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Contact Lens-Assisted Pull-Through Technique for Delivery of Tri-Folded (Endothelium in) DMEK Grafts Minimizes Surgical Time and Cell Loss

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Purpose: To evaluate the feasibility and outcomes of contact lens-assisted bimanual pull-through delivery of Descemet membrane endothelial keratoplasty (DMEK) tissue trifolded with the endothelium inward.

Design: Prospective, noncomparative, interventional case series.

Participants: Forty-two consecutive eyes of 42 patients with Fuchs endothelial dystrophy with or without cataract.

Intervention: Standardized DMEK was performed as a single procedure (n = 9) or in combination with phacoemulsification and implantation of a posterior chamber intraocular lens (n = 33) using prestripped donor tissue punched to a diameter of 8.25 mm and then trifolded with the endothelium in. Using a sterile soft contact lens as scaffold, the tissue was loaded in this configuration into a disposable cartridge and delivered into the anterior chamber under continuous irrigation using a bimanual pull-through technique to facilitate spontaneous proper unfolding.

Main Outcome Measures: Surgical time, intraoperative and postoperative complications, visual acuity 3 and 6 months after surgery, and endothelial cell loss 6 months after surgery.

Results: Surgery was uneventful in all cases and the time required for the DMEK procedure (from Descemet scoring until final air filling) never exceeded 20 minutes (average, 17.1±1.6 minutes). The only complication observed after surgery was graft detachment (10 of 42 eyes [23.8%]), successfully managed in all cases by single rebubbling within 6 days from surgery. In all eyes with a minimum postoperative follow-up of 6 months (n = 20), best spectacle-corrected visual acuity was 20/25 or better and the average endothelial cell density (±standard deviation) was 2363.8±82.7 cells/mm^2 (range, 2258–2490 cells/mm^2). The cell loss calculated as a percentage of the preoperative value determined at the eye bank (range, 2500–2700 cells/mm^2) was 9.9±2.1% (range, 4.1%–11.9%).

Conclusions: Delivering DMEK tissue, trifolded with the endothelium inward, reduces surgical trauma to donor cells and facilitates spontaneous unfolding, thus minimizing surgical time. *Ophthalmology 2015;■:1–8 © 2015 by the American Academy of Ophthalmology.*

Supplemental video available at www.aaojournal.org.

During the last decade, endothelial keratoplasty has become the gold standard for the treatment of endothelial decompensation. The annual report of the Eye Bank Association of America showed that in only 2 years, between 2005 and 2007, the number of Descemet stripping endothelial keratoplasty procedures performed in the United States increased by 10 fold and that this number has been constantly higher than 20 000 since 2011. Instead, Descemet membrane endothelial keratoplasty (DMEK) has gained popularity much more slowly, and in 2014, fewer than 3000 surgeries were counted. Despite the appeal of DMEK in terms of its minimally invasive nature, the fast recovery of optimal vision,[1–3] and the extremely low incidence of postoperative immunologic rejection,[4] the technique still offers major challenges, mainly related to delivery, unfolding, and positioning of the graft.[5,6] In addition, with current techniques, donor tissue is rolled with the endothelium outward, thus exposing it to friction against the device walls during both loading and delivery.[1]

To minimize endothelial damage, Muraine et al[7] modified the DMEK technique by trifolding the stripped donor tissue with the endothelium inward, which then was injected into the anterior chamber in a manner similar to that used with conventional tissue rolls (endothelium outward). However, transferring the tissue roll from the

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donor cornea onto the cartridge in its modified configuration is difficult, and unfolding, as well as proper positioning, were not standardized. In an attempt at overcoming the limitations of the technique reported by Muraine et al, we used a sterile soft contact lens as scaffold to load the graft in its trifolded configuration into a cartridge for delivery by means of a bimanual pull-through technique. We present herein the outcomes of the first 42 consecutive eyes operated on with this technique.

Methods

We reviewed the charts of all patients with decompensated endothelium who underwent surgery according to the technique described in detail below and were included in a prospective clinical study undertaken at our institution in June 2014 and still in progress. The study followed the tenets of the 1964 Declaration of Helsinki and was approved by the local ethics committee; detailed informed consent was provided to all patients undergoing surgery. Best spectacle-corrected visual acuity better than 20/30 and peripheral endothelial cell density (ECD) higher than 2000 cells/mm^2 in the absence of central corneal edema were the only exclusion criteria.

Before surgery, demographic data were recorded and every patient underwent a complete ophthalmologic evaluation including slit-lamp examination, best spectacle-corrected visual acuity, refraction, tonometry, funduscopy, as well as central (when possible) and peripheral endothelial microscopy (EM-3000; Tomey Erlangen, Germany). In addition, the power of the intraocular lens to be implanted was determined by means of optical biometry (Lenstar LS900; Haag-Streit, Bern, Switzerland).

