Descemet Stripping Automated Endothelial Keratoplasty in Fuchs’ Endothelial Dystrophy versus Pseudophakic Bullous Keratopathy

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Abstract

Purpose: To compare clinical and confocal scan outcomes after Descemet stripping automated endothelial keratoplasty (DSAEK) performed for Fuchs’ endothelial dystrophy (FED) versus pseudophakic bullous keratopathy (PBK).

Methods: This retrospective comparative study included 47 consecutive eyes of 39 patients with the diagnosis of FED (n = 29, group 1) or PBK (n = 18, group 2) that underwent DSAEK. Clinical outcomes were compared between the study groups. At the final follow-up examination, confocal microscopy was used to measure and compare central corneal and graft thickness as well as endothelial cell density and morphology between the two groups.

Results: Mean age at the time of surgery was 65.2 ± 11.8 and 69.4 ± 12.5 years in groups 1 and 2, respectively (P = 0.27). Follow-up period was 23.6 ± 14.0 months in group 1 and 25.6 ± 15.7 months in group 2 (P = 0.79). Postoperative best spectacle-corrected visual acuity was significantly better in group 1 than in group 2 until postoperative month 6. Afterwards, the two study groups were comparable in this regard. At the final follow-up examination, spherical equivalent refractive error was +0.39 ± 1.46 diopters (D) in group 1 and +0.80 ± 1.47 D in group 2 (P = 0.45). Postoperative keratometric astigmatism was 1.02 ± 0.83 D and 2.36 ± 0.67 D, respectively (P < 0.001). Mean central graft thickness was 98.0 ± 33.3 μm in group 1 and 107.6 ± 28.0 μm in group 2 (P = 0.45). No statistically significant difference was observed between the two groups in terms of the postoperative endothelial cell density.

Conclusion: The outcomes of DSAEK surgery were comparable between FED and PBK. All grafts were clear despite the lower than normal endothelial cell counts.

Keywords: Confocal Scan; Descemet Stripping Automated Endothelial Keratoplasty; Fuchs’ Endothelial Dystrophy; Outcomes; Pseudophakic Bullous Keratopathy

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INTRODUCTION

Penetrating keratoplasty (PK) is no longer considered the primary procedure for all corneal disorders. Along with...
recent developments in corneal transplantation, selective replacement of a diseased corneal layer is performed. Nowadays, the trend is to perform Descemet stripping automated endothelial keratoplasty (DSAEK) for patients with only endothelial dysfunction.\(^1\) Currently, 89% of patients with Fuchs’ endothelial dystrophy and 55% of subjects with post-cataract corneal edema are treated with endothelial keratoplasty.\(^2\) This selective approach has several advantages over PK in terms of more rapid visual rehabilitation, less surgically-induced astigmatism, less incidence of graft rejection, and preservation of biomechanical properties. Moreover, the risk of traumatic wound dehiscence is decreased by DSAEK. Despite the above-mentioned advantages, complications such as high intraocular pressure (IOP) may occur after this type of corneal transplantation leading to graft failure.\(^3,4\) Furthermore, there is a large surgically induced loss of endothelial cells (approximately 25% to 50%) during the time frame of 6 months to one year.\(^5,6\) Comparative studies between DSAEK and PK have shown that DSAEK has a greater initial endothelial cell loss.\(^7,8\)

The present study aimed to evaluate and compare clinical and confocal scan outcomes of DSAEK in the treatment of Fuchs’ endothelial dystrophy versus pseudophakic bullous keratopathy.

**METHODS**

In this retrospective comparative study, 47 consecutive eyes of 39 patients who underwent DSAEK between January 2008 and September 2014 were enrolled. Indications for DSAEK included Fuchs’ endothelial dystrophy and pseudophakic bullous keratopathy. The presence of other ocular comorbidities except the indication for corneal transplantation led to patient exclusion. Participants had all sutures removed at least 3 months before entering the study. This study was approved by the Institutional Ethics Committee of the Ophthalmic Research Center, Shahid Beheshti University of Medical Sciences Tehran, Iran. Preoperatively, complete ocular examinations including uncorrected visual acuity (UCVA) and best spectacle-corrected visual acuity (BSCVA) using the Snellen acuity chart (expressed in logMAR notations), slit-lamp examination, tonometry, dilated funduscoppy, and manifest refraction (when possible) were performed.

