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Descemet stripping automated endothelial keratoplasty 3-year graft and endothelial cell survival compared with penetrating keratoplasty

Marianne O. Price, PhD[1], **Mark Gorovoy, MD**[2], **Francis W. Price Jr., MD**[3], **Beth A. Benetz, CRA, MA**[4], **Harry J. Menegay, PhD**[4], and **Jonathan H. Lass, MD**[4,5]

[1]Cornea Research Foundation of America, Indianapolis, Indiana

[2]Gorovoy Eye Specialists, Ft. Myers, Florida

[3]Price Vision Group, Indianapolis, Indiana

[4]Department of Ophthalmology and Visual Sciences, Case Western Reserve University School of Medicine and University Hospitals Eye Institute, Cleveland, Ohio

[5]Department of Epidemiology and Biostatistics, Case Western Reserve University School of Medicine, Cleveland, Ohio

Abstract

Purpose—To assess 3-year outcomes of Descemet stripping automated endothelial keratoplasty (DSAEK) in comparison with penetrating keratoplasty (PKP) from the Cornea Donor Study (CDS).

Design—Prospective, multicenter, nonrandomized clinical trial.

Participants—A total of 173 subjects undergoing DSAEK for a moderate risk condition (principally Fuchs' dystrophy or pseudophakic corneal edema) compared with 1101 subjects undergoing PKP from the CDS.

Methods—The DSAEK procedures were performed by two experienced surgeons using the same donor and similar recipient criteria as for the CDS PKP procedures, performed by 68 surgeons. Graft success was assessed by Kaplan Meier survival analysis. Central endothelial cell density (ECD) was determined from baseline donor and postoperative central endothelial images by the reading center used in the CDS Specular Microscopy Ancillary Study.

Main Outcome Measures—Graft clarity and endothelial cell density

Correspondence: Marianne O. Price, PhD, Cornea Research Foundation of America, 9002 N. Meridian St., Ste. 212, Indianapolis, IN 46260. mprice@cornea.org..

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Results—The donor and recipient demographics were comparable in the DSAEK and PKP groups, except the proportion of Fuchs' dystrophy cases was higher in the DSAEK cohort. The 3-year survival rate did not differ significantly between DSAEK and PKP procedures performed for either Fuchs' dystrophy (96% for both, P=0.81) or non-Fuchs cases (86% vs. 84%, respectively, P=0.41). Principal causes of graft failure/regraft within 3 years after DSAEK and PKP were immunologic graft rejection (0.6% vs. 3.1%), endothelial decompensation in the absence of documented rejection (1.7% vs 2.1%), unsatisfactory visual or refractive outcome (1.7% vs. 0.5%), and infection (0% vs. 1.1%), respectively. The 3-year predicted probability of a rejection episode was 9% with DSAEK vs. 20% with PKP (P=0.0005). The median 3-year cell loss for DSAEK and PKP was 46% and 51%, respectively (P=0.33) in Fuchs's dystrophy cases, and 59% and 61%, respectively (P=0.70), in the non-Fuchs' cases. At 3 years, use of a smaller DSAEK insertion incision was associated with significantly higher cell loss (60% vs. 33% for 3.2- and 5.0-mm incisions, respectively, P=0.0007) but not a significant difference in graft survival (P=0.45).

Conclusions—The graft success rate and endothelial cell loss were comparable at 3 years for DSAEK and PKP procedures. A 5-mm DSAEK incision width was associated with significantly less cell loss than a 3.2-mm incision.