All surgical procedures were video-recorded and the time elapsing between the beginning of descemetorhexis and the final air filling was noted (Video 1, available at www.aaojournal.org). Patients were scheduled for assessment of best spectacle-corrected visual acuity 3 and 6 months after DMEK and assessment of ECD 6 months after DMEK. Postoperative ECD was compared with that measured before surgery by the eye bank for the donor corneas using light microscopy after vital staining with trypan blue, and cell loss was determined as a percentage of the preoperative in vitro value. Intraoperative and postoperative complications also were recorded.

Surgical Procedure

In all patients, anesthesia and akinesia were obtained by means of peribulbar injection of 10 ml of a 0.75% ropivacaine solution. Epithelial edema affecting visualization of the intraocular structures was managed by removal of the epithelium from the central area approximately 8 mm in diameter. Then, when necessary (n = 33 eyes), bimanual phacoemulsification was performed using a 0.5-mm long and 2.75-mm wide clear-cornea tunnel, located inferotemporally in all right eyes and supranasally in all left eyes. In all cases, a hydrophobic intraocular lens (iSert 250; Hoya, Tokyo, Japan) was implanted into the capsular bag expanded by the injection of viscoelastic substance (IAL-F; Fidia Farmaceutici, Abano Terme, Italy), which then was removed carefully from the anterior chamber by prolonged irrigation and aspiration. The endothelium–Descemet complex was scored with a Price hook (Moria SA, Antony, France) and removed under air from the central 9 mm of the recipient cornea, possibly in a single piece. An inferior peripheral iridotomy was performed using vitreoretinal guillotine scissors under continuous irrigation from a specially designed anterior chamber maintainer (ACM; Moria SA) inserted at the 12-o'clock position.

According to the technique described by Terry et al,[8] each donor cornea (donor age range, 55–64 years) was prestripped at the eye bank over a 9.5-mm central area, with the exception of the peripheral edge for approximately 1 clock hour, which was marked on the scleral rim using gentian violet. The stripped endothelium was repositioned onto the stromal bed, and liquid was removed from the peripheral endothelial surface to facilitate adherence, before gently reimmersing the tissue into the storage medium. During surgery, the cornea was laid onto the trephination block of an 8.25-mm Barron punch (Katena Products, Inc., Denville, NJ) stained with trypan blue (VisionBlue, D.O.R.C., The Netherlands) to outline better the edge of the stripped area and punched partial thickness. The crown of detached endothelium outside of the punched area included the hinge of incomplete stripping and was removed. The tips of a dedicated anatomic forceps (Moria SA) were used to lift the edge of the DMEK graft, which then was trifolded with the endothelium inward (Fig 1A, B) and stained again with trypan blue. A sterile therapeutic soft contact lens commercially available (Sooft, Montegiorgio, Italy) was laid next to the trifolded graft, which was grasped at its very edge of the unfolded part with the same forceps and dragged onto the contact lens in its trifolded architecture (Fig 1C). As shown in Fig 1D, the contact lens was moved onto the back entrance of the funnel of a commercially available intraocular lens cartridge (MDJ Company, La-Monniere-le-montel, France), which was filled with balanced salt solution (BSS) from its distal part. A dedicated anatomic microincision forceps (Moria SA) was inserted into the distal entrance of the cartridge to reach the contact lens surface and grasp the edge of the DMEK graft at the center of its unfolded part (Fig 2A). The graft then was pulled into the funnel, taking care to make the unfolded part slide onto the floor of the funnel (Fig 2C). As shown schematically in Figure 2B, D, coming in contact with the BSS solution, the DMEK roll opened up partly, thus adhering to the funnel wall but maintaining the endothelium in its facing inward configuration, and therefore preventing possible damage resulting from the contact with the plastic. The back entrance of the cartridge funnel was sealed with a silicone plug mounted on the prototype of a dedicated handle to avoid reflux of liquid and graft loss during delivery.

Figure 3 shows intraoperative pictures (Fig 3A, C) and drawings (Fig 3B, D) illustrating that the cartridge then was turned by 180°, thus making the floor become the ceiling of the funnel, and was inserted into the main wound. An additional side entry was created supranasally in all right eyes and inferotemporally in all left eyes for insertion of the microincision forceps. Then, similar to the Descemet stripping endothelial keratoplasty technique, the DMEK graft was delivered bimanually through the clear-cornea tunnel under low-flow continuous irrigation from a dedicated ACM with a lateral 0.5-mm port, which, unlike conventional ACMs, would prevent creation of a jet fluid stream directed against the DMEK graft, and therefore would eliminate possible interference with tissue unfolding. After delivery into the anterior chamber, the descemetic surface of the unfolded part of the DMEK graft, initially in contact with the cartridge ceiling, was now facing the internal surface of the recipient cornea, as required for proper attachment (Fig 4A). Gentle tapping onto the cornea surface was used to facilitate unfolding of the lateral folds (Fig 4B, C), which invariably occurred because of the natural tendency of the tissue to roll with the endothelium outward from its initial inward position. In some cases, also twisting the forceps or gently moving the graft inside the anterior chamber was used to unfold it. As soon as