

# Patient-Reported Outcomes After Corneal Transplantation

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**Purpose:** To characterize vision-related quality of life after penetrating keratoplasty (PKP), deep anterior lamellar keratoplasty (DALK), Descemet stripping automated endothelial keratoplasty (DSAEK), and Descemet membrane endothelial keratoplasty (DMEK) using the National Eye Institute Visual Function Questionnaire (NEI-VFQ 9).

**Methods:** Using the Sight Outcomes Research Collaborative ophthalmology electronic health record repository, questionnaire responses were obtained from 103 PKP patients, 24 DALK patients, 42 DSAEK patients, and 50 DMEK patients undergoing post-operative examination. No exclusions were made based on pre-operative diagnosis, age, complications, or comorbidities. Associations between clinical characteristics and vision-related quality of life were analyzed using nonparametric and linear regression methods.

**Results:** Patients were surveyed an average of 1.5 years post-operatively (range 24 d to 4.4 yrs). Participants who had undergone DALK, DMEK, DSAEK, and PKP had median composite VFQ scores of 77.8, 84.2, 76.1, and 70.6, respectively ( $P = 0.002$ ). There were no significant differences in VFQ scores between patients treated with DMEK versus DSAEK ( $P = 0.440$ ) or between patients treated with PKP versus DALK ( $P = 1.000$ ). Higher postoperative acuities in the operative and fellow eyes were associated with higher VFQ scores ( $P < 0.001$  and  $P < 0.001$ ). When controlling for postoperative acuity by regression modeling, surgery type was not associated with patient-reported composite VFQ scores.

**Conclusions:** In this study, patient-reported vision-related quality of life was similar among DMEK and DSAEK participants and also among DALK and PKP participants. When controlling for post-operative acuity, vision-related quality of life was similar among all study participants, irrespective of the keratoplasty technique.

**Key Words:** corneal transplantation, patient-reported outcomes, vision-related quality of life

(*Cornea* 2021;40:1316–1321)

Corneal transplantation techniques have undergone considerable evolution over the past 20 years. Innovations in surgical technique and advancements in eye bank tissue processing have led to a greater variety of keratoplasty techniques, yielding improved visual results and faster recovery times. Metrics for evaluating postoperative outcomes have historically focused on conventional measures, including visual acuity (VA), astigmatism, graft clarity, endothelial cell density, and complication profile. However, there is a relative paucity of literature describing patient-reported outcomes (PROs) after corneal transplantation—how transplants affect everyday visual function and quality of life.

There is increasing recognition that traditionally reported clinical measures do not adequately capture the patient experience.<sup>1–3</sup> The metrics for determining the efficacy and success of a given treatment are expanding to acknowledge the patient experience, with greater emphasis on patient attitudes and perceived quality of life.<sup>2</sup> The National Eye Institute Visual Function Questionnaire (NEI-VFQ) was originally designed as a 51-item survey to assess the impact of common eye diseases on vision-related quality of life.<sup>4</sup> Although comprehensive, the length of the original survey challenges its feasibility in clinical and research settings. Responding to the need for shorter questionnaires, the developers of the original survey subsequently created a 25-item questionnaire, the NEI-VFQ 25,<sup>5</sup> and a 9-item questionnaire, the NEI-VFQ 9.<sup>6</sup> At our institution, the VFQ-9 was an executable PRO measure to administer to clinical patients.

The purpose of this study was to characterize vision-related quality of life among corneal transplant recipients based on their responses to the NEI-VFQ 9. The perspectives of patients who had undergone penetrating keratoplasty (PKP), deep anterior lamellar keratoplasty (DALK), Descemet stripping automated endothelial keratoplasty (DSAEK), and Descemet membrane endothelial keratoplasty (DMEK) were compared. In addition, relationships between patient-reported NEI-VFQ 9 scores and in-office conventional clinical outcome measures were examined.

Received for publication August 19, 2020; revision received January 6, 2021; accepted January 11, 2021. Published online ahead of print March 5, 2021.

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Supported by a Grant to the Department of Ophthalmology and Visual Sciences from Eversight.

G. E. Dunbar reported receiving a grant from Eversight. M. A. Woodward reported receiving grants from National Institutes of Health (NIH-1R01EY031033) and the Michigan Institute for Clinical & Health Research (MICHR). The remaining authors have no conflicts of interest to disclose.

Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site ([www.corneajrnl.com](http://www.corneajrnl.com)).

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## MATERIALS AND METHODS

### Study Population

This cross-sectional cohort study examined the electronic health record data of patients in the Sight Outcomes Research Collaborative Ophthalmology Data Repository. The database contains patient demographic and clinical information; International Classification of Diseases, Ninth Revision and 10th Revision (ICD-9 and ICD-10) diagnosis codes; service dates for all clinical and operative encounters; and Current Procedural Terminology codes. We identified individuals who had undergone keratoplasty (Current Procedural Terminology 65710, 65730, 65750, 65755, and 65756) with the cornea section at the University of Michigan, Ann Arbor, Michigan, between July 2014 and July 2019. Consecutive patients who had undergone PKP, DALK, DSAEK, or DMEK were eligible for study participation if they were at least 18 years of age and had completed a NEI-VFQ 9 at a postoperative clinical examination (hereafter referred to as VFQ). No exclusions were made based on preoperative diagnosis, postoperative complications, or visual comorbidities. The ICD code of graft rejection was also queried for a subgroup analysis (ICD T86.840). The study was approved by the University of Michigan Institutional Review Board.

### Assessment of Visual Function

At the institution, all patients are given the VFQ at the time of a clinical encounter approximately once per year. In rare cases, a physician may assign the VFQ although this is not standard practice. Patients self-administer the questionnaire. The survey includes questions on general vision, near vision, distance vision, driving, peripheral vision, role limitation, and well-being/mental health (published survey accessed at DOI: 10.1016/j.ajo.2009.09.008, PMID: 20103058). The VFQ was annually administered to all patients evaluated by the cornea section during routine exams, including corneal transplant recipients. This study analyzed surveys completed by corneal transplant recipients at postoperative clinical visits. In the event that an individual completed the VFQ survey at multiple clinical visits, the questionnaire closest to the date of surgery was included in the study analysis.

### Primary and Secondary Outcomes

The study's primary outcome was the composite NEI-VFQ 9 score. The composite score was a mean of the 9 individual item scores or a mean of 8 items if a patient reported that they did not drive because of reasons other than their eyesight. The composite score ranged from 0 as the worst possible questionnaire score (poor self-reported visual function) to 100 as the best possible score. Additional data extracted from the electronic health record included participant age, race, sex, date of surgery, type of surgery, indication for surgery, preoperative best-corrected VA (BCVA) of the operative and fellow eyes, postoperative BCVA of the operative and fellow eyes, and time between surgery and questionnaire.

### Statistical Analysis

Demographics of the participant sample were summarized with means, SD, frequencies, and percentages. In instances where nonparametric tests were performed, medians and interquartile ranges (IQR) were reported. Kruskal–Wallis tests, Mann–Whitney–Wilcoxon rank sum tests, and univariate linear regression models were used to analyze the association between the composite VFQ score and demographic variables, surgery type, surgery indication, and BCVA. A Dunn test was performed to analyze multiple comparisons of the VFQ and surgery type using a Bonferroni correction. A multivariate linear regression model was performed to analyze the association between VFQ and surgery type adjusting for the preoperative BCVA of the operative and fellow eyes. An F test was performed to test for adjusted differences in the VFQ score of DALK compared with PKP. DSAEK and DMEK responses were pooled, and PKP and DALK were pooled for the VFQ subscale analysis because there were no significant differences between the surgery types and VFQ scores. Fisher exact tests and Mann–Whitney–Wilcoxon rank sum tests were performed to analyze the association of the combined surgery types and the VFQ subscales. VFQ and Logarithm of the Minimum Angle of Resolution (LogMAR) VA were compared between subjects who did and did not experience an episode of rejection between the time of surgery and questionnaire with Mann–Whitney–Wilcoxon rank sum tests. All analyses were performed in R 3.6.1 (Vienna, Austria).

