Patient Satisfaction With Expanded Polytetrafluoroethylene (Softform) Implants to the Perioral Region

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Objective: To assess clinical results in patients undergoing implantation of expanded polytetrafluoroethylene (Softform) for perioral enhancement (melolabial fold, melomental fold, upper lip, and lower lip).

Design: Fifty patients had undergone Softform implantation by a single surgeon. A retrospective telephone survey (25 questions) was conducted. Of 50 patients, 38 (76%) were contacted. The mean interval between the procedure and survey was 22.7 months (range, 2-40 months). Responses were submitted for statistical analysis. A pathological review was performed on specimens removed from 2 patients.

Results: Two patients (4%) developed postoperative infections that resolved with use of oral antibiotics; 5 patients (10%) requested repositioning owing to dissatisfaction with placement; and 5 patients (10%) requested implant removal. Composite scores indicated that patients were “slightly” satisfied with the procedure outcome. Of the 38 patients contacted, 24 (63%) would undergo additional implants and 20 (53%) would recommend the procedure to others. Results were not significantly influenced by site, size, or history of prior augmentation procedures. Histologic review indicated that implants elicit a chronic inflammatory reaction and that blood vessels infiltrate the porous walls of the implant.

Conclusion: With proper patient selection, Softform represents a potential option for those individuals considering perioral enhancement.

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GORE-TEX (W. L. Gore and Associates, Flagstaff, Ariz) is the registered trademark name for expanded, fibrillated polytetrafluoroethylene (e-PTFE). A tubular form of e-PTFE (Softform; Collagen Corporation, Palo Alto, Calif) has been used for enhancement procedures of the face (eg, lip enlargement and flattening of rhytids). Since 1998, 3 different widths of e-PTFE tubing have been commercially available (2.5, 3.2, and 4.0 mm). However, to date, there have been no published reports reviewing patient satisfaction with implants to the perioral complex.

METHODS

Softform was implanted in 50 patients by the senior author (P.A.A.) between 1998 and 2001. Implants were placed in 4 anatomic areas: the melomental fold, melolabial fold, upper lip, and lower lip. In the experience of the senior author, it is best to introduce 2 smaller implants into the upper lip and a single implant for the lower lip. For the melolabial folds, single implants are placed inferomedial to the crease.

A survey consisting of 25 questions was prepared with the assistance of the Statistical Consulting Service, Department of Statistics, University of Toronto, Toronto, Ontario. Patients were contacted by a single physician (S.J.W.) by telephone, and responses were recorded. Where appropriate, results are presented as the mean ± SEM. To test for group differences, analyses of variance was applied.

Pathological review was performed on specimens removed at the request of 2 patients. Implants were fixed in 10% neutral-buffered formalin and processed for paraffin embedding. Sections were cut onto glass slides at a thickness of 5 µm and stained with hematoxylin-eosin. Alternatively, slides (treated with Silane adhesive, DAKO Diagnostics Canada, Mississauga, Ontario) were processed for immunohistochemical studies. Immunoperoxidase analyses were performed with the streptavidin-biotin method, using NovaRED (Vector Laboratories Canada, Burlington, Ontario) as chromogen and hematoxylin as counterstain. The primary antibody reagents used were rabbit polyclonal antihuman von Willebrand factor (anti-Factor VIII; DAKO Diagnostics Canada), which has specificity for endothe-
Of the 50 patients (43 women [86%] and 7 men [14%]), 38 (76%) were contacted. The remaining patients were lost to follow-up, resided out of the country, or did not respond to telephone messages. The mean interval between procedure and survey was 22.7 months (range, 2-40 months). There was no significant difference in ages between sexes (women, 51 years [range, 21-71 years]; men, 58 years [range, 29-77 years]). Eleven (29%) of the 38 patients had undergone at least 1 cosmetic procedure prior to implantation. Furthermore, 16 patients (42%) had received previous injections with temporary fillers (collagen or hyaluronic acid products [Perlane and Restylane; Q-Med Esthetics, Uppsala, Sweden]), 2 (5%) had injections of permanent filler (polymethylmethacrylate [Artecoll; Canderm Pharma Inc, St Laurent, Quebec]), while 9 patients (24%) had no prior interventions. (Of note, Perlane, Restylane, and Artecoll have been approved for use in Canada and Europe, but not in the United States at the time of the survey.)

