Acellular Dermis for Facial Soft Tissue Augmentation

Preliminary Report

Peter D. Costantino, MD; Satish Govindaraj, MD; David H. Hiltzik, BA; Daniel Buchbinder, DMD, MD; Mark L. Urken, MD

Objective: To evaluate the efficacy of acellular dermis as a viable alternative for soft tissue augmentation in facial reconstruction.

Design: A prospective, nonrandomized observational study consisting of 10 patients who underwent soft tissue augmentation with acellular dermis.

Setting: A tertiary care university medical center in an urban setting.

Patients: Ten patients who had undergone soft tissue augmentation using acellular dermis participated in this study. Postimplantation follow-up was 17 to 36 months.

Intervention: The amount and location for placement of the acellular dermis was left to the discretion of the surgeon. All implants were placed in the subdermal tissues.

Main Outcome Measures: The adequacy of acellular dermis for soft tissue augmentation was assessed by subjective evaluation of implant volume persistence, postoperative complications, and the restoration of normal contour.

Results: Of 10 patients who underwent implantation, 9 had no complications and 1 had a recurrent sterile abscess or mucocele at the implantation site. A 22-month postimplantation tissue sampling of acellular dermis in a patient with recurrent tumor revealed approximately 80% to 85% volume persistence.

Conclusion: Preliminary experience with acellular dermis indicates that it shows promise in soft tissue augmentation.

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Facial deformities resulting from isolated soft tissue volume loss are relatively common but difficult to correct. These defects most frequently result from trauma, infection, or oncologic surgery, and their appropriate reconstruction requires that the corrective “filling” material possess similar mechanical characteristics as human soft tissue and skin. The spectrum of implant materials suitable for facial soft tissue defect augmentation includes local tissue transfer, regional vascularized flaps, microvascular tissue transfers, and synthetic or semisynthetic biomaterials. Although local and regional flaps bring vascularized soft tissue into the area requiring reconstruction, the volume and composition of such tissue might be limited or inappropriate. This is particularly true for defects requiring subdermal placement of the synthetic implant. Examples of such an implant include silicone elastomer and porous high-density polyethylene. These materials are frequently inappropriate for deformities resulting from isolated soft tissue volume loss. Recently, use of expanded porous polytetrafluoroethylene has gained popularity for isolated soft tissue augmentation and replacement. Although useful, this synthetic polymer remains as a permanent nonvascularized implant for the lifetime of the patient and carries with it the concurrent risk of immediate or long-term infection or extrusion.

A relatively new material consisting of acellular cadaver dermis (AlloDerm; LifeCell Corporation, The Woodlands, Tex, and Stryker Leibinger Inc, Kalamazoo, Mich, and receives research funding from these companies as well. None of the other authors have a financial interest in either of these companies.
PATIENTS AND METHODS

This preliminary study consists of 10 patients who underwent soft tissue augmentation using acellular dermis at a tertiary care medical center in an urban setting. Because this material is approved for this application by the Food and Drug Administration, investigational review board approval was not required. Patients were specifically counseled as to the risks and benefits of using acellular dermis and cadaveric grafts. Other reconstructive options were offered to the patient, including autogenous vascularized tissue, autogenous nonvascularized tissue, and a synthetic biomaterial (Gore-Tex; Gore Corp, Dallas, Tex). The patient population consisted of the first 10 individuals (age, 34-74 years; 7 women and 3 men) who consented to acellular dermis as their preferred method of augmentation. These individuals all had isolated soft tissue volume deficits resulting in facial deformity. No additional inclusion or exclusion criteria were used beyond the requirements that the patients be aged 18 years or older, capable of providing their own informed consent, and sufficiently healthy to safely undergo the proposed reconstructive procedure.

Outcome evaluation was done with respect to restoration of facial contour, presence of postoperative complications, and implant volume maintenance. Restoration of facial contour and postoperative complications were assessed by comparison of preoperative and postoperative photographs and clinical evaluation, respectively. Photographs were evaluated by the surgeon and the patient. Because of the difficulty in accurately assessing volume after implantation, this variable was evaluated by the persistent restoration of facial contour at follow-up and in greater detail in one patient who necessitated resection of previously implanted acellular dermis secondary to tumor recurrence at an adjacent site. This enabled direct visualization of the implanted material. A detailed review of 2 patients is included in the “Results” section.

