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Name: Jordan Thompson, MD

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Year of Training: ☐ 1st Year ☐ 2nd Year ☑ 3rd Year

Email: jmthomps1@gmail.com

Best daytime phone: *(Clinic phone, Cell phone, Pager)* 320-220-3073

Sponsoring Faculty Member: Charles Bouchard, MD

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A Multicenter Study Evaluating the Risk Factors and Outcomes of Repeat Descemet's Stripping Endothelial Keratoplasty (DSEK)

Authors:

Jordan Thompson MD[1], Alexander Truong[1], Hudson Stern[2], Ali Djallilian MD[2], M. Soledad Cortina MD[2], Elmer Tu MD[2], Paula Johnson[3], David Verdier MD[3], Lorene Rafol[4], David Lubeck MD[4], Tanya Spektor MD[5], Colin Jorgenson[5], Jonathan Rubenstein MD[5], Parag Majmudar MD[6], Rushi Talati[7], Surendra Basti MD[7], Robert Feder MD[7], Shahzad Mian MD[8], Neelam Balasubramanian[1], Jasmin Sandhu MD[1], Bruce Gaynes OD, Pharm D[1], Charles Bouchard MD[1]

Affiliations:

1. Loyola University Medical Center, Department of Ophthalmology, Maywood IL
2. University of Illinois at Chicago, Department of Ophthalmology, Chicago IL
3. Verdier Eye Center, Grand Rapids MI
4. Arbor Centers for Eye Care, Homewood IL
5. Rush University Medical Center, Chicago IL
6. Chicago Cornea Consultants, Chicago IL
7. Northwestern University, Department of Ophthalmology, Chicago IL
8. University of Michigan, Kellogg Eye Center, Ann Arbor MI

Corresponding Author:

Jordan Thompson MD
Loyola University Medical Center
Department of Ophthalmology
2160 S 1st Ave, Maywood, IL 60153
jmthomps1@gmail.com; 320-220-3073

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The authors do not have any conflicts of interests to disclose

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Abstract

Purpose: Endothelial keratoplasty (EK) describes a group of surgical procedures for managing corneal endothelial dysfunction. The most common is Descemet's stripping endothelial keratoplasty (DSEK). The procedure may be repeated in the event of a failed DSEK from several causes. There have been several reports examining various combinations of repeat keratoplasty techniques for failed grafts (full and partial-thickness). Since the number of repeat DSEK cases is typically low at any single center, our aim was to collaborate with the Eversight Eye Bank to establish a multicenter study to evaluate a large number of repeat DSEK cases. The goal of our study is to report the risk factors and outcomes of the repeat DSEK procedures from multiple sites/surgeons to provide a more realistic assessment of the results.

Methods: We performed an IRB-approved, multicenter, retrospective chart review of patients who had a repeat DSEK following a prior failed DSEK. Eversight Eye Bank provided detailed donor information including age, sex, pre- and post-cut corneal thickness, endothelial cell densities, graft thickness and death to preservation time. Five different Midwest academic centers and two private practice centers participated in the study. Information extracted from the participant charts included: recipient demographics, pre-op and post-op visual acuities, initial and repeat DSEK indications, central corneal thickness, number of glaucoma drops pre- and post-repeat DSEK, post-op endothelial cell counts, central corneal thickness and co-morbid ocular and systemic diseases.

Results: A total of 120 eyes from 120 patients who underwent repeat DSEK were identified among the study sites. The average age was 70 ± 12 years with a female-to-

male ratio of 1.45:1. The average time from initial to repeat DSEK for all patients was approximately 1.9 years and significantly differed per indication. The most common indication for initial DSEK was Fuch's endothelial dystrophy (31%, N=38). The most common indication for repeat DSEK was late endothelial graft failure without rejection (52%, N=63). Average pre- and 12 month post-repeat DSEK best corrected distance visual acuities (BCDVA) were 20/693 and 20/89, respectively. The mean repeat donor graft thickness was 153 ± 43 microns. The mean initial and repeat donor endothelial cell counts were 2767 ± 264 cells/mm^2 and 2744 ± 272 cells/mm^2, respectively. Initial and repeat graft re-bubble rates were 34% (N = 40) and 15% (N = 18). The presence of glaucoma, prior glaucoma surgery or a history of PKP did not significantly affect the visual outcomes; however, there was a trend towards better visual outcomes in patients with an absence of glaucoma, anti-hypertensive eye drops and glaucoma surgery. Patients with higher pre-operative intraocular pressures prior to repeat DSEK had statistically significant improvements in post-operative visual acuities.

