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Descemet membrane endothelial keratoplasty: graft rejection, failure and survival

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PART 1

Graft failure, Graft Survival and Repeat DMEK



CHAPTER 2

10-Year Clinical Outcome of the First Patient Undergoing Descemet Membrane Endothelial Keratoplasty

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ABSTRACT

Purpose: To describe the 10-year clinical outcome of the first patient worldwide who underwent Descemet membrane endothelial keratoplasty (DMEK).

Methods: In 2006, a 63-year-old man presented at the Melles Cornea Clinic, Rotterdam, with bilateral Fuchs endothelial dystrophy and cataract. After phacoemulsification, in vivo DMEK was performed in the left eye and 10 months later in the right eye. Best spectacle-corrected visual acuity (BSCVA), endothelial cell density, pachymetry, and complications were recorded every 6 months over a 10-year period.

Results: BSCVA in the left eye improved from 20/60 (0.3) before surgery to 20/17 (1.2) at 1 month, and remained stable over 10 years, ranging from 20/20 (1.0) to 20/13 (1.5). BSCVA in the right eye improved from 20/50 (0.4) preoperative and 20/60 (0.3) at 1 month to 20/25 (0.8) at 3 months and 20/17 (1.2) at 6 months, ranging from 20/25 (0.8) to 20/17 (1.2) over 9 years. Both eyes underwent YAG-laser-capsulotomy to manage posterior capsule opacification at 5 and 4 years after DMEK, respectively. Endothelial cell density in the right and left eyes, respectively, decreased by 43% and 45% at 1 year, 52% and 59% at 5 years, and 72% and 68% at 10/9 years, respectively. No intraoperative or postoperative complications occurred; at the last follow-up, both corneas were clear.

Conclusions: The first DMEK patient worldwide may show all short and long-term characteristics of this endothelial keratoplasty technique: outstanding patient satisfaction, quick visual recovery, low incidence of complications, and graft longevity. Published studies in the past decade would suggest that this case was the start of a new era in corneal transplantation.

INTRODUCTION

In the past decades, the Netherlands Institute for Innovative Ocular Surgery (NIIOS) has introduced several surgical techniques for the treatment of corneal endothelial disease, now referred to as “deep lamellar endothelial keratoplasty,” “Descemet stripping (automated) endothelial keratoplasty,” and most recently “Descemet membrane endothelial keratoplasty” (DMEK), that is, the selective replacement of Descemet membrane (DM) and its endothelium.¹ The concept of DMEK was first introduced in 1998, and the first patient was operated in 2006.² Since then, DMEK has shown clinical outcomes that may surpass all earlier (endothelial) keratoplasty techniques, with unprecedented visual outcomes and acceptable donor endothelial cell survival.^{3,4} Today, the number of DMEK procedures performed may increase every year,⁵ and the technique may have the potential to soon become the preferred treatment option for endothelial disorders.

The aim of this study was to evaluate the first DMEK case performed, now reaching its 10-year follow-up.

CASE REPORT

In 2006, a 63-year-old Dutch man was referred to the Melles Cornea Clinic Rotterdam because of bilateral cataract and Fuchs endothelial dystrophy with decreasing best spectacle-corrected visual acuity (BSCVA) to 20/50 (0.4) in the right eye and 20/60 (0.3) in the left eye. DMEK was performed in the left eye 6 weeks after phacoemulsification. Ten months after initial DMEK, the same procedures were performed in the right eye. The study was approved by the Institutional Review Board, and the patient signed an Institutional Review Board–approved informed consent form for research participation. The study adhered to the Declaration of Helsinki.

Donor age was 54 and 59 years for the grafts in the patient’s left and right eyes, respectively. From donor globes obtained less than 36 hours postmortem, corneoscleral buttons were excised and stored in organ culture at 31°C. Preoperative donor endothelial cell density (ECD) and viability were evaluated with an inverted light microscope (Axiovert 40; Zeiss, Göttingen, Germany). After 2 weeks of culture, the endothelial cell morphology and viability were evaluated, and the corneoscleral buttons were mounted endothelial side up on a custom-made

holder. After trephination, the DM was stripped from the posterior stroma with microforceps, so that a 9.0-mm diameter DM sheet with its endothelium was obtained.⁶ The DM formed a roll spontaneously, with the endothelium on the outside and was stored in organ culture medium until the time of transplantation.

DMEK was performed as previously described.² With a custom-made scraper (Melles scraper; DORC International, Zuidland, the Netherlands) and/or a reversed Sinsky hook (DORC International), a 9.0-mm descemetorhexis was created under air. After staining with 0.06% trypan blue solution (VisionBlue; DORC International), the DMEK graft was sucked into a Pasteur pipette (Hippocratech, Rotterdam, the Netherlands) and injected through a 3.5-mm limbal tunnel incision into the recipient anterior chamber. The graft was oriented with the endothelial side facing the recipient iris before it was unfolded over the iris and lifted against the recipient posterior stroma by injecting an air bubble underneath the graft. Then, the anterior chamber was filled completely with air for 30 minutes followed by air/fluid exchange.² Peripheral iridotomy was performed before DMEK. Postoperative medication included topical antibiotics and steroids; 1 year after surgery, fluorometholone drops were used twice a week.

The DMEK procedures in both eyes were uneventful and corneas cleared quickly (Figure 1). In the first eye (left eye), BSCVA improved from 20/60 (0.3) before surgery to 20/17 (1.2) at 1 month, and remained stable over 10 years, ranging from 20/20 (1.0) to 20/13 (1.5). In the second eye (right eye), BSCVA improved from 20/50 (0.4) preoperative and 20/60 (0.3) at 1 month to 20/25 (0.8) at 3 months and 20/17 (1.2) at 6 months, ranging from 20/25 (0.8) to 20/17 (1.2) over 9 years. At 5 and 4 years after DMEK, respectively, both eyes underwent YAG-laser-capsulotomy for posterior capsule opacification.