Keywords

Descemet stripping endothelial keratoplasty; posterior lamellar keratoplasty; DSAEK; DSEK endothelial cell loss

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Penetrating keratoplasty (PKP) had long been the gold standard for treatment of endothelial dysfunction, but due to the procedure's limitations including delayed visual recovery, unpredictable refractive changes, ocular surface complications, and risk of losing the eye to suprachoroidal hemorrhage, Descemet stripping automated endothelial keratoplasty (DSAEK) has become the preferred method of treating endothelial dysfunction. DSAEK provides faster visual recovery with minimal refractive change, and essentially eliminates ocular surface complications and the risk of losing the eye to intraoperative suprachoroidal hemorrhage or postoperative trauma.[1]

However, limited medium- to long-term data on the comparative graft survival and endothelial cell loss is available for these two procedures. The best way to compare graft survival would be with a prospective, randomized clinical trial, but few, if any, patients or surgeons would agree to participate, given DSAEK's short-term advantages. Therefore, we designed a prospective, multicenter interventional DSAEK study, using the same donor and similar recipient criteria as used in the large, multicenter Cornea Donor Study (CDS), with assessment of endothelial cell density (ECD) by the same central specular microscopy reading center utilized in the Specular Microscopy Ancillary Study (SMAS) of the CDS.[2-4] In the original one-year study, DSAEK and PKP had comparable graft survival, but endothelial cell loss was greater with DSAEK.[3] Also, in a post hoc analysis, mean endothelial cell loss was greater at one year with use of a 3.2-mm incision vs. a 5.0-mm incision for DSAEK graft insertion.[5]

To further assess the relative graft survival and endothelial cell loss with these two procedures over a longer time period, this prospective study was extended for an additional two-year period. Here we report 3-year graft survival and endothelial cell loss outcomes.

Materials and Methods

Study Design

In this prospective interventional study, subjects were treated with DSAEK at Gorovoy Eye Specialists (Fort Myers, FL) or Price Vision Group (Indianapolis, IN) between June 2006 and September 2007. The University Hospitals Case Medical Center (Cleveland, OH) Institutional Review Board approved the study, and written informed consent was provided by all participants. Originally, this study was designed with one-year follow up,[3] and subsequently subjects were invited to participate in a 2-year extension. This is the first report of the 2- and 3-year outcomes. The DSAEK outcomes were compared with the publicly available data from the CDS and the SMAS.

In both the DSAEK and CDS cohorts, eligible subjects had conditions at moderate risk for graft failure from endothelial decompensation (principally Fuchs' endothelial corneal dystrophy or pseudophakic corneal edema) and only one eye was enrolled per subject.[2,3] Exclusion criteria included: uncontrolled glaucoma, uncontrolled uveitis, 2 or more quadrants of neovascularization, prior placement of a glaucoma shunt, or prior failed graft. The donor eligibility criteria in both the DSAEK and CDS cohorts included age between 10 and 75 years old, an eye-bank determined ECD of 2300 to 3300 cells/mm^2, death to surgery time of no more than 5 days, and death to preservation time of ≤ 12 hours if the body was refrigerated, or ≤ 8 hours if not.[2,3,6,7]

The Case Western Reserve University (CWRU) Vision Research Coordinating Center (Cleveland, Ohio) coordinated the two participating clinical sites and five eye banks with data collection forms that paralleled those used in the CDS and SMAS, collected and analyzed the data, and audited the clinical sites.[2,3,8]

Surgical techniques and postoperative management for the DSAEK group have been previously described. [3,5] In brief, two surgeons (FWP and MG) performed the DSAEK procedures using topical anesthesia and monitored intravenous sedation. A 3.2-mm corneal incision (n=103) or 5-mm temporal scleral tunnel or corneal incision (n=70) was made and Descemet membrane and endothelium was removed from the planned graft area. The donor cornea was dissected with a microkeratome and cut to a diameter of 8.25 to 9.0 mm, depending on the recipient corneal diameter. The donor cornea was folded over into a "taco" configuration and inserted using single-point fixation forceps (n=167) or it was pulled into the eye through a funnel glide (n=6). The PKP procedures in the CDS, performed by 68 surgeons at 45 sites, using their individual surgical techniques and postoperative care regimen have been described.[2,7] The endothelial cell loss and graft survival rate through 5-years were previously reported for the CDS and SMAS cohorts.[2,4,7,8]

