ORIGINAL ARTICLE

Septal Perforation Repair With Acellular Human Dermal Allograft

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Background: Connective tissue autografts are commonly used as interpositional grafts between septal flaps in the repair of septal perforations. The most common graft materials used include temporalis fascia and pericranium, both of which are accompanied by donor site morbidity, do not provide septal bulk, and are exceedingly thin and difficult to manage.

Objective: To study the use of an acellular human dermal allograft (AlloDerm, LifeCell Corp, The Woodlands, Tex) as a connective tissue interpositional graft in septal perforation repair.

Setting: Private facial plastic surgery and reconstructive practice of 1 of the authors (R.W.H.K.), Houston, Tex, and the private and university practice of another author (H.F.), Alexandria, Egypt.

Patients: Twelve consecutive patients with septal perforation who received the acellular dermal allograft constituted this evaluation. The causes of the septal perforations were previous nasal surgery, previous nasal cautery, or cocaine use by the patient.

Design: Interposition grafting between mucoperichondrial flaps for septal perforation repair was accomplished with decellularized human dermal grafts. Follow-up periods ranged from 3 to 14 months.

Main Outcome Measures: The repair was considered successful when, on postoperative examination at 3 months, the right and left mucoperichondrial flaps were entirely healed. From the experience of 1 author (R.W.H.K.) with the repair of more than 75 septal perforations, no perforation that was healed at 3 months broke down at a later date, unless trauma or cocaine use occurred after the operation. An outcome was considered acceptable but nondesirable if a perforation was still present after the operation but the number and severity of the patient's symptoms were reduced and the perforation was considerably smaller than before the operation.

Results: Eleven of the 12 patients had successful outcomes with complete closure of their perforations. The 1 remaining patient had an acceptable result but incomplete closure; his initial perforation of 3 cm was reduced to 5 mm, making him asymptomatic after surgery.

Conclusion: Acellular human dermal grafts can be used as connective tissue interpositional grafts in the repair of septal perforations with success rates similar to the use of temporalis fascia, mastoid periosteum, or pericranium. One distinct advantage is the absence of donor-site morbidity. In addition, this graft material is thicker and easier to place and suture and may give more substance to the repaired septum.

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TO ACHIEVE a 90% or greater success rate with repairs of septal perforation in patients with perforations less than 3 cm requires not only bilateral repair of the mucoperichondrial flaps via transposition of the flaps with suture closure of the previous existing defect, but also the interposition of a connective tissue autograft between the repaired flaps.[1-7] Numerous autografts have been used for this purpose; the most favored grafting material is temporalis fascia. Pericranium and mastoid periosteum have been used less often but with similar success rates.[2,7] Temporalis fascia and pericranium are extremely thin grafts with very low metabolic requirements and have been shown to act as excellent templates for overlying tissue migration and vascularization. Mastoid periosteum has been used with the hope of adding bulk to the thickness of the resultant repaired septal membranes. It also has been used with the still unproved hope that bone might be regenerated between the septal flaps.[2] The need for a connective tissue interpositional graft is generally accepted by all authors who use intranasal mucosal flap advancements. The interposed graft maintains a barrier between the corresponding repaired flaps during healing and, therefore, decreases the risk of incisional breakdown and reperforation.

MATERIALS AND METHODS

MATERIALS

The acellular dermal graft is processed from human donor skin obtained from approved tissue banks. In processing, the epidermis is removed, and the remaining dermal layer is washed in detergent solutions to remove cellular components. After the tissue has been decellularized, the acellular collagen matrix is then cryoprotected and rapidly freeze-dried by a patented process to preserve biochemical and structural integrity. This packaged acellular dermis can be stored under refrigeration for at least 2 years. Rehydration of the freeze-dried dermis for a minimum of 10 minutes in physiologic saline using a normal sterile procedure yields a pliable collagen template for cell repopulation.