## RESULTS

### Demographics

A total of 219 patients met inclusion criteria and completed the VFQ. Each participant provided a single set of survey responses. No patient within the study was administered a questionnaire after a fellow eye corneal transplant surgery. Table 1 summarizes the demographic characteristics of the participant sample overall and by surgery type. The study population included 103 patients (47%) who underwent PKP, 50 patients (22.8%) who underwent DMEK, 42 patients (19.2%) who underwent DSAEK, and 24 patients (11.0%) who underwent DALK. Mean recipient age was 61 years (SD = 18.1) with a range from 19 to 92 years. The participants were 48.4% male, and 16.2% reported a race other than White. Most of the participants had transplantation for endothelial disease (36.1%). The average age of the DALK, DMEK, DSAEK, and PKP recipients was 42.5 (SD = 17.9), 72.8 (SD = 8.8), 68.7 (SD = 14.6), and 56.4 (SD = 17.6) years, respectively ( $P < 0.001$ ). The amount of time between surgery and administration of the VFQ was similar between the groups ( $P = 0.118$ ; see Supplemental Figure, Supplemental Digital Content 1, <http://links.lww.com/ICO/B183>). Table 2 summarizes the preoperative and postoperative acuities of the operative and fellow eyes. The median preoperative BCVAs for the operative eyes of DALK, DMEK, DSAEK, and PKP participants were 20/125, 20/50, 20/200, and 20/796, respectively ( $P < 0.001$ ). The postoperative BCVAs for the operative eyes of DALK, DMEK, DSAEK, and PKP participants were 20/40, 20/25, 20/50,

**TABLE 1.** Demographics of the Participant Sample

Demographic Characteristics	Overall (N = 219)	DALK (N = 24)	DMEK (N = 50)	DSAEK (N = 42)	PKP (N = 103)	P*
<b>Race</b>						
Race category other than White (%)	35 (16.2%)	6 (25.0%)	4 (8.2%)	2 (4.9%)	23 (22.5%)	0.010
White	181 (83.8%)	18 (75.0%)	45 (91.8%)	39 (95.1%)	79 (77.5%)	
<b>Sex</b>						
Female	113 (51.6%)	11 (45.8%)	32 (64.0%)	21 (50.0%)	49 (47.6%)	0.250
Male	106 (48.4%)	13 (54.2%)	18 (36.0%)	21 (50.0%)	54 (52.4%)	
<b>Age</b>						
Mean (SD)	61.0 (18.1)	42.5 (17.9)	72.8 (8.8)	68.7 (14.6)	56.4 (17.6)	<0.001
<b>Surgery indication</b>						
Other	11 (5.0%)	1 (4.2%)	0 (0.0%)	2 (4.8%)	8 (7.8%)	<0.001
Corneal melt/perforation/infection	15 (6.8%)	2 (8.3%)	0 (0.0%)	0 (0.0%)	13 (12.6%)	
Corneal scar	30 (13.7%)	9 (37.5%)	0 (0.0%)	0 (0.0%)	21 (20.4%)	
Endothelial disease	79 (36.1%)	0 (0.0%)	47 (94.0%)	25 (59.5%)	7 (6.8%)	
Graft failure	47 (21.5%)	0 (0.0%)	3 (6.0%)	15 (35.7%)	29 (28.2%)	
Keratoconus/corneal ectasia	37 (16.9%)	12 (50.0%)	0 (0.0%)	0 (0.0%)	25 (24.3%)	
<b>Years between surgery and NEI-VFQ 9</b>						
Mean (SD, Snellen equivalent)	1.5 (1.1)	1.3 (1.1)	1.2 (1.1)	1.6 (1.1)	1.7 (1.2)	0.118

\*Chi-square (Fisher exact tests when cell counts <5) tests were performed on all categorical variables. ANOVA was performed on continuous measures except for VA in which case the Kruskal-Wallis test was performed.  
ANOVA, analysis of variance.

and 20/100, respectively ( $P < 0.001$ ). There were no other significant differences in surgery type and demographics or clinical characteristics.

