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CORNEA

New technique seeks to avoid transplant in keratoconus patients with thin, irregular corneas

by Liz Hillman EyeWorld Staff Writer

"[We're] trying to give these patients with severe cones the ability to avoid transplantation by enhancing their tissue and allowing subsequent crosslinking and PRK in some of them." —Peter Hersh, MD

Corneal tissue addition for keratoconus thickens the cornea with a donor lenticule

The approval of crosslinking in the U.S. for treatment of progressive keratoconus and corneal ectasia was a huge boon for the keratoconic population in the country. But some patients are not candidates due to thin corneas, and the procedure meant to halt progression does not improve irregular corneas. This is where Peter Hersh, MD, director, Cornea and Laser Eye Institute, Hersh Vision Group, Teaneck, New Jersey, and his colleagues got an idea.

"All crosslinking does is diminish the rate of progression going forward," Dr. Hersh said. "It doesn't improve corneal topography in most cases. Intacs [Addition Technology, Lombard, Illinois] certainly has a place, and we've had good experiences with Intacs in the right [keratoconus] patients, showing a lot of improvement in corneal symmetry and corneal shape, but we wanted to try to bring these things one step further."

For the last year, Dr. Hersh has been enrolling and treating patients in a clinical trial evaluating the safety and efficacy of corneal tissue addition for keratoconus (CTAK). The idea includes sizing (and potentially shaping) preserved corneal tissue from an eye bank and inserting it into a corneal pocket, similar to that created for intracorneal inlays like KAMRA (AcuFocus, Irvine, California). This technique could thicken the cornea enough for the patient to safely have crosslinking and/or could help smooth the cornea to aid the patient in spectacle or contact lens wear or even allow for refractive surgery, such as PRK.

"The theory behind CTAK is since the keratoconic cornea is inherently thin, in some cases too thin for crosslinking or too irregular for a good result with Intacs, these patients would normally have to have [deep anterior lamellar keratoplasty] or penetrating keratoplasty," Dr. Hersh said. "The idea here was can we use this preserved corneal tissue as a tissue addition procedure to enhance the corneal thickness and structure with the hope of getting us a surface that would then allow for crosslinking or topography-guided PRK in patients who would otherwise only be transplant candidates."

To start, Dr. Hersh said they evaluate the patient's cornea using topography, OCT, refraction, and other measurements to determine corneal contour and thickness distribution to decide whether the patient would benefit from a tissue addition procedure. Working with Halo preserved corneal tissue from Lions VisionGift (Portland, Oregon), Dr. Hersh said they order the thickness of corneal tissue they need. A femtosecond laser is then used to prepare a lenticule of desired diameter and thickness. Dr. Hersh said they've worked with lenticules 3–6 mm in diameter and 250–300 µm thick. An excimer laser has been used to perform a refractive correction on the lenticule, depending on the patient's cornea and desired CTAK effect. "For instance, if they have a very steep area we'll do a large myopic correction in the lenticule so that the convex area is over the steep area," Dr. Hersh said.

The center of the lenticule is marked, as well as the center of the cornea where they plan on placing the lenticule, and it is inserted through a femtosecond lasercreated pocket. Dr. Hersh said they have done focal CTAK on thin areas of the cornea, as well as broader grafts. After at least 3 months, the patient could then have crosslinking or PRK/crosslinking. Only a handful of patients have had CTAK, according to Dr. Hersh, with the longest patient follow-up being about 6 months thus far. Following patients with OCT, Dr. Hersh said they're initially seeing a 50% thickening, then the lenticule dehydrates to the desired thickness and clears over the subsequent days and weeks. The graft appears to be well tolerated without inflammation and no reaction around the graft.

"Our hope is that over time, it is simply incorporated into the cornea with the ingrowth of keratocytes,"

Dr. Hersh said. In some of the smaller grafts, Dr. Hersh acknowledged, some steepening of the cornea has been observed, which is not what they want even though corneal structure is improved. In these cases, however, they've performed subsequent PRK with satisfactory results.

"We have had good results in patients where we have done lenticule corrections with good topographic results and are now looking forward to either contact lenses or perhaps doing PRK on those patients," Dr. Hersh said.

Patients with thin corneas who might initially appear to be a good candidate for CTAK should be ruled out if they have central corneal scarring or reticulated scarring and striae where there is no room to place the graft. "Those patients need to go onto transplantation," he said. "Patients we're doing [CTAK on] are typically candidates for transplant, typically contact lens intolerant, or they have a dramatic difference between one eye and the other eye and we want to try to balance those eyes out."

The trial is ongoing to refine the technique. "[We're] trying to give these patients with severe cones the ability to avoid transplantation by enhancing their tissue and allowing subsequent crosslinking and PRK in some of them," Dr. Hersh said, adding that they're figuring out the proper algorithms for shaping, positioning, and fashioning the lenticules. "We'll learn a lot more over the next year or so."

Editors' note: Dr. Hersh has no financial interests related to his comments.

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