

CLINICAL TECHNIQUES

Experience and Evaluation of a New, Saline-Filled Implant for Cosmetic Lip Augmentation

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21 Purpose: The purpose of this article is to discuss the author's experience with a new saline-filled lip implant technology in an initial series of patients.

Materials and Methods: The novel saline-fillable implant (VeraFil; Evera Medical) is composed of a thin expanded polytetrafluoroethylene outer membrane bonded, only at the ends of the device, to a silicone inner membrane creating a slip plane between layers and is intended to heal with mild cellular incorporation and to remain soft and elastic over time. At implantation, the saline volume is adjusted as desired through a temporary fill tube and a self-sealing microvalve. The author's previous experience with lip implants is presented as a detail of the surgical placement of this technologically unique implant. The author's series of 25 implants over a 7-month period is reviewed as well as international experience with more than 475 implants of the same type.

Results: In the author's series of 25 implants, there was no mechanical failure or displacement, and there was no incidence of extrusion or infection. Two implants were removed and repositioned because of improper placement. In the worldwide experience, 475 implants have been placed by 45 surgeons. A total of 399 implants were placed in the lips, 90 in the nasolabial folds, 4 in the tear trough region, and 2 in the chin. As of June 9, 2007, 102 implants have been in place for more than 1 year, 32 of which have been in place for more than 18 months. There has been 1 confirmed infection and 1 suspected infection as well as a single case of dehiscence (surgeon's first case) through the incision. One implant shifted superiorly in the lip and was removed and replaced. There have been no cases of late extrusions. In the early experience, there were 3 valve failures resulting in loss of volume fill in devices implanted in the nasolabial grooves.

In all 3 cases, these devices were constructed of an out-of-specification valve tubing and had been reinforced with suture tied around the valve. Since improving material sourcing, there have been no known valve failures. No implants have ruptured, and none have been surrounded by thick capsules.

Conclusion: The VeraFil saline-filled implant is a new technology for lip augmentation. The implant is unique in design, and materials and can be placed in less than 15 minutes. All patients in the author's initial series have been happy with the augmentation result and the natural look and feel, and no patient has complained about loss or change of oral function. There has been no incidence of infection, rejection, implant deflation, migration, or device failure in the author's series, which has mirrored the worldwide experience of at least 475 implants. The VeraFil saline-filled lip implant appears to be a viable and promising technology that could be a welcomed addition to the armamentarium of the cosmetic surgeon dealing with lip enhancement.

Lip enhancement is as old as society itself and has served to adorn and differentiate individuals for grooming, esthetics, and courtship. Many means of augmenting the lips have been described, including injectable fillers and fat, SMAS, cadaveric dermis, **22** expanded polytetrafluoroethylene (ePTFE), and other synthetic materials.¹⁻¹⁰ Until recently, injectable filler options in the United States were limited to bovine collagen. The past 5 years has provided a virtual filler revolution with the introduction of nonanimal, stabilized, hyaluronic acid preparations; hydroxyappetite-based fillers; fillers containing L polylactic acid; and methylmethacrylate microspheres, to name a few. The introduction of these new products is fueled by a larger than ever popularity of minimally invasive cosmetic procedures. Although filler injection remains one of the most popular cosmetic procedures, it is not an optimum treatment option for some patients. There exist many patients who are needle phobic and/or disdain

Received for publication August 16, 2007.

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Figure 1. Earlier expanded polytetrafluoroethylene implants frequently became hardened and impeded esthetics and animation.

the need for continual injection maintenance required with most fillers. Also, in this climate where breast and facial implants are so popular, a certain segment of the population is intrigued by the more permanent option of lip implants.

The general concept of lip augmentation using implanted materials is not new and has fallen in and out of favor over the years.¹¹⁻¹³ In the early 1990s, Gore-Tex (ePTFE) became a popular implant material, and although it was biocompatible and successful in many patients, problems with the look, feel, and animation were common. The ePTFE, whether in multistrands or solid implants, frequently became hardened and palpable and sometimes affected animation (Figure 1).

