Descemet Membrane Endothelial Keratoplasty: Ten-Year Graft Survival and Clinical Outcomes

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• PURPOSE: To evaluate the 10-year graft survival and clinical outcomes of the first case series after Descemet membrane endothelial keratoplasty (DMEK).
• DESIGN: Retrospective, interventional case series.
• METHODS: After excluding the very first 25 DMEK eyes that constitute the technique learning curve, the following 100 consecutive primary DMEK eyes (88 patients) were included. Main outcome parameters (survival, best-corrected visual acuity [BCVA], central endothelial cell density [ECD], and central corneal thickness [CCT]) were evaluated up to 10 years postoperatively, and postoperative complications were documented.
• RESULTS: At 5 and 10 years after DMEK, 68 and 57 of 100 eyes, respectively, were still available for analysis. Of those eyes, 82% and 89% reached a BCVA of ≥20/25 (decimal VA ≥0.8) at 5- and 10 years postoperatively, respectively. Preoperative donor ECD decreased by 59% at 5 years and 68% at 10 years postoperatively. CCT averaged 668 ±74 μm preoperatively and 540 ± 33 μm and 553 ± 43 μm at 5 and 10 years, respectively, after surgery. Within 10 years, 4% of eyes developed allograft rejection, no primary graft failures occurred, and 6% of the eyes developed secondary graft failure. Graft survival probability was 0.83 (95% confidence interval [CI], 0.75-0.92) and 0.79 (95% CI, 0.70-0.88) at 5 and 10 years postoperatively, respectively.
• CONCLUSIONS: Most eyes that underwent surgery in the pioneering phase of DMEK showed excellent and stable clinical outcomes with low postoperative complication rates and promising graft longevity over the first decade after surgery. This suggests that DMEK may be a safe long-term treatment option for corneal endothelial diseases. (Am J Ophthalmol 2020;217:114–120. © 2020 Elsevier Inc. All rights reserved.)

AJO.com Supplemental Material available at AJO.com.
Accepted for publication Apr 3, 2020.

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THE FIRST DESCEMET MEMBRANE ENDOTHELIAL KERATOplasty (DMEK) surgery was performed in 2006.[1,2] Now, more than a decade later, this selective endothelial keratoplasty technique has gained wide global acceptance and is being offered as a standard procedure for the treatment of corneal endothelial disorders.[3–5] The increasing popularity of DMEK results from the excellent visual recovery and clinical outcomes accompanied by low allograft rejection rates as reported in several short-term studies.[6–11] The first mid-term results showed promising graft survival rates comparable to earlier endothelial keratoplasty techniques, where clinical outcomes remained stable, and postoperative complication rates remained low.[12–16] However, so far, no studies of long-term outcomes are available.

The present study evaluated the 10-year clinical outcomes and graft survival rates for the first 100 consecutive DMEK cases (cases 26-125), excluding the very first 25 DMEK cases, which were defined here as the learning curve of the technique. These 25 DMEK cases were excluded because they do not represent the classical learning curve of a surgeon but rather the technique learning curve as those were the very first 25 DMEK surgeries ever performed. During the first months, when DMEK began to be performed, the technique was standardized and, for example, the protocol for treating eyes with a graft detachment was adapted (the first eyes with a graft detachment underwent resurgery already within the first weeks after DMEK).[17]

This study presents the first 10-year graft survival data for a large cohort of DMEK eyes and assessed whether clinical outcomes remained stable up to 10 years after DMEK.

SUBJECTS AND METHODS

• PATIENT DATA: One hundred consecutive eyes of 88 patients that underwent primary DMEK surgery for Fuchs endothelial corneal dystrophy (94%), failed previous transplant (4%), or bullous keratopathy (2%) between October 2007 and June 2009 were evaluated retrospectively. Mean recipient age was 68 ± 12 years (range, 41-89 years), and 84% of eyes were pseudophakic (Table 1). Of the first 125 consecutive primary DMEK surgeries, the first 25

