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Comparison of Sulfur Hexafluoride 20% versus Air Tamponade in Descemet Membrane Endothelial Keratoplasty

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Purpose: To compare clinical outcomes using 20% sulfur hexafluoride (SF_6) versus 100% air as a tamponade for graft attachment in Descemet membrane endothelial keratoplasty (DMEK).

Design: Retrospective, comparative, interventional case series.

Participants: Pseudophakic patients with Fuchs' endothelial dystrophy or pseudophakic bullous keratopathy that underwent DMEK using either 20% SF_6 (group 1; 42 eyes) or 100% air (group 2; 39 eyes) tamponade between April 2010 and August 2011.

Methods: A bimanual infusion technique was used to introduce and position the donor endothelium–Descemet membrane graft tissue. Outcome measures were analyzed at the following time points: before surgery, 3 and 6 months after surgery, and at yearly intervals up to at least 3 years.

Main Outcome Measures: Corrected distance visual acuity (CDVA), manifest refraction, pachymetry, central endothelial cell count (cECC), complications, and rebubbling rates.

Results: Three years after surgery, mean CDVA improved from 0.48±0.45 logarithm of the minimum angle of resolution (logMAR) to 0.04±0.23 in group 1 ($P < 0.001$) and from 0.67±0.45 logMAR to 0.09±0.13 logMAR in group 2 ($P < 0.001$). The percentage of eyes with CDVA of 20/25 or more was 85.71% (36/42 eyes) in group 1 and 82.05% (32/39 eyes) in group 2 ($P = 0.43$). Mean preoperative cECCs and at last follow-up were: group 1, 2525±338 cells/mm^2 and 1758 ± 398 cells/mm^2 (mean cell loss, 30±11%; $P = 0.008$); and group 2, 2492±204 cells/mm^2 and 1678±373 cells/mm^2 (mean cell loss, 32±13%; $P = 0.008$). Endothelial cell loss was similar in both groups ($P = 0.65$). Intracameral air reinjection was needed in 1 patient in group 1 (2.38%) and in 5 patients in group 2 (12.8%). The rebubbling rate was significantly higher in group 2 ($P = 0.004$). No episodes of immunologic graft rejection were documented.

Conclusions: Although clinical outcomes and corneal endothelial cell loss were similar in both groups, tamponade with 20% SF_6 yielded a significantly lower incidence of graft detachments that may warrant its routine use in DMEK. Longer-term, randomized studies are needed to recommend this approach fully. *Ophthalmology 2015;122:1757-1764 © 2015 by the American Academy of Ophthalmology.*

Supplemental material is available at www.aaojournal.org.

Endothelial keratoplasty quickly has become the standard of care in the treatment of visually significant corneal endothelial disease.[1–3] Compared with other endothelial keratoplasty techniques, Descemet membrane endothelial keratoplasty (DMEK) has demonstrated its superiority in terms of visual outcome, visual recovery period, induction of posterior corneal high-order aberrations and visual distortions, and risk of immunologic graft rejection.[4–9]

The main complication of DMEK surgery is incomplete attachment of the graft in the early postoperative course.[10] Early experience with DMEK yielded air reinjection rates ranging from 50% to 77%.[6,11,12] Further refinements in surgical technique have decreased the need for repeat air reinjection to between 0% and 20%, depending on the series.[13–15]

Most cases of endothelium–Descemet membrane (EDM) graft detachment occur in the early postoperative period (24–72 hours after surgery). Therefore, achieving tamponade with a longer-lasting agent (e.g., 20% sulfur hexafluoride [SF_6] instead of 100% air) during this critical period could decrease the need for air reinjections and consequently could avoid further endothelial damage and other complications. In a pilot study including 15 pseudophakic eyes undergoing DMEK with 20% SF_6 as tamponade, we observed a reinjection rate of 6.6%. This rate seemed lower than our previous experience using air as tamponade.[16] However, safety concerns about the toxicity over the corneal endothelium remain.[17] The purpose of this study was to compare clinical outcomes and corneal endothelial cell survival after DMEK using 20% SF_6 versus 100% air to tamponade the donor graft.

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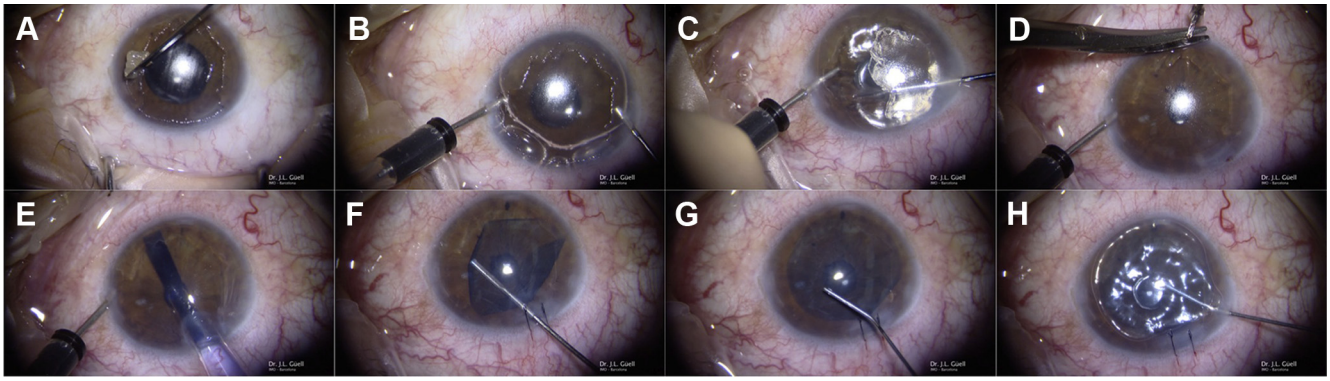

