Endothelial Cell Loss After Descemet's Membrane Endothelial Keratoplasty for Fuchs' Endothelial Dystrophy: DMEK Compared to Triple DMEK



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- PURPOSE: This study compared the outcomes after Descemet's membrane endothelial keratoplasty (DMEK) in pseudophakic patients with the outcomes after DMEK combined with cataract surgery (triple-DMEK) in patients with Fuchs' endothelial dystrophy (FED).
- DESIGN: Retrospective, single-institution, interventional, consecutive case series.
- METHODS: Outcomes of 114 DMEKs in patients with FED at a minimum of 1-year follow-up were reviewed. A total of 34 eyes (29 patients) were pseudophakic and underwent only DMEK (DMEK-only), and 80 eyes (56 patients) underwent triple-DMEK. Main outcome measurements included endothelial cell loss (ECL), best-corrected visual acuity (BCVA), central corneal thickness (CCT), and complications.
- RESULTS: At 1 month, ECL was 25% (±16%) and 35% (±15%) in DMEK-only and triple-DMEK groups, respectively. At 1 year, ECL was 33% (±13%) and 41% (±16%) in DMEK-only and triple-DMEK groups, respectively. There was statistically significantly less ECL after DMEK-only than after triple-DMEK at both 1 month (95% confidence interval [CI]: 1.67-15.02; P = .016) and 1 year (95% CI: 1.06-14.07; P =.034). CCT was significantly lower after DMEK-only than after triple-DMEK at 1 month but not at 1 year. BCVA was excellent and similar in the 2 groups. There were no cases of graft failure. Graft rejection and rebubbling rates were similar in DMEK-only and triple-DMEK groups: rejection occured in 8.8% and 8.75% of cases respectively (P = .50), and rebubbling in 2.9% and 2.5% respectively (P = .44).
- CONCLUSIONS: Both the DMEK-only and the triple-DMEK groups had low rebubbling rates and good visual outcomes, but the combined triple-DMEK procedure resulted in significantly greater loss of endothelial cells than DMEK-only surgery at both 1 month and 1 year. (Am J Ophthalmol 2020;218:1–6. © 2020

AJO.com Supplemental Material available at AJO.com. Accepted for publication May 1, 2020.

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ESCEMET'S MEMBRANE ENDOTHELIAL KERATOplasty (DMEK) is regarded as a modern standard in the management of corneal endothelial dysfunction. 1-3 In DMEK, the endothelium Descemet's membrane replaced are corresponding layers from a healthy donor cornea, without the additional layer of donor stroma which accompanies DM and endothelium in Descemet's stripping endothelial keratoplasty. DMEK has been shown to achieve faster visual rehabilitation, better visual outcomes, and lower rates of rejection than Descemet's stripping endothelial keratoplasty. 4-6 The reduction reported in endothelial cell density (ECD) following DMEK is 25%-40% within the first 6 months and is comparable to earlier endothelial keratoplasty techniques.^{7–9} The present authors previously noted that variability in donor tissue characteristics such as donor age, endothelial cell counts, and tissue preservation techniques may affect endothelial cell survival during and after the surgery. 10

The most common indication for endothelial keratoplasty in the developed world is Fuchs' endothelial dystrophy (FED). Patients with FED are at higher risk of developing corneal decompensation following cataract surgery. DMEK can be performed as a staged procedure before or after cataract surgery or combined with phacoemulsification in patients with both endothelial dysfunction and cataract. A study by Chaurasia and associates reported similar 6-month outcomes in DMEK in patients who were pseudophakic or undergoing concurrent cataract surgery.

The aim of the present study was to compare 1-month and 1-year outcomes of DMEK-only in pseudophakic eyes versus DMEK combined with cataract surgery (triple-DMEK) with respect to ECD decrease in patients with FED. Best-corrected visual acuity (BCVA), central corneal thickness (CCT), and complications were also recorded.