METHODS

Nasal septal perforations present a unique challenge to the surgeon because the perforation defect involves not 1, but 3 distinct, yet contiguous layers; ie, 2 mucoperichondrial flaps and a central, usually cartilaginous, defect. The larger the vertical height of the perforation, the more difficult the repair. Because the goals of operations to repair a perforation should be to close the perforation and to restore normal function, the use of intranasal advancement flaps achieves normal nasal structure and function. Other methods that use skin grafts or buccal mucosa grafts close the perforation but leave the patient with a dry crusting nose because respiratory nasal mucosa is not present. Gollom,[6] Fairbanks,[7] Kridel,[1,3,4] Kridel et al,[2] and Goodman and Strelzow[5] all have advocated the use of bilateral mucosal transpositional flaps taken from the floor of the nose with the interposition of a connective tissue graft as a necessary component (**Figure 1**). The connective tissue graft helps prevent reperforation of the septal flaps as healing occurs and serves as a template for mucosal migration. Occasionally a perforation cannot be closed completely on 1 or both sides, and the connective tissue interpositional graft can serve as a template for migration of the overlying healing flaps. Gollom[6] and Fairbanks[7] reported their results using the endonasal approach, whereas Kridel et al,[2] Kridel,[3] and Goodman and Strelzow[5] reported their results using the external open approach to obtain improved visualization. The acellular dermal graft can be used with either approach.

With the external open approach, the columellar incision is made, the nasal skin is retracted, the dome cartilages are separated, and the medial crura are retracted laterally to gain access to the caudal end of the septum. Bilateral mucoperichondrial flaps are first developed at the edge of the caudal septum, and the elevation is carried posteriorly toward the perforation. Superior mucoperichondrial pockets are developed along with the flap elevation just beneath the junction of the upper lateral cartilages and the septum. The upper lateral cartilages are then sharply separated from the septum using a knife blade that leaves the mucoperichondrial flap still attached to the now laterally retracted upper lateral cartilage (**Figure 2**). This technique provides excellent visualization of the dorsal portion of the septum and allows access to its posterior portion. Using a Cottle elevator or a ball-ended elevator, the dissection is continued all around the perforation. The edges of the perforation are entered, and each whole mucoperichondrial flap is separated from the residual septal cartilage and bone. The flap elevation continues laterally along the maxillary crest and floor of the nose, extending just under the inferior turbinate on both sides. The posterior dissection extends at least 1 cm beyond the border of the perforation.

An anterior-to-posterior longitudinal incision is made, paralleling the attachment of the inferior turbinate beneath the inferior turbinate, so that a bipedicle flap is created (**Figure 3**). This provides nasal floor mucosa that can be advanced superiorly and medially to close the perforation. The flap must be totally mobilized to achieve maximum tension-free closure. Then the flap is advanced to assure that there is enough mucosa for closure. If not, more mucoperichondrium must be advanced down from the roof superiorly. The mucoperichondrium may be elevated from the undersurface of the upper lateral cartilage, preserving all of its blood supply, or a cut may be made in the mucoperichondrium superiorly at the septal–upper lateral cartilage junction, or slightly lower, creating a bipedicle flap to advance inferiorly. If the latter method is used, it can only be performed on 1 side, or bare septal cartilage would be left bilaterally that might perforate superiorly.

Once enough slack has been provided by the advancement of the flaps, the perforation in each flap is closed using interrupted 4-0 or 5-0 chromic gut or plain gut sutures. If any granulation tissue is present on the edges of the perforation, it is removed to provide fresh edges that are more likely to heal. At this point, the acellular human dermal allograft is used.

The required size of the graft to be harvested depends on the size of the perforation encountered and may need to be exceptionally large. The graft must be larger than the perforation so that it can overlap the original perforation site peripherally. Harvesting a 4- to 6-cm diameter graft is not unusual. The harvest of such a graft requires wide undermining, which leaves a raw area, creates a potential space for hematoma formation that must be drained, and often is accompanied by postoperative discomfort. Additional operative time is needed for harvesting of the graft, and substantial postoperative care is required. Also, because fascia is so thin, it is possible during harvesting to slit the graft inadvertently, making that portion of the graft useless. When mastoid periosteum is harvested, there generally is great patient discomfort at the donor site in addition to the usual risk of greater auricular nerve injury.

