# Modified pre-descements endothelial keratoplasty (PDEK) and the effect of using Viscoat® in minimizing endothelial cell loss during tissue preparation

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**Conflict of interest:** Authors declare there were no competing interests.

**Abstract**

***Objective:*** To prepare large sized Pre-Descemet's endothelial keratoplasty (PDEK) lenticule with stromal (PDEK-S) and to assess the effect of using Viscoat® in minimizing endothelial cell loss during its preparation.

***Methods:*** Paired corneas were randomly assigned for Pre-Descemet's endothelial keratoplasty (PDEK) donor lenticule preparation in two groups depending on the application of Viscoat. Type-1 air bubble was formed with a 30-gauge needle, bevel up with a 3-cc volume syringe. Stromal tissues were excised from the periphery. The percentage of endothelial cell loss before and after dissection was estimated with Trypan blue Photo.

***Results:*** A total of 20 paired eyes were used. The average donor age was 57years. A 15% of endothelial cell loss induced by the preparation process was observed in both groups. The percentage of Endothelial Cell Loss was not significantly associated with the use of Viscoat during preparation (p - 0.87). We observed that larger diameter donor lenticules were associated with younger donors (p- 0.028). The largest diameter of Pre-Descemet's endothelial keratoplasty (PDEK) lenticule was 9.5mm.

***Conclusion:*** The use of Viscoat as an endothelial shield during Pre-Descemet's endothelial keratoplasty (PDEK) donor lenticule preparation has no significant effect in reducing the percentage of endothelial cell loss. The size of Pre-Decrement's endothelial keratoplasty (PDEK) donor lenticule can be increased by adding thin stroma at the periphery (PDEK-S). PDEK-S allows the utility of corneas from younger patients for endothelial keratoplasty and Younger aged donors are associated with larger sized donor lenticules.

**Key words:** Endothelial, keratoplasty, descemet's stripping, pre-descemet's endothelial keratoplasty.

## Background

Endothelial Keratoplasty was first successfully implanted by Melles under the name of posterior lamellar keratoplasty using a scleral-limbal approach with a series of curved blade dissection technique manually in late 1990s. He later modified it by only stripping Descemet membrane off the recipient without any stromal removal which is now termed as Descemet's stripping with endothelial keratoplasty (DSEK) and later Gorovoy introduced the use of an automated microkeratome for the donor lamellar dissection with the name Descemet's stripping automated endothelial keratoplasty (DSAEK). Melles later managed to peel the thinnest possible donor tissue of an endothelial graft with only Descemet's membrane and a healthy endothelium which he termed it as Descemet's membrane endothelial keratoplasty (DMEK)[1].

Currently there are three types of endothelial keratoplasty techniques namely, Descemet's stripping endothelial keratoplasty (DSEK/DSAEK), Descemet's membrane endothelial keratoplasty (DMEK) and Pre-Descemet's endothelial keratoplasty (PDEK), which have globally gained

preference over penetrating keratoplasty for endothelial dysfunction due to lower complication rates better visual and refractive outcomes and faster visual recovery than DSEK. Even though DMEK provides these advantages and lower risk of graft rejection[2] 1% at 1 and 2 years[3], many surgeons have not adopted DMEK due to its steep learning curve and the challenge of tissue handling compared to DSEK leads to higher complication rates especially during preparation and transportation[4, 5, 6].

Pre-Descemet's endothelial keratoplasty (PDEK) came into practice after the discovery of a novel pre-Decrement's layer by Prof. Dua, hence named Dua's layer, which is a tough posterior layer just before Descemet's membrane[7]. PDEK is basically the thicker layer of type 1 bubble in deep anterior lamellar keratoplasty as compared to a Type 2 bubble which the thinner graft used for DMEK. DSEK of course is thicker than either of those two types of bubble produced dissections as it has a variable amount of stroma in it [8, 9].