A product using a new manufacturing process was marketed in the late 1990s. Although fabricated out of ePTFE, the structure and feel were quite different than that of previous Gore-Tex. The Advanta lip implant (Oceanbreeze Medical, Amherst, NH) contained a dual porosity composition with an open porosity inner core and a medium porosity outer core.¹⁴⁻¹⁶ This process imparted a very silky smooth and pliable feel to the implants, which provided significant advantages over previous ePTFE products. The Advanta implant is available in round or oval configuration, and this author published a series of 72 implants in 42 patients in 2006.^{17,18} Although a step forward for lip implantation, this implant is palpable and can be visible during extreme animation. In addition, the implant must be carefully tapered to avoid a noticeable and palpable step off toward the end of the implant. The patient

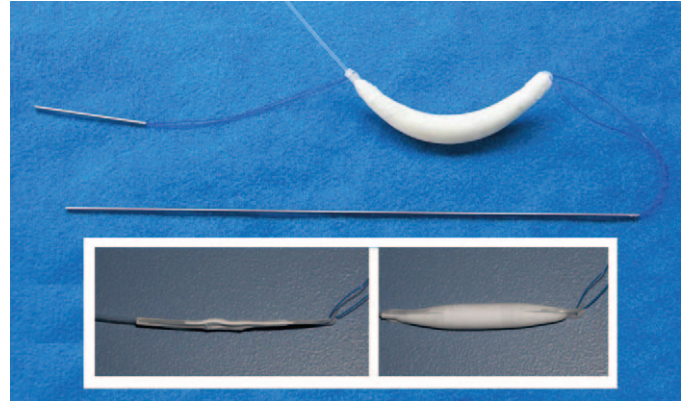


Figure 2. Photograph of VeraFil implant with filler tube and tether sutures attached. The implant is flat for insertion and is then filled with saline after placement (insert).

acceptance is generally favorable, but in some cases, hardening or stiffening of the implants occurs that can lead patients to request removal. Given these sequelae, this implant remains a viable alternative to contemporary lip augmentation.

Recently, a new implant has entered the facial implant augmentation market. The Verafil technology, which can be manufactured in a variety of anatomic shapes including lip implants (Evera Medical Inc, Foster City, Calif), used unique methods of construction to achieve an implant that matches the viscoelastic properties of the tissue into which it is placed. In the United States, the technology is marked as VeraFil, which is approved by the Food and Drug Administration for augmentation and reconstruction in and around the orbit. This author has used this implant on an off-label basis for lip enhancement. Outside the United States, the same device is marketed as FulFil, which has a CE Mark indicated bore broadly as an implant for facial plastic and reconstructive surgery, including lip implants. The implant consists of a tubular-shaped polymeric device composed of a bilayered laminate of silicone and ePTFE that can be flaccidly filled with saline (Figure 2).

The outer layer of the VeraFil technology is composed of a thin (approximately 0.002 in.) ePTFE membrane that is laminated to a silicone (polydimethylsiloxane) membrane, of similar thickness. The 2 layers are attached by adhesive bonding only at the ends of the device, creating a slip plane between the layers. Several design elements of the implant are meant to minimize the problem of stiffening and erosion. The ePTFE outer membrane is produced with an intranodal distance of approximately 60 μ , which induces tissue

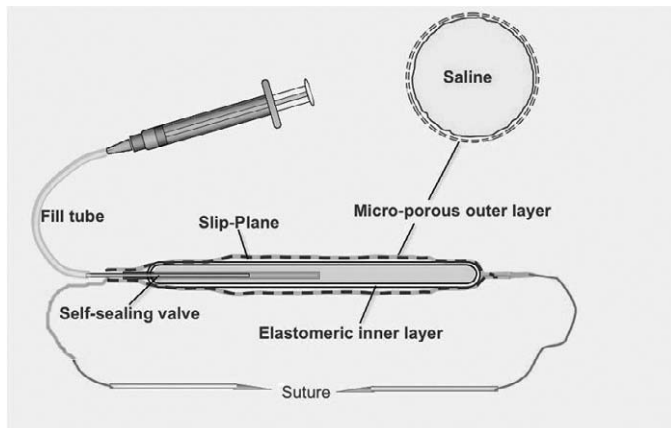


Figure 3. Schematic diagram of VeraFil lip implant.