All procedures were performed by the same surgeon (MAJ). When indicated, eyes with significant lens opacity were simultaneously treated with phacoemulsification and posterior chamber intraocular lens implantation before DSAEK (triple procedure). Phacoemulsification was performed through a single-plane 2.8-mm clear corneal incision at the superotemporal quadrant in right eyes and supronasal quadrant in left eyes. Standard phacoemulsification was performed and a foldable one-piece monofocal IOL (AcrySof SN60WF, Alcon Laboratories Inc., Fort Worth, Tex, USA) was inserted into the capsular bag. At the conclusion of cataract surgery, the ocular viscoelastic device (OVD) was completely removed from the anterior chamber and capsular bag. To reduce the likelihood of unintended postoperative hyperopia, we empirically aimed for a more myopic postoperative outcome by targeting a postoperative refraction of \(\pm 1.0\) to \(-2.0\) diopters (D).

To perform DSAEK, the central recipient epithelium was marked to outline where to strip descemetic membrane (DM) and place the donor tissue. The anterior chamber was filled with air through a paracentesis incision, and the recipient DM was scored in a circular pattern under the area of the epithelial marking using a reverse Sinskey hook. The DM and endothelium were stripped using a Descemet stripper and removed through a 3.5-mm posterior limbal incision while the anterior chamber was formed using an anterior chamber maintainer.

A precut corneal tissue prepared by the Central Eye Bank of Islamic Republic of Iran using a microkeratome equipped with a 350-μm head (Moria Inc., Doylestown, PA, USA) was procured in Optisol GS (Baush and Lomb, Rochester, NY, USA). No marks were made on the graft stroma. The donor tissue was cut from the endothelial side using a Barron donor punch (Katena, Denville, NJ, USA) with a trephine before the anterior stroma was removed. The size of trephine (between 7.50 and 8.25 mm) was selected 2 mm less than the vertical corneal diameter. A small amount of dispersive viscoelastic (Coatel, Bausch & Lomb, Waterford, Ireland) was placed on the endothelial surface. The donor lamella was inserted into the anterior chamber using the pull-through technique with a Busin glide. An air bubble was introduced to unfold and attach the donor lamella to the posterior stromal surface. After securing the wound with interrupted 10-0 nylon sutures, the reverse Sinskey hook was inserted from the paracentesis incision for donor centering, and the anterior chamber was filled completely with air for 10 minutes. To prevent direct trauma to the endothelium, the lenticule edge was grasped during repositioning with the reverse Sinskey hook. Afterward, the air was reduced to approximately 60% of the anterior chamber volume. No venting incisions were created in the recipient cornea.

Postoperatively, patients were examined on days 1, 3, 7, and 30. Follow-up examinations were performed at months 3, 6, and 12 after operation and at least 3 months after complete suture removal and every 6 months thereafter. Postoperatively, all of the patients received topical chloramphenicol and topical hypertonic 5% sodium chloride eye drops every 6 hours for 14 days and topical 0.1% betamethasone eye drops every 4 hours tapered off over 2 to 3 months. Pseudophakic patients were maintained on steroid eye drop one drop per day for a long-term to prevent graft rejection. If indicated, topical lubricants were added to hasten the

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epithelial healing. Acute endothelial rejection reactions of the corneal transplants were treated by frequent topical 0.1% betamethasone eye drops and occasional systemic prednisolone. High intraocular pressure (IOP > 21 mmHg) was treated using topical antiglaucoma medications (except carbonic anhydrase inhibitors).

An ocular examination including UCVA and BSCVA, slit-lamp biomicroscopy, manifest refraction, keratometry, and intraocular pressure (IOP) using Goldmann applanation tonometry was performed at each postoperative follow-up examination. All measurements were achieved at the same location with the same equipment.

At the final follow-up examination, confocal microscopy (Confoscan 3; NIDEK Technology, Padova, Italy) was used to measure central corneal and graft thickness and endothelial cell density. The full thickness of the central cornea was scanned from the endothelium to the epithelial surface, and a maximum of 350 digital images (25 images per second) were captured with a digital video camera. Using three Z-scan graphs in each cornea, central corneal thickness (distance between the epithelial and endothelial reflectivity peaks) and central graft thickness (distance between the interface and endothelial reflectivity peaks) were calculated and averaged. A clear image of the endothelial layer was selected for endothelial evaluation. Automatic cell count processing within a 0.1 mm² standardized region of interest in the central cornea was performed to obtain postoperative endothelial cell density.