### Vision-Related Quality of Life

The mean composite VFQ score for all eyes after keratoplasty was 72.7 (SD = 19.1) (range 9–100), and the median composite VFQ score was 76.1 (Fig. 1). The median VFQ scores for DALK, DMEK, DSAEK, and PKP surgery types were 77.8 (IQR = 30.7), 84.2 (IQR = 18.3), 76.1 (IQR = 24.4), and 70.6 (IQR = 25.9), respectively ( $P = 0.002$ ) (Table 3). DMEK and PKP patients had significant differences in VFQ scores ( $P < 0.001$ ). There was no significant difference in scores between DALK and PKP patients ( $P = 1.000$ ) nor between DMEK and DSAEK patients ( $P = 0.440$ ). There were no significant differences in composite VFQ scores by surgery indication, sex, or race. Table 4 shows univariable and multivariable linear regression models with the outcome of composite VFQ scores. In univariable models, preoperative and postoperative BCVAs of the operative eye were negatively associated with composite VFQ scores ( $P = 0.005$ , beta coefficient ( $\beta$ ) =  $-3.66$ , CI =  $-6.2$ ,  $-1.1$ ;  $P < 0.001$ ,  $\beta$  =  $-6.53$ , CI =  $-8.9$ ,  $-4.2$ , respectively). Preoperative and postoperative BCVAs of the fellow eye were negatively associated with composite VFQ scores ( $P < 0.001$ ,  $\beta$  =  $-6.07$ , CI =  $-8.3$ ,  $-3.9$ ;  $P < 0.001$ ,  $\beta$  =  $-6.24$ , CI =  $-8.3$ ,  $-4.2$ ). Age was not significantly associated with composite VFQ scores. In multivariable analysis, the surgery type was not significantly associated with composite VFQ scores.

A total of 35 subjects experienced a graft rejection episode after surgery but before completing the VFQ (16.0%). Those subjects with no rejection episodes had a mean VFQ

score of 73.6 (SD = 18.1) compared with a mean VFQ score of 68.2 (SD = 60.2) for those with a rejection episode ( $P = 0.3287$ ). Similarly, those patients with no rejection between surgery and questionnaire had a mean LogMAR VA of 0.66 (SD = 0.86) compared with a mean LogMAR VA of 1.13 (SD = 1.51) for those with a rejection episode ( $P = 0.0144$ ).

### Subscale Responses on NEI-VFQ 9

Question 1 of the NEI-VFQ 9 asks patients to rate their general vision from excellent to very poor (with an option for complete blindness). DSAEK and DMEK participants had 45.7% reporting “good” vision compared with 33.1% of PKP and DALK patients reporting “good” vision ( $P < 0.001$ ). When asked about their worries, 21.7% of DMEK and DSAEK participants reported spending “none of their time” worrying about their vision compared with 12.6% of PKP and DALK participants who reported spending “none of their time” worrying about their vision ( $P = 0.004$ ). When asked about peripheral vision, 57.6% of DSAEK and DMEK participants reported having “no difficulty at all” with the noticing objects off to the side while walking compared with 39.2% of PKP and DALK participants who reported having “no difficulty at all” ( $P = 0.005$ ). The pooled responses of DSAEK and DMEK participants did not differ from the responses of DALK and PKP participants for other questionnaire items (addressing near vision, distance vision, and role limitation).

### DISCUSSION

In this study, patients did not have significant differences in vision-related quality of life, as measured by the composite NEI-VFQ 9, between DMEK and DSAEK graft

**TABLE 2.** Preoperative and Postoperative BCVA of the Operative and Fellow Eyes

VA	Overall (N = 219)	DALK (N = 24)	DMEK (N = 50)	DSAEK (N = 42)	PKP (N = 103)	P*
Preoperative BCVA operative eye						
Median LogMAR (IQR, Snellen)	1.1 (1.2, 20/250)	0.8 (0.9, 20/125)	0.4 (0.5, 20/50)	1 (0.9, 20/200)	1.6 (1.4, 20/796)	<0.001
Range	0.0 to 4.3	0.0 to 4.3	0.0 to 3.4	0.0 to 3.3	0.0 to 4.3	
Preoperative BCVA fellow eye						
Median LogMAR (IQR, Snellen)	0.2 (0.4, 20/32)	0.1 (0.4, 20/25)	0.2 (0.2, 20/32)	0.2 (0.4, 20/32)	0.2 (0.4, 20/32)	0.992
Range	-0.1 to 8.3	-0.1 to 1.3	0.0 to 0.9	-0.1 to 8.3	-0.1 to 8.3	
Postoperative BCVA operative eye						
Median LogMAR (IQR, Snellen)	0.4 (0.8, 20/50)	0.3 (0.3, 20/40)	0.1 (0.2, 20/25.2)	0.4 (0.4, 20/50.2)	0.7 (1.0, 20/100)	<0.001
Range	-0.1 to 8.3	0.0 to 4.3	-0.1 to 1.2	0.0 to 3.3	-0.1 to 8.3	
Postoperative BCVA fellow eye						
Median LogMAR (IQR, Snellen)	0.1 (0.3, 20/25)	0.2 (0.3, 20/32)	0.1 (0.2, 20/25.2)	0.2 (0.3, 20/32)	0.1 (0.3, 20/25)	0.555
Range	-0.1 to 8.3	-0.1 to 3.3	-0.1 to 1.0	-0.1 to 8.3	-0.1 to 8.3	

