ORIGINAL ARTICLE

Efficacy of "Thick" Acellular Human Dermis (AlloDerm) for Lower Eyelid Reconstruction

Comparison With Hard Palate and Thin AlloDerm Grafts

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Objectives: To evaluate the efficacy of thick acellular human dermis (thick AlloDerm [LifeCell Corporation, The Woodlands, Tex]) grafts for posterior and middle lamellae reconstruction to correct lower eyelid retraction and to compare the long-term efficacy of thick AlloDerm with thin AlloDerm and hard palate grafts.

Methods: Retrospective analysis of patients undergoing lower eyelid reconstruction, which encompassed subperiosteal midface lifting, middle lamellae scar lysis, and placement of lower eyelid thick AlloDerm graft. Analysis included 21 surgical procedures in 11 patients. All patients had undergone at least 1 previous lower eyelid surgery with resultant lower eyelid retraction and scleral show. Preoperative and postoperative photographs were used for analysis. Measurements of the corneal diameter and distance from pupil center to lower eyelid margin were obtained, standardized, and compared.

Results: Of 21 procedures, 16 (8 of 11 patients) demonstrated improvement of lower eyelid position. The mean improvement of the median marginal reflex distance was 1.6 mm (range, 0.4-2.2 mm). The average follow-up after surgery was 215 days (range, 3-12 months). Of 21 procedures (3 patients), 5 failed to demonstrate improvement of lower eyelid position, with the mean final eyelid position lower postoperatively by 0.8 mm (range, 0.4-1.4 mm).

Conclusions: We demonstrated long-lasting improvement of lower eyelid position with placement of thick AlloDerm grafts during lower eyelid reconstruction. The patients in our study had undergone previous lower eyelid blepharoplasty with resultant middle lamellae tethering. Surgical correction included subperiosteal midface lift and middle lamellae scar lysis, in addition to thick AlloDerm graft placement to the lower eyelid. The results are comparable to hard palate grafts but perhaps superior to thin AlloDerm grafts.

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LOWER EYELID RETRACTION IS defined as the inferior malposition of the lower eyelid margin with or without eyelid malrotation. It presents clinically with scleral show; round, sad-looking eyes; and possible lateral canthal tendon laxity, which result in symptoms of ocular irritation, including photophobia, excessive tearing, and nocturnal lagophthalmos. These patients require frequent ocular lubricants, including artificial tears and ointments, which provide only minimal alleviation of these symptoms.[1] Severe eyelid malposition can occur following transcutaneous lower eyelid blepharoplasty in up to 15% to 20% of patients.[2,3] However, lower eyelid malposition can occur after any procedure that violates the lower eyelid, including midface lifting procedures, fat redraping, composite rhytidectomy, or fracture repair.[1]

The lower eyelid is supported by the lateral and medial canthal tendons, the capsulopalpebral fascia (or lower eyelid retractors), the tarsus, and the orbicularis oculi muscle.[1,4] Three types of lower eyelid malpositioning can occur after blepharoplasty, depending on the location of cicatrization and resulting relative tissue inadequacy. These cicatricial deformities can occur in any of the eyelid lamellae: the anterior (skin and orbicularis muscle), middle (orbital septum), or posterior lamella (tarsus and conjunctiva). When tissue inadequacy occurs primarily in the anterior lamella, ectropion is the result as the tight lower eyelid skin pulls the eyelid margin outward. When the cicatrix occurs predominantly in the posterior lamella, cica-

tricial entropion results as the contracted conjunctiva and/or tarsus pulls the eyelid inward. Cicatrization of the middle lamella may result in eyelid retraction, especially after lower eyelid blepharoplasty.[1,5,6] Furthermore, because the orbital septum adheres firmly to the orbital rim as part of the arcus marginalis, any scarring of the middle lamella will tether the lower eyelid to the inferior orbital rim. An additional component to eyelid malposition is midface descent resulting in vertical inadequacy of the inferior lamellae. Midface or suborbicularis oculi fat descent in conjunction with cicatricial lower eyelid changes and large eye morphology causes severe lower eyelid malposition. A combined midface-lift with lower eyelid spacer graft is required in the most challenging cases.[7]