Pre-Descemet's endothelial keratoplasty (PDEK), which lies between ultrathin DSEK (60 to 100 microns) and DMEK (15microns) in terms of thickness of the donor disc, involves removal of patient's Descemet's membrane with its endothelium and transplantation of the pre-Descemet's, or Dua's, layer, Descemet's membrane and endothelium. Pre-Descemet's endothelial keratoplasty (PDEK) graft thickness is advantageous as it only is 25 to 30 microns, eliminates the irregularities inherently induced with microkeratomes that track the dissection from anterior surface of the cornea and vary bases on speed of the pass across the cornea there by like DMEK maximizing the potential for post-operative visual outcomes[7].

Pre-Descemet's endothelial keratoplasty (PDEK) uses a big type-1 air bubble to separate the donor's Descemet's membrane and endothelium from the stroma. With type 1 big bubble a pre-Descemet's layer remains attached to the Descemet's membrane, there by proving a thicker tissue as it contains, a pre-Descemet's layer, Descemet's membrane and endothelium. Most importantly the preservation of the pre-Descemet's layer with in the graft allows for the free movement and easy unfolding of the graft with in the host anterior chamber, which greatly reduces the risk of graft tear unlike in DMEK where the graft is very thin and flimsy[10].

The most significant advantage of Pre-Descemet's endothelial keratoplasty (PDEK) is that it is not donor's age dependent, as the younger donors have higher number of endothelial cells and thinner Descemet's membrane which determines the post-operative anticipated outcomes, unlike in DMEK where below the age of 40 is nearly impossible as the graft scrolling will be so tight. Even in terms of the incidences of graft rejection Pre-Descemet's endothelial keratoplasty (PDEK) is much superior to full thickness transplant[7] as it does not involve the entire stromal layer, which has keratocytes, hence less antigenic load. Stuart A.j et al reported endothelial cell loss 6 months post transplantation in PDEK (24.8%) was reported to be slightly better than DMEK (32.9%)[11].

As an evolving technique Pre-Descemet's endothelial keratoplasty (PDEK) has some limitation as the graft size is limited by the diameter of the type 1 big air bubble 7.5mm to 8.0 mm, which might influence the size of the Pre-Descemet's endothelial keratoplasty (PDEK) donor disc. Our study mainly focused on refining PDEK by including a peripheral thin stromal ring on the peripheral pre-Descemet's layer (hence PDEK-S) which can increase the size of the PDEK donor disc as required. The other challenge reported is the need to use scissors to excise the graft instead of a trephine which might reduce the number of endothelial cells to be transplanted during excision. This limitation might be balanced by the advantage of having a younger donor with a higher number of endothelial cells10. Also, limitation of the manual excision of the graft with scissors[4] now can be minimized by avoiding dissection at the center but only from far periphery with gentle pressure of pull and peel technique. We believed the use of protective ophthalmic viscoelastic devices can reduce the risk of endothelial cell loss throughout the preparation process. Recently Andrew et al have reported new ways of cutting and trephination of PDEK tissues currently in as of yet to be unreported trials[4].

Bedard et al reported that during Pre-Descemet's endothelial keratoplasty (PDEK) tissue preparation a reticular pattern of endothelial cell loss was observed with higher inflation pressure led to higher endothelial cell loss. They also noticed increasing donor age and shorted preservation time are associated with a less endothelial cell loss[12]. Alejandro Saint-Jean et al demonstrated that the use of slow and gentle inflation pressure with a step by step injection technique yields a safe and better way of getting the required Type-1 larger air bubble[13]. Saief Altaan et al, after a comparative study, revealed endothelial cell loss during PDEK with air bubble is much less than endothelial cell loss during DMEK making pneumo dissection a viable graft preparation technique[14].

Pre-Descemet's endothelial keratoplasty (PDEK) could be the future of endothelial keratoplasty and a good alternative to DSEK and DMEK, as it can be practiced by any interested corneal surgeon in any parts of the world. As we mentioned earlier the Refined PDEK (PDEK-S) can resolve the challenges of having a big sized PDEK donor disc. Other advantages include relative ease of harvesting &

preparation without sophisticated and costly instruments compared to DSEK and the ease of unfolding in the host anterior chamber without risk of tearing relative to DMEK. These advantages could be especially helpful for younger or novice surgeons. Most importantly the remaining tissue on the donor cornea that contains Epithelium, bowman's and full stromal layer can be used for another anterior lamellar keratoplasty procedure as we should not waste it considering the global shortage of such vital human tissue. One cornea can be used for two major procedures which greatly reduces financial and emotional burden both on the surgeon and patients side, a kind of hitting two birds with one stone.