Of the 38 patients contacted, 30 (79%) cited the surgeon (P.A.A.) as principal source of information on Softform and 36 (95%) believed that they had received an adequate amount of information prior to implantation. Most patients (24 [63%]) reported that the level of discomfort was within expectations, while 7 patients (18%) indicated that discomfort exceeded expectations. Postoperative edema was less than expected for most patients (31 [82%]). Only 1 respondent (3%) believed that the incision sites were very noticeable, 13 (34%) considered them slightly visible, and 25 (66%) did not find them noticeable.

A total of 88 sites received implants in the 50 individuals. Of the 50 patients, 24 (48%) received implants to a single site, 15 (30%) to 2 sites, 8 (16%) to 3 sites, and 3 (6%) to 4 sites. For most regions (69 of 88 sites), the intermediate-sized implant (3.2-mm diameter) was used (Figure 1). This reflects a combination of factors: (1) the 4.0-mm implant was not introduced until 1999, (2) surgeon recommendations (P.A.A.), and (3) a patient preference for a more “conservative” enhancement rather than “dramatic” augmentation. In general, the upper lip was the area where a more significant enhancement was most commonly desired. Accordingly, this area received the 4.0-mm implants most often (4 of 9). The region that most commonly received the small implants (2.4 mm) was the melolental fold (3 of 9).

The patients were questioned about the level of awareness of the implant; 20 (53%) of 38 patients reported that they were “not at all conscious,” 6 (16%) found the implant to be “sometimes bothersome,” and 8 (21%) reported that they were “always conscious” of the implant. Patients were asked if the implants were more noticeable or caused discomfort when drinking liquids, eating solids, laughing or smiling, speaking, or kissing. Of these, the most commonly cited activity (7 patients [18%]) was laughing or smiling, while 4 patients (11%) noticed the implants when applying lipstick. Of the 38 respondents, 27 (71%) denied experiencing any discomfort, while 11 (29%) reported some discomfort with lip motion.

Only a minority of patients received any comments about their postimplant appearance (13 patients [34%]), with favorable comments equaling negative comments. To more accurately gauge patient satisfaction, a 5-point scale was created (1 = very unsatisfied; 2 = slightly unsatisfied; 3 = neutral; 4 = slightly satisfied; and 5 = very satisfied). The degree of patient satisfaction was not a function of patient age. For all patients, a score of 3.47±0.22 was obtained (neutral to slightly satisfied). Figure 2 indicates the satisfaction levels reported for all patients: 18 (47%) indicated that they were slightly or very satisfied with the implants; 12 (32%) reported that they were slightly or very unsatisfied; and 8 (21%) indicated that they were neutral as to their thoughts about the implants.

Interestingly, 18 (47%) of 38 patients reported that they were more pleased in the immediate postoperative period. As edema resolved, they were less able to notice the enhancement. The highest satisfaction levels were reported for patients who had not undergone prior proce-
dures (4.09 ± 0.29). Patients with previous exposure to temporary fillers (ie, collagen or hyaluronic acid) had a mean score of 3.63 ± 0.32. Patients who had undergone prior surgery (3.00 ± 0.52) or had injection with permanent fillers (Artecoll) reported the lowest satisfaction (3.0 ± 0.41) with Softform.

Patients were questioned about their willingness to receive an additional implant in the future. Most patients (24 [63%] of 38) responded affirmatively, while 14 patients (37%) indicated that they would decline. Cost of the implant was not a deterrent to implantation (7 patients [18%]). Few patients (13 [34%]) were able to accurately recall the size of the implant used for augmentation (small, medium, or large). Approximately one third of patients (14 [37%]) would replace an existing implant with a larger size. Half of patients would recommend the implants to friends or family members.

