

SoftformTM for Facial Rejuvenation: Historical Review, Operative Techniques, and Recent Advances

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ABSTRACT *The deep nasolabial fold and other facial furrows and wrinkles have challenged the facial plastic surgeon. A variety of techniques have been used in the past to correct these troublesome defects. Advances in the last five years in new materials and design have created a subcutaneous implant that has excellent properties. This article reviews the development and use of SoftformTM facial implant.*

KEY WORDS: SoftformTM; expanded polytetrafluoroethylene; EPTFE; implants; nasolabial fold; wrinkles; face; operative techniques

Aesthetic surgeons have long sought a material to correct facial defects. Despite advances in techniques, deep wrinkles and folds cannot be consistently reversed by injectable fillers. An ideal implant has not yet been discovered.¹ There exists no material to date that is fully biocompatible and elicits no inflammatory response. The ideal implant also would be easy to shape, readily available, permanent, and easy to remove if necessary.

HISTORICAL REVIEW

Autogenous material has always been considered the gold standard of implants.² Fat, muscle, bone, or cartilage may be harvested from the patient. Although these materials are biocompatible, they are not without problems. Donor site morbidity, warping, resorption over time, and uneven correction are only some of the difficulties encoun-

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tered with autologous implants.¹⁻⁵ More recently homografts are being used for correction of facial defects and injectable homographic material is currently under investigation. Different alloplastic materials have been employed over time, and often abandoned. Synthetic materials include collagen, silicone, and expanded polytetrafluoroethylene (EPTFE). Unfortunately, many implants have been associated with complications such as infection, extrusion, or inflammatory reactions, thus limiting their wide acceptance and use.

Gore-Tex and EPTFE

W. L. Gore developed expanded polytetrafluoroethylene (EPTFE) in 1969.⁶ It is composed of nodules of solid polytetrafluoroethylene interconnected by thin flexible fibrils of polytetrafluoroethylene. The material has a microporous architecture, with a 10 to 30 μm pore size.³ Surgical interest in EPTFE was generated when a cardiovascular surgeon observed Gore demonstrating the properties of the material.⁴ The material, Gore-Tex, was studied extensively in the 1970s, primarily as a vascular replacement graft.⁷ There is extensive literature describing Gore-Tex's success in vascular surgery. Over 5 million vascular replacement procedures have been performed without a reported case of rejection. The utility of this material further expanded when EPTFE was used for abdominal wall replacement in the early 1980s. Applications for its use are found in general, cardiovascular, and urogynecologic surgery.³⁻⁷

The use of EPTFE soft-tissue patch in facial plastic surgery was first reported in rodents after short-term subcutaneous implantation. The implant has also been used by multiple authors to fill in nasal and glabellar creases and augment malar bones and chins with much success. Maas et al. (1993)⁴ provided long term followup, by subcutaneously implanting the graft in rabbits and sacrificing the animals at three weeks, six months and 12 months. The animals were observed for wound infection, seroma, or hematoma formation. Tissue specimens were examined en bloc to assess for implant stability, which was found to increase over time. Histologically, using light and scanning electron microscopy, there was minimal inflammatory cell reaction which diminished and stabilized over time. The implant provided minimal fibrous tissue ingrowth, just sufficient to confer stability over time. A delicate fibrous capsule was formed over the implant, suggesting it could be removed if necessary.

EPTFE Applications

Several studies have looked at EPTFE for nasal dorsal augmentation.^{1-3,8} Owsley and Taylor (1994)³ had the largest study, analyzing 106 patients over a five-year period. The Gore-Tex patch was used in a wide variety of cases, from extensive nasal dorsal reconstruction to small, localized nasal defects or irregularities. Postoperative followup revealed a stable implant material with no complications related to the graft material. The authors have recently re-examined these patients and confirm their failure rate of less than 1%. A second retrospective report of 137 patients with 6 to 80 month followup documented a 2.2% infection rate with one additional revision for excessive augmentation.

The Gore-Tex Company in recent years refabricated the material for implantation into the subcutaneous space. Gore-Tex SAM facial implant differs from previous formulations to allow for increased expansion of the polytetrafluoroethylene (PTFE) material.⁷ This new material is thicker with decreased tensile strength and suture retention capabilities. Another version of this new formulation is composed of PTFE between fluorinated ethylene propylene. This can be produced in a 7 mm sheet and is also available as preformed chin, nasal, and cheek implants of varying sizes. These changes do not affect the tissue ingrowth characteristics of the material. These materials have all been approved by the FDA.