0002-9394/$36.00
https://doi.org/10.1016/j.ajo.2020.04.005

TABLE 1. Demographics of DMEK Eyes and Donors

Baseline Parameters	Total Group (n = 100)
Number of eyes/patients	100/88
Males/females	36/52
Mean ± SD patient age, y	68 ±12
Indication for DMEK	
FECD	94
Pseudophakic BK	2
Failed PKP/DSEK	4
Preoperative lens status	
Phakic/pseudophakic	16/84
Eyes OD/OS	53/47
Donor sex	
Males/females	56/44
Mean ± SD donor age, y	62 ±9
Donor cause of death	
Cardiovascular	54
Respiratory	23
Cancer	18
Trauma	3
Other	2
Mean ± SD graft storage time in medium, days	13.3 ±3.9

BK = bullous keratopathy; DMEK = Descemet membrane endothelial keratoplasty; DSEK = Descemet stripping endothelial keratoplasty; FECD = Fuchs endothelial corneal dystrophy; PKP = penetrating keratoplasty; SD = standard deviation.

DMEK cases operated worldwide (cases 1-25), which represented the learning curve of the DMEK technique, were excluded from the study. All patients included in this retrospective study signed an informed consent prior to surgery for research participation, and the study was carried out according to the Declaration of Helsinki. No institutional review board or Ethics Committee approval was required due to the retrospective study design under national legislation.

• **DMEK GRAFT PREPARATION AND SURGERY:** Donor tissue was prepared at Amnitrans EyeBank Rotterdam, as previously described.[18] After endothelial cell morphology and viability were assessed, the DMEK grafts were stored free-floating in organ culture medium (CorneaMax; Eurobio, Courtaboeuf, France) until transplantation (Table 1).

The surgery was performed as previously described.[19] Postoperative medication included topical chloramphenicol, 0.5% 6 times daily, for the first week and 2 times daily for the second week; ketorolac tromethamine, 0.4%, and topical dexamethasone, 0.1% 4 times daily for 4 weeks, followed by fluorometholone, 0.1% 4 times daily, which was tapered to once daily over a period of 1 year. After that, it was recommended that patients continue using fluorometholone once a day or every other day indefinitely.

• **DATA COLLECTION AND STATISTICAL ANALYSIS:** Patients were examined preoperatively and at 6 and 12 months postoperatively, followed by yearly examinations up to 10 years. Outcome measurements included best-corrected visual acuity (BCVA), endothelial cell density (ECD), central corneal thickness (CCT), and complications.

BCVA was measured by using a Snellen letter chart, and outcomes were converted to the logarithm of the minimum angle of resolution units (LogMAR) for statistical analysis. Eyes with low visual potential due to ocular comorbidities unrelated to the cornea were excluded from the BCVA analysis. The percentage of excluded low visual potential eyes was 8% or less at any analyzed time point. ECD was assessed by using noncontact autofocus specular microscopy (Topcon Medical Europe BV, Capelle a/d IJssel, The Netherlands). For ECD counting, an average of 3 central measurements was used in the analysis. CCT was measured using rotating Scheimpflug corneal tomography (Pentacam HR; Oculus Optikgeräte GmbH, Wetzlar, Germany).

Graft detachment was assessed by anterior segment optical coherence tomography (Heidelberg Engineering GmbH, Heidelberg, Germany) and Scheimpflug imaging. Graft detachment was defined as minor (≤1/3 of the graft surface area) or major detachment (>1/3 of the graft surface area). Allograft rejection was defined as the presence of an endothelial rejection line or keratic precipitates (with or without an increase in corneal thickness), anterior uveitis, and/or ciliary injection on slit-lamp biomicroscopy. Primary graft failure was defined as an absence of corneal clearance in an eye with full graft attachment. Secondary graft failure (SGF) was defined as corneal decompensation after an interval of corneal clearance.

Graft survival was estimated by Kaplan-Meier survival analysis using the log-rank test. The second operated eyes of patients undergoing bilateral DMEK (n = 12) were excluded from the survival analysis. Survival time was calculated as the time between the surgery and the last available follow-up time point of an eye or as the time between the surgery and graft failure. All SGFs (endothelial failures) and retransplantations performed for graft detachment (technical failures) were included in the survival analysis.[20] Patients who were unable to attend the 10-year follow-up examination were contacted for medical record updates to be included in the graft survival analysis (n = 11).

