Multicenter Evaluation of Subcutaneous Augmentation Material Implants

Tom D. Wang, MD

Objective: To evaluate the performance of subcutaneous augmentation material preformed shapes for facial implantation.

Design: One-year prospective multicenter evaluation of implant performance.

Setting: General community hospital; private and institutional practice; and ambulatory care setting.

Patients: Eighty-two patients undergoing elective cosmetic and reconstructive procedures.

Interventions: Patients received nasal dorsal implants (31 patients); chin implants (38 patients); and malar implants (13 patients).

Main Outcome Measures: Complications and aesthetic outcome, including implant position, projection, contour, symmetry, and overall aesthetic index.

Results: Complication rates for infection that required implant removal included nasal dorsal implants, 3.2%; chin implants, 5.3%; and malar implants, 3.8%. The overall aesthetic outcome was judged by an independent panel of facial plastic surgeons on a scale from 1 (poor) to 5 (excellent): nasal dorsal implants scored 4.1; chin implants, 3.8; and malar implants, 3.6.

Conclusions: This study demonstrates that subcutaneous augmentation material preformed shapes offer a relatively safe and effective treatment alternative for permanent facial augmentation.

Arch Facial Plast Surg. 2003;5:153-154

Facial implants have been used to improve facial proportion, symmetry, and balance. A variety of implant materials are available for this purpose. The characteristics of ideal implant materials are noted as follows. They should (1) be easy to shape and secure; (2) be inert, noncarcinogenic, noninflammatory, and nonallergenic; (3) be easily available; (4) resist mechanical strain; (5) integrate into surrounding soft tissues and bone; and (6) essentially mimic normal tissue. While a variety of materials fulfills some of these criteria, none to date fulfills all of them.

Expanded polytetrafluoroethylene (ePTFE), or Gore-Tex (W. L. Gore and Associates, Flagstaff, Ariz), has been widely used as a surgical implant, most notably as a vascular graft. The use of the Gore-Tex soft tissue patch has been demonstrated to be well tolerated as a soft tissue augmentation material in rabbits by Neel. Others have noted its complication-free properties in cases of facial suspensions. Due to the favorable experience with the soft tissue patch material in facial augmentation, the subcutaneous augmentation material (SAM) facial implants were introduced by Gore-Tex to facilitate nasal, malar, and chin augmentation.

The SAM preformed shapes for facial implantation are manufactured from ePTFE that is reinforced with fluorinated ethylene propylene. Both fluorinated ethylene propylene and ePTFE are related fluoroplastics and are chemically inert. The combination of these 2 materials provides some rigidity to the otherwise soft and flexible ePTFE. This inert biomaterial, expanded to provide a microporous structure, is composed of solid nodes connected by thin fibrils of ePTFE. The internodal separation, which approximates the pore size, has an average internode distance of 22 µm, allowing for tissue ingrowth. This micropore structure is thought to enhance fixation and, therefore, decreases the potential for migration. This material did not promote significant foreign body response in previous histologic studies.

The SAM preformed shapes for implantation are available in 3 sizes for
each of the anatomic sites to accommodate individual patient requirements. These are individually sterilely packaged and are available for implantation “off-the-shelf.” Silastic sizers for each of the different sizes are available to determine the appropriate amount of augmentation. If necessary, the implant itself may be sculpted and reshaped to accommodate individual patient requirements.

METHODS

A prospective multicenter study comprising 10 surgeons from January 1, 1997, to December 31, 1997, was conducted using SAM preformed shapes for facial implantation. The patients were selected on the basis of need for mentoplasty, malarplasty, or rhinoplasty procedures and were informed of, and had agreed to, the use of the SAM implants. Standardized photographs were obtained before surgery and 3 months after surgery. Data on complications, including extrusion, infection, hematoma formation, migration, and implant removal, were collected. At the conclusion of the study, patient photographs were independently evaluated by a team of experienced facial plastic surgeons. The evaluation criteria included implant position, projection, contour, symmetry, and overall aesthetic index.

RESULTS

A total of 82 patients from 9 surgical centers received the implants during the 12-month trial period. Of the total, 31 patients received nasal dorsal implants, 38 received chin implants, and 13 underwent cheek implantation. One of the nasal implants became infected and required removal (infection rate, 3.2%). Two of the chin implants required removal, 1 for infection and 1 for aesthetic indications (removal rate, 5.3%). One of the cheek implants became infected and required removal (infection rate, 3.8%). The overall rate of removal in this cohort of patients was 4.9%. There were no reports of implant mobility or migration over the course of the trial, and there were no complications during implant removal.

The panel of facial plastic surgeons who evaluated the aesthetic outcomes of these implants graded each implant site on a scale from 1 to 5 (1, poor; 2, fair; 3, satisfactory; 4, good; 5, excellent). The aesthetic index for the chin implants was rated at 3.8; cheek implants, 3.6; and nasal implants, 4.1.

COMMENT

Dissatisfaction with autogenous tissue implants has led to the development and use of various alloplastic materials. Although ePTFE has been used as a vascular graft material for decades, it represents a relatively new material for facial implant application. The current multicenter evaluation was conducted to assess the risks and benefits of SAM preformed shapes for facial implantation.

The rate of implant removal for all indications was 4.9%. The overall rate of actual implant infection was 3.7%, with 1 implant being infected in each of the 3 categories. The infected chin implant was placed through an intraoral approach, as was the infected cheek implant. The implants were handled according to product recommendations, including minimal contact with latex gloves, and handled with instrumentation that had not come in contact with the patient. The infection rate is consistent with rates reported in the literature for other alloplastic implants, as well as for Gore-Tex implants.

When indicated, the implants were removed without complication or need for difficult dissection. The implants were not otherwise fixated. There were no reports of mobility or migration of any of the implants. Various participating surgeons noted that the material was easy to sculpt and implant. The overall aesthetic index averaged between satisfactory and good for all implants based on unbiased evaluation by an impartial panel of facial plastic surgeons.

In conclusion, this multicenter evaluation demonstrates that the SAM preformed shapes for facial implantation offer a relatively safe and effective treatment alternative for permanent augmentation. The availability of the SAM implants and ease of handling renders them an attractive alternative for patients requiring nasal, malar, or chin augmentations.

Accepted for publication October 23, 2002.

Corresponding author: Tom D. Wang, MD, Division of Facial Plastic and Reconstructive Surgery, Oregon Health & Science University, Mail Code PV-01, 3181 SW Sam Jackson Park Rd, Portland, OR 97201 (e-mail: wangt@ohsu.edu).

REFERENCES