American Academy of Ophthalmology
The Eye M.D. Association

Vision-related Quality of Life Before and After Keratoplasty for Fuchs' Endothelial Dystrophy

Eleanor R. Trousdale, BS,[1] *David O. Hodge, MS,*[2] *Keith H. Baratz, MD,*[1] *Leo J. Maguire, MD,*[1] *William M. Bourne, MD,*[1] *Sanjay V. Patel, MD*[1]

Purpose: To assess vision-related quality of life in Fuchs' dystrophy and changes in vision-related quality of life after 3 types of keratoplasty (penetrating keratoplasty [PK], deep lamellar endothelial keratoplasty [DLEK], and Descemet stripping endothelial keratoplasty [DSEK]).

Design: Prospective, observational case series.

Participants: Sixty-three subjects with Fuchs' endothelial dystrophy: 12 subjects (12 eyes) received PK, 11 subjects (11 eyes) received DLEK, and 40 subjects (40 eyes) received DSEK.

Methods: Subjects were examined before keratoplasty and at regular intervals through 3 years after keratoplasty. At each examination, vision-related quality of life was assessed using the 25-item National Eye Institute Visual Functioning Questionnaire; best spectacle-corrected and uncorrected visual acuities were measured by using the electronic Early Treatment of Diabetic Retinopathy Study protocol; keratometric cylinder was measured by a manual keratometer. Disability glare was measured with a straylight meter.

Main Outcome Measures: Vision-related quality of life composite score.

Results: Vision-related quality of life composite score for all eyes with Fuchs' dystrophy before keratoplasty was 72±11 (n = 63) and did not differ between groups ($P = 0.88$). Vision-related quality of life improved by 6 months (PK, $P = 0.008$; DLEK, $P = 0.03$; DSEK, $P < 0.001$), with continued improvement between 6 months and 3 years after PK ($P = 0.01$) and DSEK ($P = 0.004$). At 6 months, the composite score was higher after DSEK than after PK ($P = 0.006$). At 3 years, there were no differences in composite scores between the 3 treatments ($P = 0.33$; mean minimum detectable difference, 8 [$\alpha = 0.05$; $\beta = 0.20$]). After keratoplasty, quality of life was correlated with uncorrected visual acuity at 1 year ($r = -0.38$; $P = 0.001$) and at 3 years ($r = -0.36$; $P = 0.02$), with disability glare at 3 years ($r = -0.41$; $P = 0.02$), and with best-corrected visual acuity at 6 months ($r = -0.34$; $P = 0.03$), but not thereafter.

Conclusions: Vision-related quality of life in patients with Fuchs' endothelial dystrophy is significantly impaired but improves after keratoplasty, irrespective of the technique. The improvement is faster after DSEK than after PK, and this might be explained in part by rapid improvement in uncorrected visual acuity after DSEK. This study affirms an advantage of endothelial keratoplasty over PK with respect to patient-reported outcomes. *Ophthalmology 2014;121:2147-2152 © 2014 by the American Academy of Ophthalmology.*

Corneal transplantation techniques for the treatment of endothelial diseases have rapidly evolved over the last 15 years from full-thickness penetrating keratoplasty (PK) to a variety of partial-thickness endothelial keratoplasty (EK) procedures.[1,2] The rapid adoption of EK by corneal surgeons can be explained by simpler postoperative management, including lack of suture removal and suture-associated complications, a predictable postoperative refractive error, and a tectonically stronger globe. Although there are no randomized controlled trials comparing Descemet-stripping endothelial keratoplasty (DSEK) and PK to definitively establish whether DSEK results in better vision and graft survival, and despite many patients being unable to attain a visual acuity of 20/20 after DSEK,[3] DSEK has become the procedure of choice for corneal endothelial disease.[4] Although the management advantages of DSEK over PK from the surgeon's perspective are well known, little is known about the impact of EK on patient-reported outcomes.

The goal of this study was to determine vision-related quality of life after 3 different keratoplasty techniques (PK, deep lamellar endothelial keratoplasty [DLEK], and DSEK) for Fuchs' dystrophy. Because all subjects had Fuchs' endothelial dystrophy, we were also able to establish vision-related quality of life in this disease before surgical intervention.

Methods

Subjects

All subjects were patients requiring their first keratoplasty in either eye because of decreased vision caused by Fuchs' endothelial dystrophy and were recruited from the cornea service at Mayo Clinic, Rochester, Minnesota. Fuchs' dystrophy was defined as the presence of guttae with or without clinically definite stromal edema on slit-lamp biomicroscopy.[5] Subjects were enrolled to 2 consecutive prospective studies. In the first study, subjects were randomized to PK or DLEK between 2004 and 2006 and examined prospectively

http://dx.doi.org/10.1016/j.ophtha.2014.04.046
ISSN 0161-6420/14

through 3 years after surgery[6]; entrance best-corrected visual acuity was ≤20/40 (Snellen equivalent), and only subjects with a recipient diagnosis of Fuchs' dystrophy were included for this analysis. In the second study, subjects with Fuchs' dystrophy were prospectively examined through 3 years after DSEK[7–9]; enrollment was between 2006 and 2009, and there was no entrance visual acuity criterion. In both studies, subjects were excluded if they had significant central corneal scarring, glaucoma or previous glaucoma surgery, a history of other corneal disease, or any comorbidity affecting visual acuity, including maculopathy, optic neuropathy, and amblyopia. All eyes were either pseudophakic or had lenticular changes requiring cataract extraction at the time of keratoplasty.