Specular Microscopy and Endothelial Cell Density Determination

Donor corneas were provided by the Central Florida Lions Eye and Tissue Bank (Tampa, FL), Indiana Lions Eye and Tissue Transplant Bank (Indianapolis, IN), North Carolina Eye Bank (Winston-Salem, NC), Heartland Lions Eye Bank (St. Louis, MO) and Sightlife (Seattle, WA). Each had participated in the SMAS and was experienced with image capture techniques and transmission to the reading center. As in the SMAS, the provider eye bank electronically submitted a single image of the central endothelium of each donor cornea to the Cornea Image Analysis Reading Center (CIARC) for ECD determination. The eye bank usually imaged the donor endothelium within 1 to 2 days of donor death in both the DSAEK and SMAS PKP groups. The mean death to use time was 4 days in both groups,[3] so even though the endothelial cell density may have decreased somewhat between imaging and transplantation, this was not expected to have a significant effect on the between-group cell loss comparison. As in the SMAS, only CIARC-determined postoperative ECDs were

utilized for data analysis, but if a donor corneal image could not be analyzed or was not available, the eye bank determined ECD was used. The clinical sites electronically submitted postoperative images of the central endothelium captured by specular microscopy (Konan Medical Corp, Torrance, CA) or confocal microscopy (Nidek, Fremont, CA) at the 6-month, 1-year, 2-year, and 3-year periods. CIARC analysis procedures were as previously described.[2,4,8]

Statistical Methods

The primary outcome measures were graft clarity and endothelial cell loss at 3 years. The fraction of grafts that remained clear through 3 years was compared for the DSAEK and PKP groups using Kaplan-Meier survival analysis and the log-rank test, which takes length of follow up into account. Percent cell loss was calculated by subtracting postoperative ECD from baseline donor ECD, dividing by baseline ECD, and multiplying by 100.

Normally distributed variables were described as mean ± standard deviation and compared using a 2-sample Student t-test. Proportional demographics were compared using chi-square analysis. The 3-year ECD and cell loss were not normally distributed, so the statistics were reported as the median and interquartile range, and the groups were compared using the Wilcoxon rank-sum test. All reported P values were 2-sided. The overall significance level was set at 0.05, and a Bonferroni adjustment was applied to control the false positive rate (Type 1 error) associated with multiple comparisons. With this adjustment, P-values less than 0.002 were considered statistically significant. Statistical analyses were performed with SAS software (version 9.3, SAS Inc., Cary, NC).

Results

Recipient and Donor Characteristics

A total of 173 DSAEK eyes (173 subjects) were enrolled in the initial study. The mean age was 72±11 years, 60% were female, and 98% were Caucasian. The demographics of the DSAEK cohort were similar to the PKP cohort in the SMAS, as previously described,[3] but the DSAEK group had a significantly higher incidence of Fuchs' dystrophy (85% vs. 64%, P<0.0001) and lower incidence of pseudophakic/aphakic corneal edema (13% vs. 32%). The donor criteria in this study were the same as in the CDS and donor age, ECD, death to preservation and death to surgery times did not differ significantly between the DSAEK and PKP groups (all P>0.03).

Graft Success

Of the 173 DSAEK subjects enrolled in the study, 111 (64%) were examined and found to have clear grafts at 3 years, 44 (25%) had clear grafts when last examined, but withdrew or were lost to follow up before the 3-year exam, 11 (6.4%) died, and 7 (4%) experienced graft failure. The cumulative probability of DSAEK graft survival at 3 years was 94%.

Fuchs' dystrophy was the most prevalent diagnosis in both the PKP and DSAEK groups. The 3-year graft survival rate was 96% for both DSAEK and PKP (P=0.81) in eyes treated for Fuchs' dystrophy, and it was 86% with DSAEK vs. 84% with PKP (P=0.41) in eyes treated for other preoperative diagnoses, mainly pseudophakic/aphakic cornea edema.

