

Use of Porcine Acellular Dermal Matrix (Enduragen) Grafts in Eyelids: A Review of 69 Patients and 129 Eyelids

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Background: Spacer grafts in the eyelid are used in both reconstructive and aesthetic procedures. The authors report their experience using a new acellular porcine dermal graft (Enduragen) in 129 eyelids.

Methods: A retrospective chart review was performed that included every case in which Enduragen was used by the two primary authors in the upper or lower eyelid. Patient demographics, type of procedure performed, and complications were reviewed.

Results: Sixty-nine patients and a total of 129 eyelids were included in the study. Eight procedures were spacers in the upper lid, 104 were for spacers in the lower lid, and 17 were for lateral canthal reinforcement. Twenty-two procedures were in primary cases and 47 were in eyelids for secondary reconstructions, for a total of 69 patients. There were 13 eyelid complications, for a complication rate of 10 percent. Nine cases required surgical revision, and there were four cases of infection, all of which were successfully treated with oral and topical antibiotics.

Conclusions: Enduragen has proved to be a very satisfactory substitute for ear cartilage and fascia in eyelid surgery in both reconstructive and primary eyelid cases. It seems to be far superior to other commercially available tissue substitutes because of its predictability of structure and robust behavior. All problems that were encountered in this series seemed to be related more to technical errors than to any deficiency in or reaction to the Enduragen. The increased strength, rigidity, and durability give support to the lids comparable to that obtained with autogenous ear cartilage and fascia. (*Plast. Reconstr. Surg.* 122: 1206, 2008.)

In reconstructive and sometimes primary eyelid surgery, it is necessary to include graft materials for soft-tissue support. The first spacer grafts in the eyelids were composed of eye bank preserved sclera.¹ Historically, many grafts used have been autologous and have included cartilage (most commonly ear, but also nasal and rib cartilage), palatal mucosa, dermis, temporalis fascia, and fascia lata.²⁻¹¹ All of these have the advantage of being autologous tissue with excellent recipient tolerance, but in some cases, the surgeon is limited by the amount of tissue available and the inconvenience of a second surgical site. Ear cartilage and fascia grafts have been particularly useful in our hands with regard to eyelid surgery.

When it is convenient to avoid donor-site morbidity, other materials are sometimes used, such as human cadaveric acellular dermis (AlloDerm; LifeCell Corp., Branchburg, N.J.)¹² or high-density polyethylene (Medpor; Porex Surgical, Inc., Newnan, Ga.).¹³ These all share the advantage of not requiring an additional operation to obtain donor material; however, they vary in effectiveness, permanence, and tissue tolerance. In the eyelid, we had initial enthusiasm with AlloDerm, but we were later less eager to use it because of reabsorption, long-term failures, and inconsistencies in the product itself (data not published).

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In the last 2 years, we have used a relatively new product to the United States: Enduragen, a porcine acellular dermal collagen matrix manufactured by Tissue Science Laboratories (Aldershot, United Kingdom). It was first approved for use in Europe in 1997 and is now distributed in the United States by Porex Surgical for use in the head and neck. Because of its tensile strength, tissue tolerance, and longevity, the same implant material is distributed in other markets, such as orthopedics and urology, under different trade names such as Zimmer Collagen and Pelvicol. It is also used as an alternative to mesh in abdominal wall repair under the name Permacol. Multiple reports testify to the efficacy, safety, and longevity of Permacol in hernia repair.¹⁴⁻¹⁷ To date, no one has reported on the use of Enduragen in the eyelid. This is a report on our experience using Enduragen as a spacer graft in 69 patients and 129 eyelids for both reconstructive and aesthetic procedures as a substitute for autogenous ear cartilage and fascia.

PATIENTS AND METHODS

Data Collection and Patient Chart Review

A retrospective chart review was performed that included every case in which Enduragen was used by the two primary authors (C.M., F.R.N.) in the upper or lower eyelid. Patient demographics, type of procedure performed, and complications were reviewed.

Materials

Two different sizes of Enduragen were used in eyelids in this series depending on the need. A 1-mm-thick piece (tailored from a 40 × 10 × 1-mm segment supplied from the manufacturer) was used as a spacer in the upper and lower eyelids as a substitute for ear cartilage. This was often cut down to a 5-mm height but varied depending on needs. The average height was 6 mm for lower lid spacers. A 0.5-mm-thick piece (tailored from a 50 × 20 × 0.5-mm segment supplied from the manufacturer) was used as a substitute for autogenous fascia for lateral canthal reinforcement grafts.