The use of PTFE in the treatment of facial wrinkling and contouring has been more controversial.^{1,6-10} PTFE was first reported for these uses in 1991. Mole (1992)⁶ reported results from 120 procedures from 1985 to 1990. He recommended placing the implant as superficially as possible, but never more superficial than the subcutaneous tissue.⁶ Two patients required implant removal for foreign body reaction. Temporary periods of visibility of the implant were also noted, and were thought to be due to spontaneous or secondary edema. Patient dissatisfaction was also noted, although not quantified. Five patients developed infectious complications. Mole felt that there might be a learning curve to the procedure, and that it should be used as an adjuvant procedure rather than on its own.

Artz and Dinner (1994)⁵ employed the use of Gore-Tex strips using a trocar through a stab wound. Their 15 month followup showed great success with high patient satisfaction. They reported no complications related to infection, inflammation, or induration. In contrast to Mole, all patients were placed on antibiotics for three days after the procedure; no perioperative antibiotics were given. Many other reports, however, have listed patient dissatisfaction with the implant as

well as extrusion, infection, and curling necessitating its removal.⁷⁻¹⁰

Development of Softform[™]

Concern about these problems led Maas et al. (1988)¹¹ to investigate different implant designs. A study was undertaken at the University of California at San Francisco to determine whether the tissue stability of ePTFE in a porcine model could be affected by the shape of the implant. Strips and cords of ePTFE induced a limited amount of fibrous ingrowth that was insufficient for high levels of stability and resulted in a rate of exposure of approximately 4%. A tubed form of the material resulted in an ingrowth of fibrous tissue through the lumen of the structure that significantly improved stability, resulting in an exposure rate of <1%. In addition, the convex surface of the tube appeared to improve tissue augmentation of the overlying soft tissue. These encouraging results led to the development of a tubed system of delivery for ePTFE and eventual FDA clearance for marketing and distribution under the trade name Softform[™].

Softform[™] Applications

Softform[™] is manufactured and marketed by the Collagen Corporation (Santa Barbara, CA) as a facial implant.¹² The implant is a tubular-shaped ePTFE mounted on a closed trocar delivery system. The tubular design allows tissue ingrowth to help stabilize the implant in mobile areas such as the lips and nasolabial folds. The device and implant have FDA approval for subdermal augmentation treatment of deep furrow such as nasolabial folds, oral commissures, and vermilion border definition enhancement.

Clinical trials using Softform[™] were performed at the University of California at San Francisco (data unpublished). Thirty-three patients received a total of 73 implants with a followup period of 12 to 20 months. Correction as determined independently by the patient and physician were uniformly rated as excellent. Sites for augmentation included the upper and lower lips, the nasolabial folds, scars, and soft tissue defects.

A low rate of complications from the Softform[™] implant was noted and in all cases was related to inaccurate placement at the time of the procedure. In such cases the material was removed easily and replaced to satisfaction with better accuracy. No patients in the trial experienced extrusions related to infections.

More recently, in a test of "softness," the Shore A Durometer, an instrument employed for objective

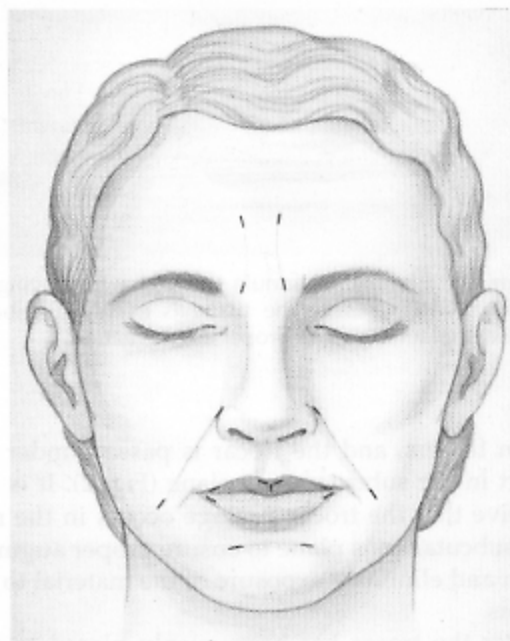


Figure 1. Markings for entry and exit sites at glabellar furrows, nasolabial folds, upper and lower lips, and horizontal chin crease.

measurements of material hardness was used. Softform[™] tubes were found to be significantly less hard than other forms of ePTFE (strips) and of silicone implants (unpublished data).