After harvesting, temporalis fascia and pericranium are usually air dried on the back table before use in surgery. The resultant very thin and often extremely transparent graft is then placed between the septal flaps. This placement must be done quickly and accurately because as soon as the graft rehydrates, it loses its gross structural stability, tends to bunch together, and is technically difficult to manage. Another disadvantage of temporalis fascia or pericranium is the extreme thinness of the graft. Because cartilage is no longer present in the perforated septal area, a very floppy, thin septum

This graft material must be aseptically rehydrated in the operating room for at least 10 minutes, but no longer than 4 hours before use. Rehydration of the graft requires 2 sterile containers (eg, kidney basins), sterile physiologic saline, and sterile thumb forceps. Multiple grafts may be rehydrated simultaneously in the same basin, with at least 50 mL of saline required for each piece. The paper backing will still be adherent to the acellular dermis initially, but separates from the graft as it rehydrates. The graft is submerged completely and soaked for at least 5 minutes. It is then transferred aseptically to the second basin, and the paper backing is discarded. The graft is submerged again and allowed to soak an additional 5 minutes. If after 10 minutes the graft is not fully pliable, it still may be inserted and, in fact, may be easier to manipulate into position. The fully rehydrated graft may remain in the second basin for up to 4 hours before application, if necessary (**Figure 4**).

Generally, 2 thickness ranges of the graft material are available from the supplier, 1 less than 1 mm and 1 greater than 1 mm. In general, a thick piece is preferable. Depending on the size of the perforation, the 2×4 cm or the 3×7 cm graft would most likely be chosen. The graft can be easily trimmed with a knife blade or with scissors to the desired size. The rehydrated graft is then placed between the repaired flaps onto 1 side of the septal cartilage remnant. To prevent postoperative migration, the graft can be sutured directly to the residual septal cartilage with interrupted sutures; care must be taken to assure that the graft is centered on the cartilaginous perforation defect (**Figure 5**).

The upper lateral cartilages are then resutured to the septum. At times, after large perforations have been repaired, it is difficult to reattach the upper lateral cartilages to the septum at their original height because of tension on the mucoperichondrial flap. In such cases, if the upper lateral cartilages were sutured back at the exact same height as they were before closing the flap, new tension would be placed on the closure. Resuturing the upper lateral cartilages to the septum at a lower level, however, would cause a pinched appearance to the nasal dorsum because the upper laterals would be lower than the central dorsal septum. In such cases, onlay grafts over the reset upper lateral cartilages may be necessary and, if there is additional acellular dermis available, it can be used for such a purpose.

Next, the septal flaps must be sutured together with a mattress suture to reapproximate both flaps closely to the innermost acellular graft, to aid in healing and revascularization of the graft and to make use of it as a template. In addition, the mattress sutures help to prevent the occurrence of a postoperative hematoma. Generally, a 4-0 chromic gut suture, using a continuous suture method, is used (**Figure 6**). The needle must be extremely sharp so that it passes freely through not only the flaps, but also the graft, so as not to cause displacement of the graft. Because the graft is relatively thick, this can create a problem, and often interrupted individual mattress sutures are used for just 1 or 2 passes before changing to a new suture with a new sharp needle. Mattress sutures are used above and below the repaired perforation so that the sutures are placed in a plane perpendicular to that of the perforation repair, thereby reinforcing the closure. A cartilaginous strut is usually placed between the medial crura and sutured to them to reconstitute nasal tip support, so postoperative ptosis does not occur. Likewise, the dome cartilages are sewn together with permanent suture to prevent postoperative tissue bossae. Routine open external rhinoplasty closure is then performed.

The repaired septal flaps are protected during their healing phase by the placement of 0.020-inch thick pliable polymeric silicone sheeting, which is placed on both sides of the septal flaps and secured by approximately 3 interrupted 4-0 or 5-0 nonabsorbable sutures, placed without tension to avoid constricting the repair site. Because the polymeric silicone sheets are transparent, the repair site can usually be visualized to assure that the mucosa has healed over before removal of the sheeting. The nose is then generally lightly packed with absorbable gelatin foam strips (such as Gelfoam, Upjohn Co, Kalamazoo, Mich) that are impregnated with an antibiotic cream or ointment. Moist gelatin foam helps to protect the exposed bony area from the area where the flaps have been rotated. The nose is then externally taped and splinted to prevent postoperative hematoma, and a drip pad is placed.

POSTOPERATIVE CARE

The patient is usually examined on the first postoperative day, and a small amount of the gelatin foam is suctioned out. Saline nose drops and antibiotic ointments are prescribed to keep the nose moist and to assist in the loosening of the gelatin foam. Gentle suctioning is performed during serial visits throughout the next week. The external nasal splint can usually be removed in about 5 to 7 days. The polymeric silicone sheeting is not removed until complete healing of the perforation can be observed, usually in 2 to 3 weeks. Postoperatively, the patient must keep the nose moist to prevent drying. Any crusts that are noted in the surgical area should not be pulled or removed, but should be lubricated with large amounts of antibacterial ointment. The patient must avoid a dry environment, noxious fumes, and tobacco smoke.

remains. Mastoid periosteum is not a better choice because it is difficult to harvest and the thickness is inconsistent.