Surgical Procedures

Upper Eyelid

In the upper eyelid, Enduragen was typically used as a spacer graft between the levator-Müller muscle and tarsal plate for upper lid advancement procedures used to treat Graves lagophthalmos or overcorrected ptosis repairs (Fig. 1). All upper lid procedures were performed using an anterior



Fig. 1. Use of Enduragen in upper lids. (Above) A patient with Graves disease and upper and lower eyelid retraction before surgery. (Center) An upper lid incision has been performed and the levator aponeurosis and Müller muscle have been separated from the superior edge of the tarsal plate, leaving only the conjunctiva intact. The amount of spacer material inserted is equivalent to the amount of retraction. (Below) Postoperative view after surgery on both upper and lower eyelids.

transcutaneous approach through skin and muscle until the terminal fibers of the levator muscle and the cephalic border of the tarsal plate were found. After release of the levator attachment to the tarsal plate, an Enduragen spacer graft, of varying height depending on needs (generally 3 to 5 mm), was then secured to the cephalic edge of the tarsal plate and the distal fibers of the levator aponeurosis using absorbable sutures, effectively extending the upper eyelid. Concomitant procedures were at times performed, including skin removal or creation of a lid crease.

Lower Eyelid

In the lower eyelid, the procedures were either to insert spacer material in the lower lid in patients with prominent eyes or to counteract middle lamellar scarring in retracted lids. Either an anterior approach through a subciliary incision or a posterior approach including a cantholysis and transconjunctival incision was used to access the lower lid retractors or scarred middle lamella (Fig. 2). In cosmetic cases, primary and some cosmetic revisional cases, the anterior approach was used to facilitate redraping of the midface (Figs. 3 and 4). Our primary indication for Enduragen in primary aesthetic cases was as a primary lower lid spacer in those patients with prominent eyes (Hertel exophthalmometric measurement usually greater than 19 mm). The recipient site for the Enduragen graft always involved a conjunctival incision and separation. The graft bridges the cut ends of the lower lid conjunctiva and retractors as a complete posterior lamellar replacement graft abutting the globe below the cornea, left to mucosalize on its own. Commonly, in revisional cases or in patients with unusual exophthalmos (i.e., Graves disease), the spacer graft is placed through a posterior incision through the conjunctiva and inferior retractors after a cantholysis has been performed for exposure (Fig. 5).

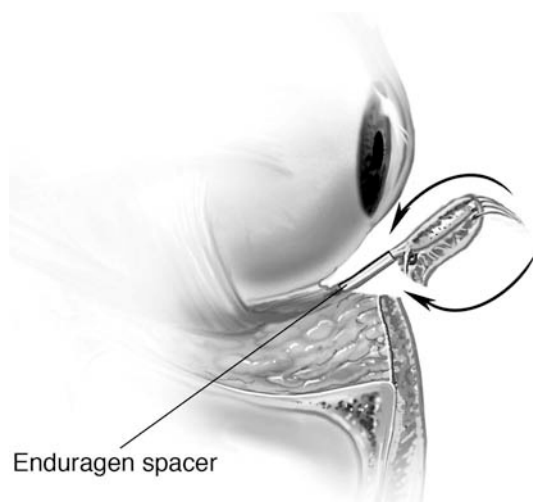


Fig. 2. Placement of an Enduragen spacer (indicated by arrows) in the lower lid. This diagram demonstrates the Enduragen spacer placed in the posterior lamella of the eyelid through a full-thickness blepharotomy beneath the inferior arcade. The spacer can also be placed from the conjunctival side with release of the conjunctiva and retractors or externally through a blepharoplasty incision, leaving the conjunctiva intact. The decision as to the best approach is based on the previous operative history and the amount of scar release needed to achieve proper lower lid position.