attachment, but because the ePTFE membrane is very thin, the fibrous ingrowth is limited, preventing the hardening related to extensive capsule formation. The limited nature of the tissue ingrowth also makes it possible to remove the implant with minimal dissection. The thin, low-durometer silicone inner layer ensures lasting suppleness and elasticity. However, since the silicone is not directly exposed to the tissue, foreign body encapsulation is not induced. The VeraFil implant is flaccidly filled with saline, which represents more than 90% of the implant mass, helping to maintain the compliant feel. The slip plane between the layers along with special manufacturing methods allows the otherwise nonextensible ePTFE, and therefore the entire implant, to stretch up to twice its baseline length. In terms of complications, the mechanism of implant erosion is thought to be related to micromotion between an implant and the surrounding tissue due to the material property mismatch. The bulk properties of this implant are intended to remain well matched to the surrounding tissue over time, minimizing the risk of erosion and migration and contributing to its natural look and feel. Inhibition of facial animation, discontinuous edge effects, or erosion have not been observed with this implant system. The implant has a self-sealing valve that allows for the addition or removal of saline as part of the implant procedure (Figure 3).

The saline and ePTFE construction have proven to be very biocompatible, and the saline fill produces a uniquely natural feel with natural-appearing animation. These implants have been placed in the lips, nasolabial folds, chin, and nasojugal groove. Again, it is important to emphasize the fact that the implant is flaccidly filled (and not ballooned), so it does not represent a high-pressured system that could be prone to rupture or

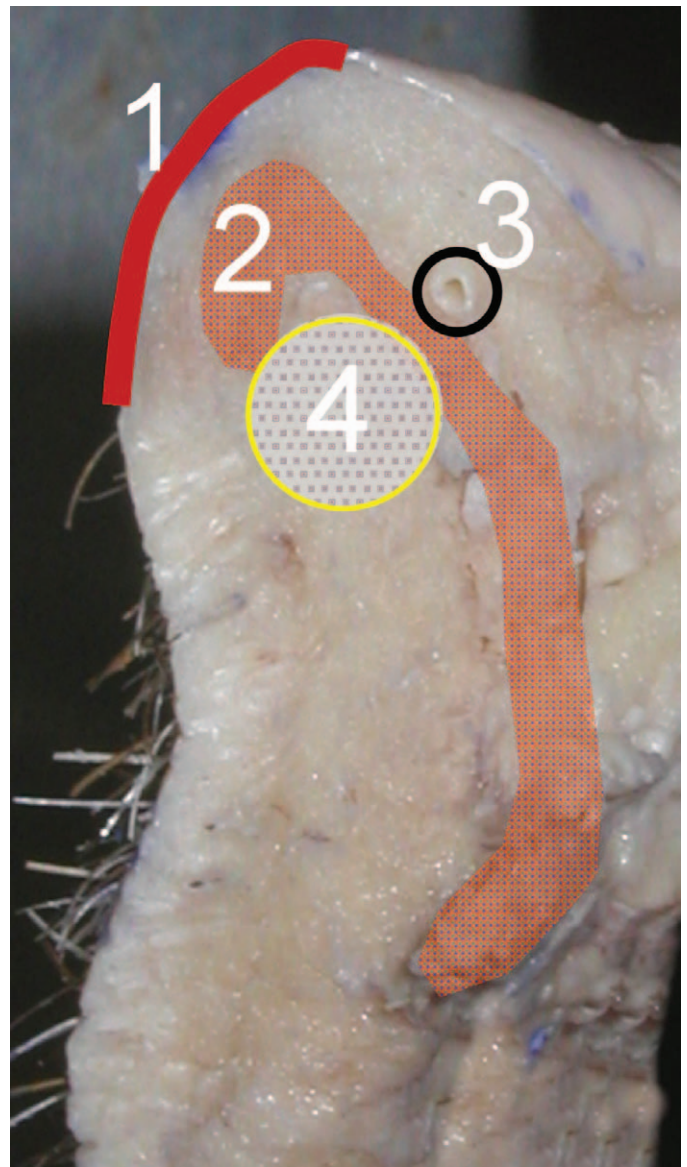


Figure 4. This cadaver lip shows the approximate locations of (1) the vermilion border, (2) the orbicularis oris muscle, (3) the labial artery, and (4) the intended placement of the implant tunnel.

pressure-induced expansile tissue changes. On the other hand, care must be taken not to substantially underfill the device (less than about 50% of the maximal labeled fill volume), as this may lead to bending or kinking of the implant.

