ARTICLE

Pedicle Descemet membrane endothelial keratoplasty performed using a new corneal punch

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Purpose: To create a Descemet membrane endothelial keratoplasty (DMEK) graft with a pedicle that allows better control of orientation, centration, and unrolling of the DMEK scroll.

Setting: Macquarie University Hospital, Sydney, NSW, Australia.

Design: Prospective nonrandomized interventional case series.

Methods: Eleven eyes of 10 patients with corneal endothelial failure underwent the modified DMEK surgery. A new corneal punch with a 7.5 mm central zone and a 3.0 mm long pedicle was used to produce a graft with a tail. The pedicle was used to orient and drag the graft into the anterior chamber, and the tail was extravasated. The graft was unrolled and centered using the pedicle, and 24% SF_6 gas was injected to applanate the graft. The pedicle was truncated. The graft manipulation time, defined as the time from graft insertion to gas injection, was measured. The patient and donor characteristics, postoperative corrected distance visual acuity (CDVA), and endothelial cell count (ECC) at 3 months were reported.

Results: Ten grafts attached with 1 requiring reinjection of gas. The CDVA improved to ≥6/9 in 9 eyes, and the remaining were limited by preexisting disease. The ECC loss for the first 5 grafts was 28% ± 5% with manipulation time of 12 ± 6 minutes. This improved to 18% ± 7% (P = .03) and 3 ± 2 minutes (P = .007) for the last 6 grafts.

Conclusions: The new corneal punch generated a keyhole-shaped DMEK graft. After a period of learning, the manipulation time was decreased, improving ECC. The pedicle seemed to improve control over orientation, unrolling, centration, and rebubbling, potentially increasing the ease of DMEK surgery. The pedicle was safely truncated without sequelae.

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Online Video

Descemet membrane endothelial keratoplasty (DMEK), first described by Melles et al., involves transplantation of the DM and endothelium to replace the diseased endothelium.[1,2] The 2018 Australian Graft Registry reported that more than 70% of patients achieved 6/12 vision or better at 6 months compared with less than 50% after Descemet-stripping automated endothelial keratoplasty (DSAEK).[3] This offers an impetus for pursuing DMEK over DSAEK as it allows many more patients to keep their driver's license and maintain their independence.

Although the past decade has seen an increase in endothelial keratoplasty, significant challenges to its adoption remain.[4,5] The learning curve for DMEK graft preparation is steep for surgeons new to the procedure. The main concern being that the surgeon might not be able to complete the DMEK if they tear the graft during preparation. In some regions, eye banks provide a harvested DMEK scroll, but this is not universal. Implantation of the DMEK graft can also be a challenge. The scroll, once inserted into the recipient's anterior chamber (AC), must be unrolled, centered, and applanated against the stroma in the correct orientation before the trypan blue–stained graft becomes transparent. Each of these steps can be challenging because the graft can only be controlled with the aid of balanced salt solution and air. Direct contact of instruments with the graft can lead to endothelial cell loss. Other challenges that might be encountered during surgery include: the graft might be injected inadvertently behind the iris, might egress, might flip upside down, might not unroll, might be decentered, and, finally, might not attach.[6–22] These challenges might translate to excessive manipulation, prolonged surgery, and primary graft failure or poor graft survival.[3] Many techniques have been

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designed to assist in the process, such as the Veldman Venn technique for orientation in the injector, the stamp to determine orientation in the AC, the modified Jones tube to deliver, and the Dapena maneuver to help unroll; however, despite these techniques, the surgical control can be challenging.[23–31] The difficulty with implantation increases further if the cornea is hazy at the time of surgery, in aphakic patients, in the presence of AC intraocular lenses, aniridia, glaucoma drainage tubes, and previous vitrectomy.[32–35] There are many centers that report excellent results with DMEK. However, there are many more surgeons who would rather perform DSAEK than confront the unpredictability of DMEK as evidenced by the greater numbers of DSAEK procedures performed each year than DMEK procedures.[3–5]

This study introduces a new punch and technique that helps meet the challenges associated with graft insertion, orientation, centration, and unrolling. The procedure is described in detail along with the visual outcomes and the time to unroll the graft.

METHODS

The study was approved by the Macquarie University Clinical Innovation and Applications Committee (MQCIAC2017005; December 8, 2017). Patients were recruited if they had corneal endothelial disease. Informed written consent was obtained from patients using the consent process preapproved by the Macquarie University Clinical Innovation and Applications Committee.