OPERATIVE TECHNIQUE

After a site for augmentation has been selected (upper and lower lips, nasolabial folds, deep facial creases, scars and tissue defects), the defect is carefully marked and local anesthetic is administered (Fig. 1). Using sterile technique, small 3 to 5 mm stab incisions are created at entry and exit sites of the rhytid or fold. The skin is gently grasped be-



Figure 2. The trocar is passed in the subcutaneous plane of the lip or under the defect with the skin grasped between the fingers.

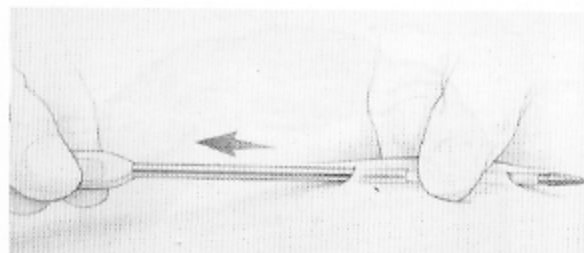


Figure 3. The metal cannula is withdrawn, leaving the trocar/implant in place. The tissue is evenly distributed over the implant to ensure proper augmentation.

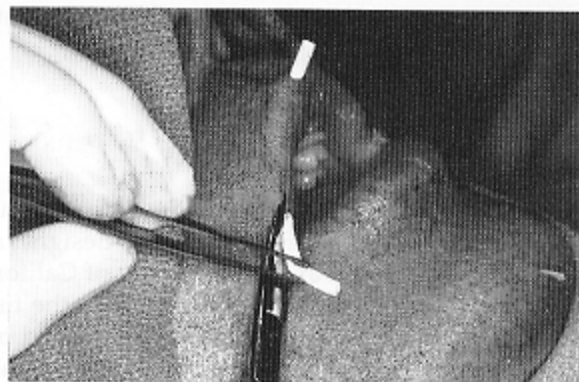


Figure 5. The Softform[®] tube is trimmed at the ends at a 45 degree angle with an extra 2 to 3mm of length on each side in anticipation of potential shortening.

tween fingers, and the trocar is passed under the defect in the subcutaneous plane (Fig. 2). It is imperative that the trocar passage occurs in the natural subcutaneous plane to ensure proper augmentation and eliminate exposure of the material to the dermis.

After the trocar has been evenly placed to traverse the crease, the plunger at the tip of the device is released. The metal cannula is withdrawn, leaving the trocar/implant in place (Fig. 3).

The trocar is advanced as the implant remains within the tissue to augment the defect (Fig. 4). The full length of the crease must be traversed or the desired results will not be obtained.

The tube is then trimmed at an angle parallel to the skin surface (Fig. 5). The implant is trimmed with an extra 2 to 3 mm of length. Prior to tucking the ends of the material into the subcutaneous tissue, the surgeon ensures that both lumen are open to allow for tissue ingrowth. The wounds are closed with interrupted fine sutures, which are removed in 3 to 5 days.

Lip Augmentation

In performing lip augmentation with Softform[®], the trocar should be centered just below the vermillion border to ensure maximal enhancement of

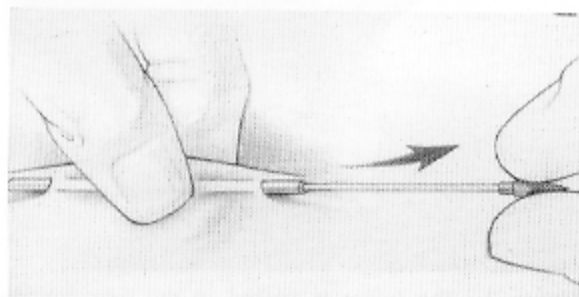


Figure 4. The trocar is advanced, leaving the implant traversing the site to be augmented.

the lip roll. From the experience of Dr. Corey Maas, senior author, if the desired effect includes retaining the cupid's bow, two separate implants are placed. Each implant should follow just below the border of the lip to retain the cupid's bow shape. A single, central, vertically-oriented exit site is then used. If retaining the shape of the cupid's bow is less important, a single implant is used to traverse the entire upper lip border (Fig. 6). The newer 9.0 cm length implants are necessary for such applications.

