Innovation in Endothelial Keratoplasty

Early results from a no-fold, small-incision, DSAEK graft injector.

BY KEITH A. WALTER, MD, AND J. BRIAN FOSTER, MD

Descemet's stripping automated endothelial keratoplasty (DSAEK) has become the preferred treatment for selective corneal endothelial cellular dysfunction associated with failed penetrating keratoplasty, bullous keratopathy, and Fuchs' endothelial dystrophy.[1] Originally described as posterior lamellar keratoplasty,[2] the DSAEK procedure has been refined by several surgeons.[3,4] A variety of surgical approaches for donor graft insertion have been described. These include utilizing large scleral tunnel incisions without donor folding, often using glide devices, sutures, injectors, or a bifold or trifold technique through a 3- to 5-mm incision. The most challenging steps of small-incision DSAEK are implanting and unfolding the donor lenticule. The various techniques include fixation sutures, a fixation cannula, and other devices to anchor the graft and to facilitate unfolding.[5-8] There is significant disagreement in the literature regarding the DSAEK insertion technique that best preserves the donor endothelium. Some investigators report better results with a forceps or sutures, and others caution against any folding.[9-13]

Surgeons also debate whether large- or small-incision DSAEK is better for the graft's long-term viability, its propensity for postoperative dislocation, and the ease of insertion in the OR. We prefer small-incision DSAEK, because it provides a more stable wound postoperatively, sutureless surgery, speed, and convenience for combining the procedure with standard phacoemulsification. In the past, the small-incision approach required folding the donor lenticule, typically using a noncompressing forceps. Balancing the attractiveness of small-incision DSAEK with the concern for endothelial injury from donor folding and forceps compression, we have developed with our colleagues a novel DSAEK injector device (tentatively named Endosaver [Ocular Systems, Inc., Winston-Salem, NC]) that allows us to insert unfolded tissue without a forceps through a 4-mm clear corneal incision (Figure 1). We currently are conducting a FDA-guided trial in order to obtain 510(k) approval.

THE SURGERY

After placing a lid speculum, we create paracenteses at the 3- and 9-o'clock positions using a guarded diamond knife. We inject sodium hyaluronate (Healon; Abbott Medical Optics Inc., Santa Ana, CA) into the anterior chamber. After creating a superior 4-mm clear corneal incision with a microkeratome, we use a 90º Moria stripper (Moria,

A

B

Figure 1. The Endosaver small-incision DSAEK graft injector top (A) and bottom (B).

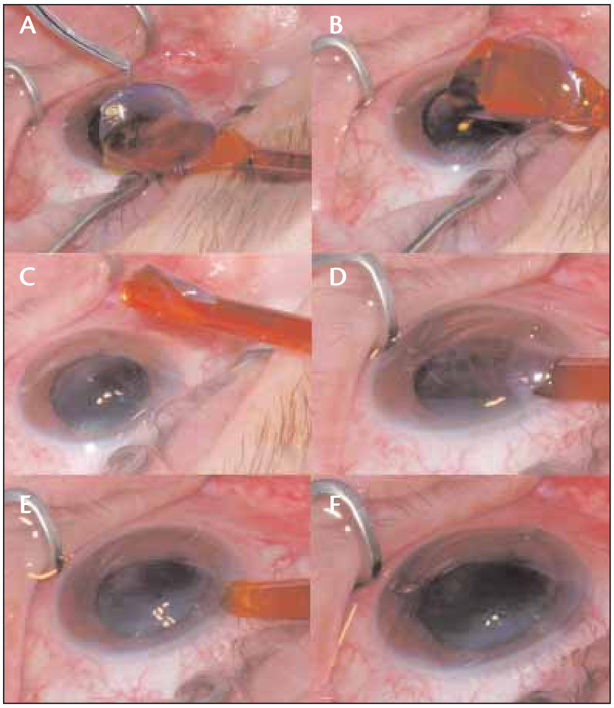

Figure 2. Loading donor lenticule on spatula (A). Rolling and retracting the graft into the device (B). Almost complete retraction of the lenticule (C). Graft insertion (D). Retraction of the device with a centered graft not requiring any additional manipulation (E). Centered graft (F).

Antony, France) to carefully peel the host endothelium and Descemet's membrane. We prepare the donor lenticule for implantation with a sharp-pointed trephine. We place the graft with the stroma downward on the Endosaver device's spatula (Figure 2A) under the operating microscope. Healon is placed on the endothelial surface. The rear dial on the Endosaver is then rotated to retract the spatula into the insertion sheath (Figure 2B). When retracted, the spatula curves inward so that the donor graft is rolled with its stromal side out until the opposite edges of the graft touch (Figure 2C). The device is rotated 180º so that the graft will unroll in the proper position, endothelial side down. Balanced salt solution is infused into the tail of the Endosaver to stabilize and deepen the anterior chamber during the graft's insertion. We start infusion while introducing the sheath into the corneal incision (Figure 2D).

