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**Back-up procedure for graft failure in
Descemet Membrane Endothelial Keratoplasty (DMEK)**

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KEYWORDS: Descemet membrane endothelial keratoplasty, Descemet stripping endothelial keratoplasty, posterior lamellar keratoplasty, corneal transplantation, Descemet membrane, endothelium, surgical technique

ABSTRACT

Purpose: To evaluate the efficacy of a secondary Descemet stripping endothelial keratoplasty (DSEK) as a back-up procedure for managing graft failure after primary Descemet membrane endothelial keratoplasty (DMEK).

Design: Non-randomized prospective clinical study.

Methods: A first group of 50 cases with Fuchs endothelial dystrophy underwent DMEK. Two to five weeks after the DMEK, ten cases showed no corneal clearance, so that a secondary DSEK was performed. To evaluate the latter eyes, best corrected visual acuity (BCVA) and endothelial cell density at 6 and 12 months were used as outcome parameters.

Results: At 6 months after secondary DSEK, 87% of the cases had a BCVA of \geq 20/40 (0.5) and one eye reached 20/25 (0.8). Donor DSEK grafts endothelial cell densities averaged 2617 (\pm 152) cells/mm² before surgery, 1510 (\pm 799) cells/mm² at 6 months, and 1602 (\pm 892) cells/mm² at 12 months after surgery .

Conclusion: In the event of a DMEK graft failure, a secondary DSEK may be an effective back-up procedure, since it may give a clinical outcome similar to that after a primary DSEK. Especially during the surgeon's learning curve, patient information may not only be directed towards DMEK, but also DSEK visual outcomes.

Since 1998, we have introduced various concepts for posterior lamellar keratoplasty, in order to manage corneal endothelial disorders.¹⁻⁵ In the United States these techniques have been popularized as ‘deep lamellar endothelial keratoplasty’ (DLEK),⁶ and (femtosecond) Descemet stripping (automated) endothelial keratoplasty (DSEK/DSAEK/FS-DSEK).⁷⁻⁹ We also described a technique for selective transplantation of Descemet membrane through a self-sealing clear corneal incision, tentatively named Descemet membrane endothelial keratoplasty (DMEK).¹⁰⁻¹²

The main complication with all of these techniques is incomplete attachment of the unsutured graft in the early postoperative course, in particular when eye bank preserved donor corneal tissue is used.^{13,14} As in DLEK and DSEK/DSAEK, graft detachment may also occur after DMEK in up to 10-30% of cases.¹⁵ In the event of DMEK graft failure with associated corneal edema, a re-DMEK may be difficult to perform, because the graft can not be visualized in the anterior chamber during surgery. Although a secondary penetrating keratoplasty could be considered, a full-thickness graft would be accompanied with the well-known risks of limited visual acuity due to astigmatism, suture related problems, and incomplete wound healing.¹

As an alternative, a secondary DSEK/DSAEK procedure may be performed, since it requires less visibility of the tissue in the anterior chamber during surgery than DMEK. Theoretically, a secondary DSEK/DSAEK may provide a visual outcome similar to that after a primary DSEK/DSAEK in a virgin eye. However, it seems important to test this hypothesis, in order to inform patients eligible for DMEK about the visual prognosis to be expected with a secondary procedure in the event of DMEK graft failure. In the current study, the feasibility and efficacy of DSEK as a back-up procedure for failed DMEK procedures were evaluated.

MATERIALS AND METHODS

Fifty eyes of 46 patients underwent DMEK for Fuchs endothelial dystrophy, in the absence of severe corneal edema and/or possibly complicating surgical factors like glaucoma devices or a shallow anterior chamber.

In the early postoperative period of ten eyes, a graft detachment or failure of the transplanted cornea to clear was observed.¹⁶ Lack of corneal clearance at two to five weeks postoperative was attributed to a nonfunctional graft due to endothelial damage or to an upside-down positioning of the posterior transplant (endothelium facing the host's stroma).¹⁶ As diffuse corneal edema in these eyes did not permit proper visualization of the recipient anterior chamber to reposition the DMEK graft, a secondary DSEK was performed two to five weeks later. Two patients were male and eight female; patient age ranged from 45 to 86 years of age (Table). All patients signed an IRB approved informed consent.

