Comparison of Outcomes Between Pull Through Descemet Membrane Endothelial Keratoplasty and Ultrathin Descemet Stripping Automated Endothelial Keratoplasty in Eyes With Fuchs' Dystrophy

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Accepted: 2021
The Egyptian Journal of Cataract and Refractive Surgery 2021,

Aim: The aim of this work is to compare between the ultrathin descemet stripping automated endothelial keratoplasty (UT-DSAEK) and the contact lens-assisted pull through (endothelium in) descemet membrane endothelial keratoplasty (DMEK) as a treatment for Fuchs' endothelial dystrophy

Methods: All consecutive patients were operated on by the same surgeon (M.B.) at Villa Serena-Villa Igea Private Hospitals, Forli, Italy, from January 2016 through June 2017 were included in a prospective study

Results: Eighty-two eyes in the DMEK group, two hundreds and fifty five eyes in the UT-DSAEK group completed 1-year follow-up Mean BCVA in DMEK patients was 0.28±0.14 preoperatively and increased to 0.87±0.22 at 3 months and to 0.97±0.21 at 6 months and then increased to 0.99±0.15 at 1 year after surgery. Increase in BCVA compared to the UT-DSAEK groups was statistically significant at 1 month (p_1<0.001, p_2<0.001), 3 months (p_1<0.001, p_2<0.001), 6 months (p_1<0.001, p_2<0.001) and even at 1 year (0.001, p_2<0.001).
Mean BCVA in UT-DSAEK< 100 μm patients was 0.29±0.14 preoperatively and increased to 0.87±0.21 at 1 year after surgery. Increase in BCVA at 3 months surgery was statistically significant (*p=0.021*) compared with the other UT-DSAEK group with grafts thicker then 100 μm indicating faster visual rehabilitation with thinner grafts but at 6 months and at 1 year there was no significant differences

Conclusions: visual recovery is significantly faster and better in the DMEK group

Keywords: DSAEK, DMEK, Fuchs' Dystrophy

Egypt J Cataract Refract 2021

Introduction

Ideal graft for endothelial keratoplasty would be giving superior visual outcomes as DMEK however with the ease of preparation and manipulation as DSEK; there was 2 ways to achieve this either by making the DMEK procedure more standardized and easy for average surgeon or refining the DSAEK graft which gives the same superior results as DMEK with less complications.

Busin et al introduced UT-DSAEK in 2012 in an attempt to achieve this goal[1]. Ultrathin DSAEK leads to grafts thinner than 131 μm, with a double microkeratome pass, and could therefore undertake a prospective evaluation of the influence of DSAEK graft thickness on visual outcomes.

On the other hand, DMEK graft delivery and positioning are still controversial steps that are managed differently by different surgeons, including various types of direct and indirect maneuvers as well as the use of intracameral air.

Muraine tackled the procedure from a different perspective. He thought that if he can deliver the folded DMEK graft with the endothelium facing inward and hold it in the AC under minimal irrigation, it would unroll spontaneously, following its natural tendency to settle down in the desired perfect position[2]. In addition, avoiding friction between the graft endothelium and the walls of the cartridge could reduce the endothelial cell loss. However, The transfer of the tissue roll from the punch block onto the cartridge in its modified configuration is not easy at all. Also unfolding, and proper positioning were not standardized. In an attempt to overcome the obstacles facing the technique reported by Muraine et al, Busin et al[3] used a sterile soft CL as a vehicle and a scaffold to transfer the roll in its trifolded configuration into a simple IOL cartridge for delivery by a bimanual pull-through technique. There is a debate about which technique is more advantageous regarding its ease, safety and efficacy. No published data has discussed this debate before, therefore, The aim of this work is to compare between the ultrathin

descemet stripping automated endothelial keratoplasty (UT-DSAEK) and the contact lens-assisted pull through (endothelium in) descemet membrane endothelial keratoplasty (DMEK) as a treatment for Fuchs' endothelial dystrophy as regard the rate of endothelial loss, graft survival and the visual outcomes 3 months after the surgery.