Bala Asymmetric Corneal Vacuum Punch

The Bala Asymmetric Corneal Vacuum Punch (Katena Products, Inc.) has a diameter of 7.5 mm and a pedicle of 3.0 mm length with a width of 1.2 mm at the tip (Figure 1). The punch, unlike conventional punches that have a horizontal planar edge, has a curved edge that slopes upward from the center toward the pedicle. There is an asymmetric notch on the cutting edge of the punch that assists in orientation of the graft in the eye. The punch is lodged in a plastic chassis that has large windows allowing clear visibility of the graft from above as it is being punched. The visibility enables the donor button position to be adjusted before punching so that the trabecular meshwork can be included as part of the pedicle. The punch block has 4 apertures for vacuum suction and a central marking well similar to the traditional Baron punch.

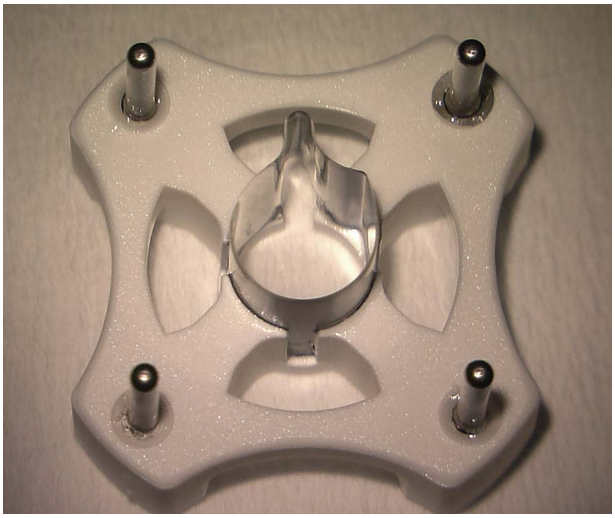

Figure 1. The Bala Asymmetric Corneal Vacuum Punch with a 7.5 mm center and a 3 mm long pedicle that tapers from 3 mm to 1.2 mm to the tip. Windows in the chassis allow the donor tissue to be visualized easily.

Graft Preparation

Corneal donor tissue was obtained from the Lions Eye Bank, Sydney, Australia, and placed on the DMEK punch block. All donors were older than 50 years, and tissues were processed using the organ culture technique. The operating microscope was tilted to 18 degrees, which was half of the tilt needed for gonioscopy. This reduced the reflections during dissection. The donor tissue was placed in the block in such a manner that the punch would create a pedicle along the long axis of the cornea and would result in the longest possible pedicle graft. The dried sclera was marked on the endothelial side with a skin-marking pen to orient the long axis (Figure 2, A).

The trabecular meshwork was stained for 30 seconds with trypan blue 0.06% (Vision Blue, D.O.R.C. International BV) and rinsed with a balanced salt solution. The donor tissue was held with nontoothed forceps at 1 corner of the block. The nondominant hand's ring finger provided a backstop while the DM–endothelial complex was separated at the trabecular meshwork for 270 degrees using the Rootman-Goldich DMEK dissector (#K3-1880, Katena Products, Inc.) by the dominant hand (Figure 2, A). Anecdotally, it was noted that it was easier to start the dissection in the short axis where the adhesions were weaker. The interface of the graft area being dissected in the periphery was periodically stained for 30 seconds to visualize any strong fibrous attachments between the DM and the stroma. The detached DM–endothelial complex showed circumlimbal white fibers on the deep surface at the far periphery (Figure 2, B). These were likely scleral fibers from the scleral spur. These were used as landmarks for graft orientation (described later). Approximately 70% to 80% of the trabecular meshwork was detached, and the DM–endothelial complex was freed to 1 to 2 mm past the Schwalbe's line into the central cornea.

Vacuum was applied to the donor button to hold the stroma in place. Using nontoothed forceps, 60% to 70% of the DM–endothelial complex was peeled. The DM–endothelial complex was flushed back to the original position on the stroma. Every attempt was made to draw out the fluid from the interface between the peeled DM–endothelial complex and the stroma by tilting the graft (unpeeled side up and peeled side down) and by using cellulose spears to draw fluid near the trabecular meshwork without touching the graft (Figure 2, C). If there was a wrinkle in the graft, which would potentially fall inside the punch, this was eliminated by pulling the trabecular meshwork more peripherally along the stroma toward the edge of the button. The donor button was positioned along the well in such a way that the tip of the punch pedicle just overlapped with the trabecular meshwork in the long axis of the cornea (endothelium facing up; Figure 2, D). Pressure was then applied on the punch along the rim in either clockwise or anticlockwise direction in a rocking motion to ensure the graft was cut and that any trapped interface fluid could escape (Figure 2, E).