On our preparation and training of stromal dissection for this study, we noticed that the technique of PDEK tissue dissection can also be used as DSEK tissue preparation without a microkeratome, as we managed to dissect 30 to 90microns thick DSEK graft on 112 corneas, which is comparable to Abdo Karim Tourkmani et al who reported graft thickness ranging from 25 to 170 microns of central DSEK graft thickness[15].

***Purpose of the Study***

The main objective of this study was to Refine Pre-Descemet's endothelial keratoplasty (PDEK) by adding thin stromal ring tissue at the periphery (PDEK-S) & assess the effect of Viscoat in minimizing endothelial cell loss during PDEK-S tissue preparation

**Materials and methods**

Paired eyes were randomly assigned as group-1 without Viscoat and group-2 with Viscoat during preparation and compared the amount of Endothelial Cell Loss by percentage.

***Outcome Measure***

The main outcomes were:

- Maximum size of Pre-Descemet's endothelial keratoplasty (PDEK)-S donor graft lenticule
- Amount of endothelial cell loss by percentage after Pre-Descemet's endothelial keratoplasty (PDEK) tissue preparation

***Inclusion criteria***

Eyes of any racial or ethnic origin were used

Fresh corneas within 14 days of harvest were used for this study.

***Exclusion criteria:***

Corneas preserved for more than 14 days were excluded for comparative study

***Study procedures and assessments***

Using pair corneas, the graft was placed on a moist chamber Teflon disc (19117) endothelium upward. We stained with vision blue 0.06% (Stephen, lax, KY-40511, USA) it for 30 seconds[14] and took a picture of stained endothelium and then performed scoring with a Y-hook (AE-2221) as it reduces the chances of having Type 2 by allowing the air to escape from the edge of the Descemet's Membrane. Type 2 air bubble separates the Descemet's membrane and endothelium from the pre-Descemet's membrane while Type 1 air bubble Splits the stroma from the pre-Descemet's (Dua's layer), Descemet's membrane and endothelium. Once we confirmed scoring is completed, we made Type -1 air bubble with a slow, a step by step gentle air injection, using a volume 3 cc syringe and 30-gauge needle, bevel up, starting 2mm away from the limbus as it was demonstrated by Alejandro Saint-Jean et al.[14]. The number of attempts of air injection was documented. Once we managed to get a Type 1 air bubble we measured the horizontal Diameter of it and took a picture to estimate the amount of endothelial cell loss( ECL ) by percentage (%) after air bubble formation. We deflated the air bubble for the ease of dissection and placed the graft on a Moria single use artificial chamber (Anthony France, Doylestown,USA) and dissected the stroma with scissors (S4 109B) & stromal dissector (Smile dissector, S-4 1715, Lexington, KY) all the way to Pre-Descemet's layer(PDL) starting from the far periphery avoiding the central part to minimize pressure and reduce ECL over the graft to be. Once we have a good grasp of the stromal tissue with a corneal forceps(S-5-1560) we pulled and peeled centrally and gently with minimal manipulation on the central part. We left a ring of thin stromal tissue at the periphery of the pre-Descemet's layer before we punch the donor disc lenticule. Group 2 had Viscoat (US-Gel, US IOL, Lexington, KY 40511 USA) over the endothelium (2ml) after we measured the pre dissection endothelium count, throughout the preparation and group 1 with no Viscoat at all. We performed photo analysis with image J / FiJi to determine the average (from three measurements) endothelial percentage of endothelial cell loss before and after dissection and optical coherence tomography (OCT) was used to measure the thickness of the donor lenticule for all the tissues used. All measurements were taken from the central 10mm of the cornea.

***Sample size***

A total of Forty (20 Paired) eyes were randomly assigned as group-1 without Viscoat and group-2 with Viscoat during preparation. All the eyes were given from the Indianapolis vision first eye bank, Indianapolis, USA, which caters all the required elements for this study and where the study was conducted. The sample size was predetermined considering the number of tissues we harvest in the specific study period from previous experience.