Reasons for graft failure/regrafts

The reasons for graft failure within the first 3 years in the DSAEK and PKP cohorts are enumerated in Table 1. The DSAEK group did not have any primary graft failures. Seven grafts (4%) failed during the 3-year study period. Four were replaced in the first year; two were related to visually significant wrinkles in the graft, one was related to stromal haze that

was subsequently determined to be in the recipient cornea, and one was associated with immunologic graft rejection. Three grafts failed in the second year due to endothelial decompensation in the absence of a documented immunologic rejection episode. No graft failures were noted in the third year. In the CDS PKP cohort, the principal reasons for graft failure or regraft within 3 years were immunologic graft rejection (3.1%), endothelial decompensation in the absence of a documented rejection episode (2.1%) and infection (1.1%);Table 1.

Incidence of immunologic graft rejection episodes

Eleven DSAEK grafts (6.4%) experienced an immunologic graft rejection episode during the 3-year follow up period. At 3 years, the predicted probability of experiencing a rejection episode was 9% with DSAEK vs. 20% with PKP in the CDS;[9] this was a statistically significant difference (P=0.0005, log rank test).

Endothelial Cell Loss

Of the 111 subjects in the DSAEK group with clear grafts at 3 years, 66 (59%) had analyzable endothelial images, 14 (13%) had clear grafts but the endothelial image was not analyzable, and 31 (28%) had clear grafts but a 3-year image was not obtained. The subjects with 3-year ECDs did not differ significantly from those without 3-year ECD in age, race, sex or indication for grafting (all P>0.05).

At 3 years, the median endothelial cell loss was comparable for the DSAEK and PKP groups (48% vs. 53%, P = 0.17, Table 2 and Figure 1). Compared with the PKP cohort, the DSAEK cohort experienced more cell loss in the first year but less cell loss in subsequent years (Figure 1). In a subgroup analysis of 31 DSAEK eyes and 205 PKP eyes that had analyzable endothelial images at 1, 2 and 3 years, the median 3-year cell loss was 42% in the DSAEK group and 51% in the PKP group (P=0.21, Table 2).

In subjects treated for Fuchs' dystrophy, the median 3-year cell loss was 46% with DSAEK (n=56) and 51% with PKP (n=225), which was not a significant difference (P=0.33). In the subjects treated for other preoperative diagnoses, the median 3-year cell loss was 59% with DSAEK (n=10) and 61% with PKP (n=90), again not a significant difference (P=0.70).

Effect of incision width

A post hoc analysis of the DSAEK data at one year revealed a significant difference in the cell loss between the two study sites, with the principal difference in surgical technique being incision width.[5] The significant difference in cell loss associated with incision width persisted throughout the 3-year follow up period (Figure 2). For the 5.0-mm and 3.2-mm incision widths, the median 3-year cell loss was 33% vs. 60%, respectively (n=29 and 37, respectively; P=0.0007). Of note, the 3-year cell loss for DSAEK performed with a 5-mm incision width was significantly lower than the 3-year cell loss with PKP in the CDS (33% vs. 53%, respectively, P=0.0017).

Despite the difference in cell loss, the 3-year probability of DSAEK survival was 97% with the 5.0-mm incision vs. 92% with the 3.2-mm incision. This was not a statistically significant difference (P=0.45).

Discussion

The key finding in this study was that 3-year graft survival and endothelial cell loss were comparable for DSAEK and PKP with essentially the same donor and recipient characteristics and ECD determined by the same reading center. Compared with the PKP

cohort, the DSAEK cohort experienced more cell loss in the first year, which was probably associated with surgical manipulation and trauma to the graft. In subsequent years, however, the DSAEK cohort experienced a lower rate of cell loss than the PKP cohort (Figure 1) which was particularly evident in the 5 mm DSAEK subjects. This is an interesting phenomenon that remains to be fully elucidated.