SUBJECTS AND METHODS

THIS STUDY WAS DESIGNED AS A SINGLE-INSTITUTION, retrospective, interventional, consecutive case series. It was approved by the authors' institutional review board

TABLE 1. Patient and Donor Demographics for DMEKa

	Total	DMEK-only Group	Triple-DMEK Group	P Value
Recipients				
Eyes/patients	114/86	34/30	80/56	_
Females	69 (60.5%)	19 (55.9%)	50 (62.5%)	.51
Age, y				
Mean \pm SD	69.6 ± 10.69	76.8 ± 8.2	66.6 ± 10.2	<.0001
Donor				
Age, y				
Mean ± SD	67.7 ± 11.0	70.0 ± 9.7	66.7 ± 11.5	.15
ECD, cells/mm ²				
Mean \pm SD	$2,639 \pm 195$	$2,630 \pm 194$	$2,643 \pm 197$.75

DMEK = Descemet's membrane endothelial keratoplasty; ECD = endothelial cell density; SD = standard deviation; triple-DMEK = DMEK combined with phacoemulsification and implantation of intraocular lens.

and adhered to the tenets of the Declaration of Helsinki. All patients signed an informed consent prior to surgery.

• RECRUITMENT AND INCLUSION: All DMEKs at this institution have been prospectively recorded in an anonymized corneal graft research database. The database was searched for all grafts meeting the following initial inclusion criteria:

Surgery. DMEK with or without combined phacoemulsification cataract surgery. Patients having DMEK-only surgery had all undergone previous cataract surgery with a posterior chamber intraocular lens (IOL) implant.

Indications. Clinically significant FED. The diagnosis of FED was based on the presence of its classical clinical signs and confirmed with in vivo confocal microscopy (IVCM) if there was any doubt. In pseudophakic cases, FED was differentiated from pseudophakic bullous keratopathy by the presence of the clinical signs of FED in the fellow eye or by IVCM demonstrating the classic strawberry-like pattern of FED, rather than the polymegathism and enlarged endothelial cells seen with pseudophakic bullous keratopathy.

Follow-up. At least 1 year of follow-up data available. A total of 114 DMEK grafts that met the inclusion criteria were divided into 2 groups: there were 34 eyes of 29 patients in the DMEK-only group and 80 eyes of 56 patients in the triple-DMEK group.

• STUDY OUTCOMES: The main outcome of the study was a comparison of mean endothelial cell loss (ECL) between the 2 groups at 1 month and at 1 year. ECL was calculated by comparing the 1-month and 1-year ECD with the donor ECD by using IVCM. Additional outcome measurements included postoperative BCVA, slit lamp biomicroscopy,

and measurement of CCT using pachymetry. The incidence of postoperative complications was also reported, specifically the rates of rebubbling, graft rejection and graft failure.

- STATISTICS: All statistical analyses were performed using Prism version 8.0.1 software (GraphPad, San Diego, California). Numerical variables were described as mean \pm SD for normally distributed data. Normality was confirmed by Shapiro-Wilk testing. A comparison between preoperative and postoperative data was performed using the Student t test and Mann-Whitney U test where applicable. A P value <.05 was considered statistically significant.
- SURGICAL TECHNIQUE: All operations were performed directly by or under the supervision of a single surgeon (E.J.H.), using a standardized technique. All patients had neodymium-yttrium aluminum garnet (Nd:YAG) laser iridotomy before surgery. Donor preparation was performed immediately before transplantation using the submerged cornea using backgrounds away (SCUBA) technique. 15 In combined cases, phacoemulsification was performed with implantation of a posterior chamber foldable acrylic IOL (Tecnis PCB100; Johnson & Johnson, New Brunswick, New Jersey) and thorough viscoelastic removal. After the patient's DM was stripped using a reverse Sinskey hook (Duckworth and Kent, United Kingdom), a Geuder injector (Geuder AG, Germany) was used to introduce the donor DM scroll. The graft was positioned centrally using a standardized no-touch technique, as previously described.⁸ Air was injected underneath the graft. All corneal incisions were tightly sutured with 10-0 nylon sutures. The anterior chamber (AC) was completely filled with air to a high intraocular pressure (IOP), assessed by digital palpation and was left in place for 10 minutes. Some air was then released to achieve palpably normal IOP.