Patients & Methods

All consecutive patients were operated on by the same surgeon (M.B.) at Villa Serena-Villa Igea Private Hospitals, Forli, Italy, from January 2016 through June 2017 were included in a prospective study aimed at evaluating the outcomes of these technique. The study followed the tenets of the 1964 Declaration of Helsinki and was approved by the local ethics committee; detailed informed consent was provided to all patients undergoing surgery.

Before surgery, demographic data were recorded and every patient underwent a complete ophthalmologic evaluation including slit-lamp examination, best spectacle-corrected visual acuity, refraction, tonometry, fundus examination, as well as central (when possible) and peripheral endothelial specular microscopy.

Each patient also underwent a complete examination at 1, 3, 6 and 12 months after surgery to record BSCVA, manifest refraction, and applanation tonometry. Baseline donor endothelial cell density was measured by the provider eye bank by means of specular microscopy. Post- operative endothelial cell density was measured with noncontact specular microscopy (EM-3000; Tomey GmbH, Erlangen, Germany). In addition, in UT-DSAEK patients, graft thickness was determined in each patient both centrally and at 2.5 mm from the center nasally and temporally using anterior segment optical coherence tomography (Spectralis HRA OCT; Heidelberg Engineering, Heidelberg, Germany).

Statistical significance between preoperative and postoperative values was tested using a Student *t* test. A *P* value less than 0.05 was considered statistically significant. Normally distributed values were reported as mean standard deviation. Kaplan-Meier analysis was used to calculate graft survival probability and cumulative probability of a rejection episode.

Surgical techniques

In all patients, akinesia and anesthesia were induced by peribulbar injection of a 0.75% ropivacaine solution. When needed, phacoemulsification was performed using a 0.5- mm long and 2.75-mm wide clear-cornea tunnel. In all cases, a hydrophobic intraocular lens (iSert 250; Hoya, Tokyo, Japan) was implanted. Descemetorhexis was performed with a Price hook (Moria SA, Antony, France) under air removing the endothelium Descmet membrane complex from the central 9 mm of the recipient cornea. An inferior peripheral iridotomy was performed using vitreoretinal guillotine scissors under continuous irrigation from a specially designed anterior chamber maintainer (ACM; Moria SA) inserted at the 12-o'clock position.

Ultra Thin DSAEK (UT-DSAEK)

The donor cornea was mounted on an artificial anterior chamber (AAC) of the ALTK system (Moria, Antony, France), and the central donor corneal thickness was measured intraoperatively using ultrasound pachymetry (SP-3000, Tomey Gmbh, Erlangen, Germany). An initial debulking cut was performed using a Carriazo-Barraquer (CB) microkeratome (Moria, Antony, France) with a 300 μm head and after turning the dovetail of the AAC of 180°, a second microkeratome-assisted dissection (refinement cut) was carried out from the direction opposite to the one of the first cut with a head selected according to a nomogram developed by Busin, to target a residual bed with a central thickness of approximately 100 μm.

The side platform of a modified Busin glide was used to scoop the tissue floating on a balanced salt solution cushion in the hollow of the punching block; the graft then was delivered into the anterior chamber with the pull-through technique through a 3-mm clear cornea wound with the help of a microincision forceps inserted through a side entry. When necessary, centering of the graft was achieved by gentle tapping on the corneal surface. The graft was attached to the posterior corneal surface by filling the anterior chamber with air injected through the temporal side entry. Leaving a full air-fill at the end of a procedure. Both the clear cornea tunnel and the side entry were sutured watertight with interrupted 10-0 nylon sutures.

