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Descemet's stripping automated endothelial keratoplasty with anterior chamber intraocular lenses: complications and 3-year outcomes

Marcus Ang,[1,2] Lim Li,[1,2] Daniel Chua,[1] Cheewai Wong,[1,2] Hla M Htoon,[2] Jodhbir S Mehta,[1,2,3,4] Donald Tan[1,2,3]

[1]Singapore National Eye Centre, Singapore, Singapore
[2]Singapore Eye Research Institute, Singapore, Singapore
[3]Department of Ophthalmology, National University Health System, Singapore, Singapore
[4]Duke, NUS Graduate Medical School, Singapore, Singapore

Correspondence to
Professor Donald Tan, Singapore National Eye Centre, 11 Third Hospital Avenue, Singapore 168751, Singapore; donald.tan.t.h@snec.com.sg

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ABSTRACT

Purpose To describe outcomes and complications following Descemet's stripping automated endothelial keratoplasty (DSAEK) in eyes with pseudophakic bullous keratopathy (BK) while retaining the anterior chamber intraocular lenses (ACIOL).

Methods We included consecutive patients who underwent DSAEK for BK at a single tertiary centre from 1 January 2008 to 1 April 2010, from our prospective cohort (Singapore Corneal Transplant Study). We compared eyes with BK, which underwent DSAEK while retaining ACIOL (n=18), to those with DSAEK alone with the posterior chamber intraocular lenses left in place as a comparison group (n=114). Main outcome measures were endothelial cell (EC) loss and graft survival.

Results The percentage EC loss at 1 year was 31.9±21.3% in the DSAEK with ACIOL group compared to 24.5±21.2% in the DSAEK group (p=0.516); however, this figure was significantly greater in the DSAEK with ACIOL group at 3 years compared to the DSAEK group (55.3±29.2% vs 33.3±20.8%; p=0.01 respectively). Graft survival was also significantly poorer in the DSAEK ACIOL group compared to the DSAEK group over 3 years (log rank p=0.002).

Conclusions We found that although eyes with BK and ACIOL that underwent DSAEK while retaining the ACIOL suffered EC loss which was not significantly greater at 1 year, EC loss and graft survival were significantly poorer compared to DSAEK controls at 3 years postoperatively.

INTRODUCTION

Corneal endothelial cell (EC) loss after intraocular surgery, especially after complicated cataract surgery leading to the placement of anterior chamber intraocular lens (ACIOL), can lead to corneal decompensation and bullous keratopathy (BK).[1] Selective replacement of damaged ECs in these eyes is now possible with endothelial keratoplasty—most commonly, in the form of Descemet's stripping automated endothelial keratoplasty (DSAEK).[2] While the advantages of DSAEK over penetrating keratoplasty are clear,[3] it has been suggested that complications such as graft dislocation and primary graft failure may be more frequent with DSAEK in the presence of an ACIOL.[4] Performing DSAEK in an eye with an ACIOL can be more challenging and carries a higher propensity for donor endothelial damage from direct endothelial contact with the ACIOL during donor insertion or donor unfolding; there is also a higher risk of donor dislocation due to the fact that air tamponade intraoperatively or postoperatively may be less effective due to direct access to the vitreous cavity in these cases.[5]

Thus, in eyes that suffer from BK with an ACIOL present, the dilemma is whether to perform a DSAEK and retain the ACIOL or perform an intraocular lens (IOL) exchange (either in conjunction or as a staged procedure). Currently, there are few studies to guide surgeons with this decision. Previous non-comparative case series of DSAEK while retaining the ACIOL reported a mean EC loss of 41% at 12 months (12 eyes)[6] to 48% at 14 months (31 eyes).[5] Complications such as graft dislocation (13%) and graft failure (16%) were reported in this study. On the other hand, a study of 11 eyes that underwent ACIOL removal with IOL exchange (sutured IOL to the sulcus or iris) reported an EC loss of 33% at 6 months, compared to an EC loss of 26% in a control group of DSAEK with posterior chamber intraocular lens (PCIOL) left in place.[7] An additional case series (11 eyes) reported 36% EC loss over a range of 9–26 months in cases of DSAEK with ACIOL removal and scleral fixated PCIOL.[8]

Collectively, these studies suggest that DSAEK with IOL exchange (sutured PCIOL) may result in a better EC retention, with comparable complications as compared to DSAEK while retaining the ACIOL. However, it has also been suggested that DSAEK while retaining the ACIOL may be a viable alternative as surgery would be less complicated as long as donor insertion is not compromised by the presence of the ACIOL. At the Singapore National Eye Centre (SNEC), we have begun to observe cases with an unexplained drop in endothelial cell density (ECD), as well as late endothelial failures, and were concerned about the long term effect of the ACIOL on the DSAEK graft. We therefore embarked on this study to compare 3-year EC loss and graft survival in eyes that suffered from BK that underwent DSAEK while retaining the ACIOL to eyes with BK and PCIOL that underwent DSAEK.