Conclusion: Our report represents the largest multi-center study describing risk factors, indications and outcomes of repeat DSEK surgery. Repeating DSEK provides a good option for improving vision following failed or decompensated initial DSEK surgery. The results of the study may provide valuable information for surgeons considering a repeat DSEK procedure.

Introduction

Historically, the procedure of choice for the management of corneal endothelial dysfunction has been penetrating (full thickness) keratoplasty (PKP). For initial and subsequent failed grafts, repeat PKP, DSEK over the PKP, or keratoprosthesis (KPro) have been used. Endothelial keratoplasty (EK) describes a group of newer techniques for the surgical management of corneal endothelial dysfunction. The most common of these includes Descemet's stripping endothelial keratoplasty (DSEK), and more recently, Descemet's membrane endothelial keratoplasty (DMEK).[1] Similar to failed PKP grafts, the endothelial keratoplasty procedure may also be repeated for various indications.

With the advent of newer lamellar keratoplasty techniques, there have been a variety of reports examining the outcomes of several combinations of repeat keratoplasty techniques for failed grafts including: 1) Repeat DSEK; 2) DSEK following PKP; 3) DMEK following DSEK or DMEK.[2-10] Because the number of repeat DSEK cases is low at any one center, we decided to collaborate with Eversight Eye Bank to establish a multicenter, multi-surgeon Midwest study to evaluate the risk factors and outcomes of the repeat DSEK procedures. The results of this large case study will provide a broad range of valuable data regarding a variety of donor, host, and surgical risk factors as well as clinical outcomes following repeat DSEK surgery.

Methods and Materials

The design of our study consisted of an IRB-approved multicenter retrospective chart review. Data from the Eversight Eye Bank was used to identify

repeat corneal transplants performed at several academic and private institutions, including Loyola University Medical Center (Maywood, IL), Rush University Medical Center (Chicago, IL), University of Illinois at Chicago (Chicago, IL), Northwestern University (Chicago, IL), University of Michigan Kellogg Eye Center (Ann Arbor, MI), Chicago Cornea Consultants (Chicago, IL), Verdier Eye Center (Grand Rapids, MI) and Arbor Center for Eye Care (Homewood, IL). The medical records were screened for patients who underwent repeat DSEK following a prior failed DSEK between January 2006 and April 2016.

The data collected in the study included donor and recipient endothelial cell density, percent of endothelial cell loss at 6 and 12 months (if available), pre- and post cut corneal donor thickness, postoperative central corneal thickness at 1, 6 and 12 months, donor graft diameter, graft insertion technique, indications for primary and repeat DSEK, re-bubble rates, best corrected visual acuities at least 6 months post repeat DSEK, associated ocular and systemic disease, prior glaucoma surgery (trabeculectomy, tube shunt, laser trabeculoplasty or diode cyclophotocoagulation) and number of glaucoma medications. Primary graft failure was defined as failure of the cornea to clear within three months of surgery.

Statistical Analysis

A univariable linear mixed effects model was used to measure the change in patients' mean logMAR visual acuities following their pre and post-operative visits. Similarly, a univariable linear mixed effects model was used to measure days from initial to repeat DSEK as a function of patients' repeat indication. In these models, random intercepts were allowed for each institution in order to account for patients

clustering within their treatment facility. When within-site correlation was sparse, conclusions were confirmed using a general linear model.

A generalized linear mixed effects model was used to estimate the odds of a re-bubble as a function of repeated surgeries. In addition to allowing random intercepts for each patient, this model also specified a binomial distribution for the outcome and a logit link was used to estimate the odds ratio. This model was also used to estimate the odds of a repeat re-bubble. The model allowed for random intercepts for each study site. A binomial distribution was specified for the outcome and a logit link was used to estimate the odds ratio. All analyses were performed using SAS version 9.4 (Cary, NC).

Results

A total number of 120 eyes from 120 patients were included in the study. The average age of patients in our study was 70 ± 12 years with a female-to-male ratio of 1.45:1. The average time from primary to repeat DSEK for all patients regardless of indication was 1.9 years. This timeframe differed depending upon the specific indication as outlined in Table 1. The mean pre-operative visual acuity prior to repeat DSEK was 20/693; and the mean post-operative visual acuities were 20/96 and 20/89 at 6 and 12 months, respectively. The mean repeat post-cut donor graft thickness and endothelial cell counts were 153 ± 43 microns and 2744 ± 272 cells/mm^2, respectively. Additional demographic data is shown in Table 2.

