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DIFFERENT TECHNIQUES IN ULTRA-THIN ENDOTHELIAL KERATOPLASTY, A COMPARATIVE STUDY OF VISUAL OUTCOME

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ABSTRACT
DMEK and DSAEK leads the new Era of Endothelial keratoplasty, visual outcome of 62 eyes were used to compare between both procedures, DMEK showed better visual outcome with UCVA 0.42±0.24 and BSCVA 0.75±0.23 after 6 months compared to 0.34±0.19 and 0.53±0.21 after 6 months of DSAEK respectively despite its steep learning curve DMEK is taking the way far to be the leading Endothelial keratoplasty procedure.

KEYWORDS: Over the past decade, endothelial keratoplasty.

INTRODUCTION

Over the past decade, endothelial keratoplasty (EK) has become the preferred treatment option of endothelial corneal disease, such as Fuchs corneal dystrophy and pseudophakic bullous keratopathy (Hamzaoglu *et al.*, 2015).

Various studies have confirmed the main advantages of Endothelial keratoplasty over penetrating keratoplasty which included better visual outcomes, faster rehabilitation and lower risk of long term complications especially those related to delayed wound healing, and graft suturing (Park *et al.*, 2014), (Rodríguez-Calvo-de-Mora *et al.*,
2014).

16 years ago deep lamellar endothelial keratoplasty (DLEK)started to replace penetrating keratoplasty as a treatment option for corneal endothelial dysfunction, produced better quality of vision, faster visual rehabilitation and stronger globe integrity than the prior surgical standard of penetrating keratoplasty ***(Terry et al.,2001), (Terry et al.,2005).***

The advance to newer endothelial keratoplasty (EK) techniques such as Descemet stripping (automated) endothelial keratoplasty (DSEK/DSAEK) has opened the door of a new era of corneal transplantation in the past decade, replacing penetrating keratoplasty as the technique of choice for treatment of endothelial disorders ***(Gorovoy et al.,2006).***

In 2006, Melles et al reported the first case of Descemet membrane endothelial keratoplasty (DMEK) in which the recipient Descemet membrane and diseased endothelium are replaced with donor Descemet membrane and healthy endothelium, representing pure anatomic replacement surgery (Melles *et al.*, 2006).

Patients and Methods

This study started as a prospective, comparative study, which was conducted at the Research Institute of Ophthalmology (RIO), Cairo, Egypt in collaboration with the Department of Ophthalmology, Beni-Suef University Hospitals, Egypt, during the period between June 2015 and October 2016.

The RIO Institutional Review Board approved the study protocol, which adhered to the tenets of the declaration of Helsinki, and written in- formed consent was obtained from all participants before inclusion.

Retrospective case series study was conducted for the same period in Queen Victoria Hospital, NHS, East Grinstead, London, UK.

Inclusion Criteria

The study included patients presenting to the cornea clinic at RIO and Queen Victoria Hospital During the period from June 2014 to April 2016 and undergoing follow-up till October 2016.

With:
- Pseudophakic bullous Keratopathy. - Fuchs Dystrophy.

Patients who agreed to be enrolled in the study and provided in- formed consent underwent one of two techniques of Endothelial kerato- plasty

- Descemet Membrane Endothelial Keratoplasty (DMEK).
- Descemet Stripping Automated Endothelial Keratoplasty (DSAEK).

Exclusion Criteria

Patients with prior ocular surgery other than cataract surgery.

Patients with complication other than Bullous keratopathy after.

Cataract Surgery

Aphakia.

Vitreous in Anterior Chamber.

Irregular Anterior Chamber.

Patients with ocular comorbidity which can affect visual potential.

like

Macular scar.

Amblyopia.

Advanced glaucoma and other optic neuropathies.

UCVA and BCVA were recorded preoperative and 1 week, 1 month, 3 months and 6 months postoperatively.

Were recorded One month, 3 months and 6 months postoperative postoperative complications, Rebubbling and Graft survival were also recorded.

Descemet Stripping Automated Endothelial Keratoplasty (DSAEK) Technique

Graft preparation

Donor grafts were mounted on artificial anterior chamber of the ALTK system of Moria microkeratome (Moria, France). Central corneal thickness was measured during surgery using ultra- sound pachymetry (PalmScan AP2000, Micro Medical Devices USA).

