Lip Augmentation With Porcine Small Intestinal Submucosa

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Objective: To relate our initial experience using an acellular, soft tissue matrix derived from porcine small intestinal submucosa (Surgisis; Cook Biotech Inc, West Lafayette, Indiana) for lip augmentation.

Design: A prospective, uncontrolled case series examining the results of lip augmentation using Surgisis in patients presenting to an academic otolaryngology/facial plastic surgery office.

Results: Nineteen Surgisis implants were placed in 8 patients. All patients tolerated the procedure and denied unnatural sensations or complications at any interval. Adverse events included transient erythema and 1 case of local cellulitis treated effectively with oral antibiotics. Four patients were satisfied with the procedure and 4 patients requested greater augmentation. Six-month follow-up was reported, and preoperative and postoperative photography was used in all cases.

Conclusions: Short-term lip augmentation was achieved in all 8 patients (4 patients had multiple strands placed). This study demonstrates technical ease and early safety. Surgisis should serve as scaffolding for ingrowth of striated muscle of the lip, potentially providing long-term augmentation. This study introduces Surgisis as a novel implant for lip augmentation.

Arch Facial Plast Surg. 2008;10(1):30-33

The lips are a vital feature of an attractive and youthful face. Full, well-defined lips impart a sense of beauty and have been a desirable trait for centuries. Over time, cumulative forces act to thin and flatten the lips. Factors affecting the shape and contour of the lips include atrophy of the subcutaneous tissues, laxity in the perioral musculature, and demineralization of the mandible and maxilla. This alteration in the appearance of the lips is an integral component of the aging face.

Discontent with these labial aging signs has spawned the development of numerous techniques to augment lip volume and form. A myriad of injectable fillers and implantable materials, both biologic and synthetic, have been used to correct or enhance lip shape. This wide variety of treatment materials attests to the notion that to date, no ideal therapy exists. While many of these substances have produced excellent results, potential problems include donor site morbidity, transmission of cell-borne pathogens, allergic reactions, lack of durability, inconsistent results, implant migration and extrusion, and infectious complications.

Surgisis (Cook Biotech Inc, West Lafayette, Indiana) is an acellular, freeze-dried, soft tissue graft derived from porcine small intestinal submucosa that may serve as an alternative to these fillers. Surgisis has been safely and effectively used in various colorectal, urologic, and otolaryngologic procedures. Small intestinal submucosa has been shown to support and maintain cell migration and spatial organization in vitro.

The graft provides an informative-rich prosthetic scaffold into which adjacent cells migrate to create replacement tissue. These properties make Surgisis a viable option for lip augmentation. The present study addresses the initial use of Surgisis for upper- and lower-lip enhancement.

METHODS

Patients presenting to the otolaryngology/facial plastic surgery clinic seeking lip augmentation or treatment of previously acquired lip de-
Effects were offered a novel therapy using Surgisis as a soft tissue filler. Patients were excluded from participation if they had an active infectious or inflammatory condition of the implant site or a history of adverse reactions to porcine products, lidocaine, or epinephrine. Previous lip augmentation was not considered an exclusion criterion, and 1 study patient underwent a prior expanded polytetrafluoroethylene (GORE-TEX; W. L. Gore and Associates, Flagstaff, Arizona) upper-lip implantation.

Eight patients ranging in age from 35 to 70 years old signed informed consent forms for the procedure and were then photographed preoperatively, using standard techniques. Six patients were seeking cosmetic lip augmentation, and 2 patients desired treatment of previously acquired partial lip defects. Six women and 2 men were treated. In total, 19 implants were placed. Ten implants were used for cosmetic augmentation of either the upper or lower lip or both. Two implants were placed to fill partial lower-lip defects, and 7 implants were placed in patients requesting additional augmentation after the initial procedure. Seven upper lips and 12 lower lips were treated.

Prior to surgical intervention, the Surgisis strand (Figure 1) was placed in an antibiotic and isotonic sodium chloride solution for a minimum of 5 minutes to rehydrate the implant. An antibiotic with gram-positive coverage was administered, and the facial region being treated was cleansed with alcohol. Alternatively 3 mL of lidocaine hydrochloride, 1%, with 1:100,000 epinephrine was injected into the treatment area. Stab incisions were created for the entrance and exit sites of the trocar on the mucosal surface of the lip approximately 1 mm from the vermilion border. The trocar was then inserted into the submucosa through the incision and passed through the full length of the area being treated (Figure 2). The Surgisis strand was trimmed and the overlying tissue was manipulated to ensure proper positioning and prevent bunching of the implant. The incisions were closed with a single 6-0 absorbable suture. Bacitracin was applied to the incisions, and ice was placed on the lips.

Patients were seen in clinic 2 to 3 weeks postoperatively and then at approximately 4-week intervals thereafter. Questionnaires administered after the procedure were used to assess patient satisfaction, presence and level of pain, duration of pain, and complications. Patient satisfaction was graded on a 10-point scale at 2, 12, and 24 weeks after the procedure. Satisfaction was further evaluated in patients who received multiple implants 2 weeks after each successive implant was placed. Procedural pain was measured on a 10-point scale. Preoperative and postoperative photography was used in all cases.

**RESULTS**

All patients undergoing lip augmentation tolerated the procedure under local anesthesia in an outpatient setting without any substantial local or systemic complications. All patients reported procedural pain as mild. Total procedure time was less than 1 hour in all cases. No procedure was terminated owing to pain or technical problems. One strand did tear from the trocar during implantation but was easily removed, and a new implant was used to complete the treatment. Preoperative and postoperative photography was used to document results (Figure 3 and Figure 4).