A multitude of factors affect the resting position of the normal lower eyelid, and pathologic changes in 1 or more of these factors may result in eyelid retraction. The incidence of postblepharoplasty lower lid retraction is directly proportional to the relative prominence of the globe, amount of overcorrection or undercorrection of horizontal eyelid laxity (commonly due to lateral canthal tendon laxity or disinsertion), relative amount of orbicularis surgery/cauterization, intraoperative and postoperative bleeding, and orbital septum inflammation with subsequent scarring, in any combination.[8,9] This contraction can be precipitated by various perioperative causes.[8,10,11] Hematoma within the surgical planes induces contraction during the healing process. An eyelid with horizontal laxity may be pulled downward by gravity under the weight of postoperative edema to heal in an inferior position. A similar phenomenon can occur in a normal eyelid with excessive postoperative swelling and chemosis, which can stent the eyelid in a depressed position and encourage postoperative retraction. An excessively tightened lower eyelid, particularly with a prominent globe, may also result in lower eyelid retraction, as the globe convexity tends to nudge the tight lower eyelid into a less tight (inferior) position. A major source of lower eyelid retraction seems to be the surgical incorporation of tissues in the plane of the lower eyelid retractors or orbital septum into the wound.[6] Once the pathophysiologic and anatomic cause of lower eyelid retraction is understood, it will be much easier to understand how to correct it.

Lower eyelid blepharoplasty is usually performed for cosmetic reasons. Thus, complications with this procedure are particularly annoying for the patient and physician. Patients with "round eye" and inferior scleral show are not only appropriately concerned with the aesthetic disfigurement but also frequently experience ocular surface problems related to lagophthalmos and exposure. Loss of vision from corneal exposure may result. Although many of these patients improve with time or with lateral canthal and lower eyelid–tightening procedures, some continue to be unhappy and symptomatic even after several canthal and eyelid tightening procedures have been performed.[8] The "Madame Butterfly" procedure, first performed in 1985 by the senior author (N.S.) has evolved over time.[5,8,12] The procedure aims to correct the problems of postblepharoplasty eyelid malposition through complete lower eyelid reconstruction of the 3 lamellae, and thereby restoring the lower eyelid to a preblepharoplasty and youthful anatomic position: tangential to the inferior limbus with the lateral canthus 2 mm higher than the medial canthus. After canthotomy, cantholysis, and intraoperative scar lysis, a subperiosteal midface-lift is performed to mobilize the anterior lamella from the cheek to the eyelid space. A graft, the dimensions of which are calculated through evaluation of preoperative lower eyelid position, is then placed in the posterior lower eyelid to act as a spacer to prevent middle and posterior lamellar contraction during healing. The lateral canthus is replaced to its anatomic position with concomitant tightening of the lower eyelid when necessary. Typical surgery is performed unilaterally with placement of a Frost suture tarsorrhaphy and patching for 1 week.

Different spacer materials have been used as grafts in the Madame Butterfly procedure.[12,13] Autogenous hard palate and thin acellular human dermis (AlloDerm; LifeCell Corporation, The Woodlands, Tex) grafts have been used by the senior author (N.S.) in the past with greatest frequency; however, more recently, the senior author has used the thick form of AlloDerm. Through retrospective analysis, this article aims to compare the efficacy of the thick AlloDerm graft with the thin AlloDerm and hard palate grafts in correcting lower eyelid retraction using the Madame Butterfly procedure.