An initial debulking cut was performed using a Carriazo-Barraquer microkeratome (Moria) with a 300 micron head. a second microker- atome-assisted dissection (refinement cut) was carried out from the direc- tion opposite to the one of the first cut.

The head used for this step was selected after measuring central corneal thickness by ultrasound pachymeter (PalmScan AP2000, Micro Medical Devices, and USA) to target leaving behind a residual bed with a central thickness of approximately 100 micron.

Pressure in the system was standardized by raising the infusion bot- tle to a height of 120 cm above the level of the artificial anterior chamber and then clamping the tubing at 50 cm from the entrance into the artificial anterior chamber. In addition, maximum care was taken to maintain a uni- form, slow movement of the hand-driven microkeratome, requiring a time between 4 and 6 seconds for each of the 2 dissections in all cases. The residual part is F marked from stroll side for orientation purpose.

Figure 1: Shows steps of DSAEK graft preparation.

Surgical steps

After administering peribulbar anesthesia (10 ml L-bupivacaine 0.75% combined with 100 IU Hyaluronidase), surgery was performed with the surgeon sitting at the 12-o'clock position. The DSAEK procedure was performed according to a standard technique described by ***(Busin M et al., 2008)*** An appropriately sized circular template mark is applied to the corneal surface to delineate the stripping area.

Descemet membrane is stripped using a reverse Sinskey hook (Med- elec instruments, Delhi, India) under Biocorneal sodium hyaluronate (Laboratoire Corneal Ophtalmologie ,Croma Pharma GmbH, France).

Peripheral stromal fibers of the stripped bed are roughened by using a scraper (Medelec instruments, Delhi, India). Busin glide (Rumex, USA) was used to scoop the tissue floating on a balanced salt solution then hold the graft endothelium up, then glide flipped and approached a 4mm clear cornea wound to pull the graft endothelium down to enter the anterior chamber by Fogla crocodile forceps (Joja instruments, India) by pull-through technique crossing anterior chamber from an opposite corneal opening 180 degrees from main opening. Air was injected in ante- rior chamber to support the graft opposite the stomal bed and patients were instructed to lie supine for two hours with IOP monitoring by ton open (Tono-Pen AVIA, Reichert Inc, USA).

After surgery patients were given prednisonole acetate (Econopred, Alcon, Egypt) every two hours for two weeks, and vigamox (Alcon, Egypt) 4 times daily for one week. then topical tobramycin 0.3%, dexam- ethasone 0.1%, and suspension combination therapy (Tobra Dex, Alcon, Egypt) every 5 hours for one month. sutures of the main wound were re- moved one month to six weeks after surgery.

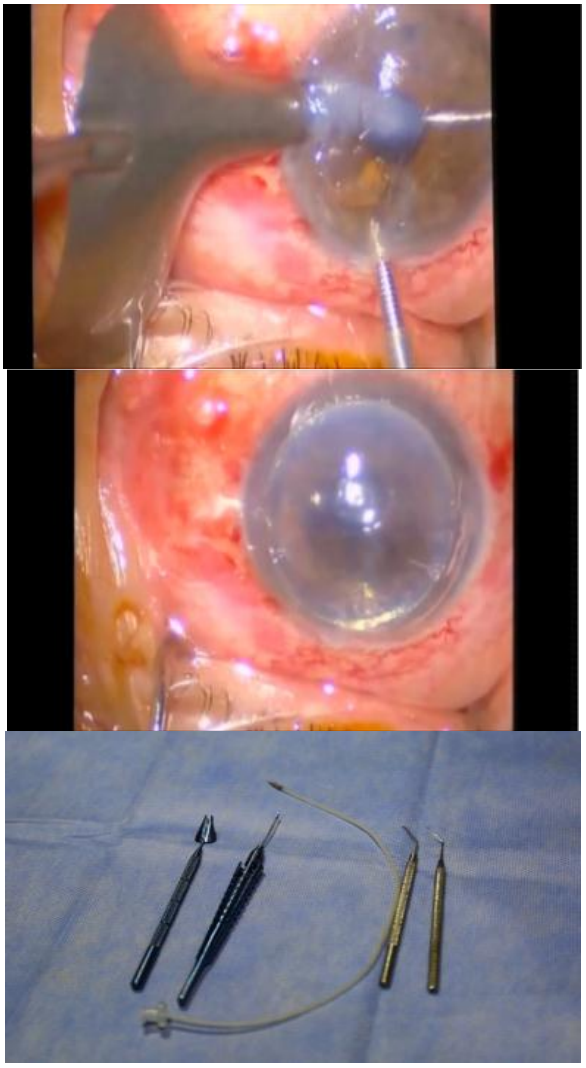

Figure 2: Surgical steps and instruments used in DSAEK.