Continuous data were analyzed by Student *t* test and categorical variables by chi-squared test. All data analysis was performed using SPSS version 25.0 software (IBM, Armonk, New York) and Excel software for Windows (Microsoft, Redmond, Washington). *P* values less than .05 were considered significant.

TABLE 2. BCVA, ECD, and Pachymetry Results Pre- and Post-DMEK

Parameter	Preoperative	Total group			
		6 mo FU	1 y FU	5 y FU	10 y FU
BCVA, Snellen (decimal)	(n = 99)	(n = 86)	(n = 79)	(n = 55)	(n = 44)
<20/40 (<0.5)	71 (72%)	8 (9%)	3 (4%)	1 (2%)	1 (2%)
≥20/40 (≥0.5)	28 (28%)	78 (91%)	76 (96%)	54 (98%)	43 (98%)
≥20/25 (≥0.8)	5 (5%)	64 (74%)	64 (81%)	45 (82%)	39 (89%)
≥20/20 (≥1.0)	0	37 (43%)	39 (49%)	29 (53%)	28 (64%)
Mean ± SD BCVA, logMAR	0.36 ± 0.20 (n = 99)	0.11 ± 0.22 (n = 86)	0.07 ± 0.12 (n = 79)	0.04 ± 0.12 (n = 55)	0.03 ± 0.1 (n = 44)
Mean ± SD ECD, cells/mm^2	2593 ± 178 (n = 100)	1711 ± 525 (n = 85)	1605 ± 530 (n = 81)	1083 ± 432 (n = 59)	845 ± 342 (n = 44)
Mean ± SD ECD decrease, %[a]		34 ± 19 (n = 85)	38 ± 19 (n = 81)	59 ± 15 (n = 59)	68 ± 13 (n = 44)
Mean ± SD pachymetry, μm	668 ± 74 (n = 79)	533 ± 42 (n = 84)	536 ± 37 (n = 81)	540 ± 33 (n = 57)	553 ± 43 (n = 44)
Mean ± SD pachymetry decrease, %[a]		20 ± 8 (n = 79)	19 ± 7 (n = 74)	18 ± 7 (n = 53)	16 ± 9 (n = 40)

BCVA = best corrected visual acuity; DMEK = Descemet membrane endothelial keratoplasty; ECD = endothelial cell density; FU = follow-up.
[a]Decrease compared to preoperative values.

RESULTS

AT 5 AND 10 YEARS AFTER DMEK, 68 AND 57 OF 100 EYES were still available for analysis, respectively (Supplemental Table). Patients who reached the 10-year follow-up were, on average, 64 ± 11 years at the time of surgery compared to 68 ± 12 years for the entire study group (P = .001).

• **BEST CORRECTED VISUAL ACUITY:** At 1-year after DMEK, 96% of the eyes had a BCVA of ≥20/40 (decimal VA ≥0.5); 81% had ≥20/25 (≥0.8); and 49% had ≥20/20 (≥1.0). At the 5-year follow-up examination, 98% of the eyes had a BCVA of ≥20/40 (0.5); 82% had ≥20/25 (≥0.8); and 53% had ≥20/20 (≥1.0). At 10-years after DMEK, 98% had BCVA ≥20/40 (0.5); 89% had BCVA ≥20/25 (≥0.8); and 64% had BCVA ≥20/20 (≥1.0) (Table 2, Figure 1). BCVA outcomes (in logMAR) between 5 and 10 years postoperatively reached a statistically significant difference (P = .022). At 10 years postoperatively, BCVA outcomes (in logMAR) did not differ between eyes with fully attached and ≤1/3 detached grafts (P = .281).

• **ENDOTHELIAL CELL DENSITY:** Average preoperative donor ECD was 2,593 ± 178 cells/mm^2 which decreased to 1,605 ± 530 cells/mm^2 at 1 year, 1,083 ± 432 cells/mm^2 at 5 years, and 845 ± 342 cells/mm^2 at 10 years postoperatively, corresponding to an ECD decline of 34%, 59%, and 68%, respectively, compared to preoperative ECD values (Table 2, Figure 2). The average annual rate of endothelial cell loss between the 1 year and 10 year follow-up examinations was −8% (range, −10.7% to −5.7%) (P < .01 between all consecutive annual follow-up time points). The average 10-year ECD was 903 ± 356 cells/mm^2 (−66%) (n = 32) in eyes with a completely attached graft and 721 ± 262 (n = 11) cells/mm^2 (−72%) in eyes with minor graft detachment (P = .128).