For all DSEK procedures, posterior lamellar grafts were obtained from donor globes less than 36 hours post mortem. In whole globes, from donors averaging 67.5 (\pm 6.1) years in age, lamellar dissections were performed manually at 80-90% stromal depth. Corneo-scleral buttons were then excised and stored by organ culture in modified minimum essential medium (EMEM) at 31° C.¹⁷ After one week of culture, endothelial cell morphology and viability were evaluated with an inverted light microscope (Axiovert 40, Zeiss, Göttingen, Germany). After provoked swelling with sucrose 1.8% and staining with trypan blue 0.04%, digital photographs were made (PixelINK PL-A662, Zeiss, Göttingen, Germany), and three central areas of endothelial cell densities were averaged.

All patients underwent a DMEK procedure performed as previously described.^{11,15} For the secondary surgery, the pre-existing 3.0 mm corneal tunnel incision was re-opened and widened up to 5.0 mm. After injecting trypan blue 0.06% (VisionBlue, DORC International,

Zuidland, Netherlands) in the recipient anterior chamber to stain the DMEK transplant (an isolated donor Descemet membrane and its endothelium), the graft was carefully extracted from the eye with fine forceps. Under air, the posterior host bed was checked for irregularities, and the anterior chamber was thoroughly irrigated to remove all remnant graft tissue.

After positioning a plastic glide through the corneal tunnel incision, extending into the anterior chamber, a DSEK graft (a donor posterior corneal disk consisting of a thin layer of posterior stroma, Descemet membrane and its endothelium), 8.5-9.0 mm in diameter, was positioned on the glide with the endothelium facing upwards. A drop of viscoelastic was applied onto the endothelial surface, and the tissue was folded in a 50/50 'taco'. Using either forceps³ or a 30G needle,¹⁷ the donor disk was then inserted into the anterior chamber. Using gentle irrigation and manipulation with air, the donor tissue was unfolded and positioned onto the recipient posterior stroma. The anterior chamber was completely filled with air for 15-30 minutes. Then, the eye was again pressurized with BSS, leaving a 50% air-fill of the anterior chamber.

All DSEK surgical procedures were recorded on DVD (Pioneer DVR-RT601H-S, Tokyo, Japan). At six and twelve months after secondary DSEK, the endothelium was photographed and evaluated *in vivo* using a Topcon SP3000p non-contact autofocus specular microscope (Topcon Corp, Tokyo, Japan). Images of the central corneal window were analyzed and manually corrected, and three measurements of endothelial cell density were averaged.¹⁸

RESULTS

Of the fifty eyes that underwent a primary DMEK, 40 eyes showed effective graft attachments; and at six months after the surgery, 95% achieved a BCVA of $\geq 20/40$ (0.5), and 75 % reached $\geq 20/25$ (0.8).

Ten eyes (20%) required a secondary DSEK because of complete or partial DMEK graft detachment (cases 1, 2, 4, 5, 7, 8 and 9); or apparent failure of the transplanted cornea to clear (cases 3, 6, and 10). Although all secondary DSEK surgeries were uneventful, three eyes showed partial graft detachment within the first week after surgery (Cases 2, 9 and 10; Table). After a re-bubbling procedure in these three eyes, 2-7 days after the secondary DSEK surgery, all ten eyes obtained a completely attached DSEK graft (Figure 1).

Of the ten eyes managed with a secondary DSEK, two had a concomitant eye disorder limiting visual potential: Case 4 had a macular hole and Case 5 a history of retinal detachment with a detached macula (Table). With these eyes excluded, seven out of the eight eyes (87%) with normal visual potential reached a BCVA of $\geq 20/40$ (0.5) at six months after surgery, and one of the eight eyes (13%) reached 20/25 (0.8) (Table). Visual outcomes were stable thereafter, except for that in Case 6, who developed a mild anterior subcapsular cataract (Figure 1; Table).

Preoperative endothelial cell density of the DSEK grafts averaged 2617 (± 152) cells/mm². At 6 and 12 months after the secondary DSEK, the donor endothelial cell densities averaged respectively 1510 (± 799) cells/mm² and 1602 (± 892) cells/mm². The decrease in pre- to postoperative cell density was significant ($p < 0.05$).

DISCUSSION

To our knowledge, this is the first clinical report that shows that in the event of DMEK graft failure, a secondary DSEK may be performed as a back-up procedure. In all cases, the secondary DSEK graft became functional, showing a postoperative course similar to that after a primary DSEK, ie DSEK in a virgin cornea. Hence, penetrating keratoplasty could be avoided in all eyes. At six months after the secondary DSEK surgery, all but one eye (87%) had a BCVA of 20/40 (0.5) or better, and one eye reached 20/25 (0.8). These statistics on visual outcome compare to that in other studies on DSEK/DSAEK, that report visual acuities up to 20/40 (≥ 0.5) in 55 to 97% of the cases, with only small percentages reaching 20/25 or better (≥ 0.8).^{8,14,19-21}