These findings confirm observations in other single center studies of substantial initial cell loss followed by modest subsequent cell loss with DSAEK. Outcomes in earlier DSAEK series performed by two of the authors (FWP and MG) suggest that the rate of cell loss between 3 and 5 years remains lower with DSAEK than with PKP, resulting in lower cumulative 5-year cell loss with DSAEK.[10,11]

The three causes of DSAEK graft failure in this study were unsatisfactory best corrected vision relative to the expected visual potential, immunologic rejection, and endothelial decompensation in the absence of documented rejection (Table 2). Due to the rapidity of visual recovery in the majority of cases and minimal activity restriction, DSAEK patients who do not achieve vision of 20/40 or better commonly are willing to undergo a regraft to obtain better vision. In a series of 1050 consecutive DSAEK grafts performed by one of the authors (FWP), 2.7% were repeated within the first year because the corrected distance vision did not match the expected visual potential.[12] Poorer than expected vision was usually associated with the presence of folds or wrinkles that can develop in the graft as it conforms to the host cornea.[12] The eye banks do not measure the curvature of the donor cornea and no attempt is made to match donor and recipient curvatures, so in some cases the curvature mismatch may be substantial leading to wrinkles in the graft. Wrinkles could also develop during graft manipulation and centration. After PKP there are also eyes that do not achieve 20/40 visual acuity, but unsatisfactory vision is not usually considered an indication for repeat PKP, because of the surgical risk and long recovery period.

The other two causes of DSAEK graft failure in this series, immunologic rejection and endothelial decompensation in the absence of a documented rejection episode, were also leading causes of PKP failure in the CDS.[7] Overall, the predicted probability of an immunologic rejection episode was lower with DSAEK than with PKP in the CDS. Factors associated with the large PKP incision that contribute to graft failure, such as unacceptable refractive outcomes, infections, epithelial defects and wound dehiscence, were not seen with DSAEK, which is performed with a small incision and causes little to no change in corneal topography.

Significantly more endothelial cell loss was noted as early as 6 months with insertion of the DSAEK graft through a smaller incision (3.2 vs. 5.0 mm),[5,13] and at 3 years the difference in cell loss with incision width remained significant (60% vs. 33%, $P<0.0001$). Although the 3-year graft survival rates did not differ by a statistically significant amount (97% vs. 92% for 5.0 and 3.2 mm incision widths, respectively, $P=0.45$), the differences in endothelial cell loss associated with variations in surgical technique could have a significant effect on longer-term graft survival, so continued surveillance is needed.

Notably, the 3-year endothelial cell loss was significantly greater in the CDS PKP cohort than it was with DSAEK performed through a 5-mm incision (33% vs. 53%, $P=0.0017$). Subsequent technique modifications and improved instrumentation are showing promise in further minimizing early endothelial cell loss with DSAEK, and these advances may well contribute to even better long-term endothelial survival and graft survival than documented with the earlier methods used in this study.[14,15]

Important strengths of this study were the prospective design, use of the CWRU Vision Research Coordinating Center for independent data collection, verification, and auditing,

and use of the same image analysis reading center used in the SMAS to provide ECD data on images of varying quality by certified readers whose readings were subjected to dual grading, adjudication, and intra-observer retesting to confirm reliability. Among the study limitations was lack of randomization to the two keratoplasty procedures, although donor and recipient characteristics were well matched. Another study limitation was the loss to follow up, which was in part attributable to the subjects originally agreeing to return for study examinations through one year and the study later being extended to 3 years. Importantly, the DSAEK subjects who had endothelial cell density measurements performed at 3 years were representative of the group as whole in terms of sex, race, age, and indication for grafting (all $P>0.30$).