This implant has undergone a number of refinements in the short time since its introduction. The product is packaged from the manufacturer in a sterile sealed container. Implant lengths are available in 3, 4, and 5.0 cm, and implant width diameters are available in 4.5, 5.5, and 6.5 mm. Injectable fill volumes vary from

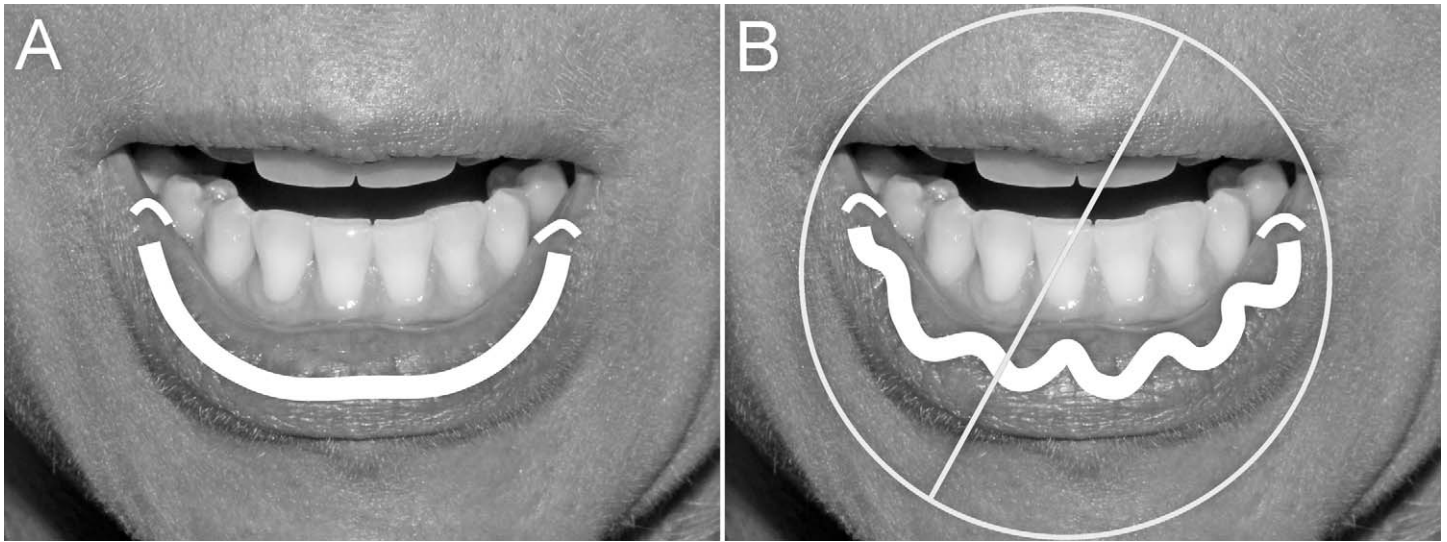


Figure 5. A straight tunnel is imperative for natural implant posture (A). A sinusoidal dissection will cause unnatural implant position and resultant unnatural animation (B).

0.25 mL of saline in the smallest implant to 0.6 mL in the largest implant. Unlike injectable dermal fillers whose volume must infiltrate into a larger volume of interstitial space, a surprisingly smaller amount of saline is required to fill these implants to the required augmentation level since all the volume goes into the anatomically correct space created at the initial dissection.

This author has placed 25 of these implants over a 7-month period to investigate ease of placement, surgeon and patient acceptance, biocompatibility, longevity, and esthetics. Given the small sample size and absence of long-term follow-up, an evidence-based statistical conclusion cannot be drawn. Nonetheless, the experience to date can direct other surgeons in the nuances of implant placement as well as to serve as a preliminary study that leads to a larger series evaluation.

Technique

Patients are started on prophylactic cephalosporin 24 hours preoperatively. If a history of severe or frequent herpetic lesions is reported, the patient is started on valacyclovir 500 mg every 12 hours, beginning 48 hours preoperatively. On the day of surgery, the patient is photographed in the upright position in frontal, oblique, and lateral repose positions as well as with full smile, pucker, and mouth wide open. Prior to dissection, the midline of each lip is marked using a surgical marker, with additional marks at 1-cm intervals away from the midline on each side.

Anesthesia

This procedure is easily performed with local anesthesia. A potent topical anesthetic (20% benzocaine, 6% lidocaine, 4% tetracaine) is applied for 5 minutes, then 4–5 mL of 2% lidocaine with 1:100 K of epinephrine is infiltrated in the lip from the commissure of one side to the commissure on the contralateral side. The local anesthetic is injected at the level of the middle of the lip. Infraorbital or mental nerve blocks can be used to augment the anesthetic.

