A novel device to visualize Descemet membrane during donor preparation for Descemet membrane endothelial keratoplasty

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The aim of this study was to describe a novel device for improved visualization of descemet membrane (DM) during donor preparation for descemet membrane endothelial keratoplasty (DMEK). Comparative analysis was performed using this device (group 1) versus conventional technique (group 2) between an experienced and a trainee surgeon. A total of 20 eyes were analyzed in each group. Average time for DM peeling by experienced surgeon was 238.8 + 17.2 s in group 1 and 382.8 + 36.3 s in group 2 (P < 0.0001), and for trainee surgeon it was 519 + 30.8 s and 686.8 + 31.9 s (P < 0.0001). Retro-illumination made it easier to identify the peripheral cut edge of DM and abnormal adhesions to the underlying stroma during peeling. In group 2, DM tear occurred in 2/10 eyes with an experienced surgeon and 4/10 eyes with a trainee surgeon. Our novel device with retro-illumination allows DM peeling for donor preparation in DMEK to be performed safely with reduced risk of tissue damage.

Key words: DMEK, donor preparation, novel device, retro-illumination



Descemet membrane endothelial keratoplasty (DMEK) is currently the preferred technique of endothelial keratoplasty, as it provides better visual outcomes, faster visual rehabilitation, and a lower risk of graft rejection compared to Descemet stripping automated endothelial keratoplasty (DSAEK).^[1] However in DMEK, donor graft preparation involves manual stripping of Descemet membrane (DM) from the donor cornea, unlike in DSAEK wherein an automated microkeratome is used to prepare the donor lenticule. Donor grafts for DMEK may be prepared by the surgeon immediately before surgery or one day in advance or may be provided as pre-stripped corneal tissue from an eye bank. Tissue wastage rate during donor DM stripping can range from 2 to 20%.^[2-6] Due to this steep learning curve of donor preparation, most DMEK surgeons rely on pre-stripped donor tissue from the eye banks. However the availability of pre-stripped tissue is not uniform worldwide, and many surgeons have to learn to strip DM from donor cornea to be able to perform DMEK procedure. Descemet membrane stripping can be performed using manual stripping, pneumatic dissection, or hydro-dissection. ^[7] Manual stripping has the highest success rate with minimal damage to donor endothelium and involves creating an initial peripheral break followed by the peeling of the DM using forceps.^[7,8] This paper provides a detailed description of the use of a new device that utilizes retro-illumination to improve the visibility of DM during the preparation of donor grafts for DMEK.

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Technique

All the tissues used for this study were deemed unsuitable for corneal transplantation because of reasons unrelated to endothelial pathology such as sepsis, and positive serology for hepatitis B surface antigen. The novel device used in this study was designed by RF and manufactured by Coronet (Network Medicals, North Yorkshire, UK) using medical-grade plastic. The device consists of a reusable battery-operated base unit with white LED lights, and a disposable transparent endothelial punch block (similar in dimensions to a conventional punch block), which securely fits onto the base unit [Fig. 1]. The LED lights in the base unit have a peripheral location to provide diffuse illumination without any glare. The proposed cost of the base unit is 400 US\$ and 20 US \$ for the disposable cap.

Paired donor corneas (n = 10) were used donor DM stripping. The novel device was used in one eye (group 1), and conventional donor preparation in the fellow eye (group 2). Comparative analysis was performed between an experienced surgeon with over 500 DMEK surgeries (RF), and a trainee surgeon routinely performing Descemet stripping endothelial keratoplasty (DSEK) but with no experience in DMEK surgery.