MATERIALS AND METHODS

We reviewed all consecutive patients who underwent DSAEK for pseudophakic BK from 1 January 2008 to 1 April 2010. We then identified eyes which underwent DSAEK while retaining the ACIOL, and compared these to cases of DSAEK in eyes with pseudophakic BK and a PCIOL. All data were obtained from our Singapore Corneal Transplant Study (SCTS), which is an audited, prospective cohort study which tracks and records all clinical data and

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outcomes in patients who undergo corneal transplants at the SNEC.[9] All surgeries were performed by the five corneal surgeons at our centre, which included cases performed or partially performed by corneal fellows in training under direct supervision. Our study followed the principles of the Declaration of Helsinki, with ethics approval obtained from our local institutional review board; patient informed consent was also obtained.

We studied the patients' demographics, clinical features, and graft outcomes over a 3 year folllow-up period. The Singapore Eye Bank provides all donor corneas with standard internal guidelines for DSAEK grafts and we obtained all donor information from their database, including donor ECD.[9] Preoperative specular microscopy of the donor tissue was performed either by certified technicians in an Eye Bank Association of America certified eye bank or by a certified eye bank technician at the Singapore Eye Bank. Postoperative specular microscopy measurements of ECD were performed using a non-contact specular microscope (Konan Medical Corp, Hyogo, Japan) at 1 year postoperatively, by trained ophthalmic technicians. Calibrations and magnifications were standardised and performed as previously described.[10] Graft failure was defined as irreversible loss of optical clarity, sufficient to compromise vision for a minimum of three consecutive months.[11] Glaucoma was diagnosed if there were also glaucomatous optic nerve head changes and/or—in patients who could perform reliably—glaucomatous visual field defects on Humphrey 24–2 full threshold test.[12] Visual acuity (VA) was measured using the Snellen VA chart and we analysed results using logarithm of the minimum angle of resolution (logMAR) equivalent units.[13]

Surgical technique

DSAEK surgeries were performed by non-folding techniques using either a Sheets glide,[10 14] or the EndoGlide donor inserter device (Angiotech, Reading, Pennsylvania, USA/Network Medical Products, North Yorkshire, UK).[15] Donors were prepared by the surgeon using an automated lamellar therapeutic keratoplasty system (ALTK, Moria SA, Antony, France). Briefly, after Descemet's membrane stripping, insertion of an anterior chamber (AC) maintainer, an inferior iridectomy, and preplaced venting incisions, the donor was pulled into the eye using either the Sheets Glide technique, or an EndoGlide device, using coaxial microforceps introduced through a nasal paracentesis. The scleral tunnel and AC maintainer wounds were secured with 10/0 nylon interrupted sutures, and a full air tamponade was performed for at least 6 min. Following this, a smaller air bubble approximating the size of the endothelial keratoplasty (EK) graft was left in the AC. Patients were examined approximately 1 h after surgery to ensure that no donor dislocation or pupillary block was present.

Postoperative care

All patients received a standard postoperative steroid regimen: prednisolone acetate 1% (Allergan, Inc, Irvine, California, USA) or dexamethasone sodium phosphate 0.1% (Bausch & Lomb, Inc, Rochester, New York, USA), and a topical antibiotic. Both steroid and antibiotic eyedrops were prescribed to be applied every 3 hours for a month, then four times daily for 2 months, which was tapered by one drop per 3 months down to one drop per day dosing by 1 year, and thereafter continued indefinitely.

Statistical analysis

Statistical analysis included descriptive statistics, where the mean and SD were calculated for the continuous variables, while frequency distribution and percentages were used for categorical variables. Comparisons between categorical variables were conducted by Fisher's exact tests, whereas Mann-Whitney U test was used for means. The estimate of odds ratio and its relative 95% CI were calculated for risk factors. Statistical Package for the Social Sciences V.17.0 (SPSS Inc, Chicago, Illinois, USA) was used to analyse the data. A value of $p<0.05$ was considered statistically significant.

