Dual-Porosity Expanded Polytetrafluoroethylene Soft Tissue Implant

A New Implant for Facial Soft Tissue Augmentation

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**Objective:** To illustrate problems observed with low-porosity expanded polytetrafluoroethylene soft tissue implants and to describe a new dual-porosity implant, the technique for insertion, and this author's preliminary experience.

**Method:** A review of 175 pieces of SoftForm (Collagen Corporation, Palo Alto, Calif) placed in 69 patients over 3 years was performed. Between October 1, 1997, and September 30, 2000, 106 Advanta implants (Atrium Medical Corporation, Hudson, NH) in 42 patients have been carried out. A new instrument for implant insertion and the procedure used is described herein.

**Results:** The low-porosity expanded polytetrafluoroethylene implants demonstrated a significant amount of problems with shrinkage and migration.

**Conclusions:** Preliminarily, the dual-porosity implants would appear to offer a lower incidence of these complications. They are subjectively softer to feel once in place. Insertion is quick and easy using the method described herein.

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MINIMALLY INVASIVE procedures are becoming more sought after by both physicians and patients. Smaller incisions and less “down time” make it easier for patients to have excellent cosmetic results with less time lost from work, less bruising, less discomfort, and less scarring. Soft tissue implants are a popular means to minimize nasolabial folds, marionette lines, and other facial soft tissue depressions, as well as to augment the lips.

The characteristics of the ideal implant material include ease of insertion, softness (minimal palpability), excellent biocompatibility, good biointegration, minimal to no patient rejection, nonabsorption, minimal shrinkage, ease of removal, predictability of long-term behavior, no propensity to migrate, ability to individualize the implant to each patient, low visibility, and affordability.1,2 A wide variety of implant types are available today for use in facial plastic surgery, including autogenous tissue (fat, dermis, and fascia); homologous implants (AlloDerm [LifeCell Corporation, Branchburg, NJ], Dermalogen [Collagenesis Inc, Beverly, Mass], fascia lata, and dura); synthetic injectables (Teflon paste, Artecoll [Artes Medical Inc, San Diego, Calif], and silicone gel); xenogenic implants (collagen and hyaluronic acid); and synthetic implants (silicone, Medpore [Porex Surgical Inc, Newnan, Ga], and expanded polytetrafluoroethylene [ePTFE]).3

**PROBLEMS OBSERVED**

It is necessary for the physician to have a clear understanding of the tissue reaction produced by the implantation of synthetic augmentation materials. Acute and chronic inflammation, thick fibrous capsule formation, biodegradation, and granuloma formation are undesirable consequences for any implant. These variables can affect implant stabilization. Unstable implants provoke increasing inflammation, which can adversely affect the device’s longevity.3,6

Between October 1997 and October 2000, 175 SoftForm implants (Collagen Corporation, Palo Alto, Calif) were placed in 69 patients; 70 pieces were implanted in the nasolabial folds, 66 in the upper lip (1 on each side), 18 in the lower lip, 18 in the marionette lines, 2 in glabella furrows, and 1 in the supramental crease. Overall, 28 implants (16%) shrunk in 10


Dr Truswell is a paid consultant for Atrium Medical Corporation and is the designer of and has commercial interest in the insertion device described herein.
patients (14%) and 8 implants (5%) migrated in 3 patients (4%). Four implants (2%), all in the lower lip, were infected, removed, and replaced a few weeks later after antibiotic treatment.

Expanded polytetrafluoroethylene (Advanta [Atrium Medical Corporation, Hudson, NH], SoftForm, and Gore-Tex [W.L. Gore & Associates Inc, Flagstaff, Ariz]) has a long track record as a safe, biocompatible, and inert implant. Until recently, the products available were low-porosity (5-30 µm) sheets and strands (Gore-Tex) and tubes (SoftForm).

My experience with low-porosity implants was less than satisfactory because of shrinkage (Figures 1, 2, and 3), migration (Figure 4 and Figure 5), and firm to hard palpability. Low-porosity ePTFE results in encapsulation of the implant and almost no cellular ingrowth. There is ingrowth of microfibrils of connective tissue into the lumen of the SoftForm implant. Without any appreciable cellular integration into the material itself, there is no strong anchor to prevent migration, product distortion, or shrinkage.