RESULTS

Postimplantation follow-up ranged from 17 to 36 months. Of 10 patients who underwent implantation, 9 had no complications and 1 had a recurrent delayed sterile abscess or mucocele near the implantation site. The specifics of this patient’s postoperative course are reviewed later in this article. Although not statistically evaluated, restoration of facial contour was achieved in 9 of 10 patients in the region(s) of acellular dermis implantation. In addition, volume maintenance based on clinical evaluation of soft tissue augmentation persistence at postoperative follow-up visits was good to excellent in all patients. In no patient did reformation of the preoperative soft tissue defect occur.

PATIENT 1

A 67-year-old woman was diagnosed as having a mucoepidermoid carcinoma of the parotid gland involving the right mandible. She originally underwent an extensive skull base resection that resulted in transposition of the temporalis muscle coupled with a total parotidectomy, sacrifice of the right facial nerve, and a right posterior segment mandibulectomy. Her immediate reconstruction consisted of a scapular microvascular free tissue transfer. Postoperative ischemia in the skin flap portion of the scapula transfer (the parascapular flap) resulted in substantial soft tissue volume loss in the right temporal fossa and right side of the face lateral to the scapular skeletal reconstruction (Figure 1A). After resection, she received full-course radiotherapy to the entire region.

The patient wanted reconstruction of the temporal and facial defects on the right side. Hydroxyapatite cement (BoneSource; Howmedica Leibinger, Dallas) was chosen to augment volume loss in the temporal fossa, whereas 3 sheets of 3-cm × 7-cm × 1-mm acellular dermis was chosen to augment soft tissue loss lateral to the scapular reconstruction below the zygoma (Figure 1B). During the surgical procedure, a static facial suspension of the right side of the upper lip and oral commissure was also performed using acellular dermis as a suspensory material. Additional procedures included scar revision over her neck, right lateral canthoplasty, and implantation of a conchal cartilage graft to the right side of the lower lid to correct her ectropion and excessive scleral show. The acellular dermis was implanted through a modified rhytidectomy incision coupled with a melolabial incision for upper lip suspension. The patient tolerated the procedure well 20 months after implantation (Figure 1C). At 22 months, tually ingrown and potentially replaced by the host’s own tissue. This implant replacement is coupled with maintenance of much of the original augmented volume over time. Acellular dermis is currently approved by the Food and Drug Administration for reconstructive applications in the head and neck. This article describes our initial experience with 10 patients who underwent isolated facial soft tissue defect augmentation using this material.
she developed a recurrence in the mandible that required resection of the previous augmentation site. This additional resection permitted biopsy of the previously placed acellular dermis (Figures 2, 3, and 4). Gross inspection and subjective evaluation based on knowledge of the original dimensions of the previously implanted acellular dermis revealed an approximately 85% volume persistence. Histological analysis revealed fibrovascular host tissue ingrowth and a well-integrated acellular dermis-host tissue interface with no evidence of tumor in the implant (Figure 5).
PATIENT 2

A 43-year-old woman was born with Clippel-Fiel syndrome. She underwent multiple craniofacial skeletal procedures in the past that resulted in extensive innerconnected dental bridgework. She wanted correction of her facial asymmetry and of the bilateral soft tissue irregularities of her lower face. She did not want any further craniofacial skeletal surgery because this would involve substantial revisions to her well-functioning dentition.

Her treatment consisted of placement of bilateral malar-submalar high-density porous polyethylene (Medpor; Porex Corp, Atlanta, Ga) implants, coupled with placement of a hard tissue replacement implant on her right side. All implants were placed through intraoral incisions and served to balance her asymmetrical facial skeletal structure. Soft tissue contour irregularities of the lower face were then addressed through application of acellular dermis through a modified rhytidectomy approach bilaterally. Several layered sheets of the material were sutured together and inserted on the right side. Single sheets of acellular dermis were implanted on the left side. The implantation sites were drained with small Penrose drains for 48 hours after implantation. This patient’s preoperative and postoperative facial contour 17 months after implantation is shown in Figure 6. There was improvement in the soft tissue contour irregularities lateral to the oral commissure in the lower third of the face.