Descemet Membrane Endothelial Keratoplasty

Donor tissue preparation

DMEK tissue was peeled by surgeon just before insertion inside an- terior chamber. Graft was placed onto a silicone block and all uveal tis- sues were removed using a hockey stick blade. Descemet membrane was then detached around the tissue edge, beginning at the iris base, over a width of 2mm using geuder dissector. Trypan blue (0.06%; Croma- Pharma GmbH, France) staining allowed for better visualization of DM, which was detached using DMEK forceps (geuder, England) from the periphery toward the center. This achieved separation of the entire DM. Correct detachment was controlled by buffered saline solution (BSS), and DM was trephined with an 8.0mm diameter trephine. Due to the elastic properties of DM, the graft naturally rolls on itself into a double roll with the endothelium facing out. Follow- ing preparation, the graft was placed into BSS and trypan blue and graft- ed the same day.

The recipient eye is prepared with two 1-mm paracentesis incisions placed to either side of a 3.2 mm

clear corneal temporal incision. The terior chamber is supported with **biocorneal**, which is removed thoroughly before graft insertion. The surface of the cornea is marked with an 8.0-mm circular template mark. The Descemet membrane is stripped by a reverse Sinskey hook to create a full 8.0-mm diameter central bare stromal bed. A 3.2-mm beveled entrance wound is created, and the stripped Descemet membrane is removed. Biocorneal is removed thoroughly with an irrigation and aspiration tip.

The graft was colored with trypan blue via two 3-minute soakings and sucked into a glass injector (single use cartridge G-38635, Geuder Laboratory, Germany). The injector was connected to a 5-mL syringe with BSS and the graft was injected through the main incision. The graft unfolded with gentle tapping on the cornea with the help of 2 cannulas. There was no direct contact during the DMEK procedure between surgi- cal instruments and the graft. Once the graft was unfolded and correctly positioned, air bubble was injected into the anterior chamber to pin the graft against the stroma. All incisions were small enough to be self-seal- ing and suturing was not needed in any procedure.

After surgery patients were given prednisonole acetate (Econopred, alcon, Egypt) every two hours for two weeks, and Vigamox (Alcon, egypt) 4 times daily for one week. Then topical tobramycin 0.3%, dexamethasone 0.1%, and suspension combination therapy (TobraDex, Alcon, Egypt) every 5 hours for one month.