An acellular human dermal graft (AlloDerm, LifeCell Corporation, The Woodlands, Tex) has been in use for several years for skin grafting for the treatment of patients with acute burns and has been shown to increase dermal thickness.[8] Its dermal matrix is incorporated into the surrounding tissue, and because the graft is acellular, it does not elicit an immune response. Because the graft reduces operative time by at least 30 minutes and avoids the comorbidity of another operative site, it is cost-effective and patient-friendly.

RESULTS

A 100% success rate was achieved in the patients in whom the acellular human allograft was placed between the flaps when total closure of the mucoperichondrial flaps was accomplished during the operation (**Table**). In 5 patients, total closure could not be achieved during the operation. For 4 of these 5 patients, in whom closure was achieved on 1 side but not on the other, the unclosed flaps healed with normal nasal mucosa over the dermal graft and closed during the healing process. For the fifth patient, whose perforation was 3 cm, neither side could be closed primarily, but the dermal graft provided a template for healing, and the residual perforation was much

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Figure 1. *In repairing a septal perforation, the mucosa under the inferior turbinate and nasal floor is elevated, freed laterally, and mobilized medially and superiorly as an advancement flap toward the septum to close the perforation. From Kridel R. The open approach for repair of septal perforations. In: Daniel RK, ed.* Aesthetic Plastic Surgery: Rhinoplasty. *Boston, Mass.: Little Brown & Co Inc; 1993:557, 560, 561. Used with permission from Lippincott-Raven Publishers.*

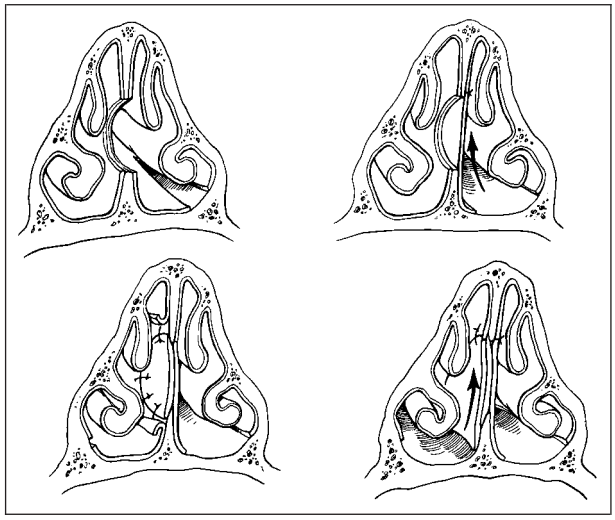

Figure 3. *The freeing up of the floor mucosa under the inferior turbinate; mobilization of the flap, allowing suture closure on 1 side; the suturing of the acellular dermal graft to the cartilage defect; and closure of the mucosal flap on the other side are shown. Copyright © 1997, Russell W. H. Kridel, MD.*

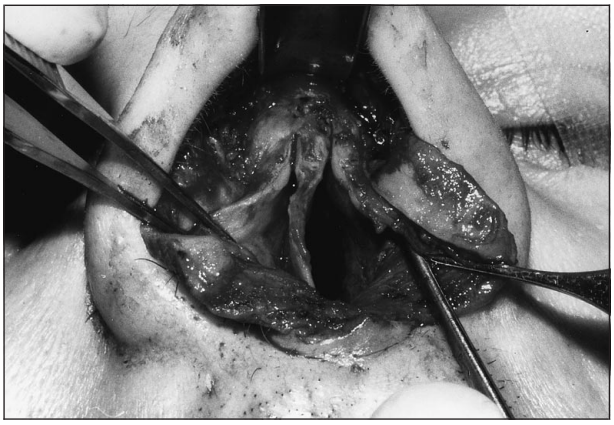

Figure 2. *The upper lateral cartilages are sharply separated from the septum and are retracted laterally. The septal mucosa remains attached to the undersurface of the upper lateral cartilages. Repair of each mucosal flap and the intervening septal cartilage is then accomplished.*