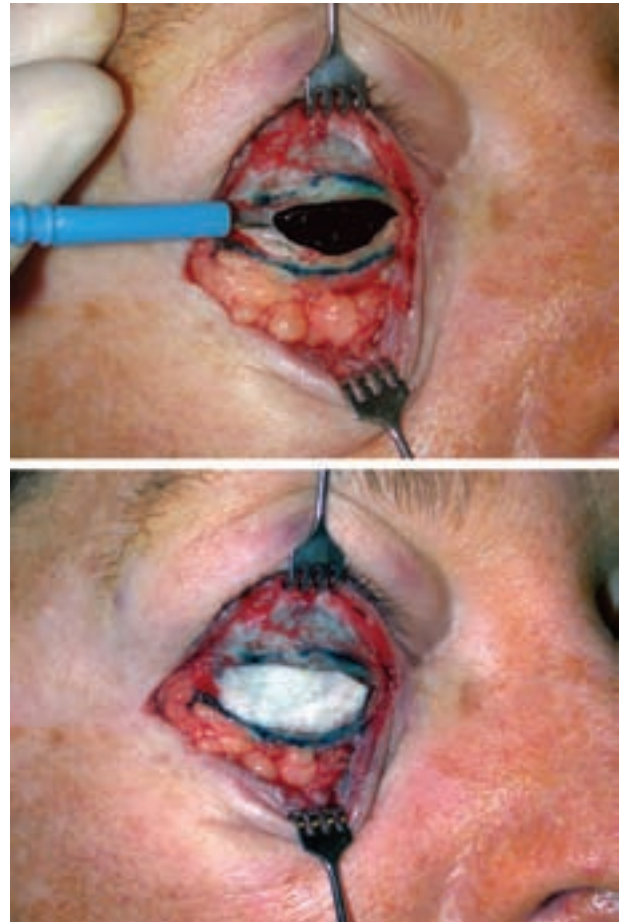


Fig. 3. Placement of the spacer by means of an external approach. (Above) An incision has been made full thickness through the posterior lamella of the lid by means of a transcutaneous subciliary approach. A black eye-protective contact lens can be seen covering the globe. The conjunctiva and lower lid retractors are being released by the electrocautery tip. (Below) The Enduragen spacer has been inserted into the defect and sutured with 6-0 plain catgut suture.

Lateral Canthus (Canthal Anchoring)

After previous surgery or injury, some patients have atrophic scarring and tissue deficiency in the lateral lid and require reinforcement in addition to conventional canthal anchoring. A 0.5-mm-thick sheet of Enduragen is used instead of autogenous fascia for these cases.

Linear Shaped Grafts

In cases of deficiency of the lateral canthus with loss of substantial eyelid tissue, either replaced by scarring or loss of substance, Enduragen grafts (0.5-mm-thick), instead of autogenous fascia, were used to reinforce the canthus for support. The grafts were used in addition to, and more recently, together with, drill hole anchoring (Figs. 6 and 7).

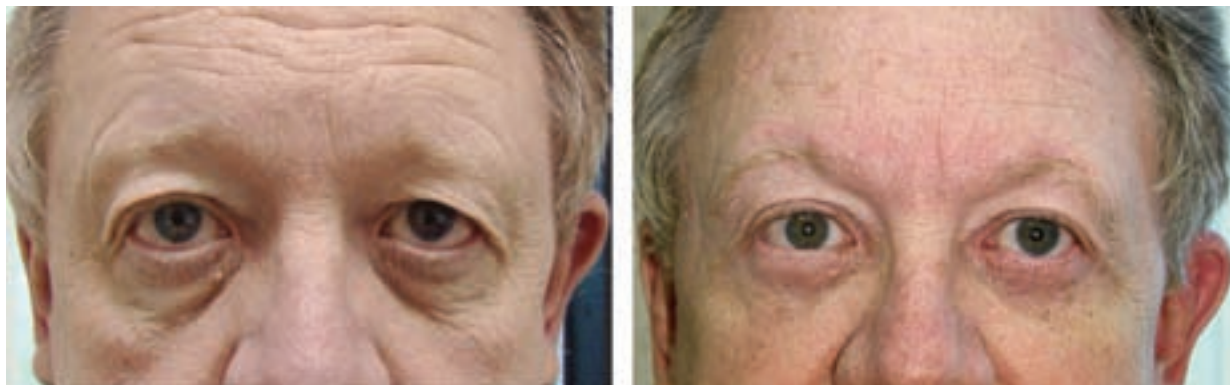


Fig. 4. Use of Enduragen spacers in the lower lid in primary cosmetic cases. A patient with prominent eyes (22-mm Hertel exophthalmometric measurement) before and after a lower lid blepharoplasty with an Enduragen spacer, midface cheek lift, and upper lid blepharoplasty with direct browpexy.