Orientation Marks

Orientation of the graft was determined using 4 features or techniques. One corner of the pedicle was inked with a skin-marking pen to help orient the graft (Figure 2, F). A cellulose eye spear was placed close to the tip of the pedicle without touching the graft, and this soaked up fluid by capillary action. Once the spear stopped expanding, it was replaced with a new spear, and a marking pen was used to mark one corner of the tip. If any ink flowed downhill toward the graft center, this was soaked up by the spear before it caused toxicity to the central region. Because the spear did not touch the graft, it did not adhere to the graft.

The second orientation mark consisted of circumferential scleral fibers from the scleral spur, which were seen on the posterior aspect of the trabecular meshwork (provided the trabecular

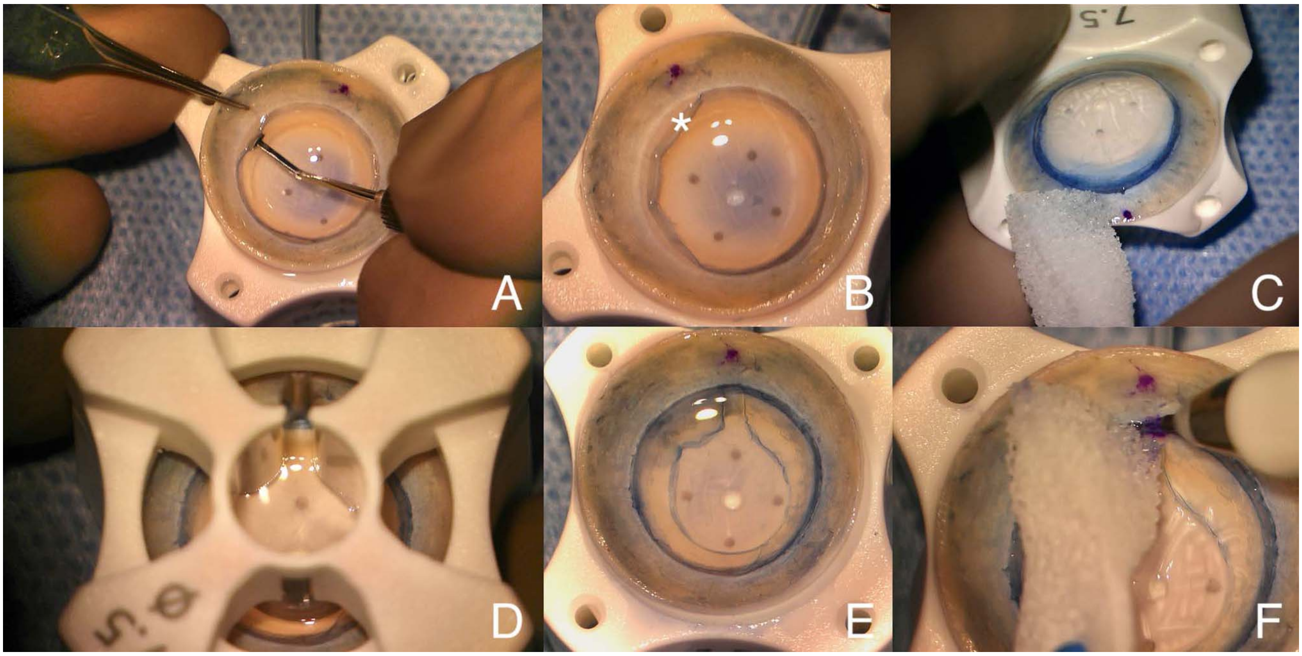

Figure 2. Graft preparation. *A*: The ink dot on scleral marks the long axis of the cornea on the endothelial side. *B*: On detaching the trabecular meshwork over the scleral spur and Schwalbe's line, circumferential or circumlimbal scleral fibers are noted on the stromal surface of the DM–endothelial complex (marked by *). The trabecular meshwork appears to be rougher on the stromal side than on the anterior chamber side. *C*: After peeling and before applying the punch, the DM–endothelium complex is repositioned on the stroma. The fluid is removed from the interface by tilting. *D*: The donor tissue is positioned on the block such that the pedicle of the punch overlaps the trabecular meshwork (marked by blue staining). *E*: The punched graft outline clearly shows the asymmetric orientation notch. *F*: The pedicle tip is marked at the right corner with a skin marker, and excess ink is soaked by the cellulose spear (DM = Descemet membrane).

meshwork was included in the pedicle; Figure 2, B). These and other features of roughness were not seen on the endothelial side of the trabecular meshwork. They were easily seen throughout the surgery and were particularly useful when the graft was loaded and after the pedicle was extravasated (Figure 3, A and B).