Patient satisfaction determined by questionnaires found that at 2 weeks after the procedure, all 8 patients were satisfied with the results. The average score was 5.8 on a 10-point scale. Following the initial procedure, 4 patients requested additional augmentation. Of the 4 patients who underwent further implantation, 1 was lost to follow-up. The remaining 3 patients had an average
satisfaction score of 7.0 two weeks after the second implant was placed. Of the 4 patients treated with only 1 implant, 1 was lost to follow-up, and the resulting average satisfaction score was 6.3 at both 12 and 24 weeks. One patient received a third implant and following this had a satisfaction score of 10.

The procedure was well tolerated in all the patients, and the average pain score was 0.5. Six patients experienced no pain, and 2 patients each rated the pain a 2.0. In these 2 patients, the pain lasted less than 48 hours.

Adverse reactions were limited to mild transient erythema in 2 patients that resolved spontaneously and 1 case of cellulitis of the upper lip following placement of the third implant. This condition was successfully treated with a 10-day course of cefdinir. All patients denied bleeding or hematoma formation, allergic reactions, and implant extrusion. Furthermore, implants were neither noticeable nor palpable, and all patients denied changes in sensation or interference in lip function.

**COMMENT**

Surgisis is an in-formation-rich prosthetic scaffold derived from porcine small intestinal submucosa. It is composed primarily of type 1 porcine collagen. In addition, 5 glycosaminoglycans are present in the matrix: hyaluronic acid, heparin, heparin sulfate, chondroitin sulfate A, and dermatan sulfate. These glycosaminoglycans have been shown to provide structural integrity to the extracellular matrix. They also modulate the healing of tissues through the deposition of collagen fibers, stimulation of angiogenesis, inhibition of coagulation, and initiation of cell proliferation and differentiation. The amount of glycosaminoglycans in Surgisis corresponds well to the amounts reported in other basement membrane–containing tissue sites and is significantly more than that seen in skin, from which AlloDerm (LifeCell Corporation, Branchburg, New Jersey) is derived.

Surgisis is terminally sterilized to eliminate cell-borne pathogens and has been shown to elicit no immunologic response from host tissue. No skin testing is required prior to use. Use in various other sites and applications have demonstrated an excellent safety profile. In this series of 8 patients (19 implants), 1 postoperative infection occurred, and this only in the patient following placement of the third implant. The procedure was performed in a sterile fashion, and this infectious complication may have been owing to the multiple instrumentations rather than the implant material itself.

The operative procedure was well tolerated in all cases under local anesthesia in an outpatient setting. All 8 patients reported minimal intraoperative and postoperative pain. Minimal bruising and swelling occurred following implantation, with all patients reporting a return to normal activity the following day.

While all patients tolerated the procedure well with few adverse reactions, the aesthetic outcome was not universally acceptable. No patient reported asymmetry or palpable implants, but the degree of lip projection and fullness was often inadequate. Godin et al. evaluated patient satisfaction based on a 10-point grading scale after using Radiesse (BioForm Inc, Franksville, Wisconsin) and Restylane (Q-Medical, Uppsala, Sweden) for facial augmentation. With Radiesse alone in the upper and lower vermilion borders, the satisfaction scores were 7.0 and 7.3, respectively. The combination of Radiesse and Restylane into the upper and lower vermilion borders yielded satisfaction scores of 7.7 and 6.5, respectively. We used a similar satisfaction scale but did not distinguish between upper- and lower-lip implants. Our reported scores were comparable: 6.3 for 1 implant, 7.0 for 2 implants, and 10 for 3 implants.

In our series, all 8 patients reported satisfaction with the procedure at 2 weeks; however, 4 patients requested greater augmentation on subsequent follow-up. One implant provided minimal augmentation in most cases, which was often insufficient in this patient population. Placing a second, and in one case a third, implant provided the more full appearance desired by our patients. An alternative to this might be the development of a thicker implant to give a more pronounced augmentation. Wall et al. assessed patient satisfaction with expanded polytetrafluoroethylene (Softform; Collagen Corporation, Palo Alto, California) lip implants and also reported that patients were more pleased in the immediate postoperative period than on subsequent visits. Furthermore, 67% of patients were willing to receive an additional implant, and 37% would replace the existing implant with a larger size. The thickness and configuration of lip implants may need to be modified to enhance patient satisfaction.

In conclusion, this study demonstrates the ease of placement and moderate short-term efficacy of lip augmentation with Surgisis, a novel soft tissue filler. Surgisis should theoretically serve as scaffolding for growth of striated muscle of the lip, potentially providing long-term augmentation. The degree of augmentation provided by 1 implant was often insufficient, but it was improved with placement of additional implants. Surgisis implantation may be an appropriate intervention for pa-
tients seeking minor lip augmentation from a biologic implant in a well-tolerated procedure. Further studies in a larger patient population are ongoing to determine long-term safety and patient satisfaction as well as the use in additional sites within the perioral complex.

Accepted for Publication: April 5, 2007.
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Author Contributions: Study concept and design: Seymour, Leventhal, and Pribitkin. Acquisition of data: Seymour, Leventhal, and Pribitkin. Analysis and interpretation of data: Seymour and Leventhal. Drafting of the manuscript: Seymour, Leventhal, and Pribitkin. Critical revision of the manuscript for important intellectual content: Seymour, Leventhal, and Pribitkin. Statistical analysis: Seymour and Leventhal. Obtained funding: Pribitkin. Administrative, technical, and material support: Pribitkin. Study supervision: Pribitkin.

Financial Disclosure: None reported.

Previous Presentations: This article was presented at the Annual Academy of Otolaryngology–Head and Neck Surgery Meeting; September 17, 2006; Toronto, Ontario, Canada.

REFERENCES

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