Fuch's endothelial dystrophy was the most frequent indication for initial DSEK (31%, N=38), followed by failed PKP (21%, N=25), pseudophakic bullous

keratopathy (19%, N=23), failed DSEK (11%, N=13), corneal decompensation following glaucoma surgery (5.8%, N=7), corneal decompensation following complicated cataract surgery (1.7%, N=2), pseudophakic bullous keratopathy with underlying Fuch's dystrophy (1.7%, N=2), trauma (0.8%, N=1), and failed DMEK (0.8%, N=1). Additionally, various *other* indications were seen in our remaining patients (7.4% N=9), which included congenital glaucoma, iridocorneal endothelial (ICE) syndrome, unspecified endothelial dystrophy or degeneration, corneal decompensation of unclear etiology and unspecified corneal edema. These results are depicted in Table 3.

The most common indication for repeat DSEK was late endothelial graft failure (52%, N=63), followed by primary graft failure (28%, N=34), graft failure following immune rejection (5.0%, N=6), graft failure following subsequent ocular surgery (3.3%, N=4) and unsatisfactory visual acuity (2.5%, N=3) (Table 3). The mean timeframe from initial to repeat DSEK for primary graft failure was 4.4 months, followed by unsatisfactory visual outcome at 7.4 months, late endothelial graft failure at 2.7 years, graft failure following surgery at 2.7 years and graft failure following immune rejection at 3.0 years (Table 1).

Improvements in visual acuity were not significantly affected by donor graft post-cut thickness (p=0.71), post-cut endothelial cell counts (p=0.22), or death-to-preservations times (p=0.54). A statistically significant improvement in post-operative visual acuity was identified in patients with higher pre-operative (pre-repeat DSEK) intraocular pressures (p=0.048). There was a statistically significant worsening in visual acuity that was observed in patients with thicker central corneal

thicknesses prior to initial DSEK surgery (p=0.049); and similarly, a trend toward worse visual outcomes was seen in patients with thicker corneas prior to repeat DSEK (p=0.10) (Table 4). Patients with a history of a PKP did not have any statistically significant changes in post-op repeat DSEK visual outcomes (p=0.58). Additional predictors of changes in visual acuity are listed in Table 5.

Glaucoma was present in the 36% (N=44) of the patients in the study. A history of glaucoma surgery (trabeculectomy, tube shunt, laser trabeculoplasty and diode cyclophotocoagulation) was identified in 32% (N=38) (Table 6). Patients with a history of glaucoma did not show a statistically significant difference in changes in visual acuity (p=0.08); however, patients without glaucoma showed a trend towards better visual improvements compared to those with glaucoma (-0.89 versus -0.59, respectively). This trend was also seen in patients not taking any glaucoma medication (-0.93 versus -0.62). Patients without a history of glaucoma surgery also revealed a trend toward better improvements in visual acuity than those who had undergone previous glaucoma surgery (-0.86 versus -0.59, respectively). Overall, there was no significant difference in visual outcomes in patients who underwent trabeculectomy, tube shunt surgery or both (p=0.65) (Table 5).

The re-bubble rates for the initial and repeat DSEK were found to be 34% (N = 40) and 15% (N = 18), respectively. This represented a statistically significant difference in that patients who required an initial DSEK re-bubble were 65% less likely to require a re-bubble after the repeat DSEK than patients who did not require an initial DSEK re-bubble (OR (95% CI): 0.35 (0.19-0.66); p=0.001). Additionally,

neither diabetes nor a history of glaucoma was a significant predictor of repeat DSEK re-bubble (Table 7).

Discussion

Repeat endothelial keratoplasty is becoming an attractive surgical option for patients with endothelial decompensation following DSEK surgery. The outcomes of repeat DSEK cases from single institutions have previously been reported.[8-10] The most common indication for repeat DSEK from Price Vision Group was inadequate visual acuity resulting from graft folds and wrinkles (76%, N=28). Of note, the authors report that this indication was likely the most common in their series due to the rapid visual recovery after DSEK and their one-year study length. Similar to our case series, the most common indication in the series by Nahum *et a*l. was late endothelial graft failure without rejection, whereas the Kim *et al.* series had an equivalent number of primary graft failures and cases of late endothelial decompensation without rejection.[9-10].

The mean time from primary to repeat DSEK as well as final visual acuity varied in the reported case series. Two of the series report an overall average of approximately 1 year to repeat grafting.[8-9] Nahum *et al.* reports a timeframe of 2.2 years, which was similar to our current study's overall average. The mean post-operative visual acuities ranged from 20/44 to 20/63 in two of the studies.[9-10] Additionally, Letko *et al.* reported a median post-operative visual acuity of 20/30; however, this strictly included patients with unsatisfactory visual acuities, largely from graft-host interface issues.