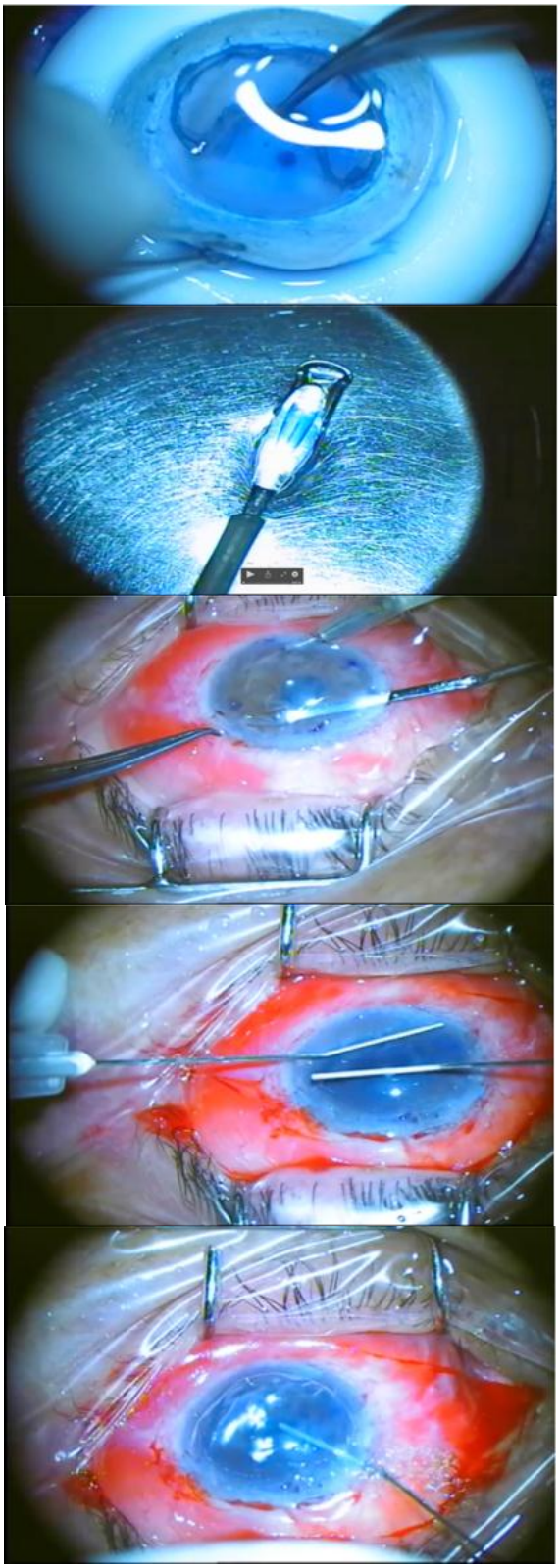

Figure 3: showing steps of DMEK instruments, graft preparation and injection.

RESULTS

Table 1: Below summarizes the outcomes and complications of the 83 patients included in the study.

Table 1: Summary of the outcomes from both study groups (n=83).

		DMEK (n=23)	DSAEK (n=60)	p-value
Primary graft failure (Y/N)		14/9	7/53	P<0.001*
Rebubbling (Y/N)		6/17	6/54	0.062
Rejection (Y/N)		None	none	----
Other Complications	++ IOP	3	12	
	Detached Graft	3	3	
	Epithelial Ingrowth	0	1	----
	Microbial Keratitis	0	1	
	None	17	42	
Further Intervention	DSAEK	1	1	----
	None	22	58	
	SST	0	1	

*Significant at the 0.05 level.

Rebubbling

6 eyes out of 23 eyes underwent DMEK procedure needed rebubbling in the first week postoperative (26.01%) 3 of them (50%) experienced graft re-detachment followed by graft failure.

Also 6 eyes out 60 eyes underwent DSAEK procedure needed rebubbling in the first week (10%), 3 of them (50%) experienced graft re-detachment followed by graft failure.

Survival analysis

The cumulative survival of the DSAEK procedure in our group of patients over 6 months of follow-up was 88.3% with a mean survival period of 5.67 months (95% CI= 5.333, 6.017), while for the DMEK procedure the cumulative survival was 39.1 % with a mean survival period of 4.022 months (95% CI= 3.021, 5.023) (p<0.001, Mantel-Cox Log rank test) (Figure 22).

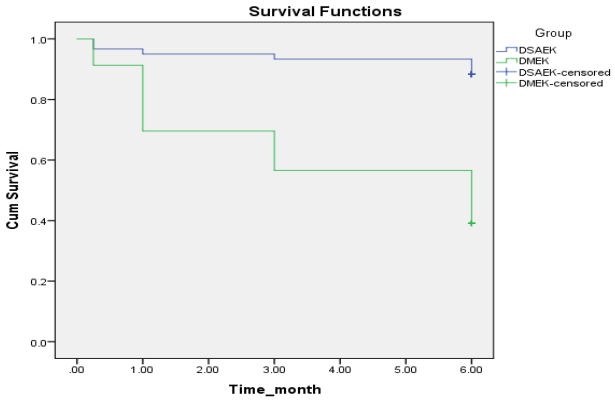

Figure 4: Kaplan-Meier Survival Analysis for all patients in both study groups (n=83).

Analysis of the successful cases (n=62)

UCVA

Table 2 summarizes the UCVA data obtained in the preoperative and postoperative visits from successful cases in both study groups.

Table 2: Summary of the UCVA data from both study groups in the preoperative and follow-up visits.