Fig. 5. Placement of Enduragen spacer using the internal approach. (*Above, left*) A male patient with eyelid retraction following a previous blepharoplasty. (*Below*) Spacer placement. The lower lid is everted after a canthotomy and cantholysis to show the spacer being sutured in place with 6-0 plain catgut. (*Above, right*) View of the patient 4 months after Enduragen was placed in the lower lids by means of the internal approach.

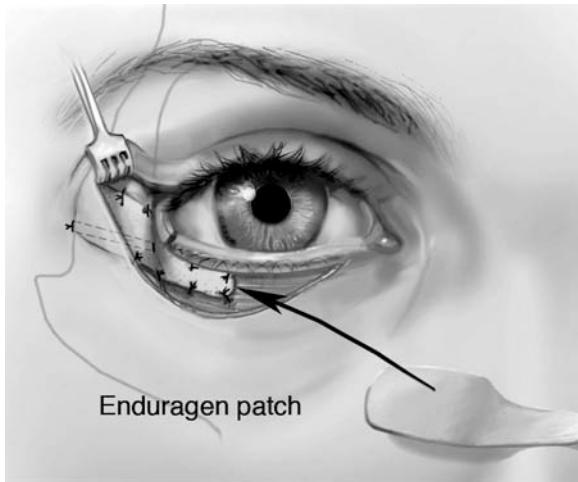


Fig. 6. Diagram shows placement of a strap of a 0.5-mm sheet of Enduragen to reinforce canthal anchoring.

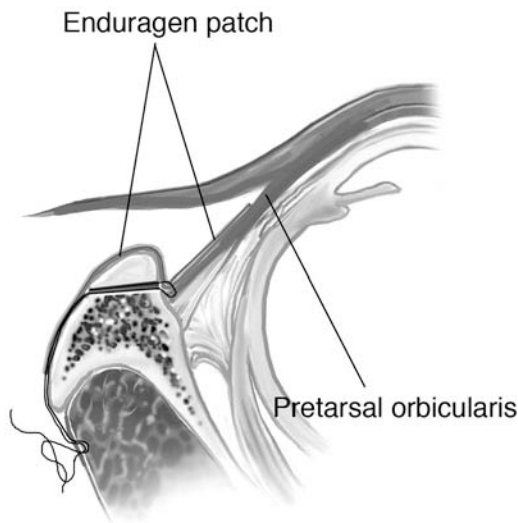


Fig. 7. Diagrammatic axial view of drill hole canthal anchoring with Enduragen bolster.

Bolster for Canthal Drill Hole Fixation

Drill hole fixation of the lateral canthus has served well to restore canthal integrity in cases that have deficient periosteum, where standard canthal anchoring techniques are not adequate.^{18,19} In cases with deficient eyelid tissue, even drill hole canthal fixation may result in release and some recurrence of lid malposition with time. Reinforcement of drill hole canthal fixation using a 0.5-mm bolster has prevented late release. The extension of the bolster over the orbital rim has also reduced complaints of postoperative irregularities in the operated area. The drill hole bolster can be used in conjunction with lower lid spacers in the more difficult patients.

Canthal Y Grafts

Some disease processes affecting eyelids (e.g., atrophic dermatochalasis syndrome, neurofibromatosis) are so destructive to eyelid tissue that a more extensive reconstruction is necessary (Fig. 8). In these cases, canthal reconstruction is accomplished by extending an additional arm of fascia into the upper lid and the lower lid in a Y-shaped configuration that is then anchored with drill hole fixation. For exposure, the skin incisions take the shape of a Y on its side. The Enduragen is then shaped appropriately either as a suspension graft or canthal Y graft and secured from the lid plate or canthal remnant to the lateral orbital rim periosteum. As before, concomitant procedures were performed as indicated.

Postoperative Care

All patients were managed with antibiotic- and steroid-containing ophthalmic ointment and drops for the first 2 weeks after surgery. A temporary tarsorrhaphy suture was placed in most cases. If chemosis was noted at the end of the procedure, it was managed with snipping of the conjunctiva and a temporary tarsorrhaphy suture. Chemosis noted in the clinic was treated with a combination of antibiotic- and steroid-containing ophthalmic ointment and a 24-hour eye patch. Severe cases were snipped in the clinic before patching. The majority of occurrences of chemosis resolved within 2 weeks of surgery.