Data were analyzed using SPSS statistical software version 21 (IBM Corp., Armonk, NY, USA). Mean and standard deviation, range, frequency and percentage were used to express data. The normal distribution of continuous variables was verified using a Kolmogorov–Smirnov test and a Q-Q plot. Comparisons between the pre- and postoperative quantitative values were performed using a paired t-test. Independent student test was used to compare quantitative measurements between the two study groups. The Chi-square and Fischer’s exact tests were applied to compare qualitative parameters between the two groups. P value less than 0.05 was considered as statistically significant. All reported P values are two-sided.

RESULTS

Out of 47 eyes of 39 patients (19, male subjects), 29 (61.7%) eyes of 21 patients were diagnosed with Fuchs’ endothelial dystrophy (group 1) and 18 (38.3%) eyes of 18 patients had pseudophakic bullous keratopathy (group 2). Mean age at the time of surgery was 65.2 ± 11.8 (range, 44 to 95) years and 69.4 ± 12.5 (range, 47 to 86) years in groups 1 and 2, respectively (P = 0.27). In group 1, 6 (20.7%) eyes underwent stand-alone DSAEK, of which, 4 (13.8%) eyes were pseudophakic at the time of corneal transplantation. Twenty-three (79.3%) eyes of group 1 received DSAEK triple procedure. All eyes of group 2 had stand-alone DSAEK. Donor trephination size was 8.10 ± 0.15 (range, 7.75 to 8.25) mm in group 1 and 7.96 ± 0.22 (range, 7.75 to 8.25) mm in group 2 (P = 0.06). Data relevant to donors are presented in Table 1. There was no significant difference between the two groups in terms of donors’ gender and age, endothelial cell density and morphology, or death-to-preservation time [Table 1].

Mean follow-up period was 23.6 ± 14.0 (range, 6 to 60) months in group 1 and 25.6 ± 15.7 (range, 6 to 77) months in group 2 (P = 0.79). Visual acuity was recorded in every participant preoperatively and then at months 1, 3, and 6 after operation. In group 1, such measurement was obtained in 24 (82.8%), 18 (62.1%), 12 (41.4%), and 6 (20.7%) eyes at years 1, 1.5, 2, and 3, respectively. In group 2, the corresponding figures were 13 (72.2%), 9 (50.0%), 7 (38.9%), and 5 (27.8%), respectively.

Preoperatively, UCVA was 0.86 ± 0.55 (range, 0.18 to 2.10) logMAR in group 1 and 1.44 ± 0.50 (range, 0.48 to 2.40) logMAR in group 2 (P = 0.001). Postoperative UCVA and BSCVA were significantly better in group 1 compared to group 2 until postoperative month 6 [Tables 2 and 3; Figure 1]. Afterwards, the two study groups were comparable regarding visual acuity [Tables 2 and 3; Figure 1]. No participants achieved a BSCVA of 20/20 at the final follow-up examination. At this time point, the percentages of eyes obtaining a BSCVA of 20/25, 20/30, 20/40, and 20/50 were 5.9%, 9.1%, 35.3%, 29.4%, and 23.5% in group 1. Corresponding figures in group 2 were 0.0%, 9.1%, 9.1%, and 36.4%, respectively (P = 0.17).

![Figure 1](image-url)
At the final follow-up examination, spherical equivalent refractive error was +0.39 ± 1.46 (range, -1.25 to +4.0) D in group 1 and +0.80 ± 1.47 (range, -1.63 to +3.0) D in group 2 (P = 0.45). Postoperative keratometric astigmatism was significantly higher in group 2 [2.36 ± 0.67 (range, 1.0 to 3.25) D] compared to group 1 [1.02 ± 0.83 (range, 0.0 to 3.0) D; P < 0.001].

Central corneal and graft thickness and endothelial cell density were measured at the final follow-up examination using confocal microscopy. Mean central corneal thickness was 566.3 ± 35.6 (range, 512.0 to 660.0) μm in group 1 and 586.7 ± 37.5 (range, 533.0 to 665.4) μm in group 2 (P = 0.17). Mean central graft thickness was 98.0 ± 33.3 (range, 51.0 to 163.0) μm in group 1 and 107.6 ± 28.0 (range 72.0 to 163.0) μm in group 2 (P = 0.45). No statistically significant difference was observed between the two groups in terms of postoperative endothelial cell density and morphology [Table 4]. Postoperative endothelial cell density measured at the final follow-up examination was 1980.9 ± 596.9 cells/mm² in group 1 and 1730.8 ± 837.2 cells/mm² in group 2 (P = 0.39). A significant decrease in endothelial cell density was observed in group 1 [1116.9 ± 594.0 (range, 163 to 2459) cells/mm²; P < 0.001] and group 2 [1445.4 ± 829.3 (range, 695 to 2710) cells/mm²; P = 0.01] which means a reduction of 35.9% and 46.0% in preoperative endothelial...
cell density in groups 1 and 2, respectively. The two study groups were comparable in terms of reduction in endothelial cell density \((P = 0.28)\).