Postoperative ECD was evaluated using a Topcon SP2000p/SP3000p noncontact autofocus specular microscope (Topcon, Tokyo, Japan). ECD of the left eye decreased from 3000 cells/mm² before surgery, to 1680 cells per square millimeter at 1 year, 1450 cells per square millimeter at 5 years, and 820 cells/mm² at 10 years (compared with preoperative values, a decrease of 43%, 52%, and 72%); ECD of the right eye decreased from 2800 cells per square millimeter to 1550 cells/mm² at 1 year, 1150 cells/mm² at 5 years, and 900 cells/mm² at 9 years (a decrease of 45%, 59%, and 68%) (Figure 2). Throughout the follow-up period, central pachymetry values varied within 544 to 567 μ m in both eyes. At the last follow-up, pachymetry measured 550 μ m in the left eye and 553 μ m in the right

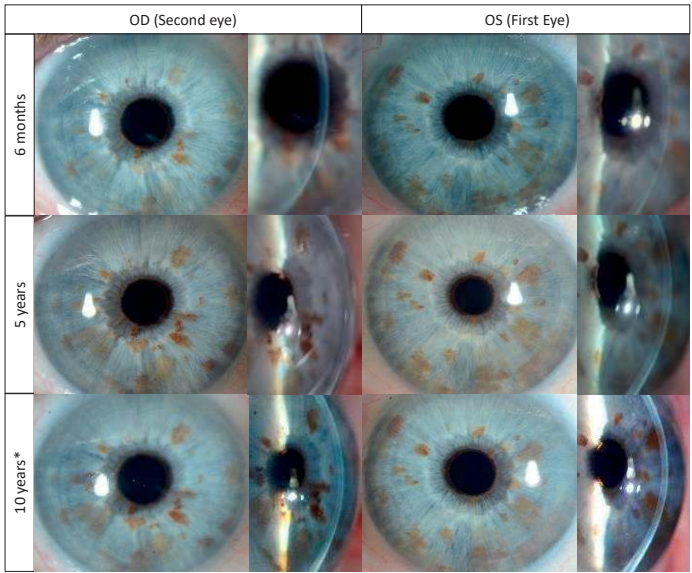


Figure 1. Preoperative and postoperative slit lamp images of the first eye (left eye) and second fellow eye (right eye) operated on with DMEK, throughout the 10-year follow-up period. *Follow-up period for the second eye (right eye) is 9 years.

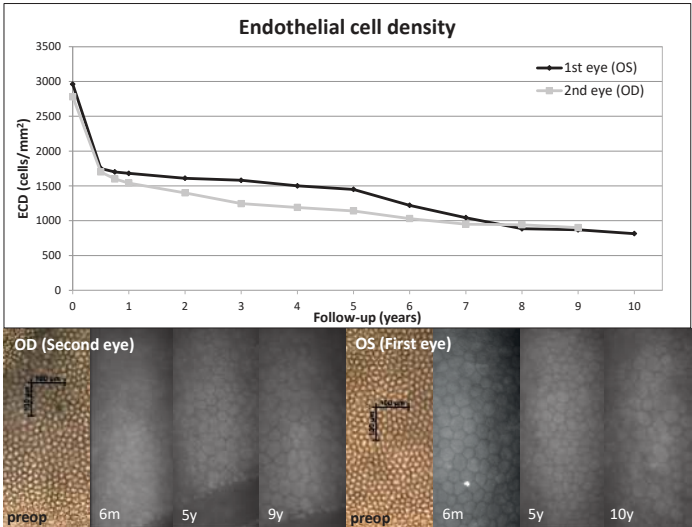


Figure 2. Graph (upper row) displaying the endothelial cell density decrease and preoperative (preop) and postoperative specular microscopy images (lower row) of the first eye (left eye) and second eye (right eye) operated on with DMEK, throughout the 10-year follow-up period.

eye, and both corneas were clear (Figure 1). No intraoperative or postoperative complications occurred throughout the follow-up period.

DISCUSSION

The first patient worldwide operated on with DMEK showed excellent clinical outcomes up to 10 years postoperatively, which may reflect the potential of the technique for the entire DMEK cohort so far. In both eyes, BSCVA quickly recovered to its full visual potential within the first months, which agrees with the majority of DMEK cases reaching $\geq 20/25$ (≥ 0.8) at 6 months.³ ECD showed a decrease of about 70% compared with preoperative values, similar to 10-year Descemet stripping endothelial keratoplasty eyes.⁷

This first DMEK case may also be indicative for the long-term graft survival after DMEK exceeding 90% at 8 years,⁴ which may in part be explained by the lack of complications associated with the procedure: suture-related and wound-healing problems were eliminated, the incidence of allograft rejection may be reduced to 1% to 2%, and the risk of glaucoma and/or other concurrent pathology may be minimized.^{1-4,8,9}

Given the unprecedented clinical outcomes and extraordinary patient satisfaction, DMEK may have the potential to be adopted as the next preferred treatment option for corneal endothelial disorders. Techniques for DMEK graft preparation and surgery have evolved into standardized “no-touch” procedures allowing step-by-step performance to shorten the learning curve. Furthermore, the possibility of obtaining pre-cut tissue from specialized eye banks may have made it easier for surgeons to start out with this new surgical technique.

After 10 years of performing DMEK, we may have entered a new era of corneal transplantation. Modifications of the DMEK technique such as hemi-DMEK and quarter-DMEK, by which multiple grafts could be recovered from one single donor cornea, may soon allow for far more efficient use of donor corneal tissue to balance the increasing demand for corneal transplants worldwide.¹⁰

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