RESULTS

The study included 132 eyes with pseudophakic BK that underwent DSAEK, of which 18 eyes had ACIOLs. All eyes with ACIOL had a similar angle-supported, open-loop ACIOL (optic size 6 mm, length 13.75 mm; Bausch and Lomb, Rochester, New York/USA) in place. We found no significant differences in baseline demographics or donor characteristics between both groups: eyes that underwent DSAEK with ACIOL, and the comparative DSAEK group (table 1). We noted and recorded all complications during the follow-up period from our SCTS database (table 2).[9]

Endothelial cell counts

The EC loss at 1 year was 31.9±21.3% in the DSAEK with ACIOL group compared to 24.5±21.2% in the DSAEK group ($p=0.516$). The EC loss was significantly higher in the DSAEK with ACIOL group at 3 years compared to DSAEK (55.3±29.2% vs 33.3±20.8%; $p=0.01$). However, due to the small sample size, we could not find any differences in ECD between the Sheets glide (four eyes) and Endoglide techniques (14 eyes) in the DSAEK with ACIOL group (mean ECD at 1 year, 1794±714 vs 2278±312, respectively; $p=0.230$).

Graft survival

All DSAEK grafts with ACIOL remained clear for 1 year postoperatively. In the comparative DSAEK group, there was one case (0.9%) of primary graft failure and two cases of graft failure (1.8%) due to endothelial failure at 1 year. No graft detachments occurred in the ACIOL group, although one (0.9%) did occur in the comparative group, with successful reattachment with air bubble re-injection and graft clarity at 1 year postoperatively. Kaplan-Meier survival analysis (figure 1) showed a significantly poorer graft survival in the DSAEK-ACIOL group versus the DSAEK group (log rank $p=0.002$).

Visual outcomes and complications

There were no significant differences in baseline, preoperative best-corrected VA (BCVA) between both groups. We also analysed visual outcomes after excluding eyes with other comorbidities (some eyes with multiple comorbidities), such as age related macular degeneration, macular scars or persistent macular oedema (n=12), retinal diseases such as severe diabetic retinopathy, vein occlusions, ocular ischaemic syndrome (n=12), or advanced glaucoma and other causes of optic neuropathy (n=12) (table 2). Mean BCVA was 20/40 (logMAR, 0.27±0.11) in the DSAEK with ACIOL group (nine eyes) versus the DSAEK group (87 eyes), with a mean postoperative BCVA of 20/40 (logMAR 0.28±0.11; $p=0.601$). There was a significantly higher proportion of eyes with DSAEK and ACIOL which developed de novo glaucoma ($p=0.009$) within 1 year. Of these, five eyes (27.8%) required glaucoma filtering surgery (trabeculectomy with topical mitomycin-C) within 1 year, which was significantly higher than in the DSAEK with PCIOL group (11 eyes, 9.6%; $p=0.029$). Of note, there was no significant difference in percentage EC loss at 1 year (23.2±4.6% vs 34.5 ±25.5%, $p=0.683$, in eyes that had glaucoma surgery

Table 1 Characteristics of patients (DSAEK, ACIOL and PCIOL with BK)

Characteristics	Total (n=132)	DSAEK		p Value
		ACIOL (n=18)	PCIOL (n=114)	
Mean age, years (±SD)	69.0 (10.0)	69.7 (12.1)	68.9 (9.7)	0.965
Gender (%)				
Male	67 (50.8)	10 (55.5)	57 (50.0)	0.801
Female	65 (49.2)	8 (44.5)	57 (50.0)	
Race (%)				
Chinese	87 (65.9)	13 (72.2)	74 (64.9)	0.892
Malay	7 (5.3)	1 (5.6)	6 (5.3)	
Indian	8 (6.1)	0 (0.0)	8 (7.0)	
Others	30 (22.7)	4 (22.2)	26 (22.8)	
Baseline/preoperative				
Visual Acuity (logMAR; mean, ±SD)	1.6 (0.7)	1.8 (0.7)	1.6 (0.8)	0.147
Preoperative glaucoma (%)	41 (31.1)	6 (33.2)	35 (30.7)	0.823
Donor characteristics				
Donor ECD (mean ±SD)	2827 (219)	2822 (277)	2827 (210)	0.878
Donor thickness (μm; mean ±SD)	186 (47)	181 (41)	187 (48)	0.778
Donor diameter (mm; mean ±SD)	8.6 (0.4)	8.7 (0.4)	8.6 (0.4)	0.600

ACIOL, anterior chamber intraocular lens; BK, bullous keratopathy; DSAEK, Descemet's stripping automated endothelial keratoplasty; ECD, endothelial cell density; logMAR, logarithm of the minimum angle of resolution; PCIOL, posterior chamber intraocular lens.

compared to those that did not, respectively) and none of the patients who had glaucoma surgery experienced graft failure. No cases of pupillary block glaucoma were noted in either group, as we routinely perform peripheral iridotomies during our DSAEK surgeries. Of note, other complications such as graft rejection episodes, epitheliopathy, and corneal infections were not more common in the ACIOL group.