*Data analysis*

A Photo analysis was done with image J / FiJi to determine the percentage of endothelial cell loss before and after tissue preparation basically at the central 10mm of corneal endothelium and an optical coherence tomography (OCT) was used to measure the thickness of the donor lenticule at the center, mid periphery and far periphery. All the data was analyzed with Statistical Analysis Software.

*Ethical Approval*

The study was approved by the Director and Members of Indianapolis, vision first eye bank research committee, Indianapolis, USA.

**Results**

A total of 20 paired eyes were used in this study with an average donor age of 57 years. The days of storage in the eye bank storage solution were ranging from 3 to 14 days with the average to be 10 days. The initial plan of hope for >90% success rate with the preparation and <15% estimated or calculated endothelial cell loss associated with the preparation were achieved The horizontal diameters of the Type 1 air bubble formed were measuring from 4mm to 8mm, marking an average diameter of 6.3mm. The maximum size of the refined PDEK with peripheral stromal ring (PDEK-S) donor lenticule were ranging from 7mm to 9.5mm which makes the average maximum diameter of the PDEK-S donor lenticule to be 8.75mm. Twenty six (65%) of the PDEK-S lenticules were measuring greater or equal to 8mm. The total average endothelial cell losses before dissection in groups-1 where we didn't use Viscoat during the preparation were 9.25% while in group-2 it was 8.75% with trypan blue stained photos. The average percentages of endothelial cell losses induced by the preparatory process after dissection in group-1 where we didn't use Viscoat were 15.50% where as in group-2 where we used Viscoat during the preparation were 14.25%. There was no statistically significant difference in using Viscoat (p-0.87).

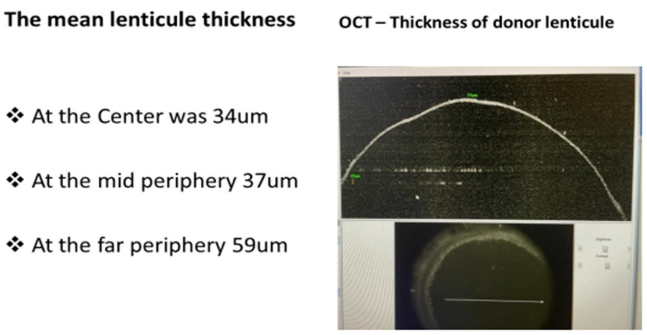


**Figure 1:** Pictorial representation of the thickness of the mean donor lenticule thickness at the center and periphery

The mean thickness of the donor lenticule was 34 microns at the center and 37 microns at the mid periphery, a reasonable thickness between ultrathin DSEK (60 to 100 microns) and PDEK (25 to 30 microns).

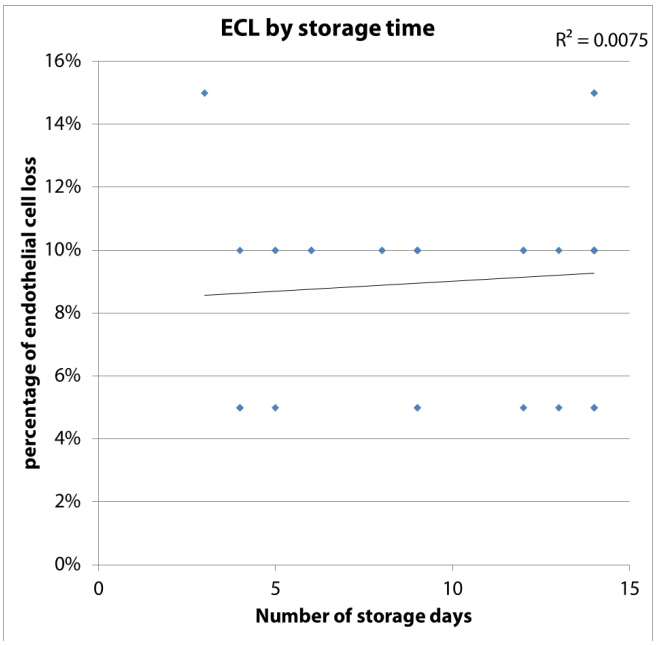


**Figure 2:** Comparing endothelial cell loss with days of storage in the solution

The Percentage of endothelial cell loss was not significantly associated with the days of storage in the storage solution. (p - 0.41)

