Clinical Outcomes in Descemet Stripping Automated Endothelial Keratoplasty With Internationally Shipped Precut Donor Corneas

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• PURPOSE: **To report the endothelial cell loss and clinical outcomes in Descemet stripping automated endothelial keratoplasty (DSAEK) with internationally shipped, precut donor corneas.**

• DESIGN: **Retrospective analysis of a noncomparative case series.**

• METHODS: **The setting was a single hospital. The clinical results of 134 eyes of 128 patients who underwent DSAEK in Kyoto, Japan, with internationally shipped precut donor corneas from Portland, Oregon, or Seattle, Washington, were evaluated. In addition, 40 precut donor corneas from Seattle were evaluated in respect to the postprecut international shipment-related loss of corneal endothelial cell density (ECD). Observation procedures were noncontact specular microscopy. The main outcome measures were the evaluation of international shipment-related ECD loss, postoperative ECD, visual recovery, and complications.**

• RESULTS: **The mean postprecut ECD loss in 40 donor corneas during international shipment was 2.3%. The mean elapsed time from cut to surgery was 63.2 ± 31.1 hours. At 6, 12, 24, and 36 months postoperatively, the mean ECD of the internationally shipped donor corneas was 2038, 1933, 1670, and 1431 cells/mm^2, respectively. The mean ECD loss at 6, 12, 24, 36 months after DSAEK was 30%, 34%, 44%, and 51%, respectively. Preoperative logarithm of the minimum angle of resolution (logMAR) best spectacle-corrected visual acuity was 1.40 ± 0.55, and at 12 months after DSAEK was 0.22 ± 0.19. Complications included graft dislocation in 12 eyes (8.9%) and graft rejection in 3 eyes (2.2%).**

• CONCLUSIONS: **The present study shows that the outcomes of DSAEK with internationally shipped precut donor corneas were acceptable and that the additional endothelial cell loss associated with international shipment was minimal and did not affect the clinical results.**

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DESCEMET STRIPPING AUTOMATED ENDOTHELIAL keratoplasty (DSAEK)[1,2] is the first-choice method for the treatment of bullous keratopathy, and precut donor corneas for this surgical procedure are provided by a variety of eye banks worldwide. DSAEK provides more rapid postoperative visual recovery, minimizes induced astigmatism, and retains the structural strength of the eye better than standard penetrating keratoplasty (PKP).[2,3]

Sufficient endothelial cell and graft survival following PKP performed with internationally shipped donor corneas have been demonstrated.[4–7] In the United States, the clinical outcomes and safety of performing DSAEK with precut donor corneas have been reported.[8–10] However, there has yet to be a report regarding the safety and clinical outcomes of DSAEK performed with internationally shipped, precut donor corneas.

The microkeratome resection of corneas is performed at eye banks, and the precut donor corneas are then often shipped internationally via air transport. In corneal transplant cases in which a domestic precut donor cornea is used, the elapsed time between the microkeratome resection and the actual surgery is usually quite short. However, when precut donor corneas are obtained by a surgeon from an overseas eye bank, the elapsed time between the cut and the surgery is longer because of the additional time required for shipment. Thus, there are concerns about graft survival associated with internationally shipped tissue due to the potential loss of corneal endothelial cell density (ECD) and viability resulting from the elongated precut-to-surgery time, the preservation medium that is used for shipment, and other shipment-associated problems. The purpose of the present study was to investigate the clinical outcomes of performing DSAEK with internationally shipped, precut donor corneas.

METHODS

THIS STUDY WAS A RETROSPECTIVE ANALYSIS OF A noncomparative case series. The study was conducted in accordance with the tenets set forth in the Declaration of Helsinki. This retrospective chart review was approved by the Institutional Review Board of Kyoto Prefectural

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University of Medicine. Informed consent for DSAEK with internationally shipped precut donor corneas was obtained from all patients.

The present study was composed of 2 separate investigations. The first investigation determined the postprecut shipment-related loss of ECD in 40 internationally shipped, precut donor corneas sent from SightLife in Seattle, Washington, and received at the Department of Ophthalmology, Kyoto Prefectural University of Medicine, Kyoto, Japan between November 2010 and October 2011. The postprecut shipment-related loss of ECD was evaluated by specular microscopy just prior to surgery. The second investigation examined the 3-year clinical outcomes of DSAEK performed with internationally shipped, precut donor corneas in 134 eyes of 128 patients who underwent DSAEK at the University Hospital of Kyoto Prefectural University of Medicine between August 2007 and August 2010. All patients who underwent DSAEK for endothelial dysfunction during the study period were included in the study and analyzed retrospectively.