The third orientation mark was the asymmetric notch located some distance from the pedicle. It was visible in the transparent delivery device and postimplantation in the eye (Supplemental Digital Content 2, Video 1, available at http://links.lww.com/JRS/A63) (Figure 2, E). The large distance from the pedicle ensured that the notch was present and recognizable even if the pedicle broke accidentally. The fourth orientation feature or technique well described as the Veldman Venn feature of the graft scroll orientation inside the delivery device.

Peeling and Loading the Graft

After marking the pedicle, the graft was grasped using nontoothed forceps near the pedicle–body junction, and the graft was completely peeled (Figure 4). It was stained with trypan blue 0.06% for 3 minutes and loaded into a modified Straiko-Jones tube (80000-DMEK, Guntherweiss) attached to a 3 mL syringe with the aid of a 14 French nasogastric catheter (Figure 5 and 6). In the event the graft rolled similar to a roller window blind, balanced salt solution was squirted until the long axis of the roll was parallel to

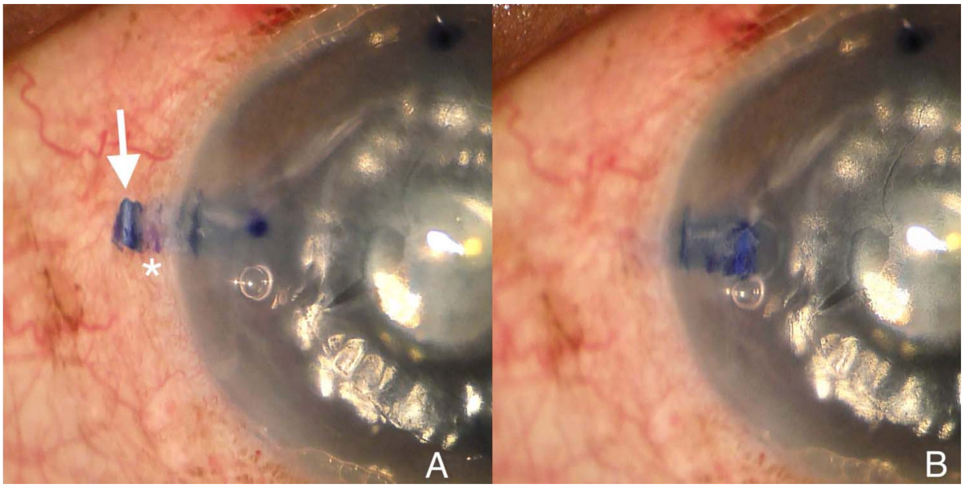

Figure 3. Two orientation landmarks on the pedicle visible after implantation. *A*: DMEK oriented correctly: the ink mark (marked by *) is on the opposite corner of the pedicle to that in Figure 2, F, and the white circumferential scleral fibers (marked by *arrow*) are indicating the stromal side of the pedicle clearly visible. *B*: If the DMEK graft was oriented incorrectly, the tail would look smoother, and the scleral fibers would not be visible (DMEK = Descemet membrane endothelial keratoplasty).

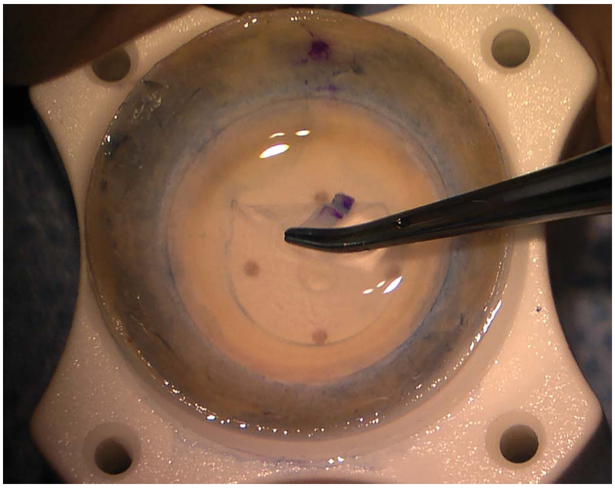

Figure 4. Peeling the graft: The Descemet membrane–endothelial complex is grasped with nontoothed forceps at the base of the pedicle and peeled.

the pedicle. The DM–endothelial complex formed the usual scroll with the endothelium on the outside. The body of the graft was loaded first so that the pedicle could be grasped by the Tan forceps during surgery. Inside the Straiko-Jones tube, orientation landmarks were clearly visible. Two of the landmarks new to this study, the circumferential scleral fibers at the tip of the pedicle and the asymmetric notch, were recognized (Figure 6).