The percentage of endothelial cell loss following repeat DSEK and the number of repeat grafts requiring re-bubbling in our case series were similar to the reported studies. We report a 37% endothelial cell loss between 12 and 24 months, compared to 47.3% and 44.0 reported by Kim and Nahum *et al.*, respectively. Our series found that 34% of the primary grafts needed re-bubbling versus 15% of the repeat grafts. Kim *et al*. reported re-bubble rates of 35% in the primary and 5.0% in the repeat grafts. Given the fact that DSEK surgery is a recently developed surgical technique during the past 10 years, the difference between initial and repeat re-bubble rates may represent a learning curve to the procedure.

Our study found no statistically significant difference in visual outcomes after repeat DSEK surgery in patients with a history of glaucoma or glaucoma surgery. However, there was a trend toward better visual outcomes in patients without a history of glaucoma, anti-hypertensive eye drops or glaucoma surgery. In comparison to the literature, patients with prior glaucoma surgery were shown to have worse outcomes in the study by Letko *et al*. who found that prior trabeculectomy or tube shunt was associated with a 5-fold increase in the risk of graft failure.[8] Interestingly, our series also showed that patients with higher pre-operative (pre-repeat DSEK) intraocular pressures had statistically significant improvements in visual acuity. The reason behind this was unclear but perhaps higher intraocular pressures are advantageous in assisting in graft adherence.

Repeat DSEK surgery has been shown to be a successful procedure for failed grafts. Outcomes have been reported in several studies; however, the data has been limited to single institution studies in either a private practice group, hospital or an

academic center. The current study represents a multi-center report that combines data from multiple academic institutions and private practice groups to highlight the outcomes in any practice setting. To our knowledge this case series is the largest and only multi-center report on repeat DSEK cases in the literature. It should provide useful information to surgeons in their evaluation and treatment plans for failed DSEK grafts.

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Tables

Repeat DSEK Indication	Mean, days (SE)	*p*
Primary Graft Failure	132 (95)	<0.001
Unsatisfactory Visual Outcome	223 (378)	.051
Late Endothelial Graft Failure	982 (72)	--
Graft Failure following surgery	980 (268)	.99
Graft Failure following immune rejection	1099 (219)	.61

Table 1: *Time from initial to repeat DSEK by repeat indication*

Note: N=109. Significance determined using a mixed effects model taking into account clustering at the site.

Host and Repeat Donor Demographics	Mean (SD)	N
Host Age (years)	70 (12)	121
Donor Age (years)	56 (13)	111
Visual Acuity		
Pre-op LogMAR	1.54 (0.79)	117
Last Post-op LogMAR	0.77 (0.72)	118
LogMAR Change from Pre-op to Post-op	-0.79 (0.89)	115
6 Month Post-op LogMAR	0.68 (0.60)	108
12 Month Post-op LogMAR	0.65 (0.62)	100
Donor ECC Pre-cut (cells/mm^2)	2763 (253)	118
Donor ECC Post-cut (cells/mm^2)	2744 (272)	120
Donor Thickness Post-cut (microns)	153 (43)	119
Pre-op IOP (mm Hg)	15.87 (4.97)	119
Pachymetry Host Prior to initial DSEK (microns)	759 (147)	84
Pachymetry 1-6 Months Post DSEK (microns)	673 (117)	79
Donor Death-to-Preservation time (hours)	11.96 (5.43)	116

Table 2. Repeat DSEK Demographics from the host and donor.

Indications for *Initial* and *Repeat* DSEK	N (%)
Initial DSEK Indication	
Fuch's	38 (31%)
Failed PKP	25 (21%)
PBK	23 (19%)
Failed DSEK	13 (11%)
Other†	9 (7.4%)
Corneal decompensation after glaucoma surgery	7 (5.8%)
Corneal decompensation after cataract surgery	2 (1.7%)
Fuch's and PBK	2 (1.7%)
Trauma	1 (0.8%)
Failed DMEK	1 (0.8%)
Repeat DSEK Indication	
Late Endothelial Graft Failure without Rejection	63 (52%)
Primary Graft Failure	34 (28%)
Graft Failure following Immune Rejection	6 (5.0%)
Graft Failure following Subsequent Surgery	4 (3.3%)
Unsatisfactory Visual Outcome	3 (2.5%)

Table 3. Indications for *primary* and *repeat* DSEK.
†Other indications include congenital glaucoma, iridocorneal endothelial (ICE) syndrome, unspecified endothelial dystrophy or degeneration, decompensation of unclear etiology and unspecified corneal edema.