In conclusion, DSAEK performed by experienced surgeons resulted in 3-year graft survival and endothelial cell loss similar to PKP performed with similar donor and recipient characteristics. Longer-term follow up of larger cohorts of DSAEK patients is needed to better assess the relative graft survival rates with these two procedures. The multi-center Cornea Preservation Time Study, which is prospectively enrolling 1330 DSAEK patients to examine the effect of preservation time on graft survival and cell loss with planned 3-year follow up, including regular ECD determinations performed by a central reading center, is expected to provide valuable insights in this regard.

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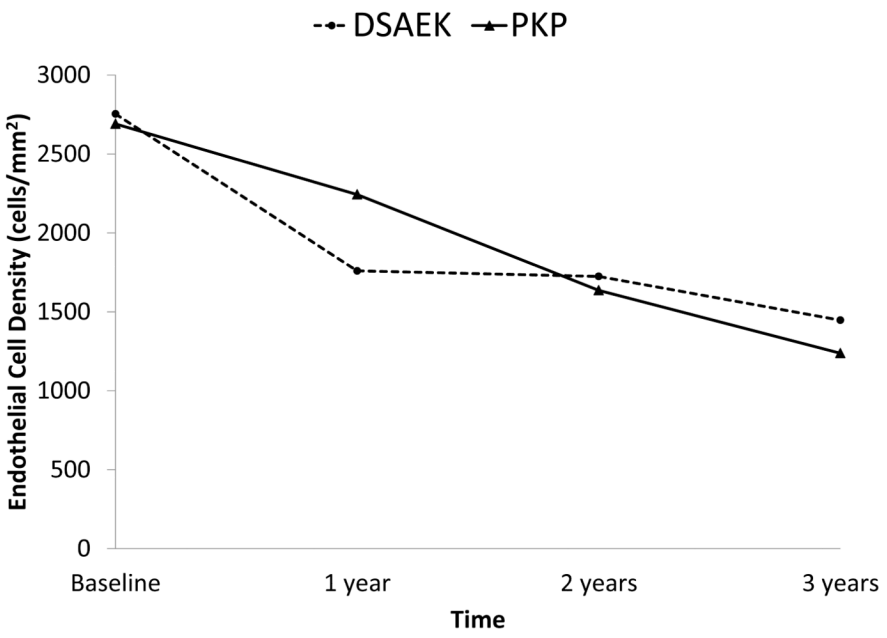

Figure 1.
Median endothelial cell density as a function of time for subjects treated with Descemet's stripping automated endothelial keratoplasty (DSAEK) or with penetrating keratoplasty (PKP) in the Specular Microscopy Ancillary Study (SMAS) of the Cornea Donor Study.