With respect to pathological findings, Softform specimens from 2 patients were examined. In the specimen removed at 6 months after implantation, there was incomplete occlusion of the lumen, with no appreciable chronic inflammation (Figure 3). However, in the specimen removed at 33 months, the lumen was completely occluded by dense stroma containing blood vessels and a moderate infiltrate of chronic inflammatory cells (Figure 4). Immunoperoxidase staining for factor VIII antigen revealed blood vessel extension into the surrounding porous walls of the implant (Figure 5). A prominent chronic inflammatory infiltrate was also present in the outer wall of the implant (Figure 6). Staining for CD45RO, a T-lymphocyte marker, confirmed that the lymphocytes in both the lumen and the outer wall of the implant were T cells (Figure 6).

**COMMENT**

When e-PTFE is polymerized, a lattice is formed by interconnected flexible strands. Pore size ranges from 0.5 to 30 µm (mean, 22 µm). Porosity determines the accessibility of the open spaces to infiltration and anchoring by connective tissue. First developed in 1969, the clinical application of e-PTFE for vascular replacement grafting in humans was described in 1971.3 In 1983, Neel4 used a rabbit model to evaluate the reconstructive potential of PTFE (e-PTFE [Gore-Tex] and PTFE-carbon [Proplast]). Because of its favorable coloring, pliability, and minimal inflammatory reaction, e-PTFE was declared the superior product. Subsequently, e-PTFE was...
described for use in temporal region augmentation,\textsuperscript{3} nasal dorsum grafting,\textsuperscript{9} facial resuspension,\textsuperscript{7-9} cervicofacial reconstruction,\textsuperscript{10,11} and ptosis and orbital floor repair procedures.\textsuperscript{12-14}

In the earliest clinical trials with e-PTFE, Cisneros and Singla\textsuperscript{13} used Gore-Tex strips for improvement in nasolabial folds. Approximately, 10\% of patients developed a transient erythema, possibly secondary to “superficial placement” of the grafts. In 1999, Robertson and Dyer\textsuperscript{16} reported their experience with carved Gore-Tex implants for the correction of prominent nasolabial folds. In their group, 2.5\% of patients developed an infection at the implant site (\textit{Staphylococcus aureus}). All infections resolved after implant repositioning and/or a course of oral antibiotics. Conrad and MacDonald\textsuperscript{17} reported that vacuum-impregnation of the Gore-Tex implants with antibiotic solution eliminated the incidence of postoperative infection. However, low infection rates (0.3\%) have also been reported when antibiotics were not routinely prescribed.\textsuperscript{15} With respect to our population, all patients received a single dose of perioperative antibiotic. Two patients (4\%) developed a postoperative infection. In both instances, resolution occurred following a course of oral antibiotics. Removal of the implant was not necessary.

In terms of chronic inflammation, e-PTFE has been reported to elicit minimal host rejection. Thus, in studies using sheep, Hanson et al\textsuperscript{14} reported an “almost total absence of a foreign-body or inflammatory cell reaction.” Similarly, in a porcine model, Maas et al\textsuperscript{18} reported a minimal inflammatory reaction in e-PTFE specimens implanted for 3, 6, and 12 months. However, in our experience, evidence of a focal, chronic inflammatory (T-cell) response was present in implants removed from 2 patients (Figure 6). There was no evidence for acute inflammatory mediators.

In a porcine model, the shape of the Gore-Tex product was found to strongly influence the frequency of implant migration (strips [4.4\%], rolls [4.41\%], and tubes [0.83\%]).\textsuperscript{19} This observation led to the introduction of the tubular form of e-PTFE, which is commercially available in 3 diameters (2.4 mm, 3.2 mm, and 4.0 mm). In our experience, several patients reported a sudden migration of the implant following a lengthy period of stability. The implant contracted and became palpable and more prominent visibly. It is hypothesized that the implant “slipped” within the fibrous capsule that envelops the specimens over time. Alternatively, the connective tissue may not have completely filled the lumen. As seen in Figures 3 and 4, connective tissue ingrowth differed between the 6-month and the 33-month implants. This difference in lumen occlusion may reflect the greater time required for complete ingrowth along the length of the tube (up to 8 cm in the lower lip). Alternatively, crimping of the end of the tube may have occurred during placement, thereby limiting the accessibility of connective tissue elements to the lumen. A third possibility is that an air-filled lumen is created on withdrawal of the trocar. To minimize these possibilities, the surgeon should confirm that the lumen is patent on both ends of the tubing following placement. In addition, prior to wound closure, an angiocatheter should be used to fill the lumen with isotonic sodium chloride solution.