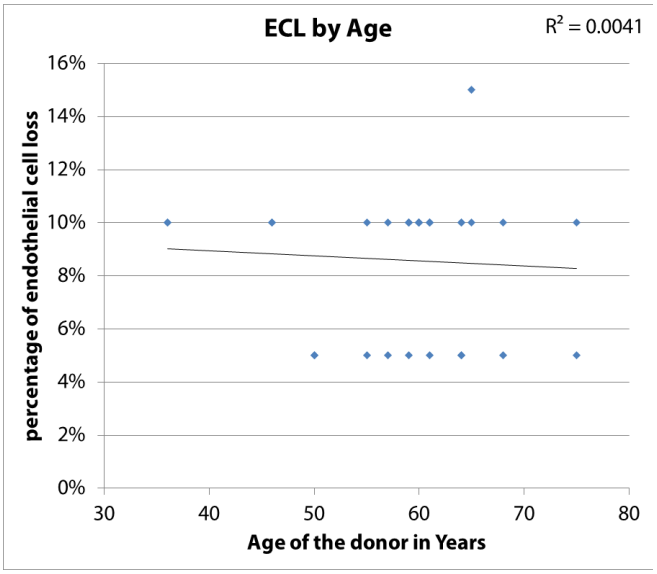


**Figure 3:** Distribution of endothelial cell loss by the age of the donors

The age of the donors was not significantly associated with the percentage of endothelial cell loss during the preparation of the PEDEK-S lenticules. (p-value 0.23)

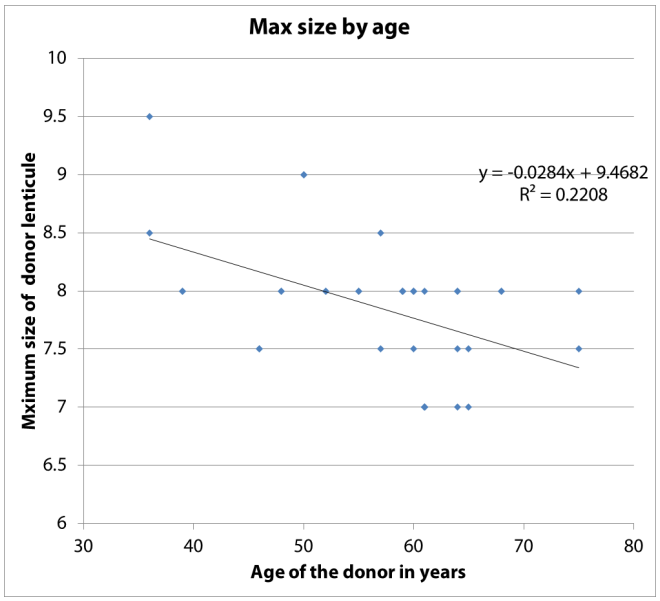


**Figure 4:** Distribution of donors age with maximum size of the PDEK-S lenticule

The maximum size of the PDEK-S lenticule was significantly associated with the age of the donors (p- 0.0284). The younger the donor the larger the diameter of the maximum size of the PDEK-S lenticule.