Statistical Analysis

A retrospective chart review was performed of all patients who had Enduragen used in their eyelids or face from January of 2005 to May of 2006. Patient totals, total number of eyelids, and the need for secondary procedures or complications were tallied.

RESULTS

A total of 69 patients were identified and included in this study, for a total of 129 eyelids in which Enduragen was used (Table 1). Eight procedures were for spacers in the upper lid, 104 procedures were for spacers in the lower lid, and 17 procedures were for lateral canthal reinforcement, for a total of 129 eyelids. Twenty-two were procedures in primary cases and 47 were in eyelids for secondary reconstructions, for a total of 69 patients. Of the primary cases, 10 had a diagnosis of Graves disease and 12 were aesthetic lower lid blepharoplasties (Table 2). There were 13 eyelid complications in this series, for a complication



Fig. 8. Y-shaped Enduragen canthal anchoring reinforcement for severe canthal deformity. (Left) A young male patient with atrophic blepharochalasis syndrome with severe canthal deformity. Previous surgery elsewhere had not helped. (Center) Intraoperative view demonstrates the use of Enduragen in a Y-shaped configuration. (Right) View of the patient 1 month after the Y-shaped Enduragen anchor reconstructive procedure on the left eye.

rate of 10 percent. Nine cases required surgical revision, and there were four cases of infection, all successfully treated with oral and topical antibiotics (Table 3).

Table 1. Patient Demographics

| Characteristics | Value (%) |
|-------------------------|-----------|
| Age, years | |
| Average | 54.7 |
| Range | 21–100 |
| Sex | |
| Male | 9 (14.5) |
| Female | 60 (85.5) |
| Total cases | |
| Total no. of patients | 69 |
| Total no. of eyelids | 129 |
| Bilateral eyelid cases | 60 |
| Unilateral eyelid cases | 9 |
| Type of cases | |
| Cosmetic revision | 41 |
| Primary cosmetic | 12 |
| Graves disease | 10 |
| Reconstructive | 6 |
| Total | 69 |

Table 2. Types of Procedures

| Procedure | No. of Eyelids |
|--------------------------|-----------------------|
| Lower lid spacers | 104 |
| Upper lid spacers | 8 |
| Drill hole canthal sling | 10 |
| Straight canthal sling | 7 (3 Y-shaped slings) |
| Total | 129 |

DISCUSSION

This is a report of our experience using porcine-derived acellular dermal matrix grafts (Enduragen) in the eyelid for both aesthetic and reconstructive procedures as a substitute for ear cartilage and autogenous fascia. We find it to be superior to previously used nonautogenous substances. Enduragen’s advantages are in uniformity and predictability of thickness, its structural integrity, its ease of use (it does not require soaking), and the fact that it appears to be of superior durability. In some cases in which late revision was necessary, as long as 6 months later, the previously

Table 3. Complications and Revisions

| Complications | No. of Eyelids |
|--|---------------------------------------|
| Total complications | 13 (10%) |
| Additional spacer needed | 4 (surgery required) |
| Infections | 4 (all cleared with oral antibiotics) |
| Trim of spacer because of excess | 3 (surgery required) |
| Additional autograft | 2 (one fascia, one ear cartilage) |
| Surgical revisions relative to diagnosis | |
| Reconstructive | 9 (all lower lids) |
| Cosmetic revision | 0 |
| Primary cosmetic | 0 |
| Graves disease | 0 |
| Total surgical revisions | 9 |

placed Enduragen was encountered and seemed for the most part to be structurally intact but partially vascularized and incorporated into the surrounding tissue (Fig. 9). Spacer grafts placed in the posterior lamella of the lower eyelid were sewn to the cut edges of the conjunctival mucosa and lower lid retractors (full blepharotomy) at a level below that of the cornea, avoiding corneal irritation and abrasion. We found that the exposed surface of the Enduragen would remucosalize within 6 to 8 weeks after placement.

