Dual-Porosity Expanded Polytetrafluoroethylene Implants for Lip, Nasolabial Groove, and Melolabial Groove Augmentation

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Objective: To evaluate the clinical outcomes with the use of a dual-porosity expanded polytetrafluoroethylene implant for midfacial rejuvenation.

Design: An institutional review board–approved retrospective chart review was conducted of all patients who underwent implantation with the dual-porosity expanded polytetrafluoroethylene implant between 2001 and 2005.

Results: A total of 170 patients, with 612 implants, were evaluated. Only 8 patients had minor complications, 3 of which necessitated implant removal. The overall results of independent observer analysis of outcomes were favorable in the majority of cases.

Conclusion: The dual-porosity expanded polytetrafluoroethylene implant is safe and reliable to use for midfacial implantation.

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A common dilemma for the plastic surgeon who performs facial surgery involves correcting depressions in the nasolabial grooves, marionette lines, and melolabial grooves. Also, many patients wish to have fuller lips, and obtaining long-term results is often difficult. Currently, there are several options for addressing these problems, including synthetic injectables, autogenous tissue, and homogenic, xenogenic, or synthetic implants. The ideal implant would be affordable, easy to insert, and nonabsorbable, and it would have minimal palpability, excellent biocompatibility, good biointegration, high patient acceptability, minimal shrinkage, ease of removal, predictable long-term behavior, no propensity to migrate, the capability to be individualized, and low visibility.1,2

Expanded polytetrafluoroethylene (ePTFE) (Gore-Tex; WL Gore & Associates Inc, Flagstaff, Ariz) implants have been used in the United States since 1971. They have applications in cardiovascular surgery, general surgery, reconstructive surgery, urology, and cosmetic surgery.3 Potential complications include extrusion, infection, migration, shrinkage, and scarring.4

Advanta (Atrium Medical Corp, Hudson, NH) ePTFE implants, which have a unique design that incorporates 2 pore sizes, became available for use in the United States in 2001. They consist of a soft, high-porosity (100-µm) center surrounded by a smooth, medium-porosity (40-µm) outer sheath. This dual-porosity material in theory increases tissue ingrowth and decreases inflammatory response. The implants are available in multiple sizes, with and without a trocar, and in round and oval shapes. We present our experience with more than 600 Advanta implants in 170 patients.

METHODS

The procedure for implantation is fairly straightforward. To decrease the risk of infection, we soak the implants in gentamicin sulfate solution before implantation. The senior author (J.G.) also likes to use implants without the trocar attached because he believes that this method leads to more precise placement and less likelihood of inadvertent skin damage when the device is inserted. A stab incision through the skin is made at both ends of the implant placement. For the nasolabial grooves, the incisions are made superiorly just below the edge of the nasal ala and inferiorly at the level of the oral commissure. For the lips, the incisions are made in the mucosa, just inside of the oral commissure. For the melolabial grooves, the incisions are made approximately 1 to 2 cm inferiorly just outside the lips.
A blunt probe is then used to dissect a subcutaneous pocket for the implant. A specially designed passer with an alligator-style grip is then used to pass the implant through the tunnel. The implant is trimmed in vivo, and the wound is irrigated with gentamicin solution and closed with 5-0 fast-absorbing plain gut sutures.

For our study, a retrospective chart review was conducted of patients who underwent ePTFE implantation at an outpatient surgery center in a cosmetic practice. Information gathered included demographic characteristics, dates of surgery and follow-up, site of implantation, postoperative complications, and overall patient satisfaction. Preoperative and postoperative photographs were evaluated by independent observers and rated on a scale of 0 to 2 (0, no improvement; 1, minimal improvement; and 2, significant improvement). This information was then entered into a Microsoft Access database.

### RESULTS

A total of 170 patients, with 612 implants, were identified. The distribution of the implants was as follows:

<table>
<thead>
<tr>
<th>Location</th>
<th>No. (%)</th>
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<tbody>
<tr>
<td>Upper lip (102)</td>
<td>17 (16.7)</td>
</tr>
<tr>
<td>Lower lip (101)</td>
<td>15 (14.9)</td>
</tr>
<tr>
<td>Nasolabial fold (112)</td>
<td>15 (13.4)</td>
</tr>
<tr>
<td>Melolabial fold (92)</td>
<td>30 (32.6)</td>
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</tbody>
</table>

Fourteen patients reported dissatisfaction with their implants, but none of the implants were removed. Minor complications were reported by 8 patients, 3 of whom required removal or trimming of their implants. The photographic comparison revealed good results overall (Table). For the upper lip, 17 patients were rated as having significant improvement; 76, minimal improvement; and 9, no improvement (mean [SD], 0.99 [0.72]; mode 1). For the lower lip, 15 patients were rated as having significant improvement; 73, minimal improvement; and 13, no improvement (mean [SD], 0.89 [0.81]; mode 1) (Figure 1).