Recipient Preparation

Four side-port incisions were made with a 1.2 mm keratome directed posteriorly at the limbus (45, 135, 225, and 315 degrees). Descemetorhexis of 8 mm under air or Helon was performed, and the host DM–endothelial complex was removed through the main incision. The complete removal of the diseased endothelium was verified with trypan blue. The temporal main incision was sized to fit the modified Straiko-Jones tube, and a 10-0 nylon suture was preplaced. A fifth side-port incision was made opposite the main incision at the nasal limbus using the 1.2 mm keratome. This incision was kept as short as possible and was enlarged to a 1.8 mm width. Its internal lip was placed just inside the descemetorhexis.

An AC maintainer was placed through the side-port incision closest to the surgeon's dominant hand. The AC maintainer was used in all but the first case. The graft orientation in the Straiko-Jones tube was confirmed using the 4 above-described features. The AC maintainer was controlled, and the modified Straiko-Jones tube with the graft was introduced into the AC (Supplemental Digital Content 2, Video 1, available at http://links.lww.com/JRS/A63).

It must be noted that the graft pedicle is not kept at the tip of Straiko-Jones tube but a few millimeters inside the tube because, at the introduction of the Straiko-Jones tube into the AC, the pressure differential can either push (high) the graft into the tube or pull (low) the graft out of the tube in an uncontrolled manner. The Tan DSAEK 23G forceps (AE4226, ASICO LLC) were introduced through the nasal incision, and the pedicle was grasped. The introduction of the forceps caused the AC to shallow, which was compensated by further increasing the AC maintainer flow.

It must be emphasized that the dominant hand was used to hold the Tan forceps. The thumb and index fingers controlled the opening or closing of the forceps, and the ring finger was used to rest the hand on the nasal bridge. A trial run was done before introducing the graft into the AC to ensure that, when pedicle was extravasated, the forceps would not shake but exit smoothly as it came out of the eye. The pedicle was grasped with the forceps in the Straiko-Jones tube and dragged across the AC. When the pedicle was about to be extravasated, the AC maintainer was turned off, fluid escaped around the forceps, and the chamber started to shallow. The pedicle was extravasated through the small incision without tremor, and the forceps were opened immediately on exiting the eye. A balanced salt solution wash was immediately applied to the open forceps by the assistant to enable the graft to separate from the forceps. This prevented the graft from being accidently pulled out of the eye with the forceps through the small nasal incision. The Straiko-Jones tube and the AC maintainer were removed, and the main incision was closed with the preplaced 10-0 nylon suture.

The graft was unrolled using well-described techniques. The graft position was adjusted by pulling, pushing, or pivoting the pedicle using wet instruments, such as wet forceps or Rycroft cannula (Supplemental Digital Content 2, Video 1, available at http://links.lww.com/JRS/A63). To applanate the graft, 24% SF_6 was injected. After 20 minutes of complete gas fill, the pedicle was truncated with Vannas scissors flush with the external wound edge of the pedicle side port. The AC was left with 80% fill for a few hours or longer, in the presence of a glaucoma drainage device. The patient was discharged home with 50% gas fill and encouraged to lie supine at home until the gas dissipated.

RESULTS

A total of 11 eyes of 10 patients were enrolled in the study. There were 5 women and 5 men with a mean age of 69 ± 12 years (Supplemental Digital Content 1, Table 1, available at http://links.lww.com/JRS/A62). Eight eyes underwent DMEK for the first time, whereas 3 had had DSAEK previously; 2 had failed DSAEKs (cases 1 and 5), and 1 had uncorrectable persistent polyopia despite clear DSAEK (case 9). The graft adhered in all but 1 case where attachment was achieved by reinjecting gas. All patients achieved improvement in vision. Nine of 11 eyes achieved 6/9 or better vision. Two patients (cases 1 and 7) with preexisting eye disease had poor visual outcomes. The first patient had idiopathic panuveitis and uncontrolled glaucoma requiring Baerveldt tube and recurrent cystoid macular edema. Patient 7 had end-stage glaucoma, which could not be determined before DMEK. The cornea had been opaque for some time causing pain, and no reliable notes were available to indicate the extent of glaucoma.

All grafts except 1 were attached. This detached graft was felt to be oriented correctly at the time of primary surgery, and therefore, the failure was believed to be the result of inadequate gas fill; 24% SF_6 gas was injected deep to the

Figure 5. The peeled Descemet membrane endothelial keratoplasty scroll: The orientation mark and scleral fibers are clearly visible on the pedicle. The graft has been lightly stained for photography.