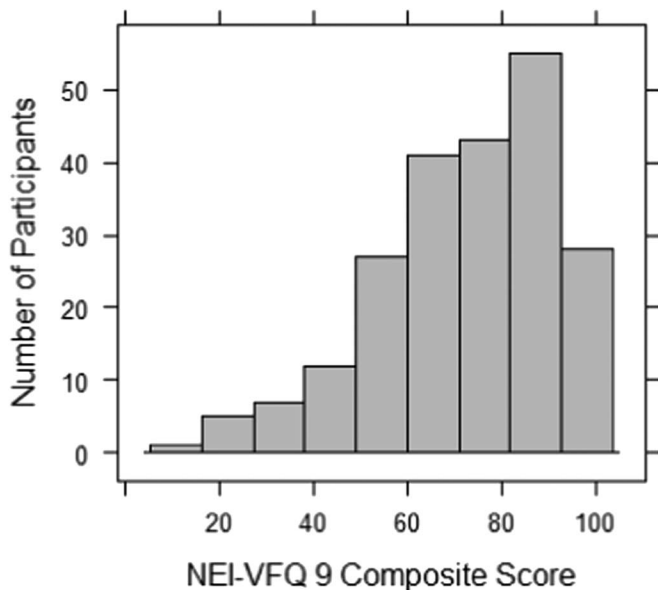
\*Chi-square (Fisher exact tests when cell counts <5) tests were performed on all categorical variables. ANOVA was performed on continuous measures except for VA in which case the Kruskal–Wallis test was performed.  
ANOVA, analysis of variance.

recipients nor between DALK and PKP graft recipients. When adjusting for postoperative VA of the operative and fellow eyes, vision-related quality of life, as measured by the composite NEI-VFQ 9, was not different between corneal transplantation recipients, irrespective of the keratoplasty technique. Although composite NEI-VFQ 9 scores were similar, significant differences were observed on subscale analysis between patients who had undergone endothelial keratoplasty as compared with penetrating or anterior lamellar keratoplasty. Patients who underwent DMEK or DSAEK noted improved general vision, noted less impairment with peripheral vision, and reported spending less time worrying about their vision compared with patients who underwent DALK or PKP. Corneal transplant recipients who had undergone DMEK surgery reported better vision-related

quality of life than individuals who had undergone PKP. Not surprisingly, patients who experienced a graft rejection episode had significantly worse VA at the time of the PRO than those who did not, but that did not translate into a significant difference in self-reported visual function. The disconnect between a significant VA difference and no significant difference in visual function scores is exactly why the researcher has emphasized the importance of reporting PROs as outcome measures because they reflect a unique dimension of health from a patient’s perspective.

It has previously been reported that vision-related quality of life can remain impaired among corneal graft recipients, even when good visual outcomes are obtained.<sup>7,8</sup> Unlike the present analysis, many of the previous studies describing PROs after corneal transplantation were conducted before the advent of DMEK and were performed as part of clinical trials that could analyze precorneal and postcorneal transplantation VFQ results.<sup>9–12</sup> Several studies have compared quality of life among corneal graft recipients after DSAEK, PKP, and DALK. A study by Puri et al<sup>10</sup> examined vision-related quality of life among 175 elderly patients who underwent PKP, DSAEK, and keratoprosthesis using the Visual Function Index-14 questionnaire. They found that both better baseline vision and transplantation by DSAEK were associated with improved vision-related quality of life. Another study by Trousdale et al<sup>9</sup> evaluated vision-related quality of life among 63 patients with Fuchs dystrophy who underwent PKP, deep lamellar endothelial keratoplasty, or DSAEK using the NEI-VFQ 25 preoperatively and postoperatively. In their series, composite NEI-VFQ 25 scores were higher among DSAEK patients compared with PKP patients at 6 months; however, there was no significant difference at 3 years. In the analyses, it is important to note that the primary indication for the corneal transplant was not controlled that has potential to influence the patient’s ultimate visual function.