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As mentioned, there were 8 complications, 3 of which resulted in implant removal. Two patients were noted to have implant asymmetry, which was corrected with simple massage of the area. One patient underwent a second exploration of the area of implantation for possible abscess. No abscess was noted, and the patient responded to treatment with oral antibiotics. In 1 case, there was an obvious impression in the upper lip, which was trimmed in the office with the patient under local anesthesia. The last patient complication involved bubbles in the lip, which simply dissipated over time.

### COMMENT

As people age, the midface and perioral region age as well. Over time, the facial retaining ligaments become lax and midfacial droop results. This descent of the midfacial soft tissue prominences from the malar imminence in-
inferiorly creates a deepening of the nasolabial grooves. With youth, the perioral area lacks rhytids and has a significant fullness, and the vermilion border is more prominent in the lower lip than in the upper lip. With age, the upper lip thins, resulting in a decrease in vermilion exposure, drooping of the lateral commissures, and reduced upper teeth display. Gravitational forces result in a downward pull of the lower lip and an increased show of the lower teeth. Fine rhytids begin to appear in both the upper and the lower lips and radiate perpendicularly from the circumference of the oral cavity, extending to the nose superiorly and the melolabial sulcus inferiorly. Long-term correction of these gravitational effects is challenging and has resulted in a range of available procedures.

Several reports in the literature have attested to the safety of ePTFE implants. We present the largest series (to our knowledge) on ePTFE implants to date, and our findings confirm the minimal complication rate and favorable long-term results with the use of these implants. As noted previously, there are several advantages to the use of the dual-porosity model over that of earlier, single-porosity implants. In a porcine model, it was shown that the dual porosity produced more tissue ingrowth at 1 year after implantation. However, the ingrowth was noted to be gradual, and although implant removal was not difficult at 30, 60, or 90 days, longitudinal dissection was required at 180 and 360 days after implantation. This increased tissue ingrowth will theoretically reduce extrusion and allow permanent maintenance of the implant position.

Our results show that although only a minority of patients had a significant improvement in their appearance, there were very few patients who experienced no improvement at all. Therefore, it appears that the Advanta implants provide subtle improvement for patients as measured subjectively by an independent observer using preoperative and postoperative photographs. There may be several reasons for the lack of improvement that was observed in some of the patients. The presence of deep nasolabial folds may have necessitated additional midface-lifting procedures for optimal results, but the procedures were not performed. Also, initial results may have been compromised by the lack of variety in implants. Early implants were only available in a 3.0-mm round design, while the selection now comes in round and oval varieties up to 6.0 mm.

Given the relative low morbidity and the long-term results, we believe that ePTFE implants should be considered in patients who want improvement of their nasolabial grooves, melolabial grooves, and upper and lower lips. It would also be interesting for future research to compare short-term results with the ePTFE implants and those with soft tissue fillers, because the results may be comparable in a side-by-side comparison.

Advanta implants are available in both round and oval forms. The senior author prefers the round implants because they do not cause contour deformities if they shift after placement. The use of round implants may be part of the reason for the low rate of long-term postoperative removal. Although there is no evidence for or against the use of antibiotics, the senior author judiciously uses them in patients who are undergoing foreign body implantation. Implants are routinely soaked before implantation; wounds are irrigated with antibiotic irrigation before closure; and patients are maintained on a postoperative regimen of antibiotics, which likely contributes to the low observed infection rate. Another advantage of permanent implants over temporary fillers is that even though the unit cost of the implant and procedure may be greater than the unit cost of the filler, this drawback is offset by the repetitive nature of filler use; therefore, there is actually a decreased overall patient cost with the use of the permanent implant. Similar to synthetic fillers, permanent implants can be easily removed in the early postoperative period if the patient is not satisfied, and the removal can be done in the office with the patient under local anesthesia.

In conclusion, Advanta ePTFE implants provide a safe, effective, and long-term option for augmentation of deep facial creases and appear to be an excellent choice for subtle improvement of the nasolabial grooves, melolabial grooves, and lips. They should be considered a useful addition to the cosmetic surgeon's armamentarium.

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Author Contributions: Dr Verret had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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REFERENCES