Figure 1. Photographs showing the surgical procedure. **A**, Corneal epithelium is removed. **B**, A 25-gauge beveled tip infusion cannula is inserted through a paracentesis, and the anterior chamber (AC) is filled with air at 20 mmHg of intraocular pressure. **C**, A central, 9-mm descemetorhexis is performed with a reversed Sinskey hook, and the recipient's Descemet membrane is removed through the 2.4-mm clear corneal incision. **D**, Inferior iridectomy using vitreoretinal forceps. **E**, The endothelium–Descemet membrane (EDM) roll is injected into the AC. **F**, The main incision is closed with 2 interrupted 10-0 nylon sutures. A Gills cannula is introduced with low-irrigation fluid flow. **G**, The EDM graft is positioned. **H**, Tamponade is achieved by injecting 20% sulfur hexafluoride gas.

Methods

Patients and Donor Selection

This was a retrospective chart review of consecutive patients undergoing DMEK between April 2010 and August 2011. All surgeries were performed by the same surgeon (J.L.G.) at the Instituto de Microcirugia Ocular, Barcelona, Spain. All patients were fully informed of the details and possible risks of the procedure. Written informed consent was obtained for both treatment and participation in the study. The study was conducted in accordance with the Institution's Good Clinical Practices and the Declaration of Helsinki. Institutional Review Board approval was obtained.

Inclusion criteria were: (1) pseudophakic patients who underwent DMEK for Fuchs' endothelial dystrophy or pseudophakic bullous keratopathy (PBK) and received either 20% SF_6 or 100% air tamponade for graft attachment; (2) absence of any history of ocular surgery other than cataract surgery; (3) uncomplicated cataract surgery; (4) good visual prognosis; (5) ability to comply with postoperative follow-up regimen; and (6) a minimum follow-up of at least 3 years. Exclusion criteria were: (1) presence of significant pre-existing ocular comorbidities that hampered visual prognosis; (2) history of complicated cataract surgery; (3) inability to comply with postoperative follow-up regimen; and (4) follow-up of fewer than 3 years. The first 60 DMEK surgeries performed by the surgeon (J.L.G.) were excluded from the analysis to reduce the risk of bias induced by the learning curve. The second eyes of the same patient also were excluded. Patients were not randomized to receive either 100% air (in 1 case) or 20% SF_6 (in the next case), which were alternatively injected in consecutive eyes for a number of months, but without preoperative randomization.

All corneas were screened for viability at a slit lamp and specular microscope immediately after procurement. Fresh corneas were stored in short-term culture in Eusol-C (Alchimia, Padova, Italy) at 4° C for a maximum of 7 days. Endothelial cell counts were obtained by specular microscopy. Organ culture allowed preservation of viable corneas for 1 month and consisted of: (1) storage in short-term culture in Eusol-C at 4°C; (2) organ culture in CorneaMax Medium (Eurobio, Cedex, France) at 31°C in an aerobic environment for 3 weeks; and (3) storage in a hyperosmolar deswelling medium containing 5% dextran T500 for 6 days before implantation (CorneaJet, Eurobio, Cedex, France). Endothelial cell counts were obtained by bright-field microscopy with trypan blue 0.06% (Vision Blue; DORC, Zuidland, The Netherlands) staining before storage in the deswelling medium. As far as donor selection is concerned, donors of all ages and both fresh and organ-cultured corneas were accepted.

Surgical Technique

The surgical technique (Fig 1; Video 1, available at www.aaojournal.org) has been described previously elsewhere and is summarized briefly herein.[16]

Donor Preparation

Donor EDM grafts were prepared using the stepwise technique of Kruse et al.[18] Briefly, the corneal–scleral button was mounted onto an 8-mm Barron Vacuum Corneal Punch (Katena, Inc., Denville, NJ), marked, and stained with trypan blue 0.06%. A narrow strip of peripheral EDM was removed approximately 1 to 1.5 mm outside the 8-mm mark using a 45° blade (Alcon Laboratories, Inc, Fort Worth, TX). The central margin then was lifted with a 45° blade and peeled off using Guell's DMEK nontoothed forceps (AE 4210; Asico LLC, Westmond, IL). The EDM was cut with an 8-mm punch, and the EDM graft was removed with Guell's DMEK forceps. Finally, the EDM lenticula additionally was stained with trypan blue 0.06% and introduced into a 1.8-mm injector cartridge (Medicell-viscoJECT; Medicell AG, Wolfhalden, Switzerland) fully filled with balanced salt solution (Alcon Laboratories, Inc) and a small air bubble in the rear part of the EDM roll. Viscoelastic was not used to avoid difficulty in achieving attachment of the EDM graft.

Recipient Preparation

Under retrobulbar anaesthesia, 2 lateral 25-gauge paracenteses were created at 3 and 9 o'clock. Through the paracentesis located on the left hand side, a 25-gauge beveled tip infusion cannula (Alcon Laboratories, Inc) was inserted. A central 9- to 10-mm descemetorhexis was performed under air (infusion pressure of 20 mmHg) with a reversed Sinskey hook (Price Endothelial Keratoplasty Hook; Moria SA, Antony, France) introduced through the other paracentesis. The recipient's descemetorhexis should have a diameter approximately 1 mm larger than the donor to avoid overlapping as much as possible. The recipient's DM was removed through a superior, 2.4-mm clear corneal incision. All patients