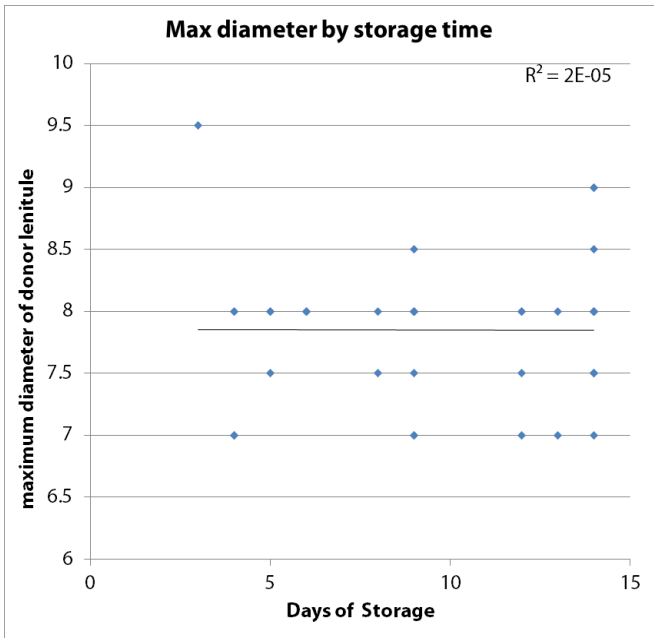


**Figure 5:** Distribution of maximum diameter of donor lenticule by the time of storage in the storage solution

There was no significant association observed between the maximum size of PDEK-S donor graft lenticule and the time of storage in the storage solution (p-0.243).

**Table 1:** Summary of detailed data before & after the preparation of PDEK-S lenticules

| 10 | 9 | 8 | 7 | 6 | 5 | 4 | 3 | 2 | 1 | No. |
|---|---|---|---|---|---|---|---|---|---|---|
| 1835L | 1835R | 1958L | 1958R | 1794L | 1794 R | 1776 R | 1776 L | 1537 R | 1537 L | Tissue registration number |
| 61 | 61 | 75 | 75 | 60 | 60 | 68 | 68 | 59 | 59 | Age of the Donors in years |
| 13 | 13 | 5 | 5 | 9 | 9 | 9 | 9 | 6 | 6 | Days of storage of eyes in the storage solution |
| 6mm | 6mm | 7mm | 7mm | 7mm | 7.5mm | 6mm | 6mm | 6.5mm | 6.5mm | Diameter of Type-1 air bubble formed |
| Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate | Speed of air bubble injection |
| 5% | 10% | 5% | 10% | 10% | 5% | 10% | 10% | 10% | 10% | Endothelial Cell Loss before dissection |
| 7 mm | 8 mm | 8 mm | 7.5 mm | 7.5 mm | 8mm | 8mm | 8mm | 8mm | 8mm | Maximum size of the PDEK-S lenticule |
| 10% | 15% | 15% | 15% | 15% | 10% | 15% | 20% | 20% | 20% | Endothelial Cell Loss after dissection |
| Used Viscoat | No Viscoat | No Viscoat | Used Viscoat | No Viscoat | Used Viscoat | No Viscoat | Used Viscoat | Used Viscoat | No Viscoat | Application of Viscoat during preparation |
| Once | Twice | Once | Thrice | Once | Once | Twice | Once | Once | Twice | Number of attempts of air bubble injection |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 20 | 19 | 18 | 17 | 16 | 15 | 14 | 13 | 12 | 11 |
| 2700L | 2700R | 2843R | 2843L | 2181L | 2181R | 1902L | 1902R | 1869L | 1869R |
| 57 | 57 | 64 | 64 | 61 | 61 | 60 | 60 | 65 | 65 |
| 14 | 14 | 8 | 8 | 4 | 4 | 12 | 12 | 12 | 12 |
| 6mm | 8mm | 4mm | 5mm | 6mm | 5mm | 5mm | 5.5mm | 7mm | 7mm |
| Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate |
| 5% | 5% | 10% | 10% | 5% | 5% | 10% | 10% | 10% | 5% |
| 8.5 mm | 7.5 mm | 8 mm | 7.5 mm | 7 mm | 7 mm | 8 mm | 8 mm | 7 mm | 7.5 mm |
| 15% | 10% | 15% | 15% | 15% | 10% | 15% | 15% | 15% | 15% |
| No Viscoat | Used Viscoat | No Viscoat | Used Viscoat | No Viscoat | Used Viscoat | Used Viscoat | No Viscoat | Used Viscoat | No Viscoat |
| Once | Once | Once | Once | Once | Once | Once | Once | Twice | Once |