Although DSEK/DSAEK has become widely accepted since its clinical outcome compares favorably to penetrating keratoplasty, DMEK may yield better results. In our study, 40 eyes had a successful DMEK surgery, of which 95% reached a BCVA of $\geq 20/40$ (≥ 0.5) and, 75 % reached $\geq 20/25$ (≥ 0.8) at six months after surgery.²² If the results of all 50 patients in our study are combined, 94% had a BCVA of $\geq 20/40$ (≥ 0.5) and, more importantly, 66% reached $\geq 20/25$ (≥ 0.8) at six months after surgery. Before commencing DMEK, it may therefore be appropriate to inform the patient, that, if a secondary DSEK is required in the event of DMEK graft failure, the prognosis on visual outcome may be reduced. However, the overall approach of a primary DMEK with a secondary DSEK, if required, may on average still compare favorably to the visual outcome after primary DSEK/DSAEK.

Endothelial cell density of the secondary DSEK grafts showed a decline of about 40% at six months after surgery. A similar decrease in pre- to postoperative endothelial cell density, ranging from 34 to 55 %, has also been reported after DSEK/DSAEK by other

investigators.^{18,21,24-27} In the further analysis of the cell density values, two findings were considered remarkable. First, some eyes (Cases 6, 7, 8 and 9; Table) showed higher endothelial cell densities at 12 months than at 6 months postoperative, although the overall difference in cell density at these time intervals proved not statistically significant. Second, the absolute cell count tended to be either relatively high (Cases 6, 8 and 9) or low (Cases 3, 4, 7 and 10; Table).

The relatively low cell densities could not be correlated to differences in tissue quality and/or surgical error, since all eyes were operated on by the same surgeon using the same technique, and all secondary DSEK procedures seemed uneventful. To our knowledge there are no previous reports describing a long-term increase in endothelial cell density after DSEK/DSAEK, so the findings may well be attributed to coincidental misreadings. If not, the most likely explanation would relate to the presence of DMEK graft in the anterior chamber for a period of two to five weeks, ie the only difference compared to the situation after a primary DSEK. Recently we reported that in eyes with a detached DMEK graft (i.e. a Descemet-roll floating freely in the anterior chamber), the transplanted corneas cleared up with a visual recovery up to 20/20 (1.0).²⁸ It was hypothesized that donor endothelial cell migration or 'seeding' could have resulted in endothelial repopulation of the recipient posterior stroma. Could the detached DMEK grafts in the present study, as temporary depots of donor cells, have contributed to increasing cell densities after a secondary DSEK? Longer follow-up may show if a cumulative load of endothelial cells transplanted in more than one surgical session, relates to different patterns of cell counts and/or distribution.

In the current study, the detachment rate of the secondary DSEK graft was of 30% (3/10; Table). In these eyes, the DSEK graft showed complete attachment after re-bubbling

of the anterior chamber. Apparently, previous DMEK detachment does not prohibit attachment of a secondary graft, transplanted with a different endothelial keratoplasty technique. However, eyes with a primary DMEK graft detachment, may have a slightly higher risk of also developing a secondary DSEK/DSAEK graft detachment for two reasons. First, the condition within the eye itself may give a higher risk of graft detachment; e.g. case 5 who underwent posterior segment surgery prior to the corneal transplant. In such eyes, it proves more difficult to maintain an air fill of the anterior chamber at the termination of the surgery to secure the graft, i.e. to obtain full attachment. Second, although the cause of DMEK graft detachment itself may not relate to an increased risk of secondary DSEK/DSAEK graft detachment, the lack of a recipient Descemet membrane results in progressive corneal decompensation. In our experience, DSEK/DSAEK graft attachment is more difficult to obtain in severely decompensated corneas, possibly due to lowered intracorneal pressure associated with corneal overhydration.²⁹

In conclusion, a secondary DSEK/DSAEK after a failed DMEK may yield a clinical outcome similar to that after primary DSEK/DSAEK in a virgin cornea. As such, DSEK/DSAEK could be considered a safe and effective back-up procedure, that to our knowledge, has not been reported previously. However, a secondary DSEK/DSAEK may not be the treatment of choice for all complicated DMEK grafts. In our series, three patients underwent a secondary DSEK, because the primary DMEK graft was attached, but did not clear within the first month (Cases 3, 6 and 10).¹⁶ Since then, we learned that some (completely attached) grafts may show delayed function up to several months postoperative, so that in retrospect the secondary DSEK intervention may have been premature in these cases. In the event of a DMEK graft detachment, re-bubbling of the DMEK graft may be a

first option, especially if the detachment is only partial. In DMEK, re-bubbling may be performed without too much delay, since Descemet membrane may show increased rigidity due to scarring within weeks. Preservation of the DMEK graft may be indicated even if it is decentered or partially detached, since it still tends to give a far better visual outcome than a secondary DSEK/DSAEK.^{22,23}