In our study, there was no difference in vision-related quality of life reported by DMEK and DSAEK corneal transplant recipients. These results parallel the findings



**Figure 1.** Distribution of the composite NEI-VFQ 9 Scores across participants.

**TABLE 3.** Univariate Analyses of Participant Composite NEI-VFQ 9 Scores

	n	Median Composite NEI-VFQ 9 Score (IQR)	P
Surgery type			0.002
DALK	24	77.8 (30.7)	
DMEK	50	84.2 (18.3)	
DSAEK	42	76.1 (24.4)	
PKP	103	70.6 (25.9)	
Surgery indication			0.125
Infectious keratitis	15	72.8 (25.6)	
Corneal scar	30	73.3 (29.7)	
Endothelial disease	79	81.1 (24.7)	
Graft failure	47	70.6 (28.4)	
Keratoconus/corneal ectasia	37	73.3 (23.1)	
Other	11	73.3 (25.0)	
Sex			0.631
Female	113	78.9 (26.7)	
Male	106	75.0 (27.3)	
Race			0.736
White	181	77.8 (27.2)	
Other	35	73.3 (27.2)	

recently published by Ang et al in the secondary analysis of the Descemet Endothelial Thickness Comparison Trial. In the Descemet Endothelial Thickness Comparison Trial secondary analysis, preoperative and postoperative NEI-VFQ 39 scores were examined among 38 patients with either Fuchs dystrophy or pseudophakic bullous keratopathy who underwent DMEK or ultrathin DSAEK.<sup>13</sup> Patients who underwent DMEK obtained 1.4 lines better VA than patients who underwent ultrathin DSAEK at 12 months postoperatively.<sup>14</sup> DMEK patients achieved greater improvement in acuity than ultrathin DSAEK patients, and both groups obtained improved vision-related quality of life. Of note, vision-related quality of life was not significantly different between the DMEK and ultrathin DSAEK groups.

There were several unique features to this analysis approach. Many patients had ocular pathology coexisting with their corneal disease and had undergone other ocular surgeries such as glaucoma surgery or vitrectomy. These patients were intentionally not excluded from the study because it is common for corneal transplant recipients to have complicated ocular anatomy and pathology. In addition, PROs submitted in the postoperative period were not excluded, so some patients may not have fully healed from their procedure. Given the different healing times for different forms of corneal transplantation, this may affect the results. Participants in this study were surveyed at random postoperative clinical encounters, but no more than a single survey from each patient was included in the analysis. Although more generalizable, this study cannot make conclusions about expected quality of life at a specific postoperative time point. In addition, cross-sectional analyses have built-in weaknesses of potential for error because of nonresponse, and characteristics of nonresponders differ from responders. Future prospective trials may further our under-

**TABLE 4.** Linear Regression Models of Outcome of the Composite NEI-VFQ 9 Score

	Estimate	CI	P
Univariable analysis			
Age	0.05	-0.1 to 0.2	0.505
Pre-op BCVA operative eye	-3.66	-6.2 to -1.1	0.005
Pre-op BCVA fellow eye	-6.07	-8.3 to -3.9	<0.001
Post-op BCVA operative eye	-6.53	-8.9 to -4.2	<0.001
Post-op BCVA fellow eye	-6.24	-8.3 to -4.2	<0.001
Multivariable analysis			
Surgery type: (Ref: DMEK)			
DALK	-3.64	-11.8 to 4.5	0.383
DSAEK	-1.57	-8.6 to 5.5	0.661
PKP	-5.06	-11.2 to 1.0	0.105
Post-op BCVA operative eye	-4.96	-7.4 to -2.6	<0.001
Post-op BCVA fellow eye	-5.61	-7.6 to -3.7	<0.001
Multivariable model.			
Pre-op, preoperative; Post-op, postoperative.			

standing of the tempo of changes in vision-related quality of life after corneal transplant surgery. Our database is not yet robust enough to compare preoperative with postoperative quality of life or longitudinal quality of life, and this will be a target for future research. In conclusion, when controlling for postoperative VA, vision-related quality of life was similar among all participants in the study, irrespective of the keratoplasty technique.

## ACKNOWLEDGMENT

The authors would like to thank Mariam Khan and Autumn Valicevic for assistance with manuscript preparation.

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