DMEK

Each donor cornea was prestripped at the eye bank over a 9.5-mm central area, with the exception of the peripheral edge for approximately 1 clock hour, which was marked on the scleral rim using gentian violet. During surgery, the cornea was laid and trephined onto the trephination block of an 8.25-mm Barron punch (Katena Products, Inc., Denville, NJ) stained with trypan blue (VisionBlue, D.O.R.C., The Netherlands). After trephination, the tips of a dedicated anatomic forceps (Moria SA) were used to trifold the DMEK graft with the endothelium inward, stained again with trypan blue, grasped at the edge of the unfolded part with the same forceps and dragged in its trifolded architecture onto a sterile therapeutic soft contact lens laid next to the trifolded graft on the punch block. The contact lens was moved onto the back entrance of the funnel of a commercially available intraocular lens cartridge, which was filled with balanced salt solution (BSS) from its distal part. A dedicated anatomic microincision forceps (Moria SA) was inserted into the distal entrance of the cartridge to reach the contact lens surface and grasp the edge of the DMEK graft. The graft then was pulled into the funnel. The back entrance of the cartridge funnel was sealed with a silicone plug mounted on the prototype of a dedicated handle to avoid reflux of liquid and graft loss during delivery. The cartridge then was turned by 180 , thus making the floor become the ceiling of the funnel, and was inserted into the main wound. Then, similar to the DSAEK technique, the DMEK graft was delivered bimanually through the clear-cornea tunnel under low-flow continuous irrigation from a dedicated ACM. Gentle tapping onto the cornea surface was used to facilitate unfolding of the lateral folds. Surgery was completed by air-tight suturing of the main wound as well as the side entries with 10- 0 nylon.

After either surgery, a pressure patch was applied and patients were instructed to lie on their backs for 2 hours before being checked at the slit lamp. If a pupillary block was present, air was released from the main wound. Beginning the next morning, dexamethasone phosphate 0.1% and tobramycin sulfate 0.3%, were administered every 2 hours, then tapered over 3 to 4 months to a single daily steroidal administration, which then was discontinued only in steroid responders and phakic patients. In every patient, all sutures were removed 4 to 6 weeks.

Results

Eighty-two eyes in the DMEK group, two hundreds and fifty five eyes in the UT-DSAEK group completed 1-year follow-up at Villa-IGEA institution. The UT-DSAEK patients were further subdivided into 2 groups according to the central graft thickness: >100 μm (77 patients) and < 100 μm (255 patients) obtained postoperatively by anterior segment OCT.

Mean BCVA in DMEK patients was 0.28±0.14 preoperatively and increased to 0.87±0.22 at 3 months and to 0.97±0.21 at 6 months and then increased to 0.99±0.15 at 1 year after surgery. Increase in BCVA compared to the UT-DSAEK groups was statistically significant at 1 month (p_1<0.001, p_2<0.001), 3 months (p_1<0.001, p_2<0.001), 6 months (p_1<0.001, p_2<0.001) and even at 1 year (0.001, p_2<0.001).

Mean BCVA in UT-DSAEK< 100 μm patients was 0.29±0.14 preoperatively and increased to 0.87±0.21 at 1 year after surgery. Increase in BCVA at 3 months surgery was statistically significant (*p=0.021*) compared with the other UT-DSAEK group with grafts thicker then 100 μm indicating faster visual rehabilitation with thinner grafts but at 6 months and at 1 year there was no significant differences between the two UT-DSAEK groups. Mean BCVA in UT-DSAEK >100 μm patients was 0.23±0.13 preoperatively and increased to 0.67±0.22 at 3 months and to 0.74±0.22 at 6 months and then increased to 0.80±0.23 at 1 year after surgery

The percentage of patients reaching a BCVA of ≥ 20/40 and ≥ 20/20 was evidently higher in the DMEK group then the other UT-DSAEK groups at 3 months, 6 months and at 1 year postoperatively confirming better and faster visual rehabilitation after DMEK.

In the DMEK group, a mean change of spherical equivalent of 0.14±0.93 D at 3 months, 0.01±1.10 D at 6 months and 0.30±1.0 D at 1 year, all these changes were statistically insignificant, while in the UT-DSAEK groups the changes were 0.55±1.21 D and 0.47±1.40 D at 3 months, 0.49±1.29 D and 0.51±1.35 D at 6 months and then increased to 0.87±0.21, 0.35±1.10 D and 0.57±1.32 D at 1 year which all proved to be insignificant changes too even in comparison to DMEK results.