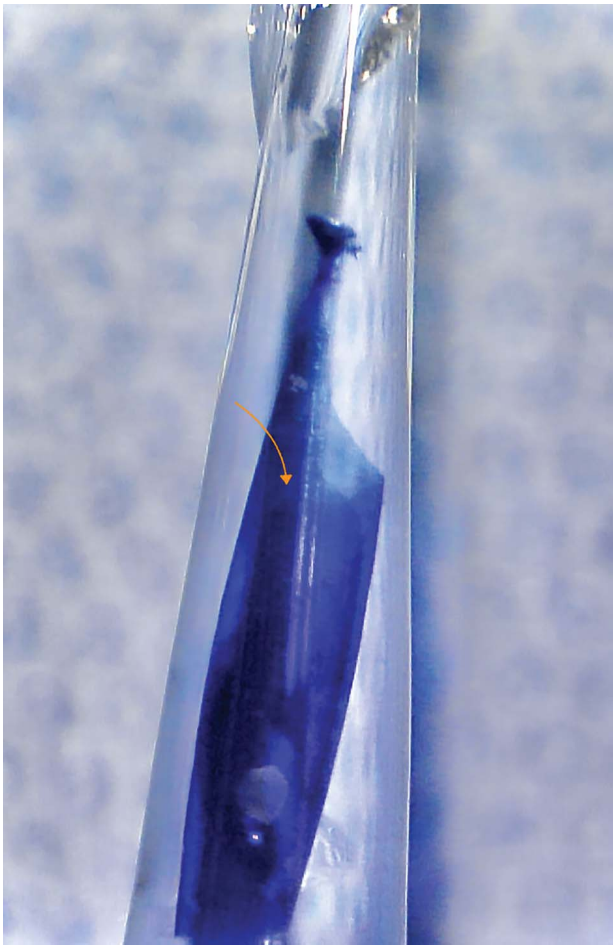

Figure 6. Stained Descemet membrane endothelial keratoplasty scroll in the modified Straiko-Jones tube. The pedicle shows roughness on the stromal size because of attached circumferential scleral fibers. The *arrow* marks the asymmetric orientation notch.

pedicle, nasal to nasal incision. Aqueous fluid was only released from a superotemporal incision after the gas was injected deep into the graft to prevent the graft position being inadvertently disturbed. The graft was not stained during the rebubbling procedure.

The graft manipulation time was defined as the duration between graft insertion and the injection of gas (Figure 7). This manipulation time significantly decreased from 12 ± 6 minutes for the first 5 cases to 3 ± 2 minutes for the last 6 cases ($P = .007$). The donor age for each of the grafts was shown for each case. For the first 5 cases, the donor age was 77 ± 4 years, which was significantly older than for the next 6 cases at 66 ± 7 years ($P = .012$).

The endothelial cell count at 3 months showed an overall reduction of 23% ± 8% compared with the cell count of the graft prior to implantation. In the first 5 cases, the loss was greater (28% ± 5%) than that in the later grafts (18% ± 7%, $P = .03$) (Supplemental Digital Content 1, Table 1, available at http://links.lww.com/JRS/A62), where the unrolling time was quicker.

DISCUSSION

Corneal punches to date have been circular, whereas the new Bala Asymmetric Corneal Vacuum Punch has an asymmetric notch and a pedicle, which enables the surgeon to divide the DMEK insertion process into 4 overall systematic steps: orientation, unrolling, centration, and holding with gas. These together constitute the mnemonic OUCH and were felt to be the main challenges of graft implantation during DMEK surgery with standard or traditional corneal punches.

Some of the patients in the cohort had several comorbidities with limited visual potential that made these cases challenging. There was a significant learning curve in the use of the new corneal punch, which plateaued after 5 cases (Figure 7). Despite these challenges, the patients in the study recovered vision well (Table 1), and indeed, 2 DSAEK patients recovered much better corrected distance visual acuity with DMEK than that with DSAEK, reconfirming the reports in the Australian Graft Registry.