METHODS

In this retrospective study, we reviewed the medical charts of consecutive patients undergoing lower eyelid reconstruction, which included subperiosteal midface-lift, middle lamellae scar lysis, and placement of lower eyelid thick AlloDerm graft, by 1 surgeon (N.S.) in 1 private practice from January 2002 to March 2003. The surgical procedures were performed in accordance with previous protocols.[13] All the patients had undergone previous lower blepharoplasty, with resultant lower eyelid retraction and scleral show. During the study, thick AlloDerm was used exclusively. Patients with less than 3-months' follow-up were excluded. After exclusion criteria were applied, we collected data on 11 patients, with a total of 21 surgical procedures using the thick form of AlloDerm. Four of the 21 procedures were performed on men.

Preoperative and postoperative photographs from each surgery were digitized. All photographs were obtained by 1 surgeon (N.S.) using a Polaroid Macro 5 SLR camera (Polaroid Corporation, Waltham, Mass) in examining rooms with identical lighting. Photographs of the longest postoperative follow-up were selected. Postoperative follow-up ranged from 3 months to 1 year with an average of 215 days. The photographs were analyzed using Jasc Paint Shop Pro software (Jasc Software Inc, Eden Prairie, Minn) for the following measurements: (1) center of pupil to lower lid margin (central LD [lid dimension]); (2) lateral limbus to lower lid margin (lateral LD); and (3) corneal diameter (**Figure 1**). Because the photographs vary in distance and framing, absolute measurements could not be obtained. To standardize the measurements, a ratio was taken of the central (and lateral) LDs to the corneal diameter of each eye in each patient, and then the ratio was multiplied by 11 to standardize to an arbitrary corneal diameter of 11 mm. Measurements of the thick AlloDerm group were then compared with those of the thin AlloDerm and hard palate groups obtained using the same parameters. The thickness of thick AlloDerm is greater than 72/999 in, whereas that of thin Allo-

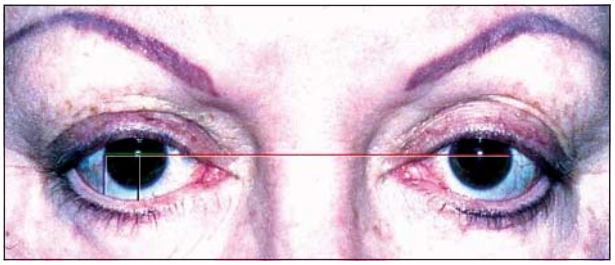

Figure 1. The distances used in our calculations were the corneal diameter of respective sides (green line) along with the center of pupil to lower lid margin (black line) and lateral limbus to lower lid margin (purple line).

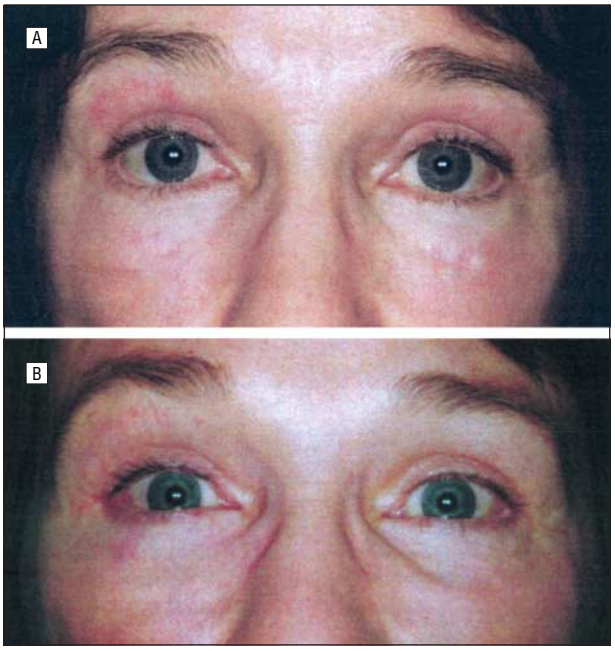

Figure 2. A patient with lower eyelid retraction who showed bilateral improvement in lower eyelid position after thick acellular human dermis (thick AlloDerm [LifeCell Corporation, The Woodlands, Tex]) graft placement. A, One month before operation; B, 5 months after operation.

