to 2000, 70 patients underwent rhinoplasty with Gore-Tex® implantation in our hospital. The Gore-Tex® implants were used for augmentation of the nasal dorsum exclusively. All the surgical procedures were performed by the senior author (H.D.V.). Patients were treated under a general anesthetic with additional local anaesthesia (mixture of marcaine 0.5% and lidocaine 1% with adrenaline 1 : 100 000) in the surgical area. In each patient an external rhinoplastic approach was used to gain exposure to the underlying bony and cartilaginous framework of the nose.

The desired area to be augmented was marked on the nasal dorsal skin before infiltration of local anaesthesia. The pocket was made nearly the exact size of the implant preventing displacement during the initial healing process. The Gore-Tex® implant was fixated using Tissue-col® or sutures. In some cases additional small pieces of autogenous cartilage grafts (septal or auricular) were additionally implanted. The alloplastic implant was handled in a 'no-touch' manner. Gore-Tex® (W.L. Gore & Associates, Flagstaff, AZ, USA) subcutaneous augmentation sheets in thicknesses of 1, 2 and 4 mm were fashioned to the appropriate shape. The implant was not removed from its sterile packaging, until the wound had been fully prepared. We used new gloves and previously unused instruments in a clean field to prepare the implant, while avoiding contact between the implant and the skin. Before insertion, the implant was soaked in a Gentamycin antibiotic solution and the pocket was irrigated with that same solution. One hour before starting the operation, the patient received one intravenous dose of 1 g flucloxacilline.

As in our usual routine, all intranasal and extranasal incisions were closed after obtaining adequate hemostasis. Adhesive tape and nasal splints were applied and left in place for 1 week. Internal dressings were removed within 3 days. Patients were sent home the same day of the surgery.

Results

This series encompases 66 patients with Gore-Tex® implantation of the nasal dorsum, including 23 males and 44 females. Age varied from 10 to 66 years (mean 35.9). Of these, 66 patients 47 (71%) underwent previous rhinoplasty, all in other institutions. The causes of the initial deformities included congenital origin (18%), trauma (24%) and surgery (58%). In each patient an external rhinoplastic approach was used for implantation of the Gore-Tex® graft.

During the postoperative follow-up, ranging from 3 months to 72 months (mean 17.9), no complications were observed in both primary and revision rhinoplasties. In one patient the Gore-Tex® implant was replaced by auricular perichondrium and cartilage, because of excessive augmentation.

Discussion

Gore-Tex® (expanded polytetrafluoroethylene or ePTFE) is a polymer of carbon bound to fluorine composed of solid nodes connected by very fine fibres in a grid pattern.[23] The pore size, which ranges from 10 to 30 μm, allows for tissue ingrowth creating stabilization of the implant, while at the same time permitting easy removal when necessary. Gore-Tex® was first introduced clinically as a vascular prosthesis in 1972.[24] Since then its application in general, cardiovascular, urogynaecological and reconstructive surgery has proven its non-allogenic and biocompatible safety in millions of cases.[16,25,26]

Using a rabbit model, Neel was in 1983 the first who experimented with Gore-Tex® implants in the field of facial plastic and reconstructive surgery.[14] He examined the histiological response of subcutaneous implantation of Gore-Tex® at 12 months postoperatively and found that only few histiocytes and giant cells accumulated at the implant site, a sign that little chronic inflammation and foreign-body reaction were present. Other histiological studies have confirmed this observation, which is in notable contrast to other alloplasts such as Mersilene.[15,27] Neel also observed that mature connective tissue formed a strong supporting envelope for the material, yet the Gore-Tex® implants could be dissected and

Table 1. Nasal dorsal augmentation with Gore-tex®

	n	Infection	Removal	Follow-up (mean*)
Rothstein & Jacob[17]	11	2	–	0–4 years (?)
Waldman[20]	17	–	1†	1–3 years (?)
Stoll[18]	24	–	–	1–2 years (?)
Owsley & O'Tayler[19]	106	–	6†	0–5 years (?)
Conrad & Gillman[21]	189‡	7	16§	0–6 years (17)
Godin *et al.*[22]	309	10	12¶	0–10 years (40.4)
Lohuis *et al.* **	66	–	1†	0–6 years (17.9)

*Mean in months.
†Due to excessive augmentation or improvement of contour.
‡In this study only 34% of the implants concerned nasal dorsal augmentations, 66% concerned implants at other sites of the nose. It was not clearly described how the complication rate was related to the implant site.
§Of the 16 implants, seven were removed because of infection and nine because of improvement of contour.
¶ Of the 12 implants, 10 were removed because of infection and two because of improvement of contour.
**Current article.

removed without difficulty. Since then, Gore-Tex® has been used with excellent results in a wide variety of applications to fill out prominent skin creases and bony depressions within the face.[28,29]