^aComparison between DMEK-only and triple-DMEK groups.

• FOLLOW-UP PROTOCOL: Patients were positioned on their backs for 2 days after surgery. The IOP was checked at 1 to 2 hours postoperatively. If the IOP was above 30 mm Hg, a small amount of air was released. The patients were followed at 1 to 2 days and 1 week and then at 1, 3, 6, and 12 months, with additional visits as clinically indicated. IOP was measured at each visit by Goldmann applanation tonometry. CCT was measured using a Pachmate 2 ultrasonic pachymeter (DGH Technology, Exton, Pennsylvania). ECD was measured at the 1-month and 1-year visits by using IVCM (Confoscan 4 machine; Nidek Technologies, Fremont, California). The best image of the endothelium was chosen from multiple images of the central cornea, and the machine's automated counting mode was used, with manual correction for any double-counted cells. ECL was calculated using donor ECD as baseline.

RESULTS

PATIENT DEMOGRAPHICS AND DONOR DETAILS ARE SUmmarized in Table 1. The mean age was significantly lower in the triple-DMEK group than in the DMEK-only group (95% CI: -14.13 to -6.301; t test, P < .001).

The Figure shows the mean central ECDs in the 2 groups. The mean preoperative donor ECDs were $2,630 \pm 194$ cells/cm² and $2,643 \pm 197$ cells/cm² in DMEK-only and triple-DMEK groups, respectively. At 1 month, the mean ECDs were $1,968 \pm 476$ cells/cm² and $1,737 \pm 422$ cells/cm² in DMEK-only and triple-DMEK groups, respectively, representing ECL of 25% and 35%, respectively, from preoperative donor ECDs. At 1 year, mean ECDs were $1,748 \pm 427$ cells/cm² and $1,511 \pm 437$ cells/cm², respectively, in DMEK-only and triple-DMEK groups, representing ECL of 33% and 41%, respectively. There was significantly less ECL in the DMEK-only group than in the triple-DMEK group at both 1 month (95% confidence interval [CI], 1.67-15.02; t test, P = .016) and 1 year (95% CI: 1.06-14.07; t test, P = .034) after surgery.

Table 2 shows pachymetry and visual outcomes. At 1 month, the average CCT was significantly lower in the DMEK-only group (543 \pm 55 μ m) than in the triple-DMEK group (572 \pm 64 μ m; Mann-Whitney U test, P=.025). At 1 year, the average CCT continued to decrease and was not significantly different between the 2 groups (t test, P=.093).

Average decimal BCVAs improved from preoperative 0.47 and 0.56 in DMEK-only and triple-DMEK groups, respectively, to 0.72 and 0.78, respectively, at 1 month and were similar between the groups (P = .353). At 1 year, the average BCVAs were 0.91 and 1.01 in DMEK-only and triple-DMEK groups, respectively, with no statistically significant differences (t test, P = .099).

Postoperative complications are summarized in Table 3. There were no cases of graft failure during the 1-year

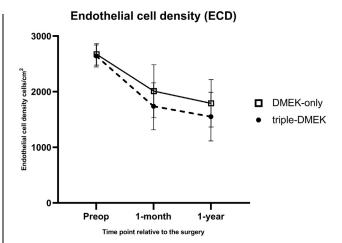


FIGURE. Endothelial cell density (ECD) up to 1 year after surgery in Descemet's membrane endothelial keratoplasty (DMEK) group (solid line) compared with that in the triple-DMEK group (dashed line). Vertical bars represent statistical deviations. Endothelial cell loss was calculated by comparing the 1-month and 1-year ECDs with donor ECDs. There was significantly greater endothelial cell loss in the triple-DMEK group than in the DMEK group at both 1-month and 1-year follow-up.

follow-up in either of the groups, whereas graft rejection for the DMEK-only and the triple-DMEK (8.8% and 8.7%, respectively) and rebubbling rates (2.9% and 2.5%, respectively) were similar in the 2 groups.