Regarding the astigmatic changes postoperatively, we found in the DMEK group a mean change of astigmatism of 1.13±0.84 D at 3 months compared to 1.17±0.82 D and 1.44±0.98 D in the two UT-DSAEK groups, at 6 months the mean changes were 0.99±0.70 D in the DMEK group compared to 1.06±0.72 D and 1.10±0.92 D in the two UT-DSAEK groups, at 1 year the mean astigmatic changes in the DMEK group were 1.09±0.73 D compared to 1.07±0.81 D and 1.25±0.85 D in the UT-DSAEK groups respectively, all these changes proved to be statistically insignificant.

The mean endothelial cell loss (ECL%) in the DMEK group at 3 months was 22.69%, it stabilized afterwards; 23.46% at 6 months and 27.80% at 1 year. After UT-DSAEK the mean ECL% at 3 months was 28.69% and 22.46%; a statistically significant difference (p=0.004) showing a greater initial loss of cells in the group with the thinner grafts, but at 6 months (30.23% vs 27.5%) and at 1 year (31.84% vs 30.96%) there were no significant differences between the two groups.

The graft survival after UT-DSAEK and DMEK at 1 year was 96.7% and 98.1% respectively. There was no statistical significance between the 2 groups (P=0.5).

Graft dislocation was statistically significantly higher after DMEK (29 eyes; 35.4%) than after UT-DSAEK (6 eyes; 2.35%). none of these dislocations lead to primary graft failure in all groups and they were all fixed by rebubbling which was done twice in 4 DMEK cases and in 1 UT-DSAEK case.

There was no case with pupillary block syndrome after DMEK and only one case (0.39%) after UT-DSAEK caused by overfill with air and treated immediately with removing air from the AC and by tension lowering eye drops, endothelial count was not affected in this case.

We had a primary graft failure rate in our study in 2 DMEK cases (2.3%), 2 cases in the UT-DSAEK< 100 µm group (1.1%) and 2 cases of the UT-DSAEK > 100 µm group (2.6%) with an overall of 4 cases in the UT-DSAEK group (1.5%), all cases due to endothelial decompensation, the differences between the groups were not significant.

Rejection rates after UT-DSAEK (5.09%) were double that after DMEK (2.4%) at 1 year follow up but this was not statistically significant (p=0.536). All cases were reversed successfully with medical treatment and none lead to graft failure.

We had 1 case of cystoid macular edema in the DMEK group (1.2%) and 1 case in the UT-DSAEK group (0.39%). One case of postoperative infection occurred in the UT-DSAEK group and was successfully treated by topical antibiotics. We also had one case of persistent epithelial defect, one case of recurrent guttata and one case of interface haze in the UT-DSAEK group (0.39%), these complications did not occur in the DMEK group and there was no statistically significant differences between the two groups regarding these complications.

Discussion

Visual outcomes

In our prospective study it was found that visual recovery is significantly faster and better in the DMEK group, Increase in BCVA compared to the UT-DSAEK groups was statistically significant at 1, 3, 6 months and even at 1 year. The percentage of patients reaching a BCVA of ≥ 20/40 and ≥ 20/20 was evidently higher in the DMEK group then the other UT-DSAEK groups at 3 months, 6 months and at 1 year postoperatively confirming better and faster visual rehabilitation after DMEK.

These findings were not far from what we found in the literature because in many studies when the VA levels of patients were compared, higher percentages of patients in the DMEK group than in the DSAEK group achieved a BCVA of 20/25 or better (50% vs. 6%[4] , 67% vs. 31%[5], 53% vs. 15%[6], and 55% vs. 13%[7]) and a BCVA of 20/20 or better (46% vs. 13%)[5].