Incision

After waiting approximately 10 minutes (or until the lip mucosa and skin blanches), incisions are made several millimeters medial to the commissure on both sides. Some surgeons keep the incisions very close to the commissures, while others bring them in more medially and undermine more laterally. Either method is acceptable as long as the incision and suture do not sit directly over the actual implant tail. This author uses a 4.0-MHz radiowave microneedle (Ellman International, Oceanside, NY) to incise for a bloodless field, but a stab of the 15 blade can also be used. The intended depth of the incision is the exact center of each lip. This would place the implant in the subcutaneous fat and connective tissue of the lip, beneath the orbicularis oris muscle. Failure to place the implant deep enough can lead to an extremely visible and palpable implant with unnatural animation. Placing the implant too deep will place it too near the oral mucosa on the underside of the

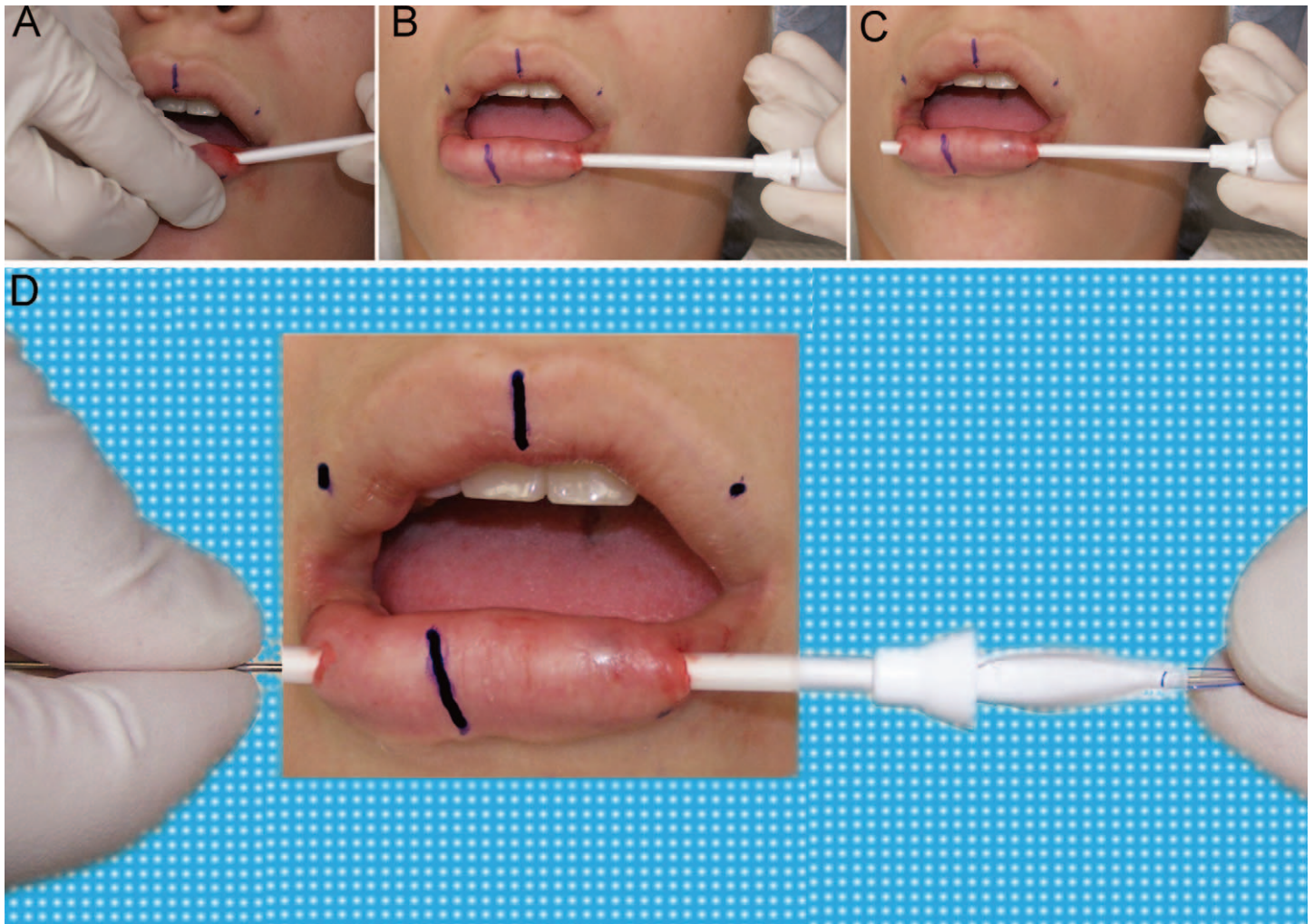


Figure 6. After the incisions are made, the trocar/cannula is advanced through the center of the lip from the proximal to the distal incision (A–C). Remaining in the same dissection plane is imperative for proper implant placement. The unfilled implant is threaded into the dissection tunnel through the trocar. This allows precision placement without dragging the implant through the soft tissues, which could damage the implant (D).

lip, causing an additional set of problems including an overly palpable implant that can be malpositioned. In effect, this places the augmentation on the wrong side of the lip.

Dissection

Dissection proceeds from 1 incision to the other to form a tunnel between the 2 incisions. This tunnel is, again, made in the very center of the lip, below the muscle and in the fat and connective tissue (Figure 4). The labial artery is generally out of harm's way as it sits in the posterior third of the lip at about the level of the incisal edge of the lower teeth (Figure 4). It is important to have both incisions placed to the same depth and the connecting dissection tunnel at that depth as well. In

effect, the surgeon is making a tunnel and placing a small balloon in that tunnel. If the tunnel is at the same and consistent depth, the balloon will lie passively in the tunnel. If the dissection is made in a serpentine fashion, the implant tunnel will porpoise, thus leading to unnatural lip posture, esthetics, and function (Figure 5).

