



# Clinical Update

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## Combination Lens Implant, Corneal Transplant Provides Functional, Cosmetic Benefits for Subset of Aniridic Patients

Before (left) and after photos of a woman who underwent combined repeat penetrating keratoplasty and Ophtec model 311 iris reconstruction lens implantation. Preoperatively, she was aphakic and completely aniridic from trauma, and her corneal graft was thick and edematous.



**A** combined iris lens implantation and corneal transplant substantially reduced glare sensitivity, light sensitivity and starburst effect in patients who were partially or completely aniridic after sustaining blunt or penetrating trauma, a Jules Stein Eye Institute study found. The simultaneous procedures also improved the aesthetic appearance of the patients' eyes. Although the long-term safety outcomes were mixed, the

first-ever report of this approach, published in the *Journal of Cataract & Refractive Surgery*, suggests a potentially important new treatment for a subset of patients whom ophthalmologists have previously had little to offer.

A multidisciplinary JSEI team, headed by Kevin M. Miller, MD, professor of clinical ophthalmology, reported on the functional and cosmetic outcomes of nine partially or completely aniridic

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## Descemet's Stripping Endothelial Keratoplasty (DSEK)

**A** new approach to posterior corneal transplantation offers important advantages over penetrating keratoplasty (PK) for the management of visually significant corneal edema in patients with Fuchs corneal dystrophy, according to a Jules Stein Eye Institute surgeon who has been performing the technique for the last year. The new procedure, Descemet's stripping endothelial keratoplasty (DSEK), is rapidly gaining acceptance as the procedure of choice for surgical management of corneal

endothelial dysfunction.<sup>1,2</sup> Anthony D. Aldave, MD, director of the Cornea Service at JSEI, now teaches the technique to cornea fellows at the Institute, as well as to other ophthalmologists who are interested in learning more about it.

The instrumentation and techniques involved in traditional full-thickness corneal transplantation have changed very little in the last 30 years. While the results are generally good—85% of patients who undergo transplantation

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## COMBINATION LENS IMPLANT *(continued from page 1)*

patients who had an Ophtec iris reconstruction lens implantation and simultaneous penetrating keratoplasty. The nine eyes treated in the study all had acquired aniridia after sustaining blunt or penetrating trauma. Whether from scarring, decompensation, or failure of a previous graft, all required corneal transplantation. Seven of the nine eyes had damage to 75-100% of the iris. Every patient reported light-induced visual disturbances that were considered clinically significant.

"These were eyes with serious problems," says Dr. Miller. "They all had corneal scars and were missing some or all of their iris tissue, making them very light- and glare-sensitive. Most were missing a lens in the eye, and most had had a retinal detachment repair. Many had also had at least one failed corneal transplant by the time we saw them. For these types of patients, there are very few options." The best doctors previously had to offer such individuals, Dr. Miller notes, was to give them a thick aphakic contact lens with an artificial iris painted on. But most patients are unable to tolerate the heavy lens.

Aniridia can be congenital or acquired; in either case, it can be associated with reduced visual acuity. Those lacking a complete, functional iris often experience visual disturbances that significantly limit their daily activities, and many also experience negative psychosocial consequences from having an unaesthetic eye.

Dr. Miller notes that this was only the second U.S. publication describing implantation of the Ophtec reconstruction lens, which is designed to reduce visual disturbances by creating an artificial pupil while providing optical correction for aphakia, and

which is currently being offered in a clinical trial. It is the first paper to report on the simultaneous Ophtec implant and corneal transplant.