Of 15 eyes that had an ECD of <1,000 cells/mm^2 (mean ECD, 807 ± 138 cells/mm^2, median 840 cell/mm^2) at 1 year postoperatively, 6 eyes were still available at the 10-year follow-up (mean ECD, 707 ± 135 cells/mm^2, median 703 cells/mm^2) (Supplemental Figure), whereas 3 eyes had undergone repeat DMEK at 30, 33, and 115 months after primary DMEK.

The other 6 eyes, which were unavailable or lost to follow-up, had an average ECD of 812 ± 170 cells/mm^2 (median, 796 cells/mm^2) at the last available follow-up at an average of 63 ± 27 months (range, 24-108 months). None of those 6 eyes showed signs of corneal decompensation at the last available follow-up.

• **PACHYMETRY:** Average preoperative CCT was 688 ± 74 μm and decreased to 536 ± 37 μm, 540 ±33 μm, and 553 ± 43 μm at 1, 5, and 10 years, respectively, after DMEK. Overall, CCT had decreased by 16% at 10 years

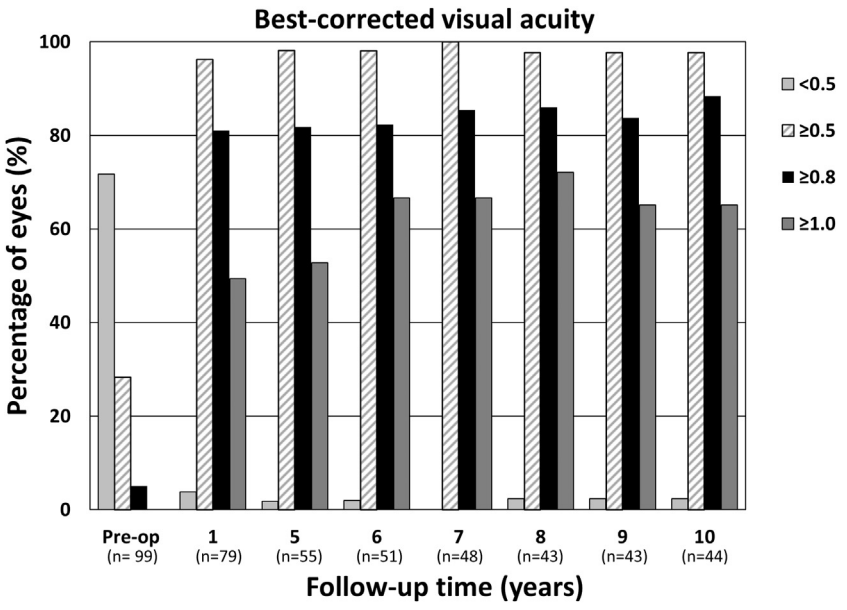


FIGURE 1. BCVA outcome up to 10 years after DMEK. Bar graphs display the percentage of eyes reaching the BCVA levels given in decimals. The number of eyes available per follow-up is given underneath the follow-up time points. BCVA = best-corrected visual acuity; DMEK = Descemet membrane endothelial keratoplasty.