A passing trocar/cannula system is included with the implant and facilitates the actual tunnel dissection as well as insertion of the implant. When the incisions are made to the proper depth of the soft tissue lip, the trocar/cannula is inserted in one incision while maintaining a homogenous dissection plane in the center of the lip. The trocar is advanced from the proximal to the distal incision (Figure 6A through C).

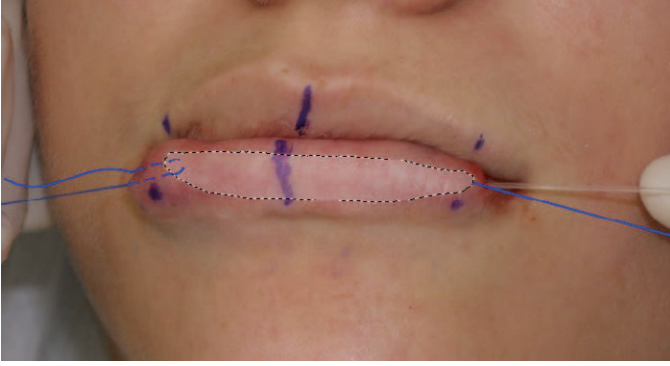


Figure 7. This schematic shows a rendition of the VeraFil implant centered in the lower lip with the tether sutures and the filler tube still attached.

If the trocar/cannula does not move freely within the tunnel or is difficult to withdraw, the tunnel is too small: the trocar/cannula should be removed and the dissection plane extended. Once the trocar/cannula passes easily through both incisions, the trocar is removed, leaving the cannula in place to accept the implant (Figure 6D). The implant is removed from its packaging, attached to a 10-mL syringe filled with 3 mL of normal saline. A vacuum is pulled on the implant to remove any residual air. The implant is then filled with enough saline to expand to its natural size, as indicated on the label, to check the implant integrity. Several similar steps are taken to inject and remove saline to purge all ambient air from the actual implant.

The implant is attached to a passing needle, which is threaded through the trocar and out the distal incision, and the implant is pulled into place with the tether sutures while the cannula is removed. The implant now resides in the tunnel and must be centered on the midline of the lip (Figure 7).

The right-to-left position can be easily adjusted by pulling on either of the tether sutures that attach to the implant ends (Figure 8). Once the implant is properly centered, it is filled with the proper amount of saline, which is dictated by the specific length and diameter of the implant. Approximately 0.45 mL are used to fill the 4.5-mm diameter implant that is 4 cm in length. Experienced surgeons may choose to add or remove an additional 0.2 mL to suit their desired result. The filler tube is then removed by gently pulling it out of the implant while stabilizing the implant by pinching the implant at its proximal end through the lip or with gentle tension on the distal passing suture (Figure 8A). A self-sealing valve contains the injected saline. Finally, the tether sutures are removed (Figure 8B),