Derm is 7-14/999 in. The hard palate graft is obtained and is thinned before implantation.

RESULTS

Of 21 procedures (8 of 11 patients), 16 demonstrated improvement of lower eyelid position. A representative example is shown in **Figure 2**. The mean preoperative central LD and lateral LD were 6.0 mm and 5.0 mm, respectively. The mean postoperative central LD and lateral LD were 4.4 mm and 4.0 mm, respectively. The mean improvement or change in eyelid height both central and lateral (preoperative central LD–postoperative central LD; preoperative lateral LD–postoperative lateral LD) were 1.6 mm and 1.1 mm, respectively, with a range of 0.4 to 2.2 mm. The average follow-up after surgery was 215 days (range, 3-12 months). **Figure 3** demonstrates the relative lower eyelid position over time for 4 patients for whom long-term follow-up was available. These results demonstrate relative stability of eyelid position after several months of graft placement.

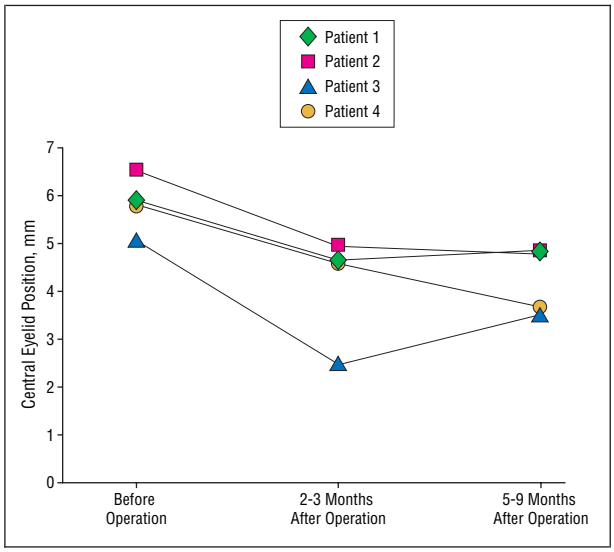

Figure 3. The location of the lower eyelid before and after thick acellular human dermis (thick AlloDerm [LifeCell Corporation, The Woodlands, Tex]) graft placement for 4 of the patients over time. Note that the eyelid position stabilizes over months, although some contraction can be expected in some of the cases.

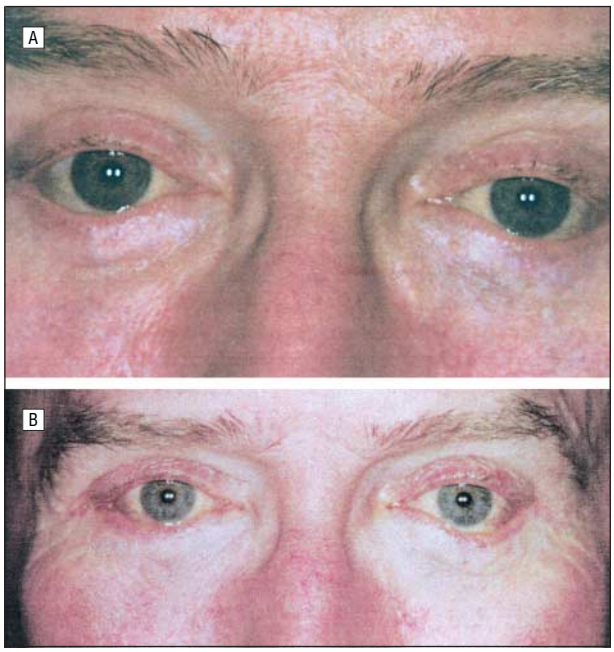

Figure 4. A patient with lower eyelid retraction who showed worsening of lower eyelid position after thick acellular human dermis (thick AlloDerm [LifeCell Corporation, The Woodlands, Tex]) graft placement in the left eye. A, One day prior to operation; B, 33 days after operation.