No complications such as vitreous loss or choroidal effusion/haemorrhage occurred intraoperatively. With respect to postoperative complications, pupillary block occurred in one eye in group 1 necessitating partial air elimination through a corneal wound. Donor graft nonattachment requiring air re-injection was observed in 2 (11.1%) eyes of group 2. These grafts were reattached after a single injection. This complication was not encountered in group 1 \((P = 0.07)\). A small amount of graft decentration not requiring repositioning was seen in 2 (7.9%) eyes of group 1 and 4 (22.2%) eyes of group 2 \((P = 0.13)\). Interface haziness \((n = 1)\) and graft folding \((n = 1)\) were observed in group 1 \((P > 0.99)\). High intraocular pressure related to corticosteroid developed in 4 (13.8%) eyes of group 1 and 4 (22.2%) eyes of group 2 \((P = 0.69)\). IOP returned to the normal level in these eyes with the administration of anti-glaucoma eye drops. Five (17.2%) eyes of group 1 and 3 (16.7%) eyes of group 2 experienced an episode of endothelial graft rejection \((P > 0.99)\) which were successfully treated with frequent topical 0.1% betamethasone eye drops. Graft failure occurred in one eye of group 1 necessitating graft exchange \((P > 0.99)\). By the time that final postoperative examination was performed, all corneas were clear.

**DISCUSSION**

For the past 50 years, PK has been the gold standard surgical procedure for patients with corneal endothelial failure. Endothelial keratoplasty techniques are relatively new surgical procedures and have become the treatment of choice for patients with corneal endothelial dysfunction.\[^1^,^2^\] The rise in popularity of these techniques can be attributed to more rapid visual recovery without the need for extensive suture removal, less surgically-induced astigmatism, less incidence of graft rejection, and preservation of biomechanical properties. Outstanding results from DSAEK have been reported in the literature.\[^6^,^10^\] There have been other cohort studies comparing outcomes of DSAEK in Fuchs' endothelial dystrophy versus pseudophakic bullous keratopathy in a larger sample size. The present study, however, was performed by a single surgeon which can add new and relevant information for the Middle-Eastern patient population.

In the present study, visual acuity was significantly better in the Fuchs' endothelial dystrophy group at months 1, 3, and 6 postoperatively, indicating that patients with pseudophakic bullous keratopathy gained visual acuity more slowly over time as compared to those with Fuchs' endothelial dystrophy. Better preoperative visual acuity in the Fuchs' endothelial dystrophy group may reflect less severe corneal edema. Postoperatively, the resultant decrease in corneal edema and tissue remodelling over time led visual acuity in the pseudophakic bullous keratopathy group became comparable to that in the Fuchs' endothelial dystrophy group after one year. The gradual improvement of visual acuity over time can be attributed to remodelling taking place in the interface between the donor button and the host stromal tissue in addition to the subepithelial and stromal tissue of the host cornea.\[^12^\] This remodelling may diminish the effects of chronic changes observed after long-standing corneal edema. Surgical technique was also different between the two cohorts. Approximately, 80% of group 1 received DSAEK triple procedure because of clinically significant cataract, whereas all eyes of group 2 had DSAEK alone. This difference could add an additional variable to the comparison. Although some previous studies advocated that cataract surgery and subsequent endothelial keratoplasty should be performed as a 2-stage surgical procedure,\[^13^\] the current predominant opinion suggests that both procedures can be carried out at the same time.\[^14^,^15^\] Terry et al\[^14^\] suggested that combined DSAEK and phacoemulsification procedure did not significantly differ in terms of clinical outcomes. This observation indicates that concurrent phacoemulsification and posterior chamber IOL implantation does not negatively impact postoperative visual acuity.

In the current study, a BSCVA of 20/40 or better was achieved in 50% of the whole study group. In articles by other investigators, this percentage was between 61.8 and 94.4%.\[^6^,^16^,^17^\] None of the participants in our study achieved a BSCVA of 20/20 and a BSCVA of 20/25 was not observed in the pseudophakic bullous keratopathy at the final follow-up examination. In this regard, our results are inferior to the results by other previous studies. Li et al\[^17^\] reported that 11.1% of their cases had
20/20 vision at month 3; this percentage increased to 47.2% after 3 years. It is not clear why our patients did not achieve a BSCVA of 20/20 after DSAEK surgery even though an apparently clear interface was observed in all cases except one. This suggests that irreversible stromal opacity had already occurred in many cases, which was likely to inhibit the complete improvement of postoperative visual acuity. Light scatter may be induced from chronic changes in the subepithelial region and stroma of host cornea, even after successful DSAEK surgery. In addition, wrinkles or folds of the donor tissue causing irregularity of the posterior corneal surface also has been associated with unsatisfactory vision after DSAEK surgery.