Debate in the literature has centered on the ideal thickness of e-PTFE implants. In the opinion of Conrad and MacDonald,\textsuperscript{17} fusiform-shaped e-PTFE (prepared at the time of the procedure) should be 4 to 8 mm thick to obtain optimal enhancement of the nasolabial fold region and up to 10 mm thick for the vermilion border. Lassus\textsuperscript{19} believed that 2-mm-thick sheets were adequate for augmentation of the perioral area. Other authors have thought that the texture of the e-PTFE limits the workable thickness of the implants. Thus, Wang et al\textsuperscript{20} used 1.8-mm-diameter implants in 17 female patients (23 lips). At 6 months, the authors measured an increase in both lip projection (0.98 mm) and exposed vermilion width (0.94 mm); however, they thought that the “implant does not result in a big enough change for an individual, if a safe amount of the material is used” and “it is usually not sufficient in those patients who want a big change in their appearance.”\textsuperscript{20} In our experience, we did not find a significant association between the diameter of implants and patient satisfaction.

When facial tissue is rolled between the finger tips, the Softform implant is palpable, regardless of diameter. However, when asked to describe their level of awareness of the implants, only 20 (53\%) of 38 patients reported awareness of the implants with facial movement. There was no statistical difference in patient awareness with larger (4.0 mm) vs smaller (2.4 mm) implants.

We examined whether the number of implants influenced patient satisfaction. Data were analyzed according to anatomic regions. In general, the highest degree of satisfaction was reported by patients who had received implants to 3 or more sites (3.89±0.39). As a group, those receiving implants exclusively to the lips reported intermediate satisfaction (3.46±0.42). The lowest satisfaction score was found with implants to the melolabial and melomental folds (3.18±0.35). For these areas, patients were unhappy if they detected any asymmetry during facial movement with respect to implant visibility or subjective “awareness” of the Softform. Although there was a trend toward greater satisfaction for certain groups, no significant implant location effect was detected at a 95\% confidence level ($P=0.47$) owing to the relatively small numbers for each group.

True complications with Gore-Tex implants are rare, although at least 1 case of lip necrosis has been reported after placement of Gore-Tex (not Softform).\textsuperscript{21} Owsley and Taylor\textsuperscript{8} reported a failure rate of less than 1\% in 106 patients undergoing implantation in the nasal dorsum. Maas et al\textsuperscript{18} reported a 3-year experience in which placement was deemed unacceptable in 3\% of patients (in the opinion of the surgeon). In our series of 50 patients, 5 patients (10\%) requested implant removal, and another 5 patients (10\%) requested that an implant be repositioned. We believe that patient dissatisfaction with implants to mobile areas of the face (eg, lips) may be greater than implants to nonmobile areas (eg, nasal dorsum). Also, we have observed that implants in elderly women are more noticeable than implants in younger women. With the lack of adequate soft tissue coverage, the outline of the graft is more pronounced. Thus, we would suggest caution in placing larger grafts (4.0 mm) in patients with particularly thin or “older” lips.
Two other observations are worthy of comment. First, the patients who reported the highest satisfaction with Softform had not undergone prior augmentation or surgical procedures. Lacking a reference for comparison, this group might be less critical than patients with a significant exposure to cosmetic procedures. In contrast, the lowest satisfaction scores were reported for individuals who had undergone prior surgery, although as a group, their scores fell within the “neutral” category.

CONCLUSIONS

A wide array of procedures and materials have been described for augmentation of the perioral region. Softform represents an attractive option for patients desiring a safe and reliable implant material. Although its biocompatibility offers the potential for “permanent” implantation, the inert nature of e-PTFE means that the “intact” implant can be removed if desired. Before the surgical procedure, it is important to counsel patients that implants may migrate. In our population, many patients commented that the degree of enhancement was less than anticipated, based on early results (when edema is present). Thus, the surgeon should follow up the patient frequently in the postoperative period to assess changes in satisfaction. Overall, approximately two thirds of patients would undergo the implantation procedure again. With proper patient education and patient selection, Softform represents a potential option for those individuals considering perioral enhancement.

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The Softform survey can be obtained from the corresponding author.

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