Possible causes (or theories) that would lead to sub-optimal vision in DSAEK and UT-DSAEK compared to DMEK are graft-host interface, graft thickness, graft shape and most importantly the recipient cornea.[8, 9] Rudolph et al[10] had also reported that DSAEK and UT-DSAEK increased posterior corneal high order aberrations (HOAs), whereas DMEK displayed only minor changes in posterior corneal HOAs, possibly explaining this way to the different visual performance. Irregularity in the thickness of DSAEK grafts and uneven cuts seem to be the main reasons for this finding. Preoperative graft stromal edema maybe one of the causes related to visual acuity after UT-

DSAEK.[11-13] Therefore explaining the minor delay in recovery of BCVA after UT-DSAEK compared to DMEK.

Refractive outcomes

Endothelial keratoplasty doesn't alter topography; therefore it only leads to minimal changes in astigmatism and spherical equivalent. But it is known to induce hyperopic shift after DSAEK of 0.7 to 1.5 D, with a median of 1.2 D.[9, 14-18] [19]. Scorcia et al [20] hypothesized that the change in posterior corneal curvature caused by the attachment of a meniscus shaped donor graft was the main cause of the hyperopic shift recorded even in UT-DSAEK.

In our study we found in the DMEK group a non-significant change of spherical equivalent at 3, 6 months and at 1 year, all these changes were statistically insignificant compared to the UT-DSAEK groups, which also showed minimal changes.

Regarding the astigmatic changes postoperatively, all these changes proved to be comparable to what was found in the literature; the mean changes in astigmatism usually range from -0.6 to +1.11 D after DMEK, with an average of +0.03 D. Guell et al[21] found a mean change of refractive astigmatism of +0.43 D 36 months after DMEK. Droustsas et al[22] compared DMEK to DSEK and detected non-significant astigmatic changes of +0.09 and +0.12 D respectively at 1 year.

Endothelial cells loss (ECL)

The ECL in our DMEK group was significantly less then what is recorded in the literature, the 2017 AAO DMEK report[23] recorded a significant decrease in mean EC density (range, 27%-46%) at 3 months was reported, and the level of reduction tapered afterward. At 6 months, the mean EC loss was 33% (range, 25%-47%).

Kruse et al[4] found that after performing DMEK using an injector to deliver the graft. Decrease in ECD within the first 3 months was statistically significant (*P* .001), the endothelial cell loss was about 40% 6 months after surgery, which is obviously a significantly higher loss compared to our study (23.46%). Melles et al[24] had an ECD of 2618±201 cells/mm2 before the surgery, which dropped to 1876±522 cells/mm2 at 6 months with an average endothelial cell loss of 28.34%, which clearly exceeds our loss at the same time period. Price's group[25] recorded an endothelial cell loss of 30%±20% 3 months and 32%±20% in 38 eyes that reached the 6-month examination after surgery exceeding also the percentage of loss found in our study.

The explanations for the higher ECD and the significantly lower ECL in our technique are many: trifolding DMEK grafts were found to cause minimal and scattered endothelial damage, without correlation with the location of the folds. Also, the tip of our end-gripping forceps has a triangular area of contact of around 0.03 mm^2, each forceps bite therefore would crash only about 75 endothelial cells of a graft with a preoperative ECD of 2500 cells/mm^2, which eliminates concerns about ECL caused by direct grasping of the tissue.

In our study after UT-DSAEK the mean ECL% at 3 months was 28.69% and 22.46%; a statistically significant difference showing a greater initial loss of cells in the group with the thinner grafts, but at 6 months (30.23% vs 27.5%) and at 1 year (31.84% vs 30.96%) there were no significant differences between the two groups.

Most important advantage of the pull through approach is that the donor endothelium remains protected during the entire procedure. Possibly damaging maneuvers such as folding the graft, squeezing the tissue through the surgical wound with a forceps, or touching the endothelial surface with various instruments while trying to unfold the graft are eliminated. In addition, the persistence of a viscoelastic coating on the internal surface of the graft protects the endothelium if the edges curl over each other while the tissue roll flattens and is dragged through the incision.[26, 27]

When we compared the ECL between our DMEK and UT-DSAEK groups, we only found a statistically significant difference at 6 months where the ECL was greater in the UT-DSAEK<100 μm then in the DMEK group. At 3 months and at 1 year there were no significant difference between the 2 techniques, which obviously favors the trifolded pull through DMEK technique as a remarkably safe one, not only versus other DMEK techniques but also versus DSAEK and UT-DSAEK.