Since the early 1990s the use of Gore-Tex® has been extended to nasal dorsal augmentation with consistent low incidence of infectious complications reported within the literature (Table 1). Stoll and Waldman saw no complications with Gore-Tex® in rhinoplasty in their series of 24 and 17 patients, respectively.[18,20] Owsley's observations were similar, reporting no infections, foreign-body reactions, extrusions or migrations with Gore-Tex® nasal implants in 106 patients over a 5-year period.[19] Rothstein found erythema overlying the implant in two of 11 patients undergoing primary reconstructive rhinoplasty for saddle deformities, which settled rapidly after antibiotic therapy.[17] Two large series were published recently by Conrad and Gillman[21] and Godin *et al.*[22] Conrad and Gillman reviewed 189 patients, who underwent 211 procedures, 3 months to 6 years after Gore-Tex® implantation rhinoplasties and reported complications requiring removal of the implant in 2.7% of the cases due to soft-tissue reaction or infection. However, in this study only 34% of the implants concerned nasal dorsal augmentations, while at the same time it was not clearly described how the complication rate was related to the implant site. Godin conducted a retrospective study of 309 patients who underwent rhinoplasty with Gore-Tex® implantation, over a 10-year period. Of these patients, 162 (52%) presented for primary rhinoplasty and 147 (48%) for revision surgery. Ten (3.2%) of the 309 grafts became infected and were removed, this occurred in two patients (1.2%) undergoing primary rhinoplasty and in eight patients (5.4%) undergoing revision rhinoplasty. Nasal septal perforation was present in three of the 10 patients who developed an infection and was considered to be a contra-indication for Gore-Tex® implantation.

In our series of 66 patients no complications in either primary (29%) or revision (71%) rhinoplasties were observed. We replaced one Gore-Tex® implant by auricular perichondrium and cartilage, because of excessive augmentation. Reasons for this low complication rate may be twofold. First, we used an external rhinoplastic approach to gain exposure to the nasal dorsum in all cases. This is in contrast with Conrad and Gillman[21], who described accessing the nasal dorsum using intercartilaginous incisions in most of their cases. We think that if an alloplastic biomaterial like Gore-Tex® is to be used, it is important to keep all incisions as far as possible from the implant material, to reduce the amount of bacterial contamination.[30] A pocket that has been exposed to the lining of the nasal mucosa (i.e. intercartilaginous incision or mucosal laceration) increases the chances of infection.[12] Second, with a mean of 17.9 months, our follow-up can be regarded as relatively short. Also the other large series (Conrad, 17 months; Godin, 40.4 months) lack serious long-term follow-up. Follow-up results with averages of 10 years or more will be required to eliminate the scepticism regarding the use of Gore-Tex® in nasal dorsal augmentation, since other alloplasts are known to extrude even after a long period of time.[10,11] Consequently, we intend to keep our group of patients under surveillance and present long-term results at a later stage.

There are several experienced surgeons who state that there is not, and there will never be, an indication for alloplasts in nasal dorsal augmentation, Gore-Tex® being no exception to that rule.[31] The nasal dorsum is covered by a relatively thin skin-soft-tissue envelope and is greatly susceptible to repetitive microtrauma. Therefore, the nasal dorsum may represent 'a low threshold' area, where implant materials well tolerated elsewhere in the body fare less well.[21] There is no doubt that autogenous cartilage grafts are the mainstay of treatment for nasal dorsal augmentation because of their low complication rate and long-term survival. However, although it is emphasized that more long-term results are required, Gore-Tex® has been shown to have a low rate of infection and migration in this and other studies. In the patient with a lack of autogenous

donor material, who declines donor site morbidity and presents with a favourable nasal dorsal recipient site, it seems reasonable to use Gore-Tex® as an alloplast.

Conclusion

Gore-Tex® has been successfully used in the field of general and vascular surgery in almost three decades of clinical experience. Intermediate results of recent investigations, including this study, also show a low rate of complications with Gore-Tex® in rhinoplastic surgery. More studies are required to determine the long-term success and morbidity. Until then it should only be used as an alternative to and never in favour of autogenous cartilage grafts in nasal dorsal augmentation.

References

1 Ortiz Monasterio F., Olmedo A. & Oscoy L.O. (1981) The use of cartilage grafts in primary aesthetic rhinoplasty. *Plast. Reconstr. Surg.* **67**, 597–605

2 Sheen J.H. (1990) Secondary rhinoplasty. In *Plastic Surgery*, Vol. 3, pp. 1895–1923. Saunders Co., Philadephia

3 Burget G.C. (1993) Costal cartilage for nasal reconstruction: harvesting through a small incision. *Persp. Plast. Surg.* **7**, 129–136

4 Stucker F.J. & Gage-White L. (1986) Survey of surgical implants. *Facial Plast. Surg. Int. Q. Monogr.* **3**, 141–144

5 Wellings D.B., Maves M.D., Schuller D.E. *et al.* (1988) Long-term results in irradiated homogenous cartilage grafts. *Arch. Otolaryngol. Head Neck Surg.* **114**, 291–295