Analysis of the data by removing the second eye of bilateral cases did not affect the statistical significance of the results (analysis was available but not shown).

DISCUSSION

THIS STUDY DEMONSTRATED THAT THERE WAS SIGNIFIcantly less ECL after the DMEK-only procedure in pseudophakic patients than in triple-DMEK patients with FED at 1 month and 1 year. In patients with cataract and FED, it may be preferable to perform phacoemulsification and DMEK as sequential rather than combined procedures. The benefit of performing DMEK prior to phacoemulsification is that biometry measurements can be more accurate, particularly in more advanced cases of FED. 16-18 On the other hand, phakic patients having DMEK are at increased risk of cataract progression, and subsequent phacoemulsification can cause accelerated cell loss in the graft. 19 Conversely, the benefit of performing phacoemulsification prior to DMEK is that in our experience some patients are satisfied with their vision after cataract removal and do not require the subsequent DMEK.²⁰ In the present study, there were no patients who remained phakic after DMEK surgery as all had cataract, and the authors believed they would benefit from concurrent phacoemulsification.

TABLE 2. Pachymetry and Visual Outcomes after DMEK^a

Time	DMEK-only Group (n $=$ 34)	Triple-DMEK Group (n $=$ 80)	P Value
Mean ± SD CCT, μm			
1 month	543 ± 55	572 ± 64	.02
1 year	517 ± 35	530 ± 38	.09
Mean \pm SD decimal BCVA			
Preoperatively	0.47 ± 0.24	0.56 ± 0.25	< .0001
1 month	0.72 ± 0.32	0.78 ± 0.30	.35
1 year	0.91 ± 0.28	1.01 ± 0.28	.10

 $BCVA = best-corrected\ visual\ acuity;\ CCT = central\ corneal\ thickness;\ DMEK = Descemet's\ membrane\ endothelial\ keratoplasty;\ SD = standard\ deviation;\ triple-DMEK = DMEK\ combined\ with\ phacoemulsification\ and\ implantation\ of\ intraocular\ lens.$

TABLE 3. Postoperative Complications at 1 year after DMEK ^a						
Complication	DMEK-only Group (n = 34)	Triple-DMEK Group (n = 80)	P Value			
Rejection	3 (8.8%)	7 (8.75%)	.50			
Failure	0	0	-			
Rebubbling	1 (2.9%)	2 (2.5%)	.44			

DMEK = Descemet's membrane endothelial keratoplasty; triple-DMEK = DMEK combined with phacoemulsification and implantation of intraocular lens.

In the DMEK-only group, prior cataract surgery had been performed in all patients.

A study by Chaurasia and associates¹⁴ concluded that combined cataract extraction and DMEK did not result in increased risk of surgical complications compared to DMEK alone. The ECL rates reported at 6 months were not significantly different between DMEK-only and triple-DMEK groups. The rebubbling rates in DMEK-only and triple-DMEK groups (30% and 29%, respectively), however, were considerably higher than reported in the present study (2.9% and 2.5%, respectively). Longer term cell loss after DMEK was reported by Birbal and associates²¹ who showed a 37% ECL at 6 months, 40% at 1 year, and 55% at 5 years, which agrees with the present findings, although that study did not compare DMEK-only with triple-DMEK cases.²¹