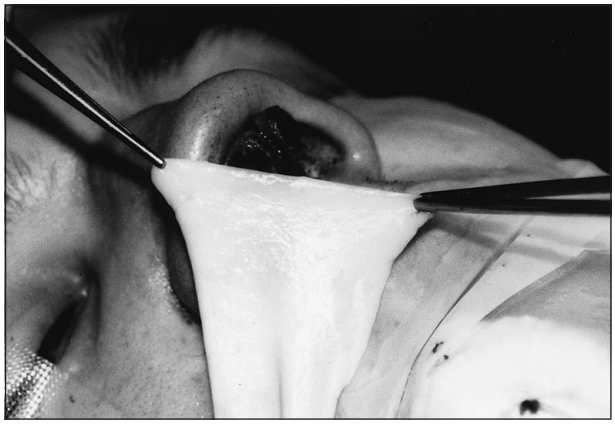

Figure 4. *When the acellular dermal graft is removed from the inner package, it is firm because of dehydration and is covered with paper backing on each side. After hydration for at least 10 minutes, the graft material is soft, pliable, and ready for use and feels like a dermal skin graft.*

smaller (5 mm). The perforation might have closed completely if the polymeric silicone sheeting had been left in place longer and the intervening dermal graft had not dried out. No rejection or infection was noted in any of the 12 patients.

COMMENT

The acellular dermal graft, processed from human donor skin, has been in use since 1992 as a dermal replacement graft for patients with acute burns. A fundamental problem in burn therapy is the permanent replacement of skin in full and deep partial-thickness burns. The use of the acellular dermis with an ultrathin, overlying split-thickness skin graft (STSG) in current burn therapy provides sufficient dermis to reduce wound scarring and contracture and decreases the donor site healing time and morbidity.[8-10] An initial multicenter study documented that results obtained with acellular dermis and ultrathin STSG grafts were at least equal to those of standard-thickness STSGs.[8] Currently, a second multicenter study is in progress to assess the long-term cosmetic and functional results of the acellular dermal graft and ultrathin STSG grafts in acute burn therapy, with additional centers studying the cosmetic and functional results of acellular dermis with reconstructive burn operations.

During the past 24 months, the acellular dermal grafts have also been used as soft tissue implants in periodontal surgical procedures, eliminating the need for autogenous palatal donor tissue. In periodontal applications, the graft material is used primarily for free gingival grafts to increase attached gingiva.[11] Additional periodontal uses of the preserved dermis are aimed at root coverage and bone regeneration.

The successful use of the acellular dermal graft as an implant in periodontal procedures prompted use of the preserved dermis as a tissue implant with plastic and reconstructive surgical procedures.[12,13] In addition to the use for repairs of septal perforations, 1 author (R.W.H.K.) has used the graft material for nasal dorsal onlays, augmentations and depressions, premaxillary plumping grafts, coverage over sharp nasal cartilage grafts, lip augmen-

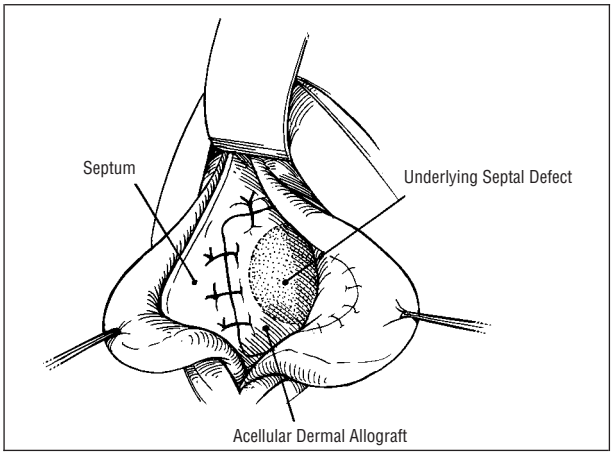

Figure 5. *The use of acellular human dermal autograft (AlloDerm, LifeCell Corp, The Woodlands, Tex) to circumferentially overlap the septal cartilage defect. Copyright © 1997, Russell W. H. Kridel, MD.*