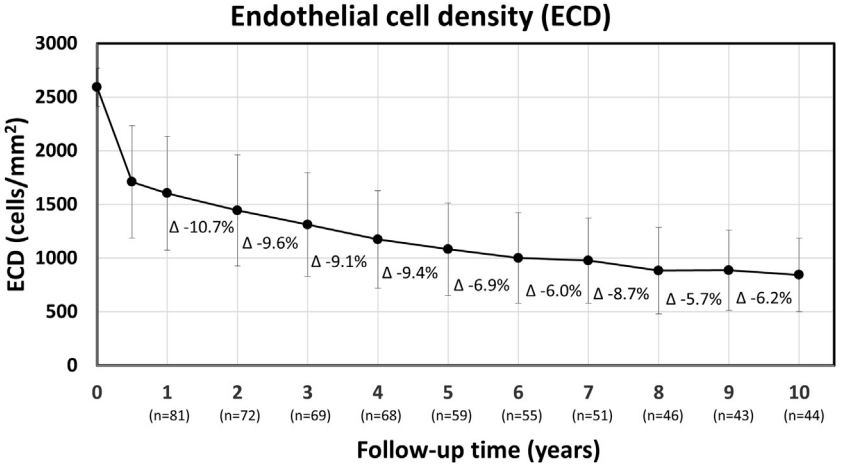


FIGURE 2. Endothelial cell density up to 10 years after Descemet membrane endothelial keratoplasty. Mean ECD values are displayed, vertical bars represent standard deviations, and delta represents the percentage of ECD decrease between time points. Number of eyes available per follow-up is given underneath the follow-up time points. ECD = endothelial cell density.

compared to preoperative CCT (Table 2), but CCT values showed a significant increase between the 5- and 10- year follow-up of 2 ± 6% ($P < .023$).

• **POSTOPERATIVE COMPLICATIONS AND RETRANSPLANTATIONS:** At 6 months postoperatively, a minor graft detachment was visible in 18 eyes (18%) and a major detachment in 11 eyes (11%). Seven eyes (7%) underwent a rebubbling procedure (on average, 7 ± 7 weeks after DMEK).

Allograft rejection was diagnosed in 4 eyes at 4, 30, 42, and 84 months after DMEK and was reversed by intensified topical steroid treatment in all but 1 eye, which resulted in SGF. In total, 6 eyes (6%) developed SGF, on average, at 60 ± 33 months (median, 60 months) after DMEK (Table 3). No primary graft failures occurred within this study group.

Of the entire cohort, 19 eyes (19%) underwent retransplantation, on average, at 29 ± 34 months (median, 11 months) after DMEK (Table 3). Indications for

TABLE 3. Postoperative Complications and Secondary Procedures after DMEK

Parameter	Total Group (n = 100)
Graft detachment[a]	
Minor (≤1/3 of graft surface area)	18
Major (>1/3 of graft surface area)	11
Allograft rejection[b]	4
Graft failure	
Primary[c]	–
Secondary[d]	6
Mean time ± SD, months	60 ± 33
Median time (range), months	60 (21-101)
Technical[e]	13
Mean time ± SD, months	10 ± 9
Median time (range), months	7 (1-31)
Secondary procedures	
Re-bubbling	7
Mean time ± SD, weeks	7 ± 7
Median time (range), weeks	8 (1 d-13 w)
Re-transplantation	19
Mean time ± SD, months	29 ± 34
Median time (range), months	11 (1-115)

d = days; DMEK = Descemet membrane endothelial keratoplasty; m = months; n = number of eyes; SD = standard deviation; w = weeks.

[a]Includes all graft detachments as observed at 6 months follow-up.

[b]Allograft rejection was diagnosed at 4, 3, 42, and 84 months after DMEK, respectively.

[c]Primary graft failure refers to an attached graft, but cornea failed to clear.

[d]Secondary graft failure refers to an attached graft with (signs of) corneal clearance, followed by corneal decompensation.

[e]Technical failure refers to grafts with persistent graft detachment.

retransplantation were "technical failures" (i.e., graft detachment [n = 13]) or SGF (n = 6). Approximately half of all retransplantations were performed within the first year after surgery (10 of 19 eyes [52.6%]), 31.6% between the 1- and 5-year follow-up examinations (6 of 19 eyes), and the remaining (3 of 19 eyes [15.8%]) after the 5-year follow-up.

• **GRAFT SURVIVAL:** The overall graft survival probability was .83 (95% confidence interval [CI], 0.75-0.92) at 5 years and 0.79 (95% CI, 0.70-0.88) at 10 years after DMEK (Figure 3).