A common postoperative complication of DMEK surgery is graft dislocation or the presence of significant interface fluid requiring rebubbling of the graft.²² A review found a mean rebubble rate of 29% for DMEK.² The rebubbling rates were similar between the present 2 groups at less than 3%, which is one of the lowest rates reported in the medical literature. These authors believe strict adherence to surgical technique plays a significant role in achieving lower graft dislocation rates. Technique includes tight suturing of all postoperative wounds to prevent the AC

decompression during the early postoperative period and high-pressure air tamponade for 10 minutes intraoperatively to remove any interface fluid. Intraoperative anterior segment optical coherence tomography can show the gradual disappearance of interface fluid during the air tamponade stage of DMEK and has demonstrated that interface fluid disappears after 10 minutes of air tamponade. ²³

A recent study by Godin and associates²⁴ compared the clinical outcomes of DMEK in patients who underwent DMEK in phakia, pseudophakia, or combined with cataract surgery. That study found that the lens status does not influence the rate of rebubbling or visual outcomes at 1-year follow-up, as shown in the present study. Godin and associates did not report the rate of ECL in those groups.²⁴ Another study reported similar visual outcomes and CCT results between DMEK alone and triple-DMEK groups; however, the limitations of that study were a small sample size and lack of ECD reporting.²⁵

The reduction in ECD is highly predictive of graft failure and is a widely used method to monitor graft survival in endothelial transplantation. ²⁶ Many factors can influence ECL following DMEK. Intraoperative fibrin release can be a complicating factor during DMEK surgery, impeding the tissue unscrolling, causing increased graft manipulation and potential tissue damage. ²⁷ The longer surgery and need

^aComparison between DMEK-only and triple-DMEK groups.

^aComparison between DMEK-only and triple-DMEK groups.

for pupillary dilation then miosis in the combined group may mean fibrin release is more likely. Crews and associates²⁸ showed that the risk of hyphema was increased in triple-DMEK than in DMEK alone, although they did not demonstrate that the presence of hyphema affected the rebubbling rate or ECL.²⁸ Another possible contributing factor during triple-DMEK may be that adequate pupil constriction is not always achievable prior to graft injection despite use of intracameral miotic agents, and this may expose the graft tissue to potentially damaging IOL contact during tissue manipulation. The present authors postulate that greater anterior segment manipulation and postoperative inflammation after combined surgery may explain the significantly higher ECL in the triple-DMEK group than in the DMEK-only group.

In summary, both groups had low rebubbling rates and good visual outcomes; however, the combined triple-DMEK procedure resulted in significantly greater ECL than the DMEK-only surgery did at both 1 month and 1 year. Further data for longer-term results are required to validate these findings and to establish whether this means that triple-DMEK grafts have a shorter survival than the DMEK-only cases. Staged cataract surgery and DMEK may be preferable to combined triple-DMEK for the management of FED. Before the results of this study were obtained, the authors' practice was to perform combined

surgery in FED patients with significant cataract and corneal decompensation. In view of these findings, more FED patients are being offered cataract surgery first, with subsequent endothelial surgery in only those with unacceptable vision. These authors have no FED patients that have had DMEK surgery and been left phakic because of concern about ECL in the age group of these patients, which are likely to require subsequent cataract surgery. Whether cataract surgery should be performed before, after, or at the same time as DMEK surgery in patients with FED and cataract depends on the degree of cataract and corneal edema, the accuracy of the biometry, and the patient's age and wishes, and these results can be used to help inform that discussion.

CREDIT AUTHORSHIP CONTRIBUTION STATEMENT

DAVID SHAHNAZARYAN: INVESTIGATION, FORMAL ANALysis, Writing - original draft, Writing - review & editing. Aida Hajjar Sese: Data curation. Emma J. Hollick: Conceptualization, Methodology, Writing - review & editing, Supervision.

ALL AUTHORS HAVE COMPLETED AND SUBMITTED THE ICMJE FORM FOR DISCLOSURE OF POTENTIAL CONFLICTS OF INTEREST and none were reported.

Funding/Support: No funding or grant support. Financial disclosures: No financial disclosures.

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