Surgical technique

Donor corneoscleral rim was placed endothelial side up on the endothelial punch block. A 10-0 mm handheld trephine (Madhu

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Instruments, New Delhi, India) was used to create a partial punch in the peripheral cornea. To stain the cut edge, trypan blue dye 0.06% (Auroblue, Aurolab, Madurai, India) was applied for 30 s and rinsed using balanced salt solution (BSS) (Alcon, Fort Worth, TX). Descemet membrane cleavage hook (Janach, Como, Italy) was used to free the peripheral cut edge of DM from underlying stromal all-around 360°. Using McPherson tying forceps, the free edge of DM was gently grasped, followed by the peeling of DM towards the opposite limbus. Retro-illumination from the device highlights the edge of DM separation. [Fig. 2], Areas of abnormal adherence between DM and underlying stroma could also be identified with the retro-illumination. The microscope illumination is kept switched off to further enhance visualization. The DM peel was stopped 2-3 mm short of completion, leaving a peripheral hinge. An "F" stamp donor marking was performed using a technique described by Veldman *et al.*^[9] The corneoscleral rim was placed endothelial side up on a Barron Vacuum punch cutting block (Katena, Denville, NJ) and a partial 8 mm trephination performed. The tissue was brought back to the illuminated endothelial punch block. A few drops of BSS applied on the endothelial surface, followed by the removal of annulus of DM beyond the 8 mm zone using McPherson forceps. The free edge of 8 mm donor DM was grasped and peeling completed to obtain a free-floating graft. Trypan blue dye was applied for 60 s to stain donor tissue [Supplemental Video 1]. In group 2, the entire steps of group 1 were performed on a Barron Vacuum punch cutting block (Katena, Denville, NJ).

The time taken for circumferential separation of 1 mm peripheral edge of DM (initiation time) and total duration for DM peeling to obtain a free-floating graft were recorded for both the groups. Any complications occurring during the donor preparation were also noted. Statistical analyses were performed using an alpha level of 0.05 to determine statistical significance. Means were compared with the Student t-test for normally distributed data. Statistical analyses were performed using SPSS software version 12.0 (SPSS Inc., Chicago, IL) and Microsoft Office Excel 2010 (Microsoft, Redmond, WA).

Results

Donor DM peeling was successfully completed in both groups. The clinical details have been compiled in Table 1. The mean donor age was comparable between the experienced and trainee surgeon. The average time taken to free the peripheral edge of DM from stroma circumferentially was 78.1 + 9.7 s in group 1, compared to 129.8 + 9.4 s in group 2 (*P* < 0.0001) for the experienced surgeon compared to 113.2 + 11.5 s and 179 + 17.9 s for the trainee surgeon (P < 0.0001). The total duration for DM peeling to achieve a free-floating DM graft was shorter in group 1 both for the experienced as well as the trainee surgeon. Average duration of 238.8 + 17.2 s in group 1 and 382.8 + 36.3 s in group 2 (P < 0.0001) for the experienced surgeon and 519 + 30.8 s and 686.8 + 31.9 s for the trainee surgeon (P < 0.0001). Retro-illumnation made it easier to identify both the peripheral edge of DM, as well as the margin of DM separation during the peeling process [Fig. 3]. Abnormal areas of adherence could be identified as well while observing the margin of DM separation. No complications occurred in group 1 for both the experienced as well as a trainee surgeon. Descemet membrane tears were noted in group 2. Peripheral radial tears (1-3 mm) occurred in 2/10 eyes (20%) for the experienced surgeon, whereas for the trainee surgeon, 4/10 eyes (40%) developed DM tears, 3 peripheral radial tears, and 1 central DM tear. These donor tissues would have required an eccentric trephination of a smaller diameter to avoid the tears in the donor graft.



Figure 1: Photograph of the novel device for DMEK donor preparation. (a) Base unit with LED light illumination and transparent endothelial punch block. (b) Base unit in a sterile transparent pouch with the endothelial punch block in position



