Evaluation of Acellular Dermal Graft (AlloDerm) Sheet for Soft Tissue Augmentation

A 1-Year Follow-up of Clinical Observations and Histological Findings

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Objectives: To evaluate and compare the long-term clinical persistence and histological appearance of subdermally implanted acellular dermal graft (AlloDerm) sheets and intradermal type I bovine collagen cross-linked with glutaraldehyde (Zyplast).

Patients: Ten adult patients (5 men and 5 women; average age, 46 years; age range, 37-59 years) not allergic to bovine collagen.

Methods: AlloDerm sheets were implanted surgically in a subdermal plane in one postauricular crease, and Zyplast was injected intradermally on the opposite side. AlloDerm and Zyplast implants were digitally photographed and their apparent volumes calculated at 1, 3, 6, 9, and 12 months after implantation. A specimen was removed at 3 and 12 months and examined histologically for collagen persistence, host tissue invasion, and inflammatory reaction.

Results: The apparent implant volume of the AlloDerm sheets decreased during the first 6 months and then stabilized over the next 6 months. By contrast, Zyplast was progressively absorbed, with complete loss of clinical effect by 6 months. Histological analysis of implanted AlloDerm sheets demonstrated progressive repopulation of the graft with minimal inflammation.

Conclusions: AlloDerm sheets seem to provide stable soft tissue augmentation after an early period of resorption and are clearly superior to Zyplast injections for long-term, large-volume, soft tissue correction. Recommendations for clinical use include routine overcorrection, with subsequent augmentation delayed by at least 6 months.

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W E PREVIOUSLY re-ported a comparative study of the macroscopic and microscopic changes of subdermally implanted acellular dermal graft (AlloDerm; LifeCell Corp, Branchburg, NJ) sheets and intradermally injected type I bovine collagen cross-linked with glutaraldehyde (Zyplast; Collagen Corp, Palo Alto, Calif).1 In this article we provide 1-year follow-up data on 10 patients.

RESULTS

CLINICAL RESULTS

Ten patients were enrolled (5 men and 5 women; average age, 46 years; age range, 37-59 years). Owing to variations in the thickness of AlloDerm sheets, the volume of implanted AlloDerm varied between 0.22 and 0.29 mL. No patients experienced any signs or symptoms of implant infection, rejection, allergic reaction, or extrusion.

AlloDerm persistence at all points was statistically greater than that for Zyplast. The mean percentage volume persistence of AlloDerm at 1, 3, 6, and 12 months was 82.8%, 48.3%, 21.9%, and 20.2%, respectively, while the mean percentage volume persistence of Zyplast at 1, 3, 6, and 12 months was 26.6%, 8.0%, 1.1%, and 0.9%, respectively (P<.001 at all times, unpaired t test) (Figure 1). Owing to equipment malfunction, most patients did not have photographs taken at the 9-month visit.

HISTOPATHOLOGIC FEATURES

Implant material was noted in all of the AlloDerm and Zyplast 3-month biopsy specimens. Intraimplant fibroblast activity was noted in all of the AlloDerm specimens but not in any of the specimens with Zyplast. Minimal peri-implant inflammation was observed around all specimens in both the AlloDerm-treated and Zyplast-treated groups. No giant cell reaction was noted in either treatment group.

Twelve-month biopsy specimens of the AlloDerm implants showed extensive host ingrowth with mature blood vessels...
PATIENTS, MATERIALS, AND METHODS

Adult patients seen at The New York Eye and Ear Infirmary, New York, between November 1, 1997, and February 28, 1998, were given the opportunity to participate in this study. Interested patients were asked to sign a consent form. Patients were tested for allergic reaction to bovine collagen in the standard fashion and observed for any adverse reaction for at least 30 days. Only patients who had previously been treated with bovine collagen without reaction or those who had negative Zyderm skin test results were allowed to participate in this study.

Participating patients were anesthetized with a topical anesthetic agent (a combination of lidocaine and prilocaine hydrochloride in an emulsion base; Astra USA, Marlborough, Mass) over both postauricular areas for a minimum of 20 minutes. Patients were then injected intradermally in 2 sites (0.50 mL of Zyplast each) in the skin overlying one mastoid (just posterior to the postauricular crease), separated by at least 2 cm, using a template referenced to the Frankfort horizontal line. The material was injected in small volumes serially and occupied no larger than a 10-mm-diameter circle; care was taken to avoid migration of the injectant into the skin directly in the postauricular crease. AlloDerm was placed behind the opposite ear. After infiltration with 1% lidocaine, a 1.5-cm horizontal incision was made and subcutaneous pockets were developed superiorly and inferiorly, again using the standard template. AlloDerm sheets (approximately 1 mm thick) were sterilely cut into circular pieces with an 8-mm-diameter dermal punch. After rehydration in 2 separate baths of sterile isotonic sodium chloride solution for 5 minutes each, a stack of five 8-mm AlloDerm disks was placed into each pocket, separated by at least 2 cm. The wound was closed with 5-0 nylon sutures, which were removed on postoperative day 7.