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3. Involved in design study (GM and JvdW); conduct of study (ID, LH, CvL, JvdW and GM); data analysis (ID, LH, JvdW and GM); collection, management and interpretation of the data (ID, JvdW and GM); and preparation, review, or approval of the manuscript (ID, JvdW and GM).
4. IRB/IC – This study was conducted in compliance with the Institutional Review Board and Informed Consent requirements, in adherence to the tenets of the Declaration of Helsinki, at the Netherlands Institute for Innovative Ocular Surgery (Study registration no N.05.14). The study was submitted to <http://www.clinicaltrials.gov>. The registration number is NCT00521898.
5. Other Acknowledgements – None.

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FIGURE LEGEND

Figure 1. Slit-lamp photographs of a transplanted cornea (black arrows), 12 months after a secondary DSEK (and a previously failed DMEK). Note that the graft is completely attached (white arrows) and the transplanted cornea is clear.

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Table

Patient				Snellen BCVA			DSEK ECD cells/mm ²			Remarks	
Age (yrs)	M/F	OD/OS	Concomitant eye conditions	Preoperative (before DMEK)	6 months postoperative (after DSEK)	12 months postoperative (after DSEK)	Preoperative	6 months postoperative	12 months postoperative		
1	61	F	OD	PPBK (Pseudophakic)	CF (1/60)	20/30 (0.6)	20/30 (0.6)	2520	1910	1790	DSEK 2 weeks after DMEK.
2	86	F	OD	FED (Pseudophakic)	20/60 (0.3)	20/40 (0.5)	n.a	2510	(2170)	n.a.	DSEK 3 weeks after DMEK; Rebubbling at 1 week after secondary surgery for partial detachment DSEK graft.
3	45	F	OD	FED (Phakic)	20/40 (0.5)	20/40 (0.5)	20/40 (0.5)	2480	490	450	DSEK 3 weeks after DMEK; Mild anterior subcapsular cataract formation at 6 months.
4	78	F	OD	FED (Pseudophakic) Pre-existing macular hole	[20/200 (0.1)]	[20/150 (0.15)]	[20//150 (0.15)]	2520	n.a.	(420)	DSEK 4 weeks after DMEK.
5	70	M	OD	FED and PPBK (Pseudophakic) Prior retinal detachment	[20/100 (0.2)]	[20/100 (0.2)]	[20/100 (0.2)]	2690	(1580)	n.a.	DSEK 4 weeks after DMEK.
6	57	F	OD	FED (Phakic)	20/40 (0.5)	20/40 (0.5)	20/50 (0.4)	2890	1990	2280	DSEK 3 weeks after DMEK; Mild anterior subcapsular cataract formation at 12 months.
7	82	F	OS	FED and PPBK (Pseudophakic)	20/80 (0.25)	20/50 (0.4)	20/50 (0.4)	2580	800	870	DSEK 3 weeks after DMEK.
8	70	F	OS	FED and PPBK (Pseudophakic)	20/100 (0.2)	20/40 (0.5)	20/40 (0.5)	2640	1820	2120	DSEK 4 weeks after DMEK.
9	70	M	OD	FED (Pseudophakic)	20/80 (0.25)	20/25 (0.8)	20/25 (0.8)	2860	2690	2860	DSEK 5 weeks after DMEK; Rebubbling at 1 week after secondary surgery for partial detachment DSEK graft.
10	57	F	OS	FED (Pseudophakic)	20/60 (0.3)	20/40 (0.5)	20/40 (0.5)	2480	870	850	DSEK 2 weeks after DMEK. Rebubbling at 2 days after secondary surgery for partial detachment DSEK graft.
BCVA at 6 months: 87% ≥ 20/40 (0.5); 13% ≥ 20/25 (0.8) (n=8)								2617 (±152) (n=10)	1510 (±799) (n=7)	1602 (±892) (n=7)	

BCVA = Best corrected visual acuity

CF = Counting fingers

DMEK = Descemet membrane endothelial keratoplasty

DSEK = Descemet stripping endothelial keratoplasty

ECD = Endothelial cell density

FED = Fuchs' endothelial dystrophy

PPBK = Pseudophakic bullous keratopathy

n.a. = Not available

Figure 1