**IMPLANT DESCRIPTION**

Expanded polytetrafluoroethylene is a stable polymer of carbon atoms. The inertness of the structure comes from a coating of fluorine atoms. Nodules of solid PTFE are
joined by fibrils of PTFE that are both thin and flexible. This structure imparts to the material its properties of strength, longevity, and flexibility. The porosity of the material allows for biointegration of various degrees by the host cells. Since the 1970s, millions of vascular grafts have been done. Their success and longevity testifies to the stability of ePTFE as an implant. The material on the market today is available in a variety of shapes, sizes, and porosities. W. L. Gore & Associates Inc offers Gore-Tex (ePTFE sheeting, multistrand implants, and round threads of varying diameter). Collagen Corporation produces SoftForm, a tubular designed implant of differing diameters that come in a disposable inserting device. Gore-Tex and SoftForm have a porosity of 5 to 30 µm. A dual-porosity implant (Advanta) has been developed to address the issues of softer palpability, less migration, and reduced shrinkage. This implant has a medium-porosity outer core of 40 µm and an open-porosity inner core of 100 µm. The inner core is exposed at the implant’s ends to the surrounding tissue. This dual-porosity structure creates a noticeably softer tissue.

In the porcine model, Advanta implants exhibited excellent tissue ingrowth compared with the low-porosity Gore-Tex implants. The high-porosity environment allowed extensive cellular growth including neo-vascularization throughout the devices. Figure 4 demonstrates considerable cellular integration into the interstices of the Advanta implant at 1 year in the porcine model. There is also little inflammatory reaction in the tissues surrounding the implant. Neovascularization is seen in the peri-implant tissue as well as within the implant itself. Foreign body giant cells are found in the middle portion of the implant. These findings were demonstrated throughout the device. In contrast, the lower-porosity Gore-Tex implant demonstrated a vascularized cellular capsule, more inflammatory cells, and fewer vascular elements within the devices (Figure 5). There were also areas devoid of cellular penetration within the Gore-Tex implant. Ease of removability of the Advanta implant was relatively uncomplicated at 1 and 3 months. At 6 and 12 months, by virtue of the cellular integration, it was necessary to perform some longitudinal dissection to facilitate removal (S. K. Williams, PhD, Protocol for Evaluating Atrium Medical Corporation ePTFE Subcutaneous Implant in the Porcine Skin Model, unpublished data, 2000).

The implants come in a variety of sizes in both round and oval shapes. All are 15 cm in length. This allows 1 implant to be used in both nasolabial folds. The round sizes are 1.8 mm, 2.5 mm, 3.0 mm, and 4.0 mm in diameter with or without a trocar attached. The oval im-
plants are 2.0 × 3.2 mm, 3.0 × 4.2 mm, and 3.5 × 6.5 mm in dimensions.

I prefer the oval shapes for enhancement of both the nasolabial folds and the lips. In my opinion, this shape fleshes out the folds more naturally than a round implant. It also allows more vertical enhancement of the lips when the long axis of the oval is so oriented. I most commonly use the large oval implant for the nasolabial folds and the medium implant for the lips. The round implants on the preattached trocar also work well in the lips if pout without vertical height increase is desired. The round device also works well in the deep glabella furrows and marionette lines. Naturally, this determination needs to be made on a patient-by-patient basis.

METHOD OF INSERTION

I have designed an instrument (Figure 6) to aid the insertion of the oval shapes. It consists of an ergonomic handle with detachable hollow shafts of 4.0-mm and 6.0-mm outside diameters. A trocar slides into the shafts and locks into the handle. The edges and point of the trocar are slightly rounded to push through rather than cut into the subcutaneous tissue.

Topical anesthetic gel is placed in the appropriate ginglyvobial sulci. For local infiltration and blockage of the infraorbital nerves (nasolabial folds and upper lip) and the mental nerves (lower lip and marionette lines), 1% lidocaine with 1:100000 epinephrine is used. A stab incision is made at the top and bottom of the nasolabial fold with a No. 11 blade. The instrument is inserted into the bottom incision, advanced through the tissue subdermally, and passed out the top incision. The button is depressed half way to release the trocar, which is removed. An alligator forceps is slid into the shaft (Figure 7). The shaft and handle are removed leaving the forceps in the preformed tunnel. The implant is grasped and drawn into place as the forceps is removed (Figure 8). The skin is stretched manually over the Advanta to seat it properly. The ends are beveled (in triangular shape for the larger implant) and dropped below the dermis (Figure 9). The incisions are closed with 1 horizontal mattress suture of 7-0 nylon (Figure 10).