COMMENT

This limited series demonstrates the utility of acellular dermis for soft tissue augmentation and replacement within the face. All of the patients, except 2, underwent reconstruction secondarily, after oncologic resection. The acellular dermis was applied to isolated soft tissue defects, alone or in conjunction with other reconstructive techniques or biomaterials. Three of 10 patients had been exposed to full-course radiotherapy before implantation of acellular dermis. Despite the suboptimal implantation environment and the aesthetically challenging nature of most of these defects, the acellular dermis was infection resistant; showed no potential for initial or delayed extrusion; and, more than 6 months after implantation, maintained a degree of softness comparable to the tactile characteristics of the surrounding native tissue. We believe that this performance is the direct result of the basic properties, composition, and architecture of acellular dermis. These properties result from a tissue processing technique that removes all cellular components from the cadaveric graft material, along with all major histocompatibility complex class I and II antigens. The processing technique achieves this without disrupting the normal microarchitecture of the collagen bundles within the dermis. The elastic components and the basement membrane structure (including the laminins) are also preserved. We believe that preservation of the basal lamina layer is vital in early vascularization of these processed grafts. The architecture of acellular dermis provides a scaffold into which the patient’s own fibroblasts can grow and eventually repopulate the augmented region. The graft material is then fully incorporated by the host’s own fibrovascular tissue until it is indistinguishable from the surrounding natural dermal matrix. This repopulation and replacement allows acellular dermis to become vascularized early in the postimplantation period (≤5 days) and makes possible the potential preservation of much of the augmented volume within the reconstruction site.

It is unlikely that all of the volume of the original implant will remain permanently, but we estimate that a significant volume of the acellular dermis is likely to persist based on its composition and architecture. Our

Figure 4. Resected specimen 22 months after implantation. Arrows indicate the 3 preserved layers of acellular dermis in the biopsy specimen. A significant degree of the implant sheet thickness has been maintained despite implantation being performed more than 1½ years earlier.

Figure 5. Histological analysis of resected acellular dermis demonstrates host tissue fibrovascular ingrowth. The individual sheets of acellular dermis can be seen, with absence of an inflammatory response. Arrows indicate the sheets of AlloDerm. Areas stained black represent the elastic fibers within the sheets of acellular dermis (Verhoeff elastic tissue stain, low magnification [× 40]).
single biopsy specimen of acellular dermis 22 months after implantation in a radiated field tends to support this opinion. It is logical to assume that additional volume contraction will occur when multiple sheets of acellular dermis are stacked in the soft tissue pocket. As fibrovascular tissue fills the spaces between sheets of acellular dermis, settling and contraction should be expected. It is probable that the greater the number of sheets combined as a single multilaminar implant, the greater the percentage of volume contracture (compared with the original composite implant thickness). Only an appropriate experimental animal study using species-specific acellular dermis, coupled with several years of clinical experience, will adequately quantify the degree of volume loss over time.

A key attribute of acellular dermis is the preservation of an intact collagen fibril microarchitecture. This is not the case with other processed (injectable) collagen preparations such as bovine or autogenous collagen. These other collagen implants contain damaged collagen strands in an amorphous orientation that elicit a macrophage response leading to substantial or complete resorption. The intact collagen fibril microarchitecture of acellular dermis coupled with the intact dermal macroarchitecture establish a matrix that is repopulated by fibrovascular tissue with a minimum amount of implant collagen degradation and potentially greater implant volume maintenance over time.