Complications

Graft dislocation and rebubbling

Although in our study postoperative graft dislocation was statistically significantly higher after DMEK (29 eyes; 35.4%) than after

UT-DSAEK (6 eyes; 2.35%), it is still much less than reported after DMEK by Price et al (63 %)[25] and Guerra et al (60%)[28] and Laaser et al (92%)[25], None of these dislocations lead to primary graft failure in all groups and they were all fixed by rebubbling which was done twice in 4 DMEK cases and in 1 UT-DSAEK case.

Price et al reported a mean air injection rate to reattach grafts was 28.8% (range, 2.4% - 82%) after DMEK, which is higher than the 14% reported after DSEK (range, 0% - 82%). In most cases, 1 air injection was enough for graft reattachment, without increasing ECL.[29]

Graft failure

We had a primary graft failure rate in our study in 2 DMEK cases (2.3%) and an overall of 4 cases in the UT-DSAEK group (1.5%), all cases due to endothelial decompensation; the differences between the groups were not significant

The low incidence of primary graft failure may be attributed to the more simple and efficient technique of graft delivery minimizing the graft rolling and the need for excessive manipulations. It can be also explained by the fact that we excluded all eyes with comorbidities like previous PK failure, glaucoma surgery and aphakic eyes which make the procedure more difficult, and also maybe explained by the high level of experience of the surgeon. Primary graft failure is considered the third most common DSAEK complication in the reviewed literature, with a range of 0% to 29% and an average primary graft failure rate of 5% among all published studies.[8] Our rate of primary failure is clearly below this average despite the use of thinner grafts, which highlights the efficiency of the techniques used in our study.

Graft rejection

Rejection rates after UT-DSAEK (5.09%) were double that after DMEK (2.4%) at 1 year follow up but this was not statistically significant (p=0.536). All cases were reversed successfully with medical treatment and none lead to graft failure.

Results were comparable to results in the literature with the AAO reporting a mean rejection rate of 1.9% after DMEK (range, 0%-5.9%) during follow-up periods ranging from 6 months to 8 years after reviewing 22 studies.[23] The largest series, consisting of 905 cases, reported a rejection rate of 1.3% during the first year.[30]

Busin et al reported Kaplan-Meier cumulative probability of a rejection attack after UT-DSAEK at 3, 6, 12 and 24 months, it was 0%, 0.4%, 2.3% and 3.2%, respectively.[19] Anshu et al[31] have reported the same cumulative probability of a rejection attack at 1 and 2 years to be 1% and 1%, respectively, for DMEK; 8% and 12%, respectively, for DSAEK; and 14% and 18%, respectively, for PK. In a different report, Guerra et al[28] found the rejection rate to be 5.6% 1 year after DMEK.

Our series indicates that the pull through DMEK is an effective procedure that carries better visual outcomes and faster visual recovery than UT-DSAEK, and putting into consideration the low incidence of primary graft failure in the DMEK group and its ECL rates that are comparable to UT-DSAEK, we can extrapolate that this DMEK technique standardization has reached a fruitful result and overcame many major obstacles previously mentioned.

The pull through DMEK technique is not free of flaws and carries some technical difficulties like the sometimes-encountered tendency of the graft to tear minimally when grasped with the end gripping forceps especially when the graft is fragile in case of old age donors, also the DMEK needed much more rebubbling than UT-DSAEK, however, the low incidence of graft failure highlights how the standardization of the technique preserved the graft and its endothelium and increased the success rate of the procedure despite the frequent need for rebubbling.

Limitation of this study is that all of the eyes were treated for Fuchs' dystrophy; additional studies on larger cohorts with bullous keratopathy or with pre-existing glaucoma would be valuable. A larger number and longer follow up is further needed to compare between the 2 groups to confirm our results.

Conclusion

Visual recovery is significantly faster and better in the DMEK group

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