**Title**: Eye banking: one cornea for multiple recipients

**Running head:** One cornea & multiple recipients

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**Abstract**

Purpose**:** Corneal transplantation is the most frequently performed transplant. In much of the world, demand for donor tissue heavily out strips supply. With developments within lamellar corneal graft surgery, the use of split corneal donor tissue to increase donor tissue supply seems a pragmatic solution to reduce the supply and demand mismatch. This is especially important with tissue supply expected to be affected by the COVID-19 pandemic.

Methods: Literature review of techniques enabling multiple transplants to be derived from a single donor and simulation of a model to quantify the number of corneas potentially saved. Results: Studies on splitting corneal donor tissue have demonstrated that up to 5 recipients may benefit from one donor scleral button. The impact of splitting donor tissue may provide a saving of up to 25.3% of donor graft tissue.

Conclusion: Splitting and preparing the donor tissue within an eye bank will improve tissue validation, donor tissue availability and may increase surgeon efficiency.

**Keywords**: Eye Bank; Split donor; Quarter DMEK; Hemi DMEK; DMEK; DSAEK; PK

**Introduction**

Corneal transplantation remains the principal treatment in the majority of cases of corneal blindness

1. Since the first successful corneal transplant was performed in humans by Edward Zirm in 1905, transplant surgery has evolved significantly. Contemporary surgical techniques improved post-operative management and introduction of targeted lamellar keratoplasty has improved transplant outcomes. As a result, trends in corneal grafting are changing, and penetrating keratoplasty (PK) is no longer the preferred technique for most corneal transplantations. It is estimated that, in most developed countries, up to 80% of corneal pathology requiring grafting can be managed with anterior lamellar keratoplasty (ALK) or endothelial keratoplasty (EK)

2. The developments in lamellar surgery now make the concept of using multiple parts of the same donor cornea to treat different patients increasingly appealing.

When Zirm performed the first successful corneal graft, he was able to harvest two 5 mm corneal buttons from one donor cornea.

1 Both were subsequently used to perform a left eye and right eye corneal transplant. The adoption of split donor surgery, however, has been slow within the field of corneal transplantation. Within other fields of medicine, the idea that multiple recipients should receive different parts of one organ is not novel. Split liver transplantation was first reported in 1988 and is now commonplace

3. Currently within eye banking services, donor sclera may be separated from the corneal button and stored for use for patching another recipient patient at a later date

4. Despite this, in current practice most donor corneas will only ever be used for one recipient due to ease of traceability.

At present the global need for corneal donor tissue significantly outweighs the available supply and an estimated 12.7 million patients are waiting for corneal transplants.

5 Since the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which has been detected in tears and conjunctival secretion, all eye banks globally have had to drastically change their practice in order to safeguard the health of retrieval teams, eye bank technicians, doctors and patients

6-8.

 Currently, the SARS-CoV-2 is impacting on the number of tissues procured and eye banks are predicting a significant shortage of corneas as soon as constraints limiting elective surgical interventions are lifted

9 . The virus is also adding additional pressure to eye bank facilities because of staff shortages due to illness and caring responsibilities linked to school closures, which are likely to continue impacting the workforce for some time. This will only exacerbate the shortage of corneal donors, that in 2016 was reported as being only 1 cornea available for every 70 needed

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In the present climate, when donor to recipient ratio are unsustainable, some important questions need addressing. If one patient requires an ALK, can the endothelium from that donor be used to treat another patient in need of an EK? If only a small region of the recipient’s endothelium is diseased, does a conventional large diameter EK need to be performed? Should part of this donor endothelium be used to treat a second, third or fourth patient and is this splitting detrimental to the endothelium? We have reviewed the evidence related to split donor corneal transplantation surgery and the potential advantages and disadvantages.