All of the needed surgical revisions occurred in the reconstructive patients and were in the lower lids. No revisions were needed in any of the primary cases. Many of the cases that needed revision were extreme cases and were referred having had multiple eyelid procedures before the operation in this series. In these cases, extreme scar contractures, previously placed grafts, and other problems were encountered. In one case, a sheet of Enduragen used for support of canthal anchoring was replaced with autogenous fascia. In two cases of lower lid spacer insertion, because of significant eye prominence, the entire vertical height of the Enduragen (1 cm) was placed in the lower lid. Inadequate trimming of the ends of the spacer occurred in these two cases, and sharp prominences (the untrimmed corner of the graft) were noted by the patient subcutaneously, requiring secondary trimming (Fig. 10). Another patient required secondary trimming, as a sharp corner of Enduragen eroded through an overlying old skin graft that had very little cushioning. When suffi-



Fig. 9. Intraoperative view of one of the patients who had revision surgery 6 months after having had Enduragen placed in the lower eyelid demonstrating the durability of Enduragen. Notice the presence of the graft in the posterior lamella 6 months after initial insertion.



Fig. 10. Postoperative view of a patient in whom an untrimmed Enduragen edge caused skin inflammation requiring trimming. The patient, with mild Graves disease, is shown after a lower lid blepharoplasty with an Enduragen spacer, a midface lift, and a lower face lift. An untrimmed 1-cm vertical width of Enduragen spacer was placed in the lower lid. There was a persistent reddened protruding area in the lateral portion of the left lower lid. This patient had transcutaneous trimming of the edge of Enduragen in the left lower lid to correct the problem.

cient, our preference is to use the 5-mm height of the Enduragen graft to avoid the possibility of exposure and irritation. In the vast majority of the cases reviewed, the 5-mm height was adequate; it was in the extreme cases in which surgery had previously been performed that we were more likely to use the full 10-mm height of the graft.

We would advise special attention to the level at which the Enduragen spacer is placed in the lower eyelid. If possible, the incision on the lid conjunctiva should be at least 10 mm below the level of the lid margin. This will protect the lower lid arcade vasculature and tarsal plate. As mentioned before, it also keeps the Enduragen off the cornea. The cases in which we placed the full 10-mm height of graft in the lower lid and incised the conjunctiva within 8 mm of the lid margin needed trimming of the Enduragen. It was simply too much graft too close to the lid margin.

Four infections occurred late after surgery, greater than 3 months postoperatively, and ultimately required oral linezolid (Zyvox; Pfizer, New York, N.Y.) for resolution. All of the cases were in difficult lower eyelid reconstructions in patients who had had multiple previous procedures, including previous spacer placement. These cases

involved spacer sandwiched on spacer in the midst of significant scar tissue with altered vascularity and reparative characteristics. We believe that the use of graft material (autologous or otherwise) in these situations has an inherently higher risk of complications and infections and does not necessarily reflect poorly on Enduragen as a graft material but is an indication that, in difficult revision cases with significant scar and previous spacer grafts, caution is warranted. Perhaps the durability of the Enduragen and the fact that it is not resorbed plays a role here. Fortunately, in all four of these cases the infections were treated successfully with oral antibiotics. Two small pyogenic granulomas were encountered adjacent to the lower lid spacer that sloughed spontaneously and were mentioned by the patients. In our experience with dealing with very difficult eyelid problems, the benefits and advantages of the Enduragen have far outweighed the complications we have encountered.

Technical considerations with Enduragen should include the knowledge that, because Enduragen is slightly more rigid than other tissue products, all edges and corners should be trimmed and tapered before closure. Also, for ease of suturing, a larger needle than that used for the standard 6-0 plain catgut (Ethicon, Inc., Somerville, N.J.) suture may be required. It is possible to suture Enduragen with a smaller needle, but this requires exact perpendicular entry into the Enduragen to avoid bending the needle. The larger needle on 6-0 fast absorbing catgut (Ethicon) avoids this problem, but the more rapid nature of absorption of the suture increases the chance that the graft may not be secured to the graft bed before loss of suture tensile strength. In more recent cases, we have begun using 6-0 Vicryl (Ethicon) to avoid this potential problem.

All things considered, Enduragen has proved to be a very satisfactory substitute for ear cartilage and fascia in eyelid surgery in both reconstructive and primary eyelid cases. It seems to be far superior to other commercially available tissue substitutes because of its predictability of structure and robust behavior. All problems that were encountered in our series seem to be related more to technical errors and severity of patient disease than to any deficiency in or reaction to the Enduragen. The increased strength, rigidity, and durability give support to the lids comparable to autogenous ear cartilage and fascia.

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