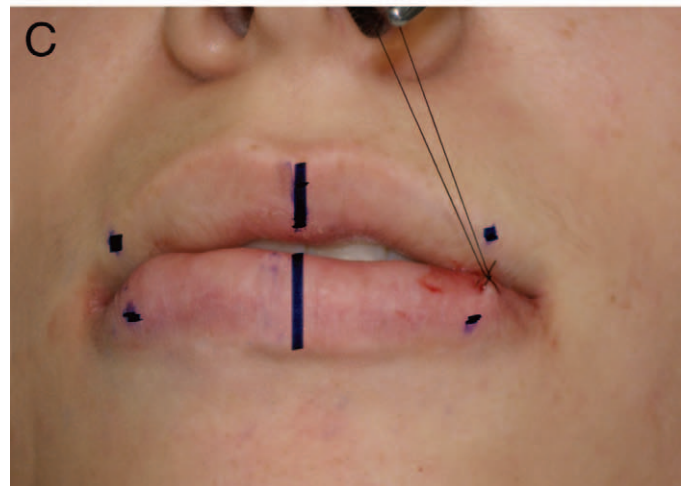
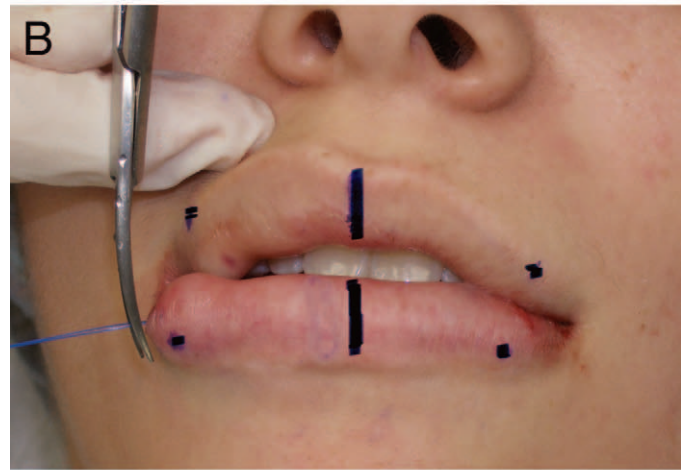
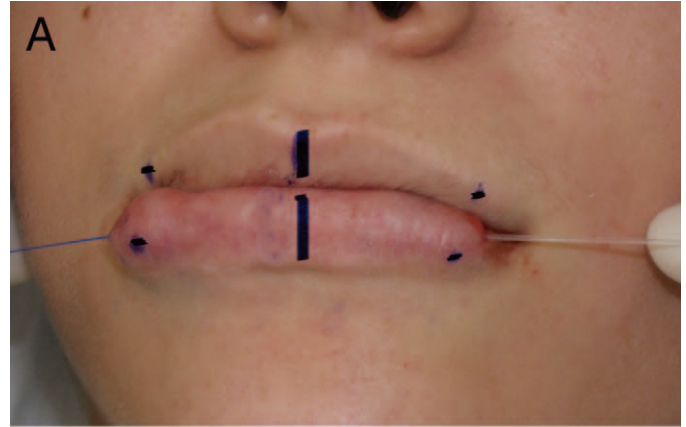


Figure 8. Figure 8A shows the fill tube being pulled out of the implant while maintaining counter pressure with the tether suture. Figure 8B shows the tether suture being cut after the fill tube has been removed, and Figure 8C shows the incision being closed with a 6-0 silk suture.

and the incisions are closed with either 6-0 gut or 6-0 nylon (Figure 8C) and left for 5 days.

Postoperative care consists of ice to the lips for the first 24 hours and limitation of extreme oral function for

the first 5 days. Patients are asked to limit talking and avoid puckering or extreme animation and to eat soft foods for several days. Patients continue antibiotics for the next week and return for follow-up. Immediate postimplant swelling is expected and generally resolves over the next 3–5 days.

In this initial series, the author has placed 25 implants over a 7-month period, with no implants being rejected or infected. All patients in the author's initial series have been happy with the augmentation result and the natural look and feel, and no patient has complained about loss or change of oral function or facial animation. Several patients have reported that the implant "passes the kiss test." Three implants were removed by the author because one end was too superficially placed. This was a result of an earlier prototype implant design that used only a single incision. The implant was placed through a cannula, but instead of an exit incision, the needle was pushed through the lip mucosa. Although this design was surgically less invasive, it encouraged a more superficial placement of the distal implant tail, which was palpable and sometimes visible through the skin. In the 2 cases of explantation, the implants were easily identified through a small stab incision with blunt dissection. Once located, the implant was punctured, and the deflated device was easily removed without disturbing the surrounding tissue. Figures 9 and 10 show before and after photographs of EveraFil implant patients.