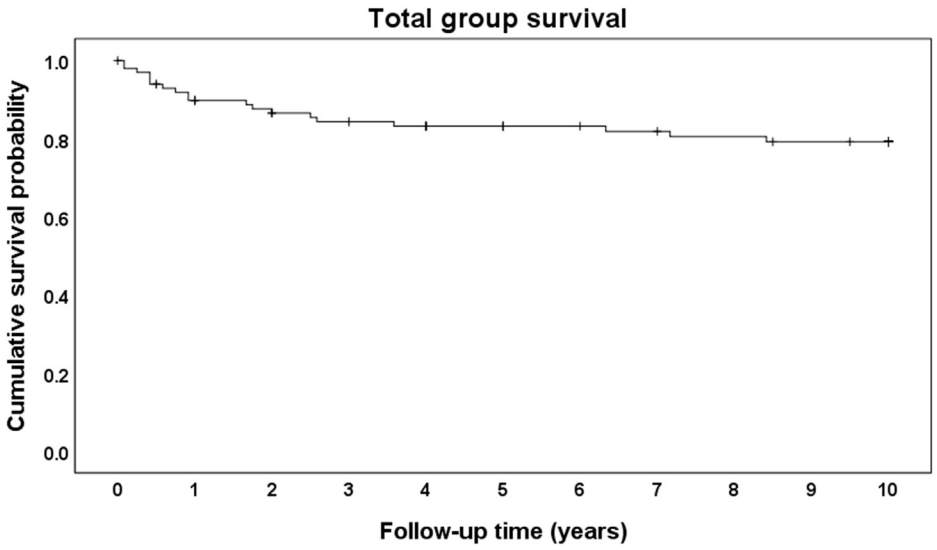
Analysis of graft survival in eyes with either complete graft attachment or minor detachment revealed a graft survival probability of 0.92 (95% CI, 0.86-0.98) at 5 years and 0.87 (95% CI, 0.79-0.95) at 10 years after DMEK (versus 0.2 [95% CI, 0.06-0.69] at both 5 and 10 years for eyes with a major graft detachment; $P = .001$). No difference in 10-year graft survival probability was observed between the first 50 cases (0.77 [95% CI, 0.65-0.89]) and the second 50 cases (0.81 [95% CI, 0.68-0.96]) of the cohort ($P = .5$). No subgroup analysis based on surgery indication was performed as only 6 eyes (6%) underwent DMEK for indications other than Fuchs endothelial corneal dystrophy. Of those 6 eyes, 2 were still clear at the 10-year follow-up, 1 underwent retransplantation 11 months after DMEK, and 3 were lost to follow-up.

DISCUSSION

THIS STUDY EVALUATED THE 10-YEAR DMEK GRAFT SURvival probability and clinical outcomes of 100 eyes of the first DMEK cohort. Overall, the outcomes are satisfactory in terms of graft survival and excellent in terms of visual outcomes considering that the cohort underwent transplantation in an early phase of technique development.

The overall 10-year graft survival probability was 79%, which is comparable to results reported for the established penetrating keratoplasty (PK) technique (78%).[21] The present authors recently reported a 5-year survival probability of 90% for a cohort of 500 DMEK eyes (including all 100 eyes of this study),[16] whereas the 5-year survival probability of the current cohort was only 83%. For the previous larger cohort, it was remarkable that the first 250 eyes had a lower survival probability than the second 250 eyes (88% versus 94%, respectively).[16] This may indicate that the DMEK learning curve extends beyond the first 25 cases (which were excluded) and may still have an influence on graft survival after performing more than 100 DMEK cases. Hence, for future studies, higher 10-year survival rates may be expected for larger cohorts (predominantly operated on for Fuchs endothelial corneal dystrophy as reported for this study) after longer DMEK experience.[13–16]

Another influencing factor on survival, which is also related to the learning curve, is graft detachment (considered a technical failure). In the current DMEK study group, the rate of eyes with a major detachment at 6 months postoperatively was relatively high at 11% (compared to 5% for the second 250 eyes of the cohort of 500 DMEK eyes). Our group had previously shown that graft survival is negatively affected by graft detachment.[16] Also in this study, significantly higher 10-year graft survival rates were observed for eyes without major detachment, namely 87% versus 20% for eyes with major detachments. Hence, the 10-year survival rate of 87% may reflect the actual survival probability after longer DMEK experience. Although in the first years after introducing DMEK, the present group, unlike other groups, often avoided a secondary air injection in eyes with significant graft detachment, as some corneas showed spontaneous clearance or reattachment,[22] presently hardly any eye with a major detachment after the first postoperative week is left untreated, and graft attachment is attempted by a rebubbling procedure.