The single complication in this initial series consisted of recurrent episodes of either infection or mucocele formation at the reconstructed neopyriform aperture of a patient who underwent reconstruction after removal of an intranasal adenoid cystic carcinoma. The reconstruction site included the entire pyriform aperture, along with the nasal and maxillary bone adjacent to the medial canthus and nasolabial fold. Other materials simultaneously implanted in this area included titanium plates and split-thickness calvarial bone grafts. Recurrent episodes of inflammation resulted after the patient began blowing her nose 6 weeks after surgery. We suspect that mucus secretions or mucosa became invaginated within the newly layered tissue planes of the pyriform aperture, resulting in recurrent episodes of inflammation. Multiple aspiration cultures from this area did not yield any organisms, although scant mucoid fluid could be periodically aspirated from the area. These episodes were treated symptomatically with antibiotics and finally resolved approximately 4 months after they began. The patient shows moderate volume loss in those previously inflamed areas. None of the other patients demonstrated any complications resulting from use of this material. Subjective evaluation demonstrated good to excellent volume maintenance in all patients without defect reformation over time. In general, the acellular dermis maintained a soft texture after implantation. Increased firmness was observed for approximately 4 to 6 months after implantation in almost every patient. This firmness abated and the augmented region became more pliable more than 6 months after implantation. None of the patients demonstrated any skin color changes or episodes of recurrent edema suggestive of a chronic inflammatory response, other than the previously mentioned patient.

Limitations of the present study are the small sample size and the degree of experience the surgeons possess in handling and applying acellular dermis as a soft tissue augmentation device. These factors might have played a role in the positive outcomes seen in this study. In addition, certain limitations in the application of acellular dermis should be addressed. First and foremost, definitive volume maintenance studies have not been performed, to our knowledge, using acellular dermis to objectively determine the degree of soft tissue augmentation that persists over time. Although the limited results seen...
in this study are promising, further evaluation is necessary before clinicians can definitively convey to patients the long-term expectations of this material. The cost of acellular dermis has been a perceived deterrent of using this material; however, when one compares the additional operative time and postoperative morbidity associated with using autogenous tissue, acellular dermis might be a more cost-effective method of soft tissue augmentation in the head and neck.

When this material is compared with other reconstructive implants, we believe that acellular dermis has demonstrated significant potential. The only other material appropriate for subdermal reconstruction of the soft tissue defects included in this limited series is vascularized tissue transfer. Most of these patients did not have adequate local tissue for transfer and therefore would have required a pedicled or microvascular transfer. We did not believe that any of the previously radiated patients would be appropriate for nonvascularized autogenous grafts. None of these patients were willing to undergo pretreatment with hyperbaric oxygen before reconstruction. In light of these limitations and suboptimal conditions, the acellular dermis performed well in most regards.

With respect to synthetic biomaterials for the reconstructive applications described in this series, we would not consider any to have been appropriate. Previous exposure to radiotherapy eliminated the use of silicone elastomer implants in that subset of patients. For several patients, silicone elastomer and porous high-density polyethylene would not have been appropriate choices because of the requirement of subdermal implantation or placement near the nasal cavity mucosa resulting in a high risk of infection or extrusion. Only expanded polytetrafluoroethylene (Gore-Tex) could have been used for some of these reconstructions.5-8 Our experience with Gore-Tex in a previously irradiated field has demonstrated at least a 50% incidence of chronic edema and erythema in the skin over the implantation site. We do not believe that use of Gore-Tex would have been appropriate for any of the previously radiated patients presented in this limited series.

In summary, for a new material, acellular dermis has performed remarkably well in our hands for the reconstruction of difficult, isolated soft tissue defects. This material is fully vascularized and becomes incorporated by the host so that it is eventually transformed into living tissue. This is the key advantage that acellular dermis has over synthetic implants. It is likely, based on its intact collagen microstructure and preserved dermal matrix macroarchitecture, that a significant volume of the implant will persist permanently. It is unlikely that the entire original implant volume will remain permanently, and it is logical that the increased layering of acellular dermis will result in greater volume loss relative to single-layer or bilayer implantation because of compaction over time. Only additional animal testing and simultaneous clinical experience will fully answer these questions. In any event, acellular dermis possesses short- and long-term advantages over current synthetic polymer and processed collagen implants. It also has advantages over autogenous nonvascularized grafts (as well as several potential disadvantages). It is up to the surgeon, in detailed consultation with the prospective patient, to select the appropriate defect for which the advantages of this new material outweigh its potential shortcomings in light of the other autogenous or synthetic reconstructive materials currently available. Acellular dermis seems to represent a “next step” in tissue engineering as it relates to the soft tissues of the craniofacial region and potentially elsewhere in the body.

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Reprints: Peter D. Costantino, MD, Department of Otolaryngology, Box 1189, The Mount Sinai Medical Center, 1 Gustave L. Levy Pl, New York, NY 10029.

REFERENCES