### Results

In the JSEI study, Dr. Miller implanted the iris reconstruction lenses, and one of three cornea surgeons performed the corneal transplants. Results varied. For all nine of the patients, uncorrected visual acuity (UCVA) was poor before the surgery due to the patients' aphakic or cataractous eyes. Eight of the nine had a UCVA of counting fingers, while the ninth had a UCVA of 20/70. After the surgery, UCVA improved in seven of the eyes. Best corrected visual acuity improved in four of the eyes and worsened in the other five. Of those five, three experienced adverse postoperative events, while two had significant irregular astigmatism that spectacle lenses could not correct. The reconstruction lens' effectiveness in reducing glare, starbursts, and photophobia in patients with partial or complete aniridia was supported by the findings that eight of the nine patients in the study experienced fewer daytime visual disturbances, and all nine reported a reduction in nighttime disturbances. No patient reported a postoperative worsening of visual disturbances.

Although the outcomes were positive overall, there was a great deal of individual variation, with some patients coming away with very good vision and others continuing to experience poor vision. "The vision results were all over the map, and that has more to do with the patients' pre-existing problems than with the surgery," says Dr. Miller.

All patients were pleased with the improvement in the appearance of their eyes after the surgery.

"The implants don't give a perfect color match, the pupil sizes differ from the patient's other eye, and often because of the suturing into the wall of the eye the implants are slightly de-centered and not perfectly symmetrical in the eye," says Dr. Miller. "However, for the most part, the cosmetic results are an improvement for the patient."

Of the three patients who experienced adverse postoperative events, none was considered to be related to the implanted lens. One patient developed advanced glaucomatous optic neuropathy after going against his doctors' advice and spending three weeks at high elevation following an intraocular gas injection. Another patient's corneal graft rejection was suspected to be due to noncompliance with corticosteroid eyedrops. A third patient, who developed a corneal abscess 18 months after the surgery, had been treated with anti-inflammatory and glaucoma medications that are believed likely to have compromised the integrity of the corneal epithelium.

### Discussion

"There can be significant complications after surgery, simply because these are very sick eyes that are already prone to problems," says Dr. Miller. "These patients require lifelong monitoring and care. It is significant, though, that we were able to substantially reduce their glare sensitivity, light sensitivity, and starburst effect. These are patients with a very disabling condition – many of them can't go out in the sun, can't drive, must wear heavy sunglasses all the time, and suffer social consequences from their condition. This isn't perfect, but for these patients, it is a major improvement." 

**DSEK** (continued from page 1)

**Figure 1.** Patient with a history of Fuchs corneal dystrophy one day after combined DSEK and cataract extraction with intraocular lens implantation. The donor corneal button is attached and well centered; an air bubble is seen superiorly.

for Fuchs corneal dystrophy demonstrate a clear corneal transplant five years after surgery—visual recovery following surgery can be prolonged and frequently limited by irregular or high corneal astigmatism. “It is estimated that approximately 40% of corneal transplants are performed for isolated corneal endothelial dysfunction, most commonly in patients with Fuchs corneal dystrophy and pseudophakic corneal edema,” explains Dr. Aldave. “Although only the corneal endothelium is dysfunctional in such patients, until recently the only treatment available was full-thickness corneal replacement via a PK.”

### Surgical Technique

In the last several years, corneal surgeons have begun substituting novel surgical techniques, called endothelial keratoplasties, for PK in the management of corneal endothelial dysfunction. DSEK, the most widely adopted of these techniques, involves peeling off the dysfunctional corneal endothelial cell layer and Descemet’s membrane. A donor cornea is used, as in PK, but prior to surgery, the donor cornea is cut with a microkeratome to create a thick anterior layer and a very thin

posterior layer that contains the donor Descemet’s membrane and endothelial cells. The posterior layer of the donor cornea is folded in half and placed through a 4-5 mm limbal or scleral tunnel incision into the anterior chamber. An air bubble is placed in the anterior chamber to unfold the donor cornea and push it into position against the recipient posterior corneal stroma. The incision is then closed with two sutures and most of the air bubble is removed 10 minutes after being placed in the anterior chamber.