Of 21 procedures (3 patients), 5 with graft placement failed to improve or actually demonstrated worsening of lower eyelid position. **Figure 4** shows an example of such a patient. The mean final eyelid position was lower postoperatively by 0.8 mm and 0.9 mm for central and lateral LD, respectively, with a range of 0.4 to 1.4 mm. Interestingly, the patient in Figure 4 showed improvement in 1 eye but worsening in the other eye after bilateral graft placement. No single factor was associated with failure to improve eyelid position after surgery, such as previous operations and hematoma formation.

COMMENT

The benefits of cosmetic surgery must always be weighed against the risks of complication. It has been known that lower eyelid blepharoplasty is less rewarding and less predictable than upper eyelid blepharoplasty. It can result in lower eyelid retraction in up 20% of patients.[2,3] Various techniques have been described to avoid such occurrences, including proper wound closure to avoid scarring orbital septum in the operative site, a light pressure dressing immediately following surgery, a Frost suture to apply upward traction on the lower eyelid during the early postoperative period, full-thickness eyelid resection during the blepharoplasty, tarsal tuck procedure, orbital fat preservation, and the transconjunctival approach to the inferior orbit and fat to avoid violating the septum and thereby reducing the risk of scar creation and subsequent lower eyelid retraction.[1,6,11,14-17] However, lower eyelid retraction can still occur despite these preventions.

Many different procedures have been proposed to correct lower eyelid retraction. Inferior retractor weakening by removal of sympathetic muscle in the lower eyelid, recession of the capsulopalpebral fascia, and various horizontal shortening procedures are just some of procedures used to treat mild cases of eyelid retraction, but they are generally ineffective for treatment of severe cases of cicatricial lower eyelid retraction.[4,18-20] For severe cases not amenable to the techniques mentioned herein, surgeons may have to resort to full-thickness skin grafting, lower eyelid "spacers," or lifting of the suborbicularis oculi fat to elevate and support the lower eyelid adequately.[16] Skin can be placed in the lower eyelid albeit at an aesthetic expense, but the middle and posterior lamella are more difficult to reconstruct because of the lack of an ideal and readily available graft material. Thus, conjunctiva and tarsus are often supplemented by "spacers," which are free grafts of "substitute" tissue that have physical and histologic properties that make them suitable to improve eyelid structures and protect the globe.[12] The required "spacers" provide additional augmentation by lengthening the lower eyelid retractors and giving vertical height and stiffness to support the lower eyelid following release of the cicatrix.

Traditionally, ophthalmic grafts have been used in the treatment of cicatricial entropion, eyelid reconstruction following trauma or malignancy when entire portions of the eyelid must be reconstructed, and in eyelid retraction.[12,13] Skin defects are replaced by skin grafts; however, when the eyelid middle and posterior lamella must be augmented, it is more difficult to find suitable donor tissue. General qualities of an ideal implantation include easy accessibility and storage, reasonable affordability, short preparation time to facilitate intraoperative decision making, and excellent handling properties of the implant, allowing intraoperative manipulation, sizing, shaping, placement, and immobilization. Once in place, the implant should produce minimal inflammation and permit native tissue ingrowth. With time, the implant should become virtually indistinguishable from native tissues, and the desired effect persists indefinitely. Finally, minimal and infrequent complications should be observed.[21,22] In the case of eyelid surgery, the ideal material must mimic a tarsal-conjunctival composite in thickness, surface quality, and resilience. Many different materials have been used, including autogenous, homologous, and synthetic grafts. Autogenous grafts have included ear cartilage, temporalis fascia, fascia lata, buccal mucosa, nasal septal cartilage, tarsus, and periosteum.[4,23-26] Homologous donor sclera and, more recently, synthetic polytetrafluorethylene grafts have been used.[27,28] However, all of these materials lack a crucial property, as evident by the large number of proposed graft materials. For instance, scleral grafts are not permanent and tend to be degraded by the body, resulting in graft shrinkage over time.[29] Fascia grafts do not replace the conjunctiva, and this can lead to ocular irritation initially and contraction as the conjunctiva heals. Auricular cartilage grafts, on the other hand, are stiff and have the advantage of providing excellent underlying support for eyelids; unfortunately, ear cartilage is much stiffer that tarsus and does not replace conjunctiva.[30] Composite grafts such as nasal septum have the distinct advantage of replacing both tarsus and conjunctiva. Unfortunately, this method has problems of poor access, limited tissue availability, and difficulty with donor site healing, leading to the possibility of poor graft survival.[31]