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| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 30 | 29 | 28 | 27 | 26 | 25 | 24 | 23 | 22 | 21 |
| 10896L | 10896R | 10760L | 10760R | 10696L | 10696R | 2995R | 2995L | 3049L | 3049R |
| 39 | 39 | 52 | 52 | 61 | 61 | 64 | 64 | 46 | 46 |
| 4 | 4 | 9 | 9 | 9 | 9 | 14 | 14 | 14 | 14 |
| 8mm | 6mm | 7mm | 5mm | 6mm | 6mm | 6mm | 6mm | 5mm | 8mm |
| Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate |
| 10% | 5% | 10% | 10% | 5% | 10% | 10% | 5% | 15% | 15% |
| 8 mm | 8 mm | 8 mm | 8 mm | 7 mm | 7 mm | 7 mm | 8 mm | 7.5 mm | 7.5 mm |
| 15% | 10% | 15% | 15% | 10% | 15% | 15% | 10% | 20% | 20% |
| No Viscoat | Used Viscoat | No Viscoat | Used Viscoat | No Viscoat | Used Viscoat | No Viscoat | Used Viscoat | No Viscoat | Used Viscoat |
| Once | Twice | Once | Once | Once | Once | Twice | Once | Once | Once |



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|---|---|---|---|---|---|---|---|---|---|
| 40 | 39 | 38 | 37 | 36 | 35 | 34 | 33 | 32 | 31 |
| 2973L | 2973R | 2864R | 2864L | 1738R | 1738L | 11116L | 11116R | 10682R | 10682L |
| 50 | 50 | 55 | 55 | 36 | 36 | 59 | 59 | 48 | 48 |
| 14 | 14 | 14 | 14 | 9 | 3 | 6 | 5 | 14 | 14 |
| 6mm | 6mm | 6mm | 7mm | 6.5mm | 6.5mm | 7mm | 7mm | 6mm | 7mm |
| Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate | Slow & titrate |
| 10% | 10% | 10% | 10% | 10% | 15% | 10% | 10% | 10% | 10% |
| 9 mm | 9 mm | 8 mm | 8 mm | 8.5 mm | 9.5 mm | 8 mm | 8 mm | 8 mm | 8 mm |
| 15% | 15% | 15% | 15% | 15% | 20% | 15% | 15% | 15% | 15% |
| Used Viscoat | No Viscoat | Used Viscoat | No Viscoat | Used Viscoat | No Viscoat | Used Viscoat | No Viscoat | Used Viscoat | No Viscoat |
| Once | Once | Once | Once | Once | Twice | Once | Once | Once | Once |



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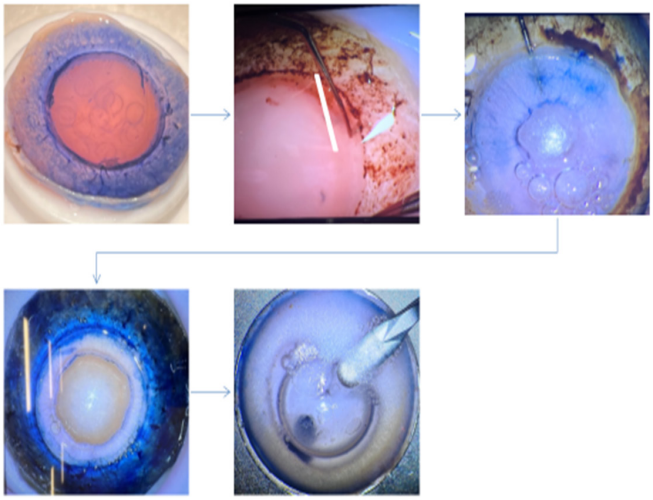