The patients returned for follow-up visits at 1 week and 1, 3, 6, 9, and 12 months after the initial injection. At each visit, the implant sites were inspected and the patients were questioned regarding pain, fever, swelling, redness, and any other local or systemic sign or symptom that had developed since the injections. Standardized lateral and posterior digital photographs were taken at 1, 3, 6, 9, and 12 months after implantation with a digital imaging system (Mirror 2000; Virtual Eyes, Kirkland, Wash). This system allowed for measurement of the surface area and lateral projection of the implant. These 2 data points were used to calculate the volume of the implant by assuming a cylindrical form of the implant and multiplying the surface area by the lateral projection. The percentage of implant persistence at 1, 3, 6, 9, and 12 months was obtained by dividing the calculated volume of the implant by the originally implanted volume. AlloDerm volume at implantation was calculated by multiplying the surface area of an 8-mm-diameter disk by the predehydration thickness of the AlloDerm sheet, as measured by the manufacturer with a 3-dimensional laser scanner.

One implant of each type was localized (using the reference template) and removed at the 3- and 12-month visits under local anesthesia, and the wound was closed with interrupted 4-0 chromic sutures. Pathologic specimens were sectioned and stained with hematoxylin-eosin and with Movat pentachrome. The sections were examined by light microscopy under low and high power and inspected for implant location and persistence, fibroblast infiltration of the implant, and short- or long-term inflammatory response. Fibroblastic activity was described as either none, or intraimplant, based on the presence and location of the fibroblasts. Inflammatory activity was described as none, peri-implant, or intraimplant, based on the presence and location of the inflammatory cells; the presence of giant cells was also noted. This study was approved by the New York Eye and Ear Infirmary Institutional Review Board for the Protection of Human Subjects.

and fibroblasts (Figure 2). No islands of Zyplast were identified in any specimen.

COMMENT

Our investigation has demonstrated the clinical superiority of AlloDerm over Zyplast for soft tissue volume augmentation. The clinical effect of AlloDerm is evident for at least 6 to 12 months after implantation. While in our model only approximately 20% of the implanted volume was evident at 6 months, further loss of volume did not seem to occur. This may be somewhat related to the stacking of AlloDerm done in our model, as the central pieces of AlloDerm must rely on vascular ingrowth from the disk periphery or through the overlying or underlying pieces of AlloDerm, rather than by direct apposition of their broader surface direct against the recipient soft tissue bed. This may predispose toward enhanced early resorption. This stacking of subdermal AlloDerm (volumetrically less than the amount of Zyplast injected) was necessary to produce a measurable degree of externally evident skin displacement. However, AlloDerm is often rolled or folded on itself in clinical scenarios such as correction of deep nasolabial folds or the atrophic lip, thus producing a “hidden” portion of the graft.

Clearly, a certain degree of overcorrection is necessary with AlloDerm, given the clinical loss of volume. The degree of overcorrection most likely varies based on local factors, such as the amount and location of AlloDerm placement, local tissue environment (irradiated tissues, placement over bone or in scar tissue, and others), and rheologic properties of surrounding tissue and skin. Additionally, secondary “touch-up” procedures should be delayed at least 6 months after implantation to allow for stabilization and equilibration of the original implant. In this study, both materials were used to augment tissue volume, not to replace it. The rate of implant resorption may differ in the setting of volume replacement as different remodeling forces may be at work.

Histologically, at 3 months, there was a significant difference in the degree of intraimplant fibroblasts, with all AlloDerm implants showing intra-implant proliferation of fibroblasts, and Zyplast revealing none. There was no significant difference in the mild degree of peri-implant inflammation noted in both groups. Biopsy specimens at 12 months confirm the invasion of AlloDerm by host fibroblasts, as
well as revascularization. Zyplast does not persist at 12 months and is mostly resorbed by 3 months. The peri-implant inflammatory cells and possibly the intraimplant fibroblasts most likely mediate this resorption, in distinction to the collagen homeostasis mediated by the fibroblasts populating the AlloDerm grafts.

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REFERENCE


Editorial Comment

Dr Sclafani et al are to be commended in their attempt to better characterize the behavior of implanted homograft dermis. Their study demonstrates expected remodeling seen in all tissue grafts as well as benefits of tissue compliance and compatibility. As it relates to the comparison to collagen, the description “clearly superior” might be overstated. An acellular dermal graft (AlloDerm; LifeCell Corp, Branchburg, NJ) shows clearly longer persistence, but is considerably more technically difficult and cannot be done as a simple office visit. Patients who receive a homograft dermal-implant also have a longer recovery. One must conclude that for intermediate-term augmentation 6 to 15 months of an acellular dermal graft is a good option. But for short-term improvements with minimal patient “downtime,” intradermal type I bovine collagen cross-linked with glutaraldehyde (Zyplast; Collegen Corp, Palo Alto, Calif) or human tissue (Dermalogen Human Tissue Matrix; Collagenesis Inc, Beverly, Calif) are better options.

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