6 Levkovits G. (1990) Irradiated homologous costal cartilage for augmentation rhinoplasty. *Ann. Plast. Surg.* **25**, 317–327

7 Rettinger G. & Pickert S. (1994) Chrondroplast as nasal dorsum implants: long-term results. In *Alloplastische Verfahren und Microchirurgische Massnahmen*, pp. 159–161. Einhorn-Presse-Verlag, Reinbeck

8 Vuyk H.D. & Adamson P.A. (1998) Biomaterials in rhinoplasty. *Clin. Otolaryngol.* **23**, 209–217

9 Flowers R.S. (1994) Nasal augmentation. *Fac. Plast. Surg. Clin. N. Am.* **2**, 339–356

10 Davis P.K. & Jones S.M. (1971) The complications of silastic implants. *Br. J. Plast. Surg.* **24**, 405–411

11 Shirakabe Y., Shirakabe T. & Kishimoto T. (1985) The classification of complications after augmentation rhinoplasty. *Aesth. Plast. Surg.* **9**, 185–192

12 Colton J.J. & Beekhuis G.J. (1992) Use of mersilene in nasal augmentation. *Fac. Plast. Surg. Int. Quart. Monogr.* **8**, 149–156

13 Adamson P.A. (1995) The over-resected nasal dorsum. *Fac. Plast. Surg. Clin. N. Am.* **3**, 407–419

14 Neel H.B. (1983) Implants of Gore-tex®. *Arch. Otolaryngol.* **109**, 427–434

15 Maas C.S., Gnepp D.R. & Bumpous J. (1993) Expanded polytetrafluoroethylene (Gore-tex® soft tissue patch) in facial augmentation. *Arch. Otolaryngol. Head Neck Surg.* **119**, 1008–1014

16 Mcauley C.E. (1984) Seven years follow-up of expanded polytetrafluoroethylene in femoropopliteal by-pass grafts. *Ann. Surg.* **199**, 37–60

17 Rothstein S.G. & Jacobs J.B. (1989) The use of goretex implants in nasal augmentation operations. *Ear Nose Throat J.* **68** (Suppl.), 41–45

18 Stoll W. (1991) The use of polytetrafluoroethylene for particular augmentation of the nasal dorsum. *Aesth. Plast. Surg.* **15**, 233–236

19 Owsley T.G. & O'Tayler C.O. (1993) The use of Gore-tex® for nasal augmentation: a retrospective analyses of 106 patients. *Plast. Reconstr. Surg.* **94**, 241–248

20 Waldman S.R. (1991) Gore-tex® for augmentation of the nasal dorsum: a preliminary report. *Ann. Plast. Surg.* **36**, 520–525

21 Conrad K. & Gillman G. (1998) A 6-year experience with the use of expanded polytetrafluoroethylene in rhinoplasty. *Plast. Reconstr. Surg.* **101**, 1675–1683

22 Godin M.S., Waldman S.R. & Johnson C.M. Jr (1999) Nasal augmentation using Gore-tex®: a 10-year experience. *Arch. Facial Plast. Surg.* **1**, 118–121

23 Boyce B. (1982) Physical characteristics of expanded polytetrafluoroethylene grafts. In *Biologic and Synthetic Vascular Prosthesis*, pp. 5553–5561. Grune & Stratton, New York

24 Soyer T., Lempineu M., Cooper P. *et al.* (1972) A new venous prosthesis. *Surgery* **72**, 864–872

25 Bauer J.J., Salky B.A., Gelernt I.M. *et al.* (1987) Repair of large abdominal wall defects with expanded polytetrafluoroethylene (PTFE). *Ann. Surg.* **206**, 765–769

26 Wool N.L., Strauss A.K. & Roseman D.L. (1985) Clinical experience with Gore-tex® soft tissue patch in hernia repair. *Proc. Inst. Med. Chicago* **38**, 246–254

27 Sclafani A.P., Thomas J.R., Cox A.J. *et al.* (1997) Clinical and histiological response of subcutaneous expanded polytetrafluoroethylene (Gore-tex®) and porous high-density polyethylene (Medpor®) implants to acute and early infection. *Arch. Otolaryngol. Head Neck Surg.* **123**, 328–336

28 Walter C. (1994) Aspects of facial correction and reconstruction by using transplants (composite grafts and implants) with special reference to surgical membrane implants. *Otolaryngol. Head Neck Surg.* **110**, 524–529

29 Schoenrock L.D. & Reppucci A.D. (1993) Gore-tex® in facial plastic surgery. *Int. J. Aesth. Restor. Surg.* **1**, 63–68

30 Stucker F.J. (1977) Use of implantation in facial deformity. *Laryngoscope* **87**, 1523–1527

31 Daniel R.K. (1998) Discussion: a 6-year experience with the use of expanded polytetrafluoroethylene in rhinoplasty. *Plast. Reconstr. Surg.* **101**, 1684