Table 2 Outcomes and complications comparing DSAEK with ACIOL and PCIOL over 1 year and 3 years of follow-up

Outcomes and complications	ACIOL (n=18)	PCIOL (n=114)	p Value
Outcomes (1 year)			
*Postoperative ECD (mean ±SD)	1910 (615)	2132 (609)	0.618
†Number of graft failure at 1 year (%)	0 (0.0)	3 (2.6)	0.486
Postoperative visual acuity			
Overall (logMAR; mean ±SD)	0.7 (0.7)	0.6 (1.1)	0.630
‡Outcomes (3 years)			
Postoperative ECD (mean ±SD)	1236 (762)	1906 (587)	0.022
Number of graft failures at 3 years (%)	7 (36.8)	12 (10.3)	0.006
§Complications			
Glaucoma	8 (44.4)	20 (17.5)	0.009
Graft rejection episode	0 (0)	2 (1.8)	0.644
Graft detachment	0 (0)	1 (0.9)	0.745
Corneal infection	0 (0)	2 (1.8)	0.644
Epitheliopathy	0 (0)	2 (1.8)	0.644
Primary graft failure	0 (0)	1 (0.9)	0.745
Recurrence of primary disease	0 (0)	0 (0)	NA
Viral/herpetic infection	0 (0)	0 (0)	NA
Suprachoroidal haemorrhage	0 (0)	0 (0)	NA
Endophthalmitis	0 (0)	0 (0)	NA

*Number of patients with valid endothelial cell density (ACIOL, n=14; PCIOL, n=101).
†Graft failure was defined as irreversible loss of optical clarity, sufficient to compromise vision for a minimum of three consecutive months.
‡Number of patients (ACIOL, n=8; PCIOL, n=39).
§Complications as recorded in our prospective SCTS database at 1 year follow-up.
ACIOL, anterior chamber intraocular lens; DSAEK, Descemet's stripping automated endothelial keratoplasty; ECD, endothelial cell density; logMAR, logarithm of the minimum angle of resolution; NA, not applicable; PCIOL, posterior chamber intraocular lens; SCTS, Singapore Corneal Transplant Study.

DISCUSSION

Our study suggests that performing DSAEK while retaining the ACIOL results in higher EC loss and graft failure over a 3-year follow-up period. Graft complications and increased EC loss may be expected when performing DSAEK while retaining the ACIOL, due to increased tissue manipulation, reduced space in the anterior chamber, and difficult intraoperative air bubble manipulation in the anterior chamber, depending on the insertion technique used.[16 17] Early on in our evolution of DSAEK surgery techniques, we switched from the traditional taco folding technique to developing the Sheets glide technique, because we experienced significant difficulties in the insertion

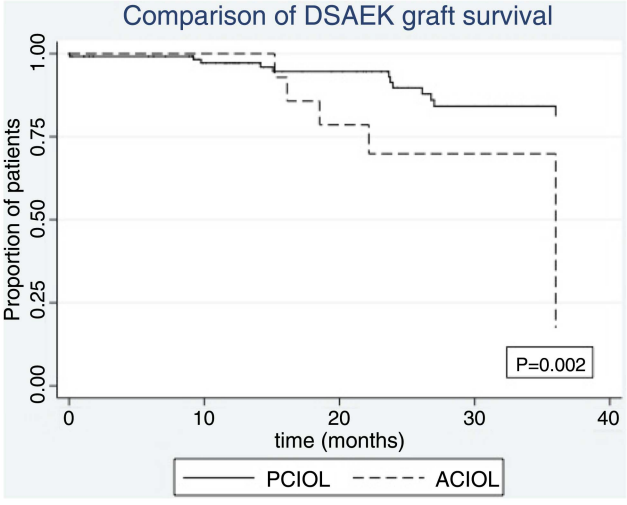

Figure 1 Kaplan-Meier survival curves comparing Descemet stripping automated endothelial keratoplasty graft survival (DSAEK), demonstrating a significantly poorer graft survival in the anterior chamber intraocular lens (ACIOL) group compared to the posterior chamber intraocular lens (PCIOL) group over 3 years (log rank p=0.002).

and unfolding of the donor in our smaller Asian eyes with shallow chambers and high vitreous pressure; we subsequently developed the EndoGlide device which evolved from our experience with the Sheets glide insertion, as the former provided a simpler, more reliable insertion approach which ultimately reduced our EC loss rate to 15% at 1 year.[10 14 18 19] Serendipitously, with both these insertion techniques, we found donor insertion in the presence of an ACIOL to be relatively uncomplicated. Nonetheless, we observed that our DSAEK technique using the Endoglide allows for a more stable anterior chamber in a closed system, thereby aiding donor insertion while reducing tissue manipulation and ACIOL contact.[15] These factors could explain the lower EC loss in our eyes that underwent DSAEK while retaining the ACIOL of 31.9% at 1 year (previous reports of DSAEK while retaining the ACIOL at 1 year ranged 41–48%).[5 6] In fact, the EC loss did not increase significantly from 6 months (30.0±25.5%; p=0.812), which suggests that this observed EC loss at 3 years was not from the initial surgical trauma. However, direct comparative studies are required in order to confirm this.