Predictors of logMAR BCDVA change	N	Beta (SE)	*p*
Donor 2 ECC (post-cut)	114	0.00037 (0.00031)	.22
Donor 2 Thickness (post-cut)	112	-0.00073 (0.00196)	.71
Mean Pre-op IOP EK2	113	-0.033 (0.017)	.048
Pachymetry (host) prior to EK1* (per 100)	80	0.137 (0.069)	.049
Pachymetry (host) prior to EK2* (per 100)	71	-0.101 (0.060)	.10
Pachymetry host 1-6 months post EK2* (per 100)	76	0.137 (0.087)	.12
Donor 2 D-P (hours)	110	0.0096 (0.0156)	.54

Table 4: *Continuous predictors of logMAR BCDVA change from EK2 pre-op to latest post-op*

Note: N=121. Significance determined using a mixed effects model taking into account clustering at the site. *Significance determined using a generalized linear model without random site effects due to low site counts.

Categorical Predictors of Change in Visual Acuity	N	Mean (SD)	*P*
Initial Indication*	97		.12
Fuchs		-0.89 (0.14)	
PBK		-0.65 (0.18)	
Failed PKP		-0.98 (0.17)	
Failed DSEK		-0.31 (0.26)	
Repeat Indication	103		.001
Primary Graft Failure		-1.10 (0.15)	.002
Unsatisfactory Visual Outcome		0.84 (0.58)	0.02
Late Endothelial Graft Failure		-0.52 (0.11)	--
Graft Failure following surgery		-1.31 (0.41)	.06
Graft Failure following immune rejection		-0.68 (0.33)	.66
Initial Re-bubble	112		.03
No		-0.64 (0.11)	
Yes		-1.03 (0.15)	
Repeat Re-bubble	112		.80
No		-0.79 (0.10)	
Yes		-0.85 (0.21)	
History of Glaucoma	115		.08
No		-0.89 (0.10)	
Yes		-0.59 (0.14)	
Diabetes	112		.76
No		-0.81 (0.11)	
Yes		-0.75 (0.17)	
Hypertension	115		.87
No		-0.77 (0.12)	
Yes		-0.80 (0.12)	
Coronary Artery Disease	115		.39
No		-0.81 (0.09)	
Yes		-0.57 (0.26)	
History of Glaucoma Surgery*	114		.15
No		-0.86 (0.10)	
Yes		-0.59 (0.15)	
Glaucoma Surgery Type*	34		.65

Neither		-0.47 (0.22)	
Trabeculectomy		-0.50 (0.26)	
Tube Shunt		-0.88 (0.26)	
Both Trabeculectomy and Tube Shunt		-0.51 (0.46)	
Glaucoma Medication	115		.07
No		-0.93 (0.12)	
Yes		-0.62 (0.13)	
History of PKP	115		.58
No		-0.92 (0.12)	
Yes		-0.77 (0.10)	

Table 5: *Categorical predictors of logMAR BCDVA change from EK2 pre-op to latest post-op*

Note: N=121. Significance determined using a mixed effects model taking into account clustering at the site. *Significance determined using a generalized linear model without random site effects due to low site counts.

Ocular and Systemic Co-morbidities	N	N (%)
History of Glaucoma	121	44 (36%)
History of PKP	121	12 (9.9%)
Diabetes	118	32 (27%)
Hypertension	120	60 (50%)
Coronary Artery Disease	121	12 (9.9%)
Glaucoma Surgery	120	38 (32%)
Glaucoma Surgery Type	38	
Trabeculectomy		10 (26%)
Tube Shunt		10 (26%)
Both Trabeculectomy and Tube Shunt		3 (7.9%)
Other (SLT and diode cyclophotocoagulation)		15 (39%)
Median Number of Glaucoma Medications Post-op (IQR)	121	0 (0 – 2)
Initial DSEK Re-bubble	118	40 (34%)
Repeat DSEK Re-bubble	118	18 (15%)

Table 6. List of ocular and systemic co-morbidities and re-bubble rates.

Repeat Re-Bubble Predictor	N	OR (95% CI)	*p*
Diabetes (Yes vs No)	115	0.51 (0.13 – 2.01)	.33
History of Glaucoma (Yes vs No)	118	0.64 (0.20 – 2.01)	.44

Table 7. Predictors of repeat DSEK re-bubble

Note: N=121. Significance determined using a generalized linear mixed model taking into account clustering at the site.