Orientation of the graft in this study was determined using 4 features: inking the graft pedicle tip at one corner, using the circumferential scleral fibers on the pedicle, the orientation notch, and the Veldman Venn technique. These features offered a greater number of cues than traditional DMEK where only the Veldman Venn technique and graft stamping are available. The latter has been reported to be toxic to the underlying endothelium. Furthermore, graft stamping or inking requires some skill to avoid a blotch and, if not applied adequately, might disappear during the procedure. The asymmetric notch is another form of stamping that is visible throughout the procedure. Its limitation is that although it can be seen postoperatively, it is visible intraoperatively only while the graft is stained with trypan blue. The pedicle, once grabbed and extravasated, maintained the graft orientation throughout the procedure. Unlike traditional DMEK where the graft is injected, in this technique, the graft was slowly dragged into the AC, mitigating the risk of retropupillary placement, accidental rotation, or excessive trauma to the DMEK scroll. Furthermore, even when the host cornea is hazy, the Tan forceps can extend across the AC and enter the transparent Straiko-Jones tube to safely pull the graft into the AC. This could potentially enable the surgeon to perform DMEK in difficult cases despite a hazy cornea (Supplemental Digital Content 2, Video 1, available at http://links.lww.com/JRS/A63).

Theoretically, there is a possibility of twisting the graft around the pedicle, causing an inverted graft orientation. This could occur if the graft pedicle had a curve or twist in the Straiko-Jones tube and was drawn out with the twist. In the cases described in this study, the graft was well secured by the forceps and was not twisted. The use of a large flush of fluid to unroll a graft in a deep AC could also flip the graft. In this study, large flushes of fluid were not applied into the AC. Furthermore, it is possible that because a significant portion of the pedicle was extravasated leaving a short stem inside the AC, the graft could not rotate around the pedicle. This would be recognized by noting the position of the asymmetric notch. Finally, in the event the graft did rotate around the pedicle because of a flush of irrigation, the process could be reversed in a deep AC.

Unrolling the graft was assisted by the presence of the pedicle because the axis of the DMEK roll was along the

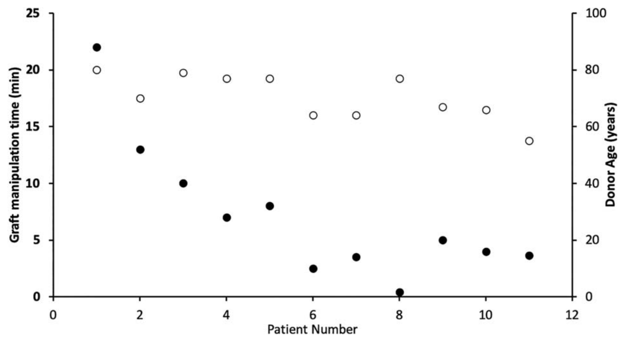

Figure 7. Graft manipulation time and donor age: The manipulation time decreases after the first 5 cases independent of donor age, suggesting it might be related to the learning curve phenomenon of the new technique.

long axis of the pedicle. In preparing the graft, the pedicle was always fashioned in the 0- to 180-degree meridian on the corneoscleral button. Anecdotally, it was found that the graft can roll similar to a roller window blind if the pedicle was placed along the short axis of the corneoscleral rim. This would put the axis of the roll perpendicular to the pedicle instead of being parallel to the long axis of the pedicle. This was easily overcome by a short burst of balanced salt solution before loading into the Straiko-Jones tube. After inserting the DMEK scroll in the correct orientation, the DMEK roll was always near the main temporal wound, and therefore, fluid could be injected into the DMEK double roll using a cannula to open the graft. The pedicle seemed to prevent a single role from reforming, although this claim would need to be verified with grafts from younger donors. The most common cause of delayed unrolling in the early cases was that the graft pedicle was pulled out excessively; this was easily corrected in the subsequent cases by pushing the pedicle into the AC using a Rycroft cannula with a droplet at its tip. The nasal incision for the pedicle had to be about 1.8 mm wide and short to prevent the pedicle from crumpling in the tunnel, potentially preventing unrolling of the graft.

Another advantage of the pedicle was that it mitigated the risk of the graft migrating to 1 corner of the AC. The pedicle could be used to push or pull the graft to allow better DMEK centration. This maneuver had to be performed at low intraocular pressure to prevent the incision from tightly closing around the pedicle. Furthermore, the incision tunnel had to be short and wide (1.8 mm) to reduce friction between the pedicle and the host stroma to allow pivoting of the graft within the incision.

Holding the graft in situ with 24% SF_6 gas was assisted by the pedicle in 2 ways. The pedicle kept the graft center close to the middle. An uncontrolled injection of gas would not undo the hard work and cause the graft to displace peripherally. The second advantage of the pedicle was demonstrated in rebubbling. Video 1 (see Supplemental Digital Content 2, available at http://links.lww.com/JRS/A63) shows a very hazy cornea with a subtotal DMEK detachment. A 30-gauge needle was inserted deep into the pedicle without removing any aqueous. This ensured that the needle would be deep to the graft and, because no fluid was removed, the graft depth would not be altered. Gas was injected slowly to raise the graft to the stroma. A paracentesis was then made and aqueous expressed slowly to maintain physiological intraocular pressure. It is noteworthy that no trypan blue stain was needed to visualize the detached DMEK graft, and the graft cleared within 5 days.