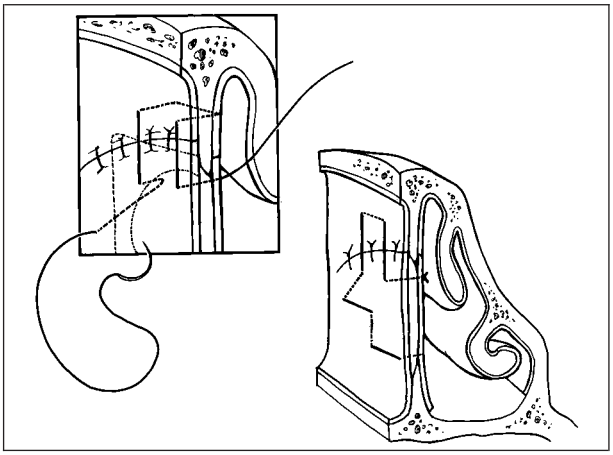

Figure 6. *After suturing the perforation closed in each mucosal flap and after suturing the acellular human dermal autograft to the residual septum, the flaps are quilted together with a continuous mattress suture, which further stabilizes the repaired flaps and helps prevent bleeding or the formation of a hematoma.*

Patient Data and Long-term Follow-up Results

Patient No./ Sex/Age, y	Cause	Size of Perforation, cm	Total Closure at Surgery	Remaining Perforation at Surgery	Total Mucosal Healing of Perforation After Surgery	Length of Follow-up, mo
1/F/33	Trauma	2.0	Yes	Total closure	Yes	13
2/M/44	Trauma	1.5	Yes	Total closure	Yes	9
3/M/41	Previous septal surgery	1.7	Yes	Total closure	Yes	14
4/M/35	Trauma, chemical dependency	3.0	No	Left side, 0.6 cm Right side, 0.8 cm	No, 5.0 mm remained	3
5/F/48	Previous septal surgery	3.0×1.5	No	2.0×1.0 cm remained on right side	Yes	13
6/M/17	von Willebrand disease	2.0×1.5	No	0.4 cm remained on right side	Yes	9
7/F/57	Trauma, previous septal surgery	0.5	Yes	Total closure	Yes	6
8/M/41	Possible chemical dependency	4.5	No	0.5 cm remained on left side	Yes	10
9/M/27	Previous septal surgery	3.5	Yes	Total closure	Yes	9
10/F/20	Previous septal surgery	2.5	Yes	Total closure	Yes	9
11/M/42	Previous septal surgery	3.0	Yes	Total closure	Yes	10
12/M/26	Previous septal surgery	4.5	No	1.0 cm remained on left side	Yes	11

tation, and nasolabial fold grafting. The dermal graft eliminates the need for autogenous donor tissue and thereby eliminates the pain and morbidity associated with the harvest of autogenous tissue.

As with the use of any allograft tissue, the transmission of infection is a concern. All allograft skin used in processing the acellular dermal graft is screened in accordance with the US Food and Drug Administration regulations for human tissue (21 CFR §1270). In addition to stringent screening guidelines, the processing of skin into this graft material safeguards against the transmission of viral disease by removing all living cells. Because replication of human pathogenic viruses occurs only intracellularly, the removal of cells from this extracellular collagen matrix eliminates sites for viral propagation. In addition, the process includes treatment of the allograft tissue with a powerful antiviral agent, demonstrated by an independent laboratory to inactivate concentrated suspensions of the human immunodeficiency virus (Quality Biotech, Camden, NJ, unpublished data, March 1993).

A second concern with the use of allograft tissue is the issue of eliciting an immune response. The cell-mediated immune response is directed primarily against cells of the epidermis and endothelial and fibroblast cells in the dermis.[14,15] In processing allograft skin into acellular dermis, the complete epidermal layer and all cellular components of the dermal layer are removed, thus eliminating the antigenic targets of cell-mediated rejection response. Remaining is an acellular, nonimmunogenic connective tissue matrix, complete with a basement membrane complex and vascular channels. Histological components of the dermal matrix include mature elastin, proteoglycans, and collagen bundles with normal banding. Proteoglycans provide a reservoir for growth factors, guide the assembly of collagen, and promote angiogenesis.[16,17] The use of acellular dermal allograft as a surface graft, such as for patients with burns, requires that the basement membrane "side" face outward, toward the overlying STSG. However, this does not seem to be a requirement when it is used as an interpositional graft with septal perforation

repairs, as it has been placed with either side against the septal cartilage with equal success.

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