	UCVA Preop.	UCVA 1 week	UCVA 1 month	UCVA 3 months	UCVA 6 months	Repeated Measures ANOVA p-value
DMEK	0.27±0.23	0.18±0.11	0.37±0.25	0.42±0.20	0.42±0.24	P<0.001*
DSAEK	0.10±0.11	0.13±0.12	0.25±0.17	0.27±0.16	0.34±0.19	
p-value	0.057	0.066	0.070	0.022*	0.370	----

*Significant at the 0.05 level

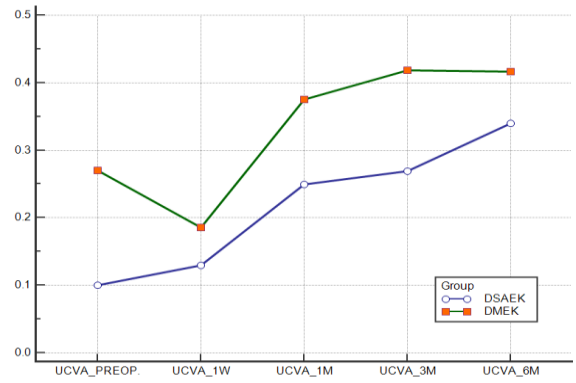

Figure 5: Line graphs showing Mean UCVA across follow-up visits in both study groups.

BCVA

Table 3: summarizes the BCVA data obtained in the preoperative and postoperative visits from successful cases in both study groups.

Table 3: Summary of the BCVA data from both study groups in the preoperative and follow-up visits.

	BCVA Preop	BCVA 1 Week	BCVA 1 Month	BCVA 3 Months	BCVA 6 Months	Repeated Measures ANOVA p-value
DMEK	0.39±0.27	0.34±0.21	0.66±0.23	0.69±0.16	0.75±0.23	P<0.001*
DSAEK	0.15±0.16	0.25±0.21	0.42±0.21	0.48±0.21	0.53±0.21	
p-value	0.027*	0.173	0.003*	0.004*	0.005*	----

*Significant at the 0.05 level

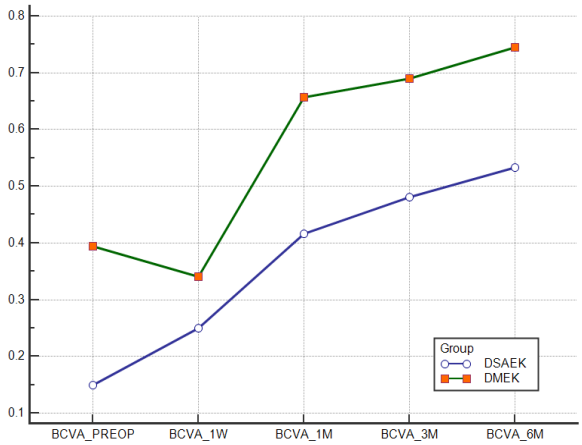

Figure 6: line graphs showing Mean BCVA across follow-up visits in both study groups.

DSAEK subgroups UCVA

Table (4) summarizes the UCVA data obtained in the preoperative and postoperative visits from successful cases in the DSAEK procedure subgroups.

Table 4: Summary of the UCVA data from DSAEK subgroups in the preoperative and follow-up visits.

	UCVA Preop.	UCVA 1 week	UCVA 1 month	UCVA 3 months	UCVA 6 months	Repeated Measures ANOVA p-value
DSAEK	0.13±0.13	0.12±0.09	0.21±0.13	0.25±0.16	0.31±0.21	P<0.001*
Ultrathin DSAEK	0.07±0.06	0.10±0.08	0.22±0.18	0.21±0.14	0.28±0.19	
p-value	0.201	0.179	0.888	0.332	0.754	----

*Significant at the 0.05 level.

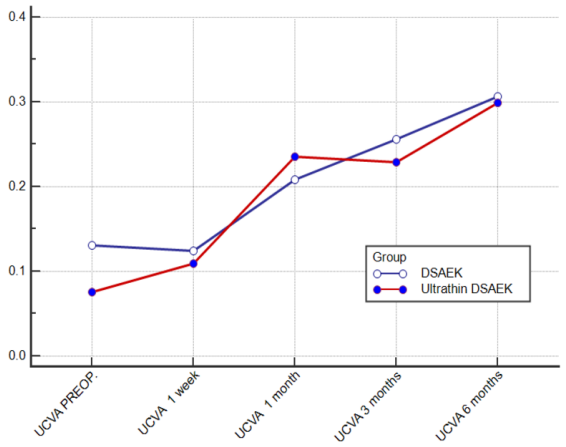

Figure 7: Line graphs showing Mean UCVA across follow-up visits in both DSAEK subgroups.