Hard palate grafts are harvested from the area between the gingiva and the palatine raphe. They have been used successfully in periodontal surgery, lip reconstruction, and tracheoplasty.[32-34] In the ophthalmic literature, the use of hard palate mucosal grafting in lower eyelid reconstruction was first described by Siegel[31] in 1985 for repair after tumor excision. Its use as a spacer graft was subsequently reported for patients with cicatricial entropion, eyelid retraction secondary to thyroid eye disease, postblepharoplasty lower eyelid retraction, lagophthalmos after surgery for paralytic ptosis, and contracted socket.[1,12,35,36] Hard palate mucosa serves as an ideal material for posterior lamellar replacement for many reasons. It is composite tissue that provides both structural support and mucous membrane replacement. Its mucosal surface nicely replaces conjunctiva, whereas its stiff structure provides eyelid support similar to that of tarsus. The dense concentration of collagen fibers in the lamina propria of the hard palate gives this tissue its stability and firmness, but at the same time it has enough flexibility to allow it to maintain its contour and act as replacement for the tarsus with excellent eyelid appearance and function, unlike ear or nasal cartilage. Acting as an internal splint, palate mucosa prevents shifting of the overlying layers. The eyelid remains stable, and therefore comfortable, for many years. In addition, hard palate mucosa is abundant, easily obtained, and easy to handle, and it takes reliably with minimal shrinkage following grafting because of easy vascularization. Furthermore, being an autograft, it is not at risk for rejection.[12,35-37]

However, hard palate grafts have their own disadvantages, including donor site morbidity (eg, postoperative discomfort or bleeding, oral candidiasis, and oronasal fistula), increased operating time for graft harvest, and occasional keratinization of the surface with potential ocular surface irritation.[12,35-37] In view of these facts, a synthetic

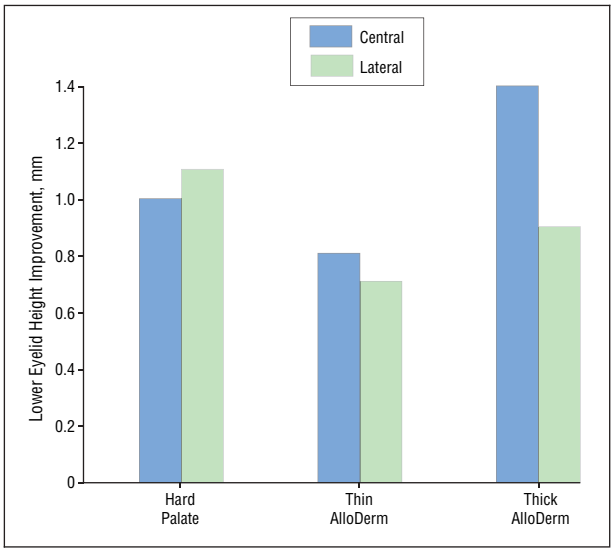

Figure 5. Comparison of 3 different grafts in lower eyelid reconstruction. Note that the lower eyelid position improves the greatest when using the thick acellular human dermis (thick AlloDerm [LifeCell Corporation, The Woodlands, Tex]) graft.