Discussion

Lip implants are not a new idea and have been used in several forms over the years.^{11–19} Early ePTFE (Gore-Tex, Soft Form) proved problematic, with contraction, hardening, and unrestricted animation.^{17–19} This author has reported experience with Advanta dual core ePTFE implants,¹⁸ which have been largely successful and biocompatible but still have the inherent characteristics of a solid implant in the very mobile lip. The new concept of a flaccidly filled soft implant is intriguing to both surgeons and patients, and if experience shows this new implant to be a viable alternative, it has the potential to significantly affect the art and science of lip augmentation.

Injectable fillers will no doubt remain the most popular option for lip augmentation and have the advantage of sculpting as opposed to merely volume augmentation. However, injectable dermal fillers required the cost and inconvenience of repeated treatments to provide the patient with enduring enhancement. With the popularity and acceptance of saline-filled breast implants, many patients will be attracted to a more



Figure 9. A 24-year-old patient with upper and lower VeraFil implants (4.5-mm diameter \times 4.0-cm length) shown before treatment (A), and 6 weeks after placement (B). The same patient exhibiting normal animation after implant placement (C and D).

permanent solution of lip enhancement. Advantages of the EveraFil implant in the early experience include a new and unique device, ease of placement (less than 15 minutes with local anesthesia), predictability, volume adjustability, natural feel and appearance, and reversibility. Significant disadvantages have not manifested in this early and small trial. At the time of



the submission of this article, a total of 475 implants have been placed internationally by 41 surgeons. Of these, 399 implants were in the lips, 90 in the nasolabial folds, 4 in the tear trough, and 2 in the chin. As of June 9, 2007, 102 implants have been in place for more than 1 year, 32 of which have been in place for more than 18 months.¹⁹ There has been 1 confirmed infection and 1 suspected infection as well as a single case of dehiscence (surgeon's first case) through the incision. One implant shifted superiorly in the lip and was removed and replaced. A total of 30 implants have been removed for cosmetic indications such as the desire for a larger implant, perceived asymmetry, or palpability, approximately 20 of which were from the lips. All but 5 have been replaced. Removal of the implants has been a straightforward procedure, with some implants removed after 1 year. There have been no cases of late extrusions. In the early experience, there were 3 valve failures resulting in a loss of volume fill in devices implanted in the nasolabial grooves. In all 3 cases, these devices were known to have been constructed from an out-of-specification valve tubing and had been reinforced with suture tied around the valve. Since improving material sourcing, there have been no known valve failures. No implants have ruptured, and none have formed excessively thick capsules. Ultrasound imaging has been used to confirm implant integrity as well as volume and position maintenance.

One relative disadvantage may lie in the attempt to use fillers in conjunction with a saline-filled implant. This author has on numerous occasions used injectable fillers to enhance Advanta dual-porosity solid ePTFE implants. With a solid implant, there is no danger of damage or deflation by the filler needle. Although a filler could be theoretically used with a saline-filled implant and has been reported as part of the worldwide experience, great care would be necessary not to puncture the membrane. Another, and minor inconvenience, is the decision on what length and diameter is appropriate for a given patient. The fact that the VeraFil implants come in a variety of sizes and shapes is advantageous, but this can be confusing for the novice surgeon. This author is working on a clear overlay template that is placed over the lips to assist in the selection of the appropriate implant.

As with any new innovation, we should reserve judgment for the test of time and approach all avenues with evidence-based science. This author has significant interest and experience with lip implants, and in this initial series, the VeraFil implant appears to have potential as a new and viable alternative to permanent lip augmentation.

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Figure 10. (A) This 45-year-old woman was treated with an upper and lower VeraFil implants and is shown on the left before treatment and on the right 3 months after the procedure. (B) This 54-year-old patient is shown on the left before treatment and on the right 1 month after placement of upper and lower (4.5-mm diameter × 4-cm length) VeraFil implants. (C) The same patient as shown in (B) in the oblique view, left before treatment; right after treatment.

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