The extravasated pedicle was transected at the outer corneal surface. Alternatives would be to transect the pedicle inside the AC with a cystotome or a Nd:YAG laser or to fold the pedicle into the incision. In case 1, the transection occurred accidently without sequelae, and this was later adopted in all cases. To date, no epithelial ingrowth has been documented in the pedicle area with the longest follow-up being 18 months. The pedicle incision was small and never sutured. Gas did not leak through this incision even when there was 100% SF_6 gas fill. This suggested there was good airtight closure and mitigated the risk of corneal epithelial migration. The manipulation of the pedicle during peeling and airtight closure of the stroma around the pedicle is likely to destroy the endothelial cells on the pedicle.

In this study, 9 of 11 eyes achieved better than 6/9 visual acuity (Supplemental Digital Content 1, Table 1, available at http://links.lww.com/JRS/A62). Two patients achieved 6/12 or worse largely because of their comorbidities. Patient 1 had had multiple episodes of cystoid macular edema and idiopathic uveitis, treated with triamcinolone. Patient 7 had end-stage glaucoma, pseudophakic bullous keratopathy, and pain. The disc was not visible for quite some time before surgery to make that assessment. Patient 9 had had an uneventful DSAEK originally but was seeing 4 to 5 images. No clear explanation was found on aberrometry or topography. After removal of the DSAEK graft and successful DMEK surgery, the symptoms resolved, and he achieved corrected distance vision of 6/9.

The manipulation time significantly decreased from 12 ± 6 minutes for the first 5 cases to 3 ± 2 minutes for the last 6 cases (P = .007). The donor age for each of the grafts was shown for each case. For the first 5 cases, the donor age was 77 ± 4 years, which was significantly older than for the next 6 cases at 66 ± 7 years (P = .012).

The average loss of endothelial cells was 23% ± 8%. The graft manipulation was substantially longer (12 ± 6 minutes) in the first 5 cases and reduced thereafter (3 ± 2 minutes, P = .007) (Figure 5). The manipulation time and the endothelial cell count loss decreased in cases 6 to 11 despite the donor age decreasing, which should have made the graft more difficult to unroll. The endothelial cell count loss was 28% ± 5% for the first 5 cases and reduced to 18% ± 7% for the next 6 cases. This suggests that most improvement might have been due to the learning curve phenomenon rather than the donor age. Although manipulation time has been reported to not correlate with endothelial cell loss, it can be considered as a surrogate marker of surgical control.[36] Knowing that the manipulation time is consistently around 5 minutes or less indicates a certain level of control despite differences between cases.

The limitations of the study are the small number of patients at a single surgery center. This could not be avoided as it was a first-in-human trial. Although the pedicle did not break in these cases, it certainly came close to it in the first case; therefore, it might be appropriate for the surgeon to still be familiar with the techniques associated with a standard DMEK without a pedicle. Placement of a bump on the graft away from the pedicle would also help confirm orientation in case the surgeon had difficulty with the graft. This problem of potential pedicle break might also be mitigated if the graft was prepared in advance by the eye bank. Currently, all grafts were done with a 7.5 mm central zone, and this would have to be altered in the future based on clinical need.

Further studies at multiple sites need to be conducted to determine whether the punch increases the efficiency of the surgery and reduces the graft detachment rate and endothelial cell loss. This study is a proof-of-concept study, advocating a change in thinking from a circular graft to a noncircular graft to improve surgical control. This new process might be further enhanced by an injector system to allow for delivery through a smaller incision.

WHAT WAS KNOWN

- Descemet membrane endothelial keratoplasty (DMEK) surgery outcome anatomically approaches a healthy cornea and gives excellent vision.
- Controlling a DMEK scroll can be challenging for surgeons.

WHAT THIS PAPER ADDS

- The use of a pedicle allowed the surgeon to control DMEK scroll orientation, its unrolling and centration. This resulted in consistently short manipulation times during surgeries.
- This modified trephination might allow for safer DMEK surgery in complex cases of anterior chamber intraocular lenses, tubes, aniridia, and aphakia.

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Disclosures: *Dr. Bala has proprietary interest in the Bala Asymmetric Corneal Vacuum Punch.*

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