Figure 2: Photographs during DMEK donor preparation. (a) retro-illumination switched on, (b) donor corneoscleral rim in position with peripheral partial trephination, (c) peripheral separation of cut edge of DM, (d and e) stripping of DM using McPherson forceps. note the margin of DM separation – yellow arrow, (f) post 8 mm central partial trephination following F stamp via stromal window, (g) peeling of central 8 mm donor graft, (h) free-floating DM graft, (i) DM graft post staining with trypan blue dye

| Table 1: Clinical details of donor tissue and peeling time of donor DM for two groups | | | |
|---|------------------------------|------------------------------|------------------|
| | Group 1 (<i>n</i> =10) | Group 2 (<i>n</i> =10) | Р |
| Initiation of edge peel | | | |
| Experienced surgeon | 78.1+9.8 s (range 63-92) | 129.8+9.4 s (range 114-146) | <i>P</i> <0.0001 |
| Trainee surgeon | 113.2+11.5 s (range 98-132) | 179.9+17.9 s (range 156-220) | <i>P</i> <0.0001 |
| DM peeling | | | |
| Experienced surgeon | 238.8+17.2 s (range 212-265) | 382+36.3 s (range 326-436) | <i>P</i> <0.0001 |
| Trainee surgeon | 519+30.8 s (range 483-576) | 686.8+31.9 s (range 628-728) | <i>P</i> <0.0001 |
| Donor tissue age | | | |
| Experienced surgeon | 60.6+5.2 years (range 52-69) | | <i>P</i> =0.12 |
| Trainee surgeon | 64.3+4.9 years (range 55-70) | | |

Discussion

Descemet membrane endothelial keratoplasty is currently the preferred technique of endothelial keratoplasty among corneal surgeons.^[1] Availability of pre-stripped and pre-loaded donor tissue from eye banks have eliminated the burden of tissue

preparation for corneal surgeons, besides reducing tissue wastage and surgical time.^[10] However in many other parts of the world surgeons planning to start with DMEK procedure, either have to import pre-stripped donor cornea from eye banks providing the same or have to learn to prepare the donor grafts themselves. A recent multicenter study involving 55



Figure 3: Photograph showing a comparative appearance of the edge of DM while donor preparation. (arrow indicates the edge of separation). (a) standard technique, (b) using retro-illumination with the novel device

surgeons found that most surgeons were still preparing their own grafts for DMEK.[11] Graft preparation failure can lead to donor tissue loss, cancellation of surgery, and associated financial loss.^[12] A survey looking at barriers to uptake of DMEK surgery among corneal surgeons who completed formal training, found that 50% of surgeons cited anxiety related to donor preparation as one of the main reasons.[13] Tissue loss rates for harvesting DMEK grafts vary between 5 and 20% depending on the experience of the surgeon and are significantly lower for the more experienced eye bank technician.^[4,14,15] Donor preparation has a steep learning curve and also depends on donor tissue characteristics and surgeon expertise.^[6] Trypan blue dye stains only the cut edges of DM, visualization of DM is still not adequate during the process of DM peeling. The transparent nature of DM also makes it difficult to identify areas of abnormal adherence to the underlying stroma. This can result in loss of integrity of donor DM during the peeling process making donor tissue unsuitable for DMEK procedure. Our novel device with retro-illumination, provides enhanced visualization of DM similar to that of the anterior capsule during capsulorrhexis with retro-illumination in cataract surgery. Improved visualization reduces the overall duration of donor preparation by almost 37% for an experienced surgeon, and by 24.4% for the trainee surgeon when compared to conventional tissue preparation techniques. The ability to visualize abnormal adhesions can also help avoid unpredictable breaks, thereby reducing tissue loss rates. This would be of great assistance both to the novice surgeon as well as the experienced surgeon for DMEK donor preparation. Eye bank technicians would be able to further reduce tissue loss rates using this novel device.

The limitations of our study include small sample size, and lack of using this technique on donor tissues with a higher risk of tissue loss rates (young age, diabetes, and prior cataract surgery). As the basic technique of donor preparation in our study remained the same as the conventional technique besides retro-illumination to improve visualization, we did not expect our novel device to introduce any further endothelial changes. However, analysis of endothelial cell counts could have further validated the safety of this novel device and needs to be performed in future studies.

Conclusion

In conclusion, our novel device for DMEK donor preparation can help improve success rates, smoothen the learning curve, and possibly avoid complications leading to loss of donor tissue for DMEK procedures.

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Conflicts of interest

There are no conflicts of interest.

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