Multiple attempted passages and excessive vertical movement of the trocar during placement should be avoided as they can result in labial vessel damage. Careful preoperative marking and a single accurate pass provide excellent results with minimal bruising.

Nasolabial Augmentation

When augmenting the nasolabial crease, the trocar is centered just below the fold to achieve maxi-

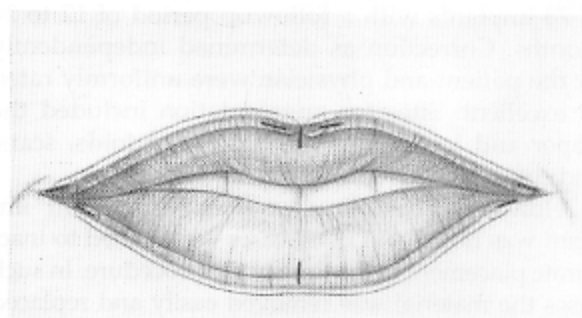


Figure 6. Incision markings for entry and exit sites of the lips. In the central upper lip, a single vertical incision or two horizontal incisions can be made if two implants are to be used in the upper lip.

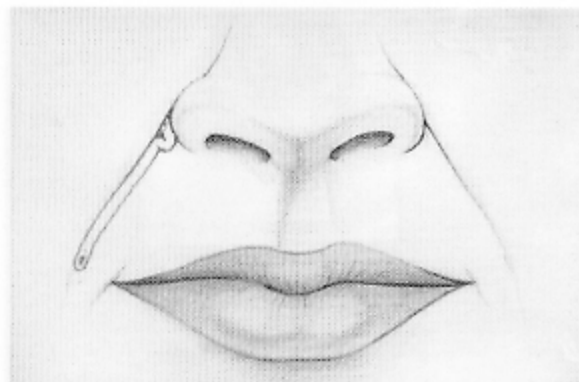
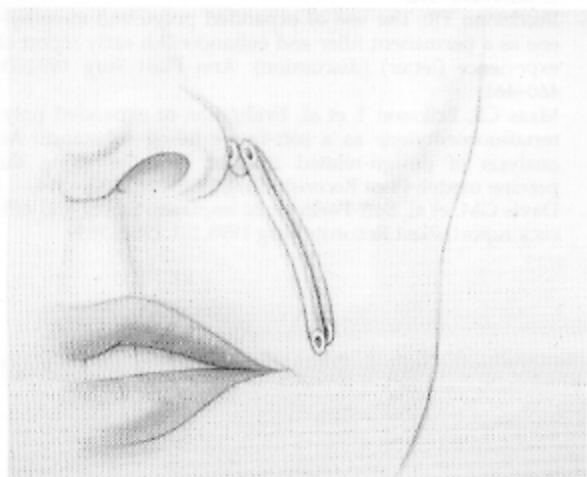
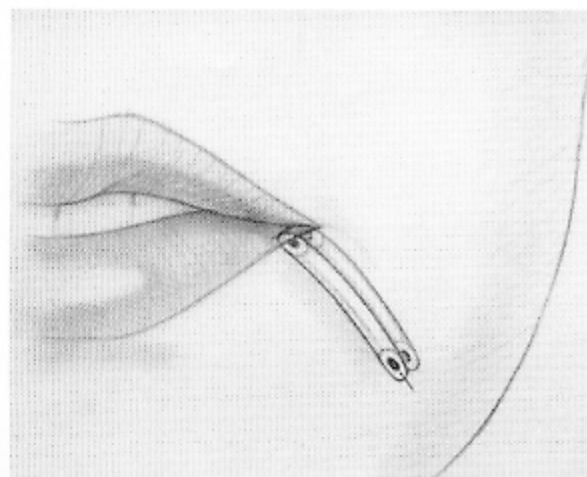


Figure 7. After the implant is trimmed at the nasofacial crease with an extra 3 to 4 mm, the end is tucked into the triangular depression to improve augmentation at this site.

mal augmentation. The implant is trimmed 3 to 4 mm beyond the exit site to allow the surgeon to tuck and fold the end into the triangular depression at the nasofacial crease (Fig. 7). This allows



A



B

Figure 8. Improved augmentation for deeper creases can be achieved by stacking the implants side by side (A) Nasolabial creases. (B) Labial creases.