Studies have found that DSAEK grafts induce an initial hyperopic shift which decreases to some extent over time. This hyperopic shift is reported to be correlated with central graft thickness, graft trephine diameter as well as the thickness gradient between the center and the periphery of the graft. In the present study, the pseudophakic bullous keratopathy group had a higher level of hyperopia as compared to the Fuchs’ endothelial dystrophy group. However, the difference did not reach a significant level. The less amount of hyperopia in the latter group is attributable to the adjustment of IOL power at the time of simultaneous cataract and DSAEK surgery. We observed a hyperopic shift of 0.7 to 1.5 D in our initial cases. Therefore, we empirically aim for a more myopic postoperative outcome by targeting a postoperative refraction of −1.00 to −2.00 D to reduce the chance for unintended hyperopic results. This target refraction was also adopted by many surgeons and described in the literature. Despite this approach, however, a hyperopia of up to +4.0 D was observed in this group. There are two approaches to improve refractive outcomes after the DSAEK triple procedure including aiming for a more myopic postoperative outcome by targeting a postoperative refraction of −1.00 to −2.00 D and optimization of the IOL constant. However, unacceptable refractive outcomes should be expected in patients who undergo DSAEK triple procedures. The four potential sources of error in IOL calculations are corneal curvature measurement, axial length measurement, effective lens position estimation, and the IOL calculation formula. Calculating corneal power in DSAEK transplantation is not a straightforward process.

In the current study, the endothelial cell density (ECD) was reduced by 35% and 46% in groups 1 and 2, respectively. The rate of ECD decline after DSAEK in the present study is almost identical to that reported in other DSAEK studies. There is a large surgically induced loss of endothelial cells (approximately 25–50%) during the time frame of 6 months to 1 year. Comparative studies between DSAEK and PK have shown that although DSAEK has a greater initial endothelial cell loss, the subsequent cell loss is at a slower rate in comparison to PK. Early high cell loss is attributable to trauma due to tissue insertion. Despite the large initial cell loss and wide range of cell counts, all of the grafts in our study remained clear, even though many cell counts were much lower than the normal adult endothelial cell density.

Fuchs’ endothelial dystrophy and pseudophakic bullous keratopathy are among indications of corneal transplantation with moderate risk for endothelial graft rejection of PK grafts. Theoretically, there is less risk of immune rejection of the transplanted corneal tissue with DSAEK because a smaller amount of tissue is transplanted and also the endothelium is located in an immune privileged location. Allan et al. reported a lower rate and severity of endothelial graft rejection reactions in endothelial keratoplasty as compared to PK. In the current study, 8 (17.0%) eyes in the entire participants had an episodes of rejection. This rate was higher than that previously reported by Allan et al. (7.5% in the first 2 postoperative years) and Jordan et al. (7.6% in the first postoperative year and 12% after the second year). This difference can be attributed to the longer follow-up of patients in our study. Furthermore, in two eyes which had an episode of graft rejection, the grafts were decentred into the angle with close iris contact. This may have been an important contributing factor to the endothelial graft rejection reaction. All eyes were successfully treated with frequent steroid eye drops, which were slowly tapered.

Marked loss of the endothelial cells is the prominent feature of graft failure in DSAEK. This complication occurred in one eye of our patients necessitating repetition of the DSAEK. This patient underwent repeat grafting a few weeks later and had a clear graft at the final follow-up examination. Repeat DSAEK can provide visual outcomes comparable to primary DSAEK, without interface haziness. We did not encounter any late-term graft failure in this study possibly due to continued low dose topical steroid use in the majority of cases.

In conclusion, the results of the current study indicate that DSAEK is an effective technique of corneal transplantation for endothelial cell dysfunction caused by Fuchs’ endothelial dystrophy and pseudophakic bullous keratopathy. This study showed that the former group gained visual acuity at a faster rate. However, no significant difference was observed between the two study groups in terms of final BSCVA, endothelial cell density, graft rejection, or postoperative complications.

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Conflicts of Interest
There are no conflicts of interest.
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