Both studies were prospectively approved by the Mayo Clinic Institutional Review Board, and informed consent was obtained from all subjects. The randomized clinical trial[6] was registered at www.clinicaltrials.gov (NCT00346138).

Operative Procedure

The operative procedures and postoperative treatment regimens have been described previously.[6,9] Briefly, PK was performed with a recipient diameter of 7.5 or 7.75 mm (mean, 7.55 mm), with the donor secured to the host using a double-running suture technique. We performed DLEK through a 9- to 10-mm scleral tunnel incision that was initiated at a depth of 350 μm. We performed DSEK through a 5- to 6-mm temporal scleral tunnel incision and inserted the donor by using a folding technique. For phakic eyes, simultaneous cataract extraction and intraocular lens insertion were performed using an open-sky technique for PK and using phacoemulsification for DLEK and DSEK. Postoperatively, all eyes were treated with a topical antibiotic for 7 days or until epithelialization was complete and with topical prednisolone acetate 1% 4 times daily, typically tapering to once daily by 3 to 6 months postoperative.

Vision-related Quality of Life

Vision-related quality of life was assessed using the 25-item National Eye Institute Visual Functioning Questionnaire (NEI-VFQ-25).[10] Questionnaires were self-administered or administered by an interviewer when necessary. The composite score was the primary outcome and was scaled from 0 to 100. Subscales were also scored from 0 to 100, with 100 being the best possible score and 0 being the worst score; subscale scores were calculated only if a patient answered all questions within a subscale. Questionnaires were administered before and at 6, 12, 24, and 36 months after keratoplasty.

Other Outcome Measures

Best spectacle-corrected and uncorrected visual acuities were measured using the standardized electronic Early Treatment of Diabetic Retinopathy Study protocol.[11] Keratometric cylinder was measured by manual keratometry (Bausch & Lomb, Rochester, NY). Disability glare, which is largely explained by intraocular forward light scatter,[12] was measured using a straylight meter (C-Quant, Oculus, Lynwood, WA).[9,13]

Statistical Analysis

The primary outcome was the improvement in composite score of the NEI-VFQ-25 after keratoplasty. Comparisons of scores across time periods within each group were completed using paired *t* tests. Initial comparisons of those scores among the 3 groups were completed using analysis of variance. Significant differences were investigated using the Student-Newman-Keuls procedure to adjust for multiple comparisons. Linear regression models were used to investigate the comparisons, adjusting for subject age, sex, visual acuity of the fellow eye and for events before a particular examination. Correlations between quality of life and vision were assessed using Pearson correlation coefficients after confirming that the data were parametric.

Results

Subjects

Sixty-three subjects were enrolled; 12 subjects received PK, 11 subjects received DLEK, and 40 subjects received DSEK. Recipient age, sex, lenticular status, and visual acuity of the fellow eye were similar between groups (Table 1). At 6 months, 62 subjects completed follow-up (PK, 12 subjects; DLEK, 11 subjects; DSEK, 39 subjects); at 1 year, 57 subjects completed follow-up (PK, 12 subjects; DLEK, 10 subjects; DSEK, 35 subjects); at 2 years, 51 subjects completed follow-up (PK, 12 subjects; DLEK, 10 subjects; DSEK, 29 subjects); and at 3 years, 44 subjects completed follow-up (PK, 12 subjects; DLEK, 11 subjects; DSEK, 21 subjects).

During the 3-year follow-up period, the fellow eye of 10 subjects underwent keratoplasty. In the PK group, the fellow eye of 2 subjects underwent DSEK at 25 and 29 months after the first eye was operated. In the DLEK group, the fellow eye of 1 subject underwent DSEK 29 months after the first eye was operated. In the

Table 1. Demographic Data of Enrolled Subjects (n = 63)

Variable	PK (n = 12)	DLEK (n = 11)	DSEK (n = 40)
Age (y)			
Mean ± SD	73±7	75±8	67±10
Range	62–86	56–85	41–87
Sex (%)			
Female	83	73	78
Male	17	27	22
Preoperative lenticular status, n (%)			
Phakic	7 (58)	4 (36)	25 (63)
Intraocular lens	5 (42)	7 (64)	15 (37)
Visual acuity of fellow eye, log MAR (Snellen equivalent)			
Mean ± SD	0.37±0.22 (20/47)	0.30±0.21 (20/40)	0.31±0.30 (20/41)
Range	0.04–0.74 (20/22–20/110)	0.10–0.64 (20/25–20/87)	−0.04 to 1.7 (20/18–20/1000)

DLEK = deep lamellar endothelial keratoplasty; DSEK = Descemet-stripping endothelial keratoplasty; logMAR = logarithm of the minimum angle of resolution; PK = penetrating keratoplasty; SD = standard deviation.
There were no differences between the treatment groups.