The procedure on the lips is done in an identical fashion. Two pieces are inserted into the upper lip to avoid ablationing the Cupid’s bow. The incisions are placed on the mucosa at the corners of the lip and on the mucosa at the downturn of the bow. One implant is used along the length of the lower lip. The tunnel is made just beneath the vermilion margin. The incisions are closed with 7-0 nylon suture.

The small round implant preattached on the trocar is used in the glabella frown lines and the marionette lines. The upper incision in the marionette line is above the vermilion of the lower lip in the corner of the mouth. These small incisions are also made with a No. 11 blade.

Patients are instructed to apply ice compresses off and on for 36 hours. They may return to work on the second postoperative day. They are also instructed not to feel or push the lip implants with their tongue for a week, stressing that even if felt or pushed gently, the incision can open and close the wound edges on either side of the suture and lead to ingress of saliva and increase the chance of infection. Antibiotics are prescribed for 1 postoperative week; acetaminophen is sufficient for any discomfort. Sutures are removed on day 5.
Figure 11 shows the preoperative condition and postoperative results after placement of a large oval Advanta implant in a patient’s nasolabial folds. Figure 12 shows the preoperative condition and postoperative results after placement of a medium oval Advanta implant in a patient’s upper and lower lips.

INITIAL CLINICAL OBSERVATIONS

Advanta implants have only been available since January 1, 2001, and these observations are preliminary. A 12-month multicenter study is presently under way to assess the product for the desirable attributes for soft tis-
sue implants mentioned in the beginning of this article as well as patient satisfaction.

The patients with problematic Gore-Tex and SoftForm implants returned to the office for remedy. All patients having undergone SoftForm implants are being surveyed to assess the status of their results (unpublished data, October 1, 1997, to September 30, 2000).

Presently, 106 Advanta implants have been inserted in 42 patients (Table). Of the 42 patients, 23 had 2 sites implanted; 27 had the large oval implant inserted in their nasolabial folds; 1 had the medium round implants inserted in her marionette lines using the Advanta implant with the preattached trocar; 9 had medium ovals in the marionette lines; 12 had the medium oval implants placed in their lips; 10 had SoftForm implants (which had shrunken) replaced with Advanta implants (6 in the nasolabial folds, 3 in the marionette lines, 2 in the lower lip, and 1 in the upper lip). Two patients had Gore-Tex sheeting (which had also shrunken) replaced with the large oval Advanta implant in her nasolabial folds (Figure 2). One patient had SoftForm implants replaced in her marionette lines because the original implant had shrunk and migrated from the original implant site (Figure 3).

One Advanta implant in the lower lip of a patient became infected 3 weeks postoperatively. This patient had surgery with general anesthesia 10 days after the Advanta insertion. Manipulation about the mouth during this event may have been a contributing factor. Systemic antibiotics failed to eradicate the infection, and the implant was subsequently removed. A second patient had double large implants placed in his nasolabial folds. The left side became infected within 3 weeks, and the left implants were subsequently removed. The left side was treated with antibiotics, and the implant was replaced a month later; however, the replacement implant also became infected and was removed. Two months later, the right implants became infected and were removed, and antibiotics were used to treat the right side. The left implant may have been replaced too early, and the right-sided infection may have been seeded from the left. Another patient had the right marionette line implant trimmed about 2 mm at the upper end for a better fit. The patients who had other ePTFE implants replaced with Advanta implants are presently more pleased with both the appearance and feel of their new implants. These subjective opinions will be surveyed in the multicenter study as well.

CONCLUSIONS

Presently, the dual-porosity Advanta implant appears to offer certain advantages that have not been available with other products on the market. The dual-porosity design has a softer feel to the hand. There is definitely better biointegration demonstrated by cellular ingrowth with neovascularization in the porcine model. As a result of this ingrowth, shrinkage and migration is apparently less with Advanta implants vs the other ePTFE implants. Removal of Advanta implants requires some dissection after 6 months in situ owing to cellular ingrowth. Palpability, shrinkage in patients, and clinical experience with removing the implants have yet to be determined. The 12-month multicenter evaluation will address these questions.

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