As all our DSAEK cases routinely undergo peripheral iridectomies, none of our cases experienced pupillary block in the early postoperative period. Delayed incidence of glaucoma after DSAEK, presumed to be secondary to corticosteroid use, is reported in up to 15–18% of cases,[3] as was found in our comparison group (17.5%). However, in our study we observed that the presence of the retained ACIOL had a three times higher risk of developing glaucoma (44.4%), compared to DSAEK alone (17.5%), in eyes that did not have pre-existing glaucoma (OR 3.76, 95% CI 1.3 to 10.7; p=0.013). Further analysis for other possible risk factors such as the preoperative presence of anterior synechiae or persistent inflammation were not significant, likely due to the small number of eyes in our study. Moreover, preoperative assessment for angle damage via gonioscopy may be difficult due to the poor view secondary to the corneal decompensation and the presence of the ACIOL. We recommend that surgeons who choose to retain the ACIOL during DSAEK for eyes with BK should perform anterior segment optical coherence tomography preoperatively, and aggressively monitor and manage any rise in intraocular pressure.

This study suggests that during DSAEK, surgeons should consider removing the ACIOL. Previous reports of DSAEK with removal of the ACIOL and concurrent IOL exchange (sutured PCIOL) reported an EC loss at 1 year of 33–36%.[7 8] Complications such as graft dislocation and primary graft failure were not found to be significantly higher in the DSAEK with IOL exchange group compared to DSAEK alone (while retaining PCIOL, similar to our control group).[7] A reported small series of three eyes also underwent successful DSAEK with iris-fixated PCIOL with EC loss of up to 45% at 1 year.[20] However, iris-fixated PCIOL during DSAEK has a reported 27% graft dislocation rate,[8] with the potential risk of intraocular haemorrhage, delayed lens dislocations, cystoid macular oedema, and iris damage.[5] On the other hand, it has been suggested that surgeons could choose to retain the ACIOL during DSAEK with careful patient selection. Suggested criteria include eyes with a deep anterior chamber ≥2.5 mm, minimal peripheral anterior synechiae, or absence of vitreous in the anterior chamber.[5] Our study also suggests that using non-folding techniques or insertion devices such as the Endoglide, which helps maintain the anterior chamber using a closed system while reducing tissue manipulation, may be useful. However, this certainly requires confirmation using direct comparative studies of donor insertion methods, with a longer follow-up period.

The limitations of our study include the limited follow-up and the small sample size—which confines our results to those that were significantly different between both groups. However, it would be difficult to attain the large numbers of eyes required to study the outcomes of DSAEK while retaining the ACIOL. We estimated that more than 400 eyes would be required in each group to perform an adequately powered study (power of 90% and α of 0.05, to detect a 5% difference between groups).[21] Moreover, our current sample size is similar to those in previous published reports.[5–8 22] Although the higher incidence of glaucoma in the ACIOL group could affect the EC loss, our sample size was underpowered to study this confounder and will require further studies to confirm this possibility. Ideally, we should perform a study comparing DSAEK while retaining the ACIOL, directly with eyes that underwent DSAEK and IOL exchange. However, the sample size would be too small in each group for any meaningful analysis; thus we compared results of DSAEK with retained ACIOL with a comparison group of DSAEK alone—a comparative group used in previous studies—to give some insight into the effect of retaining the ACIOL during DSAEK.[23]

In conclusion, we found that DSAEK while retaining the ACIOL in selected cases has greater EC loss and graft failure at 3 years follow-up. Moreover, there is a higher risk of developing de novo glaucoma in these eyes. Direct comparative studies between DSAEK-ACIOL and DSAEK with IOL exchange are required to confirm the superiority of either procedure in such eyes with corneal decompensation.

Contributors All authors met the ICJME criteria: (1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (2) drafting the article or revising it critically for important intellectual content; and (3) final approval of the version to be published.

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Patient consent Obtained.

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Data sharing statement There are no further unpublished data. All data may be obtained from the corresponding author.

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