Deep Lamellar Endothelial Keratoplasty

A new surgical cure for bullous keratopathy following cataract surgery.

BY MARK A. TERRY, MD

Corneal edema after cataract surgery is sometimes unavoidable and occurs frequently after phacoemulsification in patients with Fuchs' endothelial dystrophy or other preoperative conditions associated with marginal endothelial function. If significant corneal edema persists for 6 or more weeks after cataract surgery, then visual improvement may only be possible through surgical endothelial replacement.

For the past 100 years, the only option for endothelial replacement surgery was full-thickness penetrating keratoplasty (PKP). Although the surgical technique for PKP has been greatly refined, visual rehabilitation after the procedure is still plagued by numerous problems (Table 1). In addition, the vertical stromal wound of PKP is inherently weak and subject to rupture from mild, blunt trauma, even years after the original surgery. These liabilities of PKP call for another, more selective means of surgical endothelial replacement.

In 1993, Ko et al presented a technique of replacing the endothelium through a limbal incision.[1] Their results in an animal model were encouraging. In 1998, Melles et al further developed the technique and published their results on posterior lamellar keratoplasty in the first human surgeries.[2,3] My colleagues and I modified the technique and instruments in our laboratory and treated the first US patients in 2000 under an Institutional Review Board (IRB)-approved protocol.[4,5] We named this procedure *deep lamellar endothelial keratoplasty* (DLEK) and now have the largest, prospective clinical study of this procedure in the world.[6-13]

DLEK STEP BY STEP

The concept behind DLEK surgery is to replace the endothelium without violating the corneal surface with incisions or sutures. This approach preserves the normal corneal topography, thereby making corneal power predictable, eliminating postoperative irregular astigmatism, and obviating the need for LASIK, relaxing incisions, or contact lenses for transplant patients. Because we do not place sutures, the patient's cornea is protected from the occurrence of suture vascularization, infection, ulceration, and perforation. A lack of corneal surface wounds preserves the stromal integrity of the cornea and maintains a tectonically strong globe without increasing the risk of rupture from mild, blunt trauma.

Although the DLEK procedure is still evolving, our current protocol is based upon the 2002 case report by Melles et al[14] and involves the following steps.

1. Using a temporal approach with a diamond knife, we create a 5-mm incision in the scleral limbus (for the initial patients in our DLEK protocol, we used a 9-mm scleral access incision from the superior scleral limbus, with resection of the recipient disc via an intrastromal Terry Trephine [Bausch & Lomb, Rochester, NY]).
2. We perform dissection with Devers Dissectors (Bausch & Lomb) of a total corneal lamellar pocket at a depth of approximately 80%.
3. With intrastromal scissors (Cindy Scissors [Bausch &

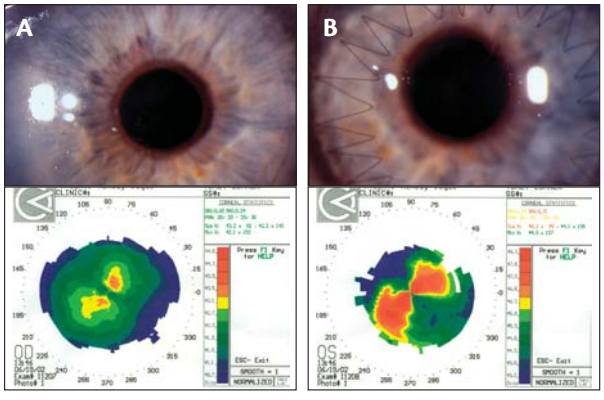

Figure 1. This patient underwent DLEK surgery on his right eye (A) and standard PKP surgery on his left eye (B). After 3 months, vision in the DLEK-treated eye was stable at 20/25 with 0.25 D of astigmatism, whereas his PKP eye still had sutures in at 9 months, a BSCVA of 20/25, and nearly 4.00 D of oblique astigmatism. As could be expected, the patient preferred his right eye for vision.

TABLE 1. COMPLICATIONS OF POST-PKP VISUAL REHABILITATION

- Irregular astigmatism
- High astigmatism
- Unpredictable myopia or hyperopic shifts
- Suture-induced corneal infections
- Vascularization
- Rejection of graft
- Loss of the eye from late suture-tract endophthalmitis

Lomb]), we resect an 8-mm-diameter disc of the posterior corneal stroma, Descemet's membrane, and endothelium.

4. We place the donor corneal-scleral cap onto an artificial anterior chamber and create a healthy donor posterior disc with the same 8-mm diameter.