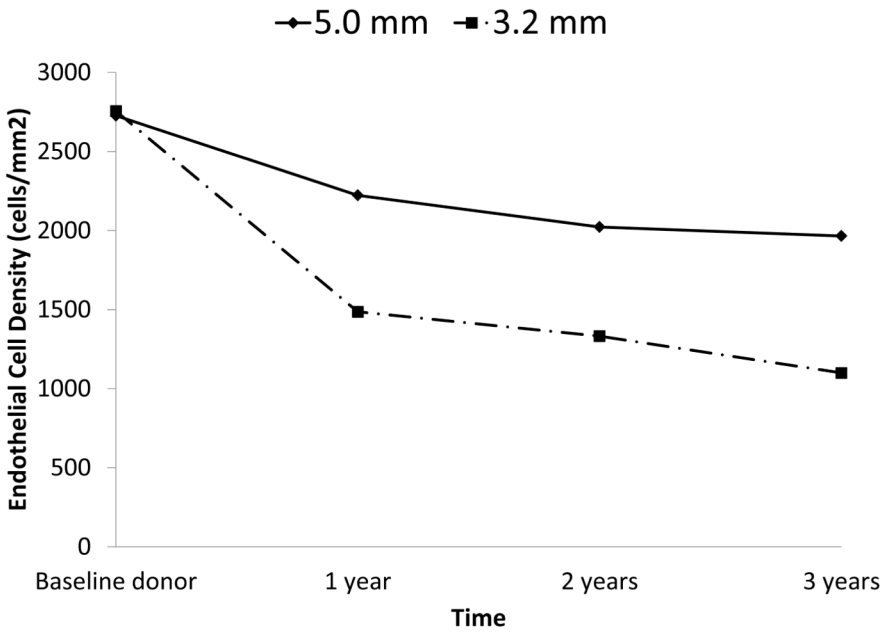

Figure 2.
Median endothelial cell density as a function of time for incision widths of 3.2 mm and 5.0 mm used with Descemet's stripping automated endothelial keratoplasty.

Table 1

Reasons for graft failure or regraft within 3 years after Descemet stripping automated endothelial keratoplasty and penetrating keratoplasty from the Cornea Donor Study

Reasons for graft failure or regraft	DSAEK (N=173)		CDS PKP (N=1101)	
	No.	(%)	No.	(%)
Primary Donor Failure	0	(0)	3	(0.3)
Rejection	1	(0.6)	34	(3.1)
Endothelial decompensation without rejection	3	(1.7)	23	(2.1)
Refractive	0	(0)	6	(0.5)
Unsatisfactory vision (20/40 or worse)	3	(1.7)	0	(0)
Infection	0	(0)	12	(1.1)
Epithelial defects	0	(0)	5	(0.5)
Corneal thinning	0	(0)	1	(0.1)
Endophthalmitis	0	(0)	1	(0.1)
Wound dehiscence	0	(0)	1	(0.1)
Hypotony	0	(0)	1	(0.1)
Glaucoma	0	(0)	2	(0.2)
Other	0	(0)	2	(0.2)

Abbreviations: DSAEK = Descemet stripping automated endothelial keratoplasty, CDS = Cornea Donor Study, PKP = penetrating keratoplasty

Table 2

Endothelial Cell Density and Cell Loss for Descemet stripping automated endothelial keratoplasty and Specular Microscopy Ancillary Study penetrating keratoplasty groups

	DSAEK		SMAS PKP		P-value
All eyes	**Median (Interquartile range)**	**No. of Eyes**	**Median (interquartile range)**	**No. of Eyes**	
Endothelial Cell Density (cells/mm^2)					
Baseline	2754 (2568-2983)	173	2731 (2513-2895)	473*	0.049
1 year	1759 (1236-2295)	104	2243 (1732-2646)	380	<0.0001
2 years	1763 (1136-2178)	79	1636 (1012-2245)	359	0.62
3 years	1447 (947-2125)	66	1238 (767-1900)	315	0.11
Endothelial cell loss (%)					
1 year	36 (17-55)	104	18 (3-36)	380	<0.0001
2 years	38 (22-61)	79	39 (18-62)	359	0.80
3 years	48 (26-65)	66	53 (27-72)	315	0.17
Eyes measured at every time point					
Endothelial Cell Density (cells/mm^2)					
Baseline	2776 (2489-3015)	31	2687 (2505-2824)	205	0.81
1 year	2008 (1602-2323)	31	2290 (1736-2683)	205	0.050
2 years	1891 (1227-2210)	31	1772 (1188-2316)	205	0.95
3 years	1660 (981-2217)	31	1337 (812-1994)	205	0.11
Endothelial cell loss (%)					
1 year	29 (12-44)	31	16 (1-36)	205	0.0081
2 years	36 (23-51)	31	33 (14-56)	205	0.50
3 years	42 (19-63)	31	51 (26-69)	205	0.21

Abbreviations: DSAEK = Descemet stripping automated endothelial keratoplasty, SMAS = Specular Microscopy Ancillary Study, PKP = penetrating keratoplasty

*Baseline endothelial cell density data is reported for the 473 SMAS PKP eyes that had at least one annual postoperative endothelial cell density measurement in years 1 through 3.