### Advantages over Traditional Full-thickness Corneal Transplantation

*Dr. Aldave notes that DSEK offers many advantages—intraoperative and postoperative—over PK for patients who are considered candidates for either procedure:*

#### Intraoperative

- Because the corneal curvature remains unchanged following DSEK, surgeons can use keratometry readings obtained before surgery to calculate the appropriate intraocular lens (IOL) dioptric power for implantation either before or at the same time as DSEK in phakic patients. This eliminates the potential for significant refractive errors that may follow the performance of a combined PK/cataract surgery. In addition, with the DSEK/cataract surgery procedure there is no need to wait a minimum of 9-12 months for the completion of selective suture removal in cases where the surgeon wishes to perform the procedures sequentially. This waiting period is necessary following a PK in order to perform reliable IOL calculations prior to cataract surgery.

- DSEK is performed through an incision that is only 1-2 mm larger than a typical cataract surgery incision. Creating a small versus a large full-thickness corneal opening significantly reduces the risk of an intraoperative suprachoroidal hemorrhage, and allows for more rapid closure of the eye should suprachoroidal hemorrhage develop during surgery.
- The surgery is commonly performed using only local anesthesia; it is typically a shorter procedure (approximately 45 minutes) than a PK, and muscle paralysis is not necessary. Both the patient and surgeon benefit from the shorter surgical time, which means less time in the operating room.

#### Postoperative

- The smaller incision used for DSEK reduces the risk of wound dehiscence and severe vision loss following ocular trauma.
- Visual recovery is generally much faster than with a PK, as suture-induced astigmatism is avoided.
- High irregular astigmatism is not a postoperative complication, since the corneal astigmatism does not change significantly following the procedure.
- The risk of corneal endothelial rejection may be reduced when less antigenic corneal tissue is transplanted.
- The risk of an exposed or broken corneal transplant suture leading to a corneal infection or an episode of corneal transplant rejection is eliminated.

**DSEK** (continued from page 3)

**Figure 2.** Same eye shown in Figure 1, two months after surgery. The donor cornea is clear and well-centered; two nylon sutures securing the scleral tunnel incision are visible under the temporal bulbar conjunctiva. Visual acuity is 20/40.

- Corneal trephination produces a neurotrophic keratopathy through the transection of the corneal nerves. Because there is no need for corneal trephination, DSEK is not associated with many of the ocular surface problems commonly encountered following a PK.

**Inclusion and Exclusion Criteria**

Patients who have isolated corneal endothelial dysfunction with visually significant corneal edema are ideal candidates for

DSEK, Dr. Aldave says. He notes that patients with corneal scarring in addition to corneal edema are typically better candidates for a PK, unless the primary goal is simply to eliminate corneal edema, because the scarring will limit the patient's vision following resolution of the edema.

Patients who have undergone previous glaucoma surgery are candidates for the new procedure, as are those with sectoral iridectomies. On the other hand, Dr. Aldave says, patients who are aphakic or have extensive iris loss are not considered good candidates, as it is difficult to keep an air bubble in the anterior chamber in such patients. "Although the presence of an anterior chamber intraocular lens makes the placement of an adequate air bubble in the anterior chamber problematic, in such cases the anterior chamber intraocular lens may be removed and replaced with an iris or trans-scleral-fixated posterior chamber intraocular lens," he explains.

DSEK can be performed for

endothelial failure after a previous PK, Dr. Aldave says, although the decision between a PK or DSEK in such cases depends in part on the amount of corneal astigmatism present.

**Conclusion**

"Because of the multiple advantages of DSEK when compared to PK," concludes Dr. Aldave, "it is my procedure of choice for the management of visually significant corneal edema in patients with Fuchs corneal dystrophy, pseudophakic corneal edema and corneal graft failure." 

**References**

1. **Price FW, Jr., Price MO.** Descemet's stripping with endothelial keratoplasty in 200 eyes: Early challenges and techniques to enhance donor adherence. *J Cataract Refract Surg* 2006;32(3):411-8.
2. **Price MO, Price FW, Jr.** Descemet's stripping with endothelial keratoplasty: comparative outcomes with microkeratome-dissected and manually dissected donor tissue. *Ophthalmology* 2006;113(11):1936-42.

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