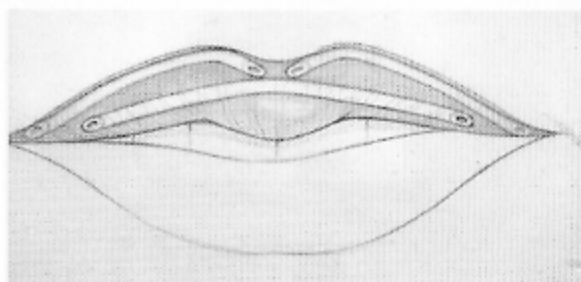


Figure 9. An additional implant at the midheight of the upper lip creates an "A-frame" structure that increases the vertical height of the lip.

for improved augmentation of the crease at this site.

RECENT ADVANCES

The sizes of the various implants differ in tubal diameter and total length to allow for appropriate amounts of augmentation to fit the aesthetic need. Current sizes include 2.4 mm, 3.2 mm and 4.0 mm diameters with 5.0 cm, 7.0 cm, and 9.0 cm lengths. Increased lengths of tubular EPTFE are needed for longer indications, such as for the lower lip. For the lower lip, the 7.0 cm implant is insufficient.

Refinements in technique include careful re-draping of the skin over the cannula to ensure a proper length to the implant. This is done prior to trimming an additional 2 to 3 mm on each side and before tucking the Softform™ under the dermis.

In addition, to treat deeper creases or to significantly augment lips implants can be stacked side by side; improved augmentation thus can be achieved (Fig. 8).

In the experience of Dr. Miller, senior author, increasing the vertical height of the upper lip can be achieved by placing an additional implant at the midheight of the lip in an "A-frame" configuration (Figs. 9 and 10).

SUMMARY

EPTFE is an excellent material for soft tissue augmentation because of its natural feel, high biocompatibility, and low infection rate. The tubular design of the SoftForm™ implant provides stability which had limiting its use in mobile facial areas. The trocar/implant delivery system helps to insure consistent results. Longterm effects are yet to be established.

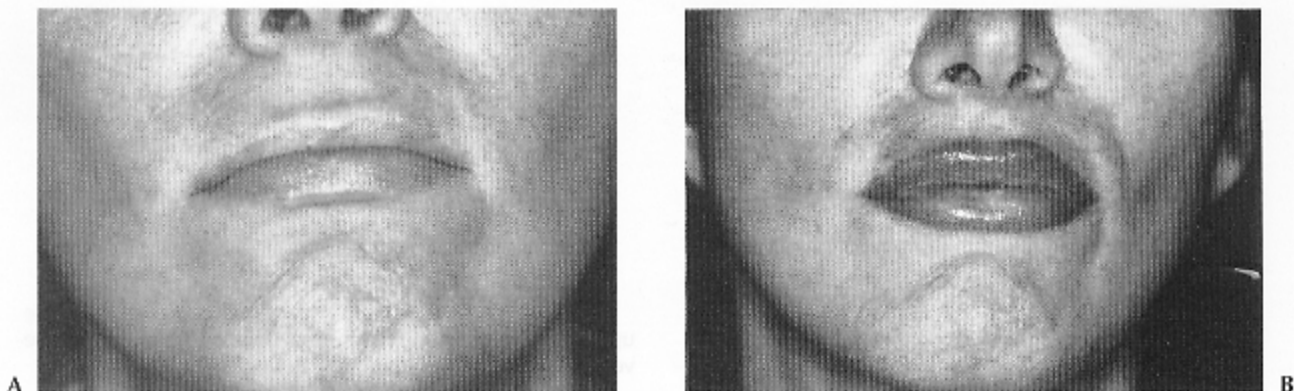


Figure 10. The upper lip vertical height has been increased by employing the "A-frame" structure. (A) Preoperative view. (B) Postprocedure photographs after augmentation of the upper and lower lips.

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