DSAEK subgroups BCVA

Table 5: Summarizes the BCVA data obtained in the preoperative and postoperative visits from successful cases in the DSAEK procedure subgroups.

Table 5: Summary of the BCVA data from DSAEK subgroups in the preoperative and follow-up visits.

	BCVA Preop.	BCVA 1 week	BCVA 1 month	BCVA 3 months	BCVA 6 months	Repeated Measures ANOVA p-value
DSAEK	0.17±0.15	0.24±0.20	0.36±0.19	0.45±0.22	0.49±0.25	P<0.001*
Ultrathin DSAEK	0.14±0.16	0.20±0.20	0.38±0.26	0.41±0.26	0.45±0.26	
p-value	0.291	0.418	0.595	0.441	0.579	----

*Significant at the 0.05 level.

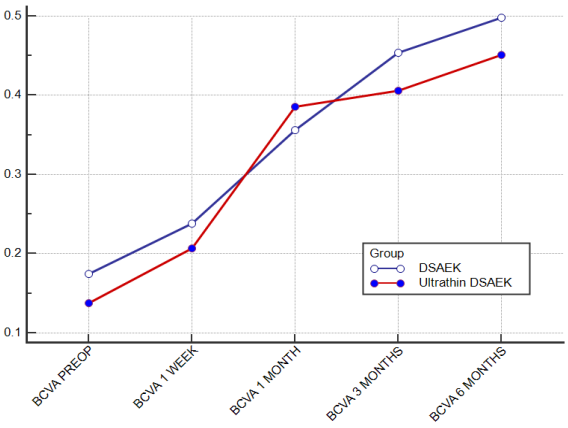

Figure 8: Line graphs showing Mean BCVA across follow-up visits in both DSAEK subgroups.

DISCUSSION

Our study evaluated the clinical outcome of a group of 83 of 68 patients 60 of which underwent Descmet Stripping Automated Endothelial Keratoplasty (DSAEK) and 23underwent Descmet Membrane Endothelial Keratoplasty (DMEK).

The first we can notice in results of our study is the higher rate of iatrogenic primary graft failure in DMEK cases, 14 eyes out of 23 eyes done, representing 60.8% in comparison to DSAEK procedure results in which primary graft failure was 11.67% (7 eyes out of 60 underwent DSAEK).

This may be because of the steep learning curve of DMEK and the challenging aspects of DMEK surgery from graft preparation to unfolding of Descmet and its proper orientation. Moreover, DSAEK procedure has been used for a longer time in relative to DMEK, which make surgeons more confident and procedure more standardized.

These failure rates are above reported rates in recent studies. ***Hamzaoglu et al*** in **2015** reported 4 cases of primary graft failure in his first 100 standardized DMEK procedures meanwhile he didn't report a single primary graft failure in his first 100 standardized DSAEK procedures in Devers eye institute.

Debellemanière *et al.* In 2017 reported 12 cases out of 109 DMEK cases included in his study (11%) of primary graft failure related to surgical technique and surgeon experience and concluded that surgical experience allowed faster graft preparation and faster unrolling time and hence help to decrease iatrogenic primary graft failure ratio.

Another cause of increasing ratio of primary graft failure is the storage time of the graft **Rodríguez-Calvo-de-Mora *et al*.** declared in their series for evaluating clinical outcome of 500 consecutive DMEK cases in **2016** that storage time in medium has a significant association with endothelial cell count decrease and stated that for each extra day in medium endothelial cell count decrease on average with 0.7%.

Indication for surgery may provide an explanation for higher primary graft failure rate, **Debellemanière *et al.* in 2017** stated that his higher rate of primary graft failure (11%) may be due to including cases with comorbidities or surgical complicating factors while studies he cited mostly included patiesnts with fuchs dystrophy.

In DSAEK, while we reported 7 cases of primary graft failure out of 60 (11.67%), **Busin and Albé, 2014** reported 8 cases of graft failure out of 285 (2.8%) classifying them into primary and secondary with graft survival probability (according to Kaplan-Meier) of 97.82% while in our study it was 88.3% for DSAEK and 39.1% for DMEK.