The mean patient age at the time of surgery was 72.2 ± 10.9 years (range, 34–88 years). Of the 134 treated eyes, 68 (51%) were female eyes and 66 (49%) were male eyes. The indications for DSAEK were argon laser iridotomy-induced bullous keratopathy (ALI-BK) in 47 eyes (35%); pseudophakic BK in 24 eyes (18%); glaucoma surgery–related BK in 24 eyes (18%); Fuchs corneal dystrophy in 17 eyes (13%); graft failure following PKP in 5 eyes (4%); aphakic BK in 3 eyes (2%); BK following posterior and anterior keratectomy in 3 eyes (2%); and other causes in 11 eyes (8%). Preoperative lens status was phakia in 47 eyes (35%); pseudophakia in 84 eyes (63%); and aphakia in 3 eyes (2%).

• **DONOR CORNEAS AND INTERNATIONAL SHIPMENT:** All precut donor corneas were provided by SightLife Eye Bank (Seattle, WA) and Lions VisionGift (Portland, OR). Each donor cornea was precut with a Carriazo Barraquer (CB) microkeratome (Moria; Antony, France) by the cornea providers. The corneas were transported as corneoscleral buttons housed within corneal viewing chambers (Krolman; Boston, MA) filled with preservation medium (Optisol GS; Bausch & Lomb, Rochester, NY). Each cornea was placed in a soft foam block to prevent excessive movement and sealed in a zip-lock plastic bag to prevent any moisture damage. The sealed foam blocks were placed into generic, thick-walled, expanded polystyrene foam shipping containers. The containers had tight-fitting lid plugs and a cardboard shell for thermal efficiency. The packaged corneas were first flown from Seattle-Tacoma Airport (Seattle, WA) to Narita Airport (Tokyo, Japan) and then transferred to the University Hospital at Kyoto Prefectural University of Medicine via overland freight transport. The flight between the United States and Narita took approximately 10–11 hours, and the subsequent overland freight transportation took approximately 7 hours. Throughout the entire shipment process (ie, both air and overland transport), the containers were maintained at 2°C–8°C in validated shipping containers. After delivery, each donor cornea was inspected by specular microscopy prior to keratoplasty.

• **SURGICAL TECHNIQUE:** Four surgeons performed DSAEK. The patients received either general or local anesthesia. Descemet membrane stripping was performed by using the reverse Sinskey hook. A 4–5 mm temporal corneal incision was created by using a 3.5 mm-wide slit knife (MANI, Tochigi, Japan) for graft insertion. The precut donor cornea was then trepanned and placed on a Busin glide spatula (MORIA, Doylestown, PA), and the endothelial side of the graft was protected by an application of a small amount of viscoelastic material. Next, the graft on a Busin glide was pulled through into the anterior chamber by using 23G gripping forceps for DSAEK (FR2271) (M.E. Technica, Tokyo, Japan) and then opened by irrigation and adjusted to the center. An air bubble was then injected into the anterior chamber for 10 minutes to promote graft attachment. The air bubble was then reduced to prevent a pupillary block.

• **POSTOPERATIVE MANAGEMENT:** Following DSAEK, each patient received a systemic dose of 4 mg betamethasone for 3 days, followed by 1 mg betamethasone for 4 days and the topical application of 0.3% gatifloxacin and 0.1% betamethasone eyedrops 4 times daily for 6 months. In each patient, this was followed by 0.1% fluorometholone 4 times daily. Steroid-responsive ocular hypertensive patients received intraocular pressure-lowering agents, and the 0.1% betamethasone was replaced with 0.1% fluorometholone.

• **CLINICAL EVALUATION:** For the clinical evaluation, best spectacle-corrected visual acuity (BSCVA) and ECD were measured. Specular microscopy of the donor cornea tissue was first performed by eye-bank technicians in the United States prior to the corneas' being shipped to Japan. The ECD before and after precutting was evaluated by using the variable frame method of cell counting with specular microscopy (EB-2000xyz; HAI Labs, Lexington, MA). The ECD of each precut donor cornea was measured just prior to surgery by use of the center method with specular microscopy (EKA-10; Konan Medical, Nishinomiya, Japan). Postoperative measurements of ECD were obtained by noncontact specular microscopy (EM-3000; TOMEY, Nagoya, Japan) at 1, 6, 12, 24, and 36 months after surgery.

• **STATISTICAL ANALYSES:** Results are expressed as mean ± SD. BSCVA was converted to logMAR to allow for averaging and statistical analysis. The Mann-Whitney U test and the Wilcoxon Kruskal-Wallis test were used for statistical analyses of the nonparametric data. Statistical significance was defined as $P < 0.05$. All statistical analyses