5. We then place Healon (Pfizer Inc., New York, NY) onto the donor endothelium, fold the disc into a taco shape (endothelium inside), and insert the folded disc into the anterior chamber.

6. Next, we unfold the disc in the recipient anterior chamber, position it with the use of an air bubble, and replace this bubble with BSS at the end of the procedure, as the donor disc of tissue self-adheres.

7. We close the scleral wound with two or three interrupted nylon sutures.

Although the DLEK procedure is quite technically challenging at first, our current level of experience allows us to complete the procedure in less than 1 hour. We have performed the DLEK procedure in phakic Fuchs' patients and have also combined the DLEK procedure with phacoemulsification cataract surgery as well as surgeries involving vitrectomy and IOL exchange.

RESULTS

We have completed 90 cases of DLEK surgery as of February 1, 2004 (36 cases with a 9-mm superior scleral access incision and 54 cases using a 5-mm temporal scleral access incision). All cases were treated under the auspices of an IRB-approved, prospective clinical protocol with a special consent form for this investigational surgery. Analysis of the first 55 consecutive patients to reach the 6-month postoperative protocol visits demonstrated that the results of DLEK surgery are far superior to those of standard PKP in terms of preserving the normal corneal topography and speeding the visual recovery time.

At 6 months, the average amount of astigmatism after DLEK surgery was 1.63 ±0.97 D in our 9-mm incision series (n=36) and 1.39 ±0.65 D in our 5-mm incision series (n=19). These results compare well to the average 4.00 to 6.00 D of astigmatism seen after standard PKP surgery.[15,16] The average spherical equivalent 6 months after DLEK was -0.45 ±1.47 D and -0.22 ±1.25 D in our 9-mm and 5-mm incision series, respectively. These amounts compare well to the spherical equivalents (range, -6.75 to +7.25 D of refractive error) reported after PKP.[17]

Initially, we were concerned that manipulating the donor tissue with DLEK surgery would cause endothelial cell damage that would result in lower endothelial cell counts postoperatively compared with those after standard PKP surgery. Our findings were the opposite. After 9-mm DLEK surgery, the average endothelial cell count at 12 months was 2,218 ±505 cells/mm^2, representing only a 22% cell loss from preoperative donor counts. After the 5-mm incision DLEK, despite folding and unfolding of the graft, the average cell count at 6 months was 2,028 ±538 cells/mm^2, representing a 27% cell loss from donor preoperative measurements. One year after PKP, the cell count has been reported as 1,958 ±718 cells/mm^2, which represents a 34% cell loss from preoperative donor counts.[18]

Patients attain useful and improved visual acuity faster after DLEK surgery versus standard PKP, and the visual results are more stable as well. The average visual acuity after DLEK surgery at 6 months was 20/40-2 (range, 20/25 to 20/200) with no patients seeing worse than 20/200. In addition, no DLEK patient required the use of a contact lens, LASIK, or relaxing incisions in order to achieve best vision. The average age of our DLEK patients was 75 years, and many had pre-existing retinal macular disease (age-related macular degeneration or old cystoid macular degeneration) prior to undergoing surgery, two factors accounting for the range of visual results achieved.

In contrast, the average visual acuity after standard PKP for Fuchs' dystrophy disease is 20/40+ (range, 20/20 to no light perception) with fully 18% of patients seeing worse than 20/200.[19] Moreover, vision after PKP may take 1 or more years to stabilize. Certainly, vision should not be considered stable until after complete suture removal.

None of our DLEK patients lost vision or an eye due to infection or trauma, whereas 5% of PKP patients suffer severe visual loss from such complications.[20] Finally, of the seven patients in our series who underwent PKP in one eye and DLEK in the other, all preferred the vision in their DLEK eye, even when the Snellen visual acuity was one line better in their PKP eye (Figure 1).

CONCLUSION

Although the early results after DLEK surgery are impressive, we expect that surgeons will continue to improve this procedure. To that end, we founded the Endo-

thelial Keratoplasty Group in 2001. This study group comprises experienced, fellowship-trained corneal surgeons from around the world who are dedicated to the ethical development of DLEK surgery under an IRB-approved scientific protocol. Members are currently gathering experience and data to make DLEK surgery faster and easier, with particular attention to improving the lamellar interface. Current work with microkeratomes, femtosecond lasers, and other instrumentation for performing DLEK surgery and other lamellar surgery should help improve outcomes. ■

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