According to previous cited studies we can conclude some explanations for our higher rate of primary graft failure in RIO, the first is that those cases were our very first cases in both DSAEK and DMEK procedures and I will quote here from **Debellemanière *et al.* in 2017** "it is difficult to compare the results of a single surgeon starting DMEK on his own after performing a single wet laboratory course to those reported by surgeons performing surgery under the supervision of a mentor" this typically what we experienced as we worked after a single wet laboratory course, moreover we work with imported grafts in the 10th day postmortem due to lack of local eyebanks which means according to **Rodríguez-Calvo-de-Mora *et al*.2016** the graft loses about 7% or more of its endothelial cell count which increase the possibility of graft failure. Graft preparation either by microkeratome in DSAEK or manually in DMEK played a role in the obviously increased graft failure rate in RIO cases.

***Hamzaoglu et al.*, 2015** standardized both DSAEK and DMEK techniques by using precut, prestripped and premarked S-stamped tissue to address the concerns of donor preparation and iatrogenic graft failure decreasing the graft failure rate between experienced and novice surgeons.

In our study rebubbling rate with air was 26.01% in DMEK cases while it was 10% in DSAEK cases ***Busin et al.*, 2013** reported 3.9% of his 285 case series of DSAEK procedure (11 cases). ***Hamzaoglu et al.*, 2015** reported 2 cases of rebubbling in DSAEK (2%) procedure and 6 cases of rebubbling (6%) in DMEK cases.

The Melles group reported a 24% rate of rebubbles in their first 225 cases ***(Dirisamer et al., 2012)***. The Price group originally reported a 62% rate of rebubbles in their first 136 cases ***(Guerra et al., 2011)***. The Kruse group reported a 74% rate of rebubbles in 61 cases of DMEK combined with cataract surgery ***(Laaser et al., 2012)***. Mark A. Terry group reported 33% rebubbling rate in their initial experience with DMEK in their first 79 cases so **Terry *et al.*, 2015** used 20% Sulfur Hexafluoride (SF6) gas for graft support to decrease rebubbling rate to 2%. rebubbling rate with **Debellemanière *et al.* in 2017** was 18.3% and they noticed highly variable rate of rebubbling in literature and concluded that it's not related to experience.

Although there was a significant difference in preoperative uncorrected visual acuity between the two groups, preoperative UCVA in DSAEK group (0.10 ± 0.11) and (0.27 ± 0.23) in DMEK group that was because most of indications for DMEK cases were fuchs dystrophy (78.3%), while in DSAEK cases 56.67% where due to pseudophakic bullous keratopathy, Our study showed a significant improvement in both uncorrected and best corrected visual acuity in both groups. In DSAEK group there was a gradual improvement of both UCVA and BCVA to reach (0.34 ± 0.19) and (0.53 ± 0.21) respectively while in DMEK group there was a drop in both UCVA and BCVA in the first week postoperative then gradual improvement to reach (0.42 ± 0.24) and (0.75 ± 0.23) respectively after 6 months.

These results are comparable to previous studies done by ***Hamzaoglu et al.*, 2015** where there was an improvement in BCVA in both standardized DSAEK and DMEK cases from 20/51 (0.40 ± 0.19) and 20/37 (0.55 ± 0.11) preoperatively to 20/32 (0.63± 0.13) and 20/26 (0.79 ± 0.13) 6 months postoperative respectively. ***Ham et al,. 2009, Droutsas et al,. 2010 and Dapena et al,.2011*** reported the same gradual improvement with time with better visual outcome with DMEK than DSAEK. **(Turnbull *et al.*, 2016)** tried to explain why visual outcome in DMEK is better than DSAEK and put graft thickness and nature of interface in terms of difference in refractive index as possible theory. **Busin, M. and Albé, E. (2014)** introduced ultrathin DSAEK (graft thickness less than 100 micron) as a technique with the same simplicity as DSAEK with improved visual outcome but this is not what happened in our study as there was no statistically significant difference in visual outcome of both DSAEK and ultrathin DSAEK.

CONCLUSION

Endothelial keratoplasty is now the standard for treatment of Enothelial corneal disease, DSAEK and ultrathin DSAEK is much more established than DMEK. with its easier learning curve, lower rate of primary graft failure, more indications applicable and availability of precut grafts, DSAEK, till now, more preferable to surgeons.

Although DMEK needs surgical experience with a steep learning curve, visual outcome is much more better than DSAEK with a more rapid recovery and better graft survival than DSAEK.

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