graft has been popularized. AlloDerm is a commercially available acellular dermal matrix derived from human cadaveric dermis. The tissue is enzymatically processed to remove immunologically responsive cells in the dermis and epidermis, leaving an acellular collagen framework with 1 basement membrane surface and one dermal surface.[13,21] It was initially introduced in 1995 for surface grafting in burn victims[38] and has had other applications, such as nasal reconstruction, lip augmentation, nipple reconstruction, hypertrophic scar revision, and contracture release.[13,39-41] Fairly recently it has gained popularity in ophthalmic facial plastic surgery including sulcus defects, implant coverage, periorbital contour defects, and eyelid retraction.[13,21,22,36,42] AlloDerm offers an alternative to autologous and other alloplastic materials; avoids harvesting autologous tissue, thereby minimizing morbidity and decreasing operating time; possesses excellent handling properties and comes in several sizes; possesses adequate rigidity to replace tarsus; and is associated with minimal inflammation and virtually no risk of immunologic rejection. In addition, its basement membrane surface is the natural substrate for epithelial migration, permitting conjunctival epithelial repopulation of the graft's surface in 2 to 3 weeks postoperatively. However, the primary disadvantage of AlloDerm grafts appears to be resorption, and it has been reported that the final eyelid position is less predictable.[1,21,36]

Until fairly recently, only the thin form of AlloDerm was available for use. The senior author (N.S.) started using thick AlloDerm in early 2002. However, there have been no studies on its efficacy. In this study, we aimed to evaluate the long-term efficacy of thick AlloDerm graft in lower eyelid reconstruction and compare these results with previous results for thin AlloDerm and hard palate grafts. All the patients in our study had a history of lower eyelid retraction secondary to uncomplicated lower eyelid surgery. The results were significant and very encouraging (**Figure 5**). Greater than 75% of the procedures were successful, with a mean improvement of 1.6 mm in lower eyelid position centrally and 1.1 mm laterally. Only 5 (24%) of 21 procedures were unsuccessful. Over time, the lower eyelid position stabilized, albeit minor contraction, as shown in Figure 3.

There have been only 2 studies in the past of which we are aware comparing thin AlloDerm and hard palate for lower eyelid spacer grafts: one was performed by Sullivan and Dailey[36] and the other was done in our private practice (Li et al, unpublished data, 2003). The former study dealt with 13 patients and found similar success rates of approximately 85% for both thin AlloDerm and hard palate but with a higher contraction rate for thin AlloDerm vs hard palate (57% vs 16%). The latter study by Li et al was performed using the same methods and surgical procedure as described in our study. The surgery was also performed by the senior investigator of the present study (N.S.). Li et al demonstrated a success rate of approximately 78% and 90% for thin AlloDerm and hard palate, respectively. The mean improvement for lid height was 0.8 mm centrally and 0.7 mm laterally for thin AlloDerm compared with 1.0 mm centrally and 1.1 mm laterally for hard palate. Both studies report high success rates for both but with a higher contraction rate for thin AlloDerm over hard palate. However, neither study examined the new thick form of AlloDerm. In our study, we demonstrated a similar success rate with improved eyelid height and a lower rate of contraction or decline of eyelid position for thick AlloDerm grafts.

There are important limitations to our study that must be taken into account when considering the implications of the data. The patients were not randomized, since it was a retrospective study. Although we do not believe there is any important systematic difference between the groups that would affect the comparison, it is possible that subtle changes in technique over time could have been present or other selection bias may have been introduced that affected the surgical outcome. In addition, other procedures, besides placing the graft, were performed during the surgery that could compound the results, making it difficult to determine which factor(s) was responsible for success or failure. Furthermore, although good quality photographic documentation was available at regular intervals for all patients, allowing quantitative and unbiased evaluation, measurements taken from photographs have inherent inaccuracy. Head tilt can affect the measurements. Using the corneal diameter as the reference for relative measurements introduces another error of measurement, although this should not affect the before and after comparisons for any individual patient and should not introduce any systematic bias between the groups.