**Figure 6:** Pictural representation of type 1 bubble forming procedure (©Zelalem Tafesse)

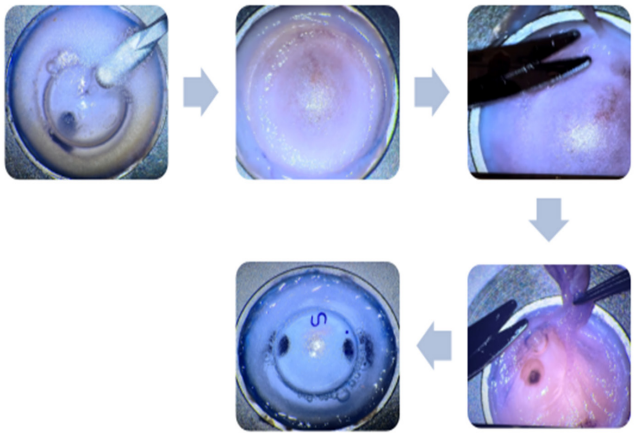

**Figure 7:** Pictural representation of the dissection procedure for tissue preparation(©Mark Soper)

## Discussion

Our study revealed that the new evolving technique, PDEK, can be the future and a great alternative to other endothelial keratoplasty techniques with a little refination. PDESK-S, a modified PDEK, by leaving a thin stromal ring at the periphery of the pre-Descemet's layer is able to resolve one of the puzzles of PDEK by increasing the size of the donor graft lenticule. Most corneal surgeons agreed on the fact that the size of graft size is limited by the diameter of the type 1 big air bubble, commonly 7.5mm to 8.0 mm, can be a disadvantage for those who needed larger sized PDEK grafts. But our findings suggested that we can prepare up to 9.5mm sized PDEK donor lenticule. As it was reflected on Figure 1 the mean thickness of the donor lenticule was 34 microns at the center and 37 microns at the mid periphery, there are the critical area or donor sizes that most surgeons prefer for grafting which has a reasonable thickness that lays between ultrathin DSEK (60 to 100 microns) and PDEK (25 to 30 microns).

The percentage of endothelial cell loss during PDEK graft tissue preparation was reported not to be worse than endothelial cell loss during DMEK tissue preparation by pneumo dissection method[16]. The percentage of endothelial cell loss in our case was found to be 15% without a significant difference between the two groups of eyes with and without using viscoat during the entire preparation process. This finding particularly is important in a resource limited area which can save unnecessary usage of Viscoat. The other interesting finding that we got was the association of the ages of the donor with the maximum size of the PDEK-S graft donor lenticule. The younger the ages of the donor the larger the maximum diameter of the PDEK-S graft donor lenticule which can explain younger patients have a greater number of endothelial cells up to the far periphery of the cornea. As we mentioned it earlier one of the greatest advantages of PDEK was its non-dependency with ages, unlike DMEK where below the age of 50 is not recommended due to the tight scrolling of the donor graft. The other advantage of the PDEK is the relative easier techniques of dissection with no much expensive instruments like in DSEAK or DSEK. As to the surgical techniques, after marking the required size, a gentle dissection at the periphery of the cornea with scissors can be made. The use of a partial trephination blades can also make the dissection of the cornea easier as it will cut most of the stroma. Peeling and pulling with a gentle continuous pressure towards the center will reduce the amount of pressure at the center of the graft where we are more interested in reducing the percentage of endothelial cell loss.

## Conclusion

The size of PDEK donor lenticule can be increased by adding thin stroma ring at the periphery (PDEK-S), our PDEK-S technique proved that. Compared with DSEK, PDEK or PDEK-S can be practiced by any interested corneal surgeon in any part of the world without expensive equipment, such as a microkeratome. We believe that Unlike with DMEK and PDEK, PDEK-S tissue is less fragile and tends to unfold more easily in the host anterior chamber due of the presence of stromal tissue. These advantages could be especially helpful for younger or novice surgeons. Most importantly, with either PDEK(S) or DMEK, the remaining donor epithelium, Bowman's layer and stromal layer can be used for an anterior lamellar keratoplasty procedure, which is important given the global shortage of donor corneas, although the demand for endothelial keratoplasty greatly outstrips demand for anterior lamellar keratoplasty. Additionally, it was noted that Younger aged donors are associated with larger sized donor lenticules. PDEK-S allows the utility of corneas from younger patients for endothelial keratoplasty. The use of Viscoat as an endothelial shield

during PDEK donor lenticule preparation has no any significant effect in reducing the percentage of endothelial cell loss.

**Limitations**

To the best understanding of the Authors, it is the first paper on PDEK-S which created a challenge of getting comparative references. But we do believe it opens up a door for future clinical investigators.

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