Once the sheath is fully inside the anterior chamber, we use a front dial on the device to retract the sheath, and the graft unrolls completely in the anterior chamber (Figure 2E and F). We inject filtered air to tamponade the graft against the host stromal bed and maintain high pressure for 10 minutes. We use a 25-gauge microvitreoretinal blade to make four midperipheral corneal slit incisions, one in each quadrant, down to the graft/host interface. This facilitates the drainage of fluid and is thought to enhance the attachment.[14] We use a Visiteck LASIK flap roller (BD, Franklin Lakes, NJ) to massage fluid out of the interface if necessary.

After 10 minutes, we reduce the air bubble to approximately 40% by filling the anterior chamber with balanced salt solution and allowing some of the air to escape. We verify that the wounds are watertight and instruct the patient to lie flat for 1 hour in the recovery area. Occasionally, a 10–0 nylon suture is needed at the clear corneal incision. At 1 hour, the patient sits up in the postoperative recovery area so that we may ensure there is no evidence of graft detachment or pupillary block. We instruct patients to lie flat as much as possible for the next 2 days.

RESULTS

In our first six cases, there were no graft dislocations. The average rate of postoperative endothelial cellular loss (n = 5) at 1 month was 30% (range, 18% to 42%). All patients underwent an examination at 1 month postoperatively. Three patients (50%) saw 20/60 or better at 1 month, and all patients (100%) saw 20/100 or better (Table).

We encountered no major complications in our first six

TABLE. PATIENT DATA FOR FIRST SIX CONSECUTIVE CASES

History	Preoperative BCVA	BCVA at 1 month	Postoperative endothelial cellular density	Preoperative endothelial cell density	% loss
Fuchs' dystrophy	20/60	20/70		2,932	
Fuchs' dystrophy	20/40	20/40	2,100	2,907	28%
Fuchs' dystrophy	20/50	20/50	1,869	3,237	42%
Fuchs' dystrophy	20/50	20/80	2,148	2,987	28%
Fuchs' dystrophy	20/70	20/70	2,073	3,068	32%
Bullous Keratopathy	20/70	20/40	2,351	2,881	18%

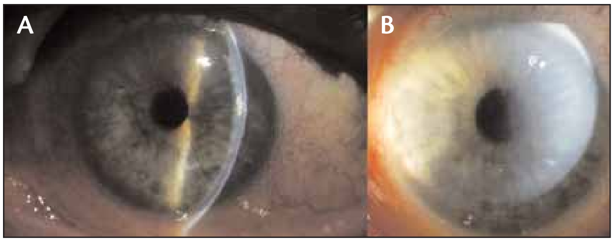

Figure 3. One day after surgery, the graft is fully attached (A and B).

cases. In our third case, the donor graft was quickly injected into the eye, because the irrigation line was turned on full force immediately instead of being gradually increased. Nonetheless, the lenticule unfolded immediately without falling back on the lens, and it remained in the proper orientation until we infused air into the anterior chamber. So far, we have observed no episodes of pupillary block, primary graft failure, or acute rejection. Our plan is to enroll 100 eyes and report detailed results in a peer-reviewed journal later this year.

DISCUSSION

The key to successful endothelial transplantation is the protection and preservation of as many donor endothelial cells as possible. A variety of insertion techniques are being explored to limit intraoperative damage to the endothelium. Most devices and techniques for graft implantation can be divided into a pushing method (bifold and trifold with forceps) or a pulling method (glide devices, suture or cannula fixation). Our device is unique in that the graft is essentially placed into the anterior chamber as the insertion sheath is retracted. As it unrolls, the donor tissue undergoes little pushing or pulling, there is no endothelial touch, and the anterior chamber remains fully deepened. In our experience, the graft unfolds without difficulty, even in eyes with a shallow anterior chamber. Occasionally, external manipulation with a LASIK roller is required if the graft is slightly decentered. In our experience, rarely is an internal positioning with a Sinskey hook required. The advantage of an external manipulation is that the endothelium is not touched. If any treatment is needed after insertion, an external manipulation is typically all that is required with our new technique.

In the past, we used a Healon-assisted trifold insertion technique with noncompressing forceps through a small incision. We agree with other investigators that significant damage to the donor endothelium can occur even when using noncompressing forceps. Since beginning to use the Endosaver device, we have noted a significant decrease in postoperative graft dislocations, from between 20% and 30% to zero so far. In the past, we also used a Healon-assisted, graft-positioning technique that may have interfered with attachment. Another possible explanation for the higher rate is endothelial damage with forceps compression or graft folding, both of which are limited with the new technique.

Innovation in endothelial keratoplasty continues at a rapid pace. We are excited to report our early results with a small-incision, no-fold graft injector. Further study is ongoing. Video of the surgery can be found at Eyetube.net. ■

eyetube Ophthalmic Video Resource

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