While allograft materials provide exceptional ease of use and good efficacy, careful consideration of the infectious risks associated with implantation must be considered. Acellular dermal matrix has been widely used in surgery for many years without evidence of direct exposure to viral transmission. The material is highly processed, and each donor is screened for viral diseases including hepatitis and human immunodeficiency virus.

Prions are naturally occurring glycoproteins that are normal constituents of neuronal cell membranes. Ab-

normal prion proteins display unique 3-dimensional structures compared with normal prion structures. This abnormal structure is resistant to protease breakdown and can convert normal prions into abnormal prions, possibly through a crystallization process. Prion diseases include Creutzfeld-Jacob disease, kuru, Gerstmann-Straussler-Scheinker disease, and fatal familial insomnia. Abnormal prions can be transmitted by contact, injection, or ingestion of prions, resulting in variant forms of Creutzfeld-Jacob disease, which is uniformly fatal. It is important to recognize that all alloplastic and xenoplastic material and even surgical instrumentation carries a theoretical risk of prion transmission.

Prion disease transmission in medicine has been documented rarely after corneal transplant (3 cases),[43,44] use of dural allograft, injection of pooled human growth hormone, and use of contaminated surgical instruments. At present, there is no screening method for abnormal prions, and the disease can only be verified by tissue biopsy. In addition to difficult disease detection, prions are resistant to standard decontamination regimens, including detergents, dry heat, formaldehyde, peroxide, ethanol, ethylene oxide, or UV radiation. Deactivation has been observed using sodium hydroxide, bleach, and steam autoclaving at 125°C for 1 hour.[43,45,46]

With regard to acellular dermal matrix tissue harvested and processed from cadaver cartilage, no reported prion transmission has been documented. In fact, cartilaginous tissue is considered a low infectivity tissue when examined in the bovine form of disease transmission. While the use of acellular dermal tissue poses a theoretical risk, the actual risk cannot be determined but appears very low. Other potential transmissible agents include commercial preparations of botulinum toxin, which uses pooled human albumin from 2000 to 10 000 donors. At present, no cases of prion disease have been related to exposure of botulinum toxin. In addition, contamination via surgical instrumentation is a consideration, since a handful of cases have been documented. Overall, while the risks of prion disease transmission are unclear, the risk of disease transmission with the use of acellular dermal matrix appears to be minimal. When considering use of acellular dermal matrix compared with hard palate grafting, it is unclear which method exposes the patient to greater overall risk. Hard palate graft harvesting encompasses rare but increased risk for infection, bleeding, and airway management difficulties due to bleeding and results in increased anesthesia time. Therefore, given the small risk of prion transmissibility, it is unclear which method poses the least overall risk during an individual procedure.

CONCLUSIONS

We demonstrated long-lasting improvement of lower eyelid position with placement of thick AlloDerm grafts during lower eyelid reconstruction, with very few patients showing worsening of eyelid position. The patients in our study had undergone previous lower eyelid blepharoplasty with resultant middle lamellae tethering. Surgical correction included subperiosteal midface-lift and middle lamellae scar lysis in addition to thick AlloDerm graft placement to the lower eyelid. Our results are comparable to hard palate grafts and perhaps superior to thin AlloDerm. In aggregate, these studies show similar rates of success and final eyelid height position. With decreased morbidity, pain, and surgical time, we believe that thick AlloDerm is a viable alternative to hard palate grafts to repair lower eyelid retraction. However, each graft material is associated with advantages and disadvantages as discussed herein, which must be considered in preoperative evaluations. Some patients prefer not to have a second surgical site and would prefer an allograft. Although AlloDerm does not require a second surgical site, it remains a cadaveric donor material, which some patients regard as unacceptable. Therefore, in each preoperative assessment, the surgeon must discuss the risks and benefits of each material with the patient and consider not only the surgical outcome but also the preferences of the patient.

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