Follow-up time (years)		0	1	2	3	4	5	6	7	8	9	10
Cumulative survival probability at FU	Estimate	-	0.88	0.86	0.85	0.83	0.83	0.83	0.82	0.80	0.79	0.79
	SE	-	0.04	0.04	0.04	0.04	0.04	0.04	0.04	0.05	0.05	0.05
Cumulative events		0	10	12	13	14	14	14	15	16	17	17
Remaining cases		88	75	70	66	63	59	55	53	51	49	48

FIGURE 3. Kaplan-Meier curve of cumulative graft survival probabilities after DMEK. Survival probabilities and number of eyes at risk per follow-up moments are presented in the table below the graph. At the 1-, 5-, and 10-year follow-up examinations, in total 87, 68, and 57 eyes, respectively, were available for analysis, of which 12, 9, and 9 second operated eyes, respectively, of patients undergoing bilateral DMEK were excluded from the survival analysis. DMEK = Descemet membrane endothelial keratoplasty.

Clinical outcomes in terms of BCVA remained excellent up to 10 years after DMEK, with 89% of the eyes achieving a BCVA of 20/25 or better. These results corroborate findings of previous mid-term studies that the high visual acuity outcomes achieved within the first months after DMEK were also maintained for the longer term (i.e., up to 10 years after DMEK).[12,13,16] Like previously reported 5-year results,[16] no differences in BCVA outcomes at 10 years were observed for eyes with attached grafts and eyes with minor graft detachments, which may indicate that minor detachments do not lead to a deterioration of visual acuity on the longer term.

Interestingly, the observed decrease of 68% in the rate of ECD at 10 years postoperatively corresponds to the ECD decrease observed after Descemet stripping endothelial keratoplasty (67%) and PK (67% to 76%),[21,23,24] even though the observed ECD decline patterns of DMEK and DSEK differ from the one after PK. Of the eyes with an ECD of less than 1,000 cells/mm^2 at 1 year postoperatively (average ECD, 807 cells/mm^2), 6 eyes remained clear, with an average ECD of 707 cells/mm^2, suggesting that these eyes hardly lost any cells after the initial high cell loss and that the endothelial cells in those eyes are still able to maintain the homeostasis regardless of the low cell count. In contrast to earlier studies[14,16] which showed higher ECD in eyes with attached grafts than in eyes with minor detachment, for the current cohort this difference did not reach statistical significance at 10 years after DMEK. This may, as for the BCVA outcomes, be due to the small sample size of eyes with a detachment at the 10-year follow-up.

Allograft rejection and SGF were shown to be the most severe mid-term complications up to 5 years after DMEK.[12,15,16,25] The same holds for the second half of the first decade after DMEK. Until 10 years postoperatively the cumulative allograft rejection rate increased slightly to 4%[12,15,16] but was still lower than the 5-year rejection rates for Descemet stripping (automated) endothelial keratoplasty and PK (5.0%-7.9% and 14%, respectively). The rate of SGF was 6%, and it may be expected that it will become the dominant complication with longer follow-up times and decreasing ECD.

Limitations of this study may be the retrospective design and the increasing number of patient drop-out which could potentially induce selection bias. Specifically, self-selection bias occurs as the patients decide to drop-out nonrandomly due to restricted mobility caused by age and/or health issues. In this study, all drop-outs were due to the patients' own choice to do the follow-ups at their own ophthalmologists (Supplemental Table). Nevertheless, this is the first larger study to report 10-year follow-up after DMEK. It should be noted, however, that survival rates reported by high-volume DMEK centers may not entirely reflect survival rates achieved by lower-volume

DMEK centers, as survival rates tend to increase with surgical experience.

In conclusion, DMEK provides excellent long-term clinical outcomes with low complication rates suggesting that DMEK is a safe treatment option for corneal endothelial diseases. Since these outcomes are based on the first DMEK surgeries worldwide, the long-term prognosis for DMEK eyes operated on nowadays may be even better and should encourage novel DMEK surgeons in their learning curve.

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

Funding/Support: This work was supported by the Rotterdamse Stichting Blindenbelangen and the Landelijke Stichting voor Blinden en Slechtzienden.

Financial disclosures: G.R.J.M. is a consultant for DORC International/Dutch Ophthalmic USA and SurgiCube International. L.B. is a consultant for DORC International. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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