**Combining Anterior and Posterior Lamellar keratoplasty**

Combining ALK with EK seems an obvious place to start. Microkeratomes have allowed preparation of a corneal anterior lamellar suitable for ALK and a posterior lamellar suitable for Descemet’s stripping automated endothelial keratoplasty (DSAEK). In 2007 a surgical technique was published by Vajpayee et al., where it was demonstrated that from a single cornea, 3 patients with varying corneal pathologies could be successfully treated

10. The first patient with an anterior stromal dystrophy received an anterior lamellar keratoplasty following a 350 microns microkeratome pass. The second patient received the posterior lamellar component of the corneal button which was used successfully to perform a Descemet’s stripping endothelial keratoplasty. The final patient with limbal epithelial stem cell failure received a cadaveric limbal stem cell transplant from the periphery of the same donor cornea. All three procedures were deemed a success

10. Sharma et al., showed that it was possible and safe to use 12 donor eyes for 24 patients by splitting each donor cornea into 2 parts to create an anterior (350 microns thick) and posterior lamella (150 microns thick)

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More recently, with the advent of true posterior lamellar keratoplasty, combining an ALK with an EK appears more appealing than ever. Descemet’s membrane endothelial keratoplasty (DMEK), which does not require a microkeratome during preparation, leaves the complete anterior lamellar corneal button intact. With intraoperative conversion from ALK to PK becoming less common, performing a DMEK following an ALK using one donor is a potential feasible option

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In a large series of 100 patients, 50 of whom underwent deep anterior lamellar keratoplasty (DALK) and 50 underwent DMEK, Hendl et al., demonstrated that the same donor cornea could be used in 47 out of the 50 (94%) cases. In the remaining 3 cases of DALK, intraoperative conversion to PK meant that a DMEK could not be harvested from the same donor tissue.

14 Other smaller case series of 10

15 and 12

16 eyes highlighted the success of splitting of donor cornea for combined DALK and DMEK procedures in 2 recipients.

Oganesyan et al., has taken this concept further, utilising a technique of performing not two or three keratoplasties from one donor, but five. Using one donor cornea their group successfully performed a ALK and 4 quarter DMEK keratoplasties

17. After stripping the Descemet’s and endothelium they divided it into 4 equal quarters using a custom trephine and transplanted each quarter DMEK into a different recipient with primary endothelial disease. The remaining intact anterior corneal button was used to perform a deep anterior lamellar keratoplasty in a patient with keratoconus

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**Splitting endothelial keratoplasty**

With EK rapidly being adopted and endothelial disease being the most common indicator for keratoplasty

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18 , maintaining tissue supply to meet demand is important. Partial DMEK surgery is a procedure that has been in development for some time. Primary endothelial conditions such as Fuchs’ endothelial corneal dystrophy (FECD) often preferentially affect the central cornea in the early disease process and

19 , therefore, a large diameter endothelial keratoplasty may not always be necessary, giving rise to the idea of smaller and split DMEK grafts. Supporting this is the knowledge that the endothelial density is greater in the periphery of a DMEK graft, and as a consequence, a partial DMEK derived from a larger diameter punch will still contain a large number of healthy endothelial cells

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In 2016, hemi-DMEK was demonstrated by Gerber-Hallbach et al

21. to be a viable alternative to DMEK. Once the DMEK tissue was stripped, it was punched and divided into two halves. Each of these could theoretically then be implanted into individual eyes/patients. In the first series of 10 patients who underwent a hemi-DMEK, the procedure was successful in 9, providing proof of concept. This potentially doubles the amount of EK tissue available in suitable cases of EK

21 . Since then, further division of the DMEK into quarters has been demonstrated to be effective with up to 2 years follow-up, despite an initial drop in the ECD 22. Birbal et al., have shown in a series of 20 patients with FECD affecting mainly the central cornea, a quarter DMEK resolved vision to ≥20/40 in 18/19 cases (95%), with 12/19 (63%) demonstrating complete corneal clearance at last follow up

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**The role of eye banks in split corneal surgery**

Eye banks may play an important role in facilitating the use of one cornea for multiple recipients. In recent years, a paradigm shift has been observed in the development of eye bank activities from simple collection, processing and distribution to now a fully functional unit providing pre-cut and pre-loaded tissues for EK

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28 . They provide validated tissue grafts, including donor medical history, graft thickness profile and endothelial cell count, as well as preparing tissue ready-for-transplant reducing time in the operating theatre.

**Graft preparation: surgeon versus eye bank**

Currently, lamellar graft preparation is performed either by specialized eye bank technicians, with subsequent delivery of a pre-cut or pre-stripped tissue to the surgeon, or by surgeons themselves in the operating theatre. When posterior lamellar transplants were first introduced, surgeons were reluctant to allow this tissue preparation to be performed in the eye bank setting, mainly due to concerns over endothelial cell survival in culture medium after preparation and during shipping

29. A number of key pieces of evidence emerged to suggest pre-prepared tissues could be a viable option for surgeons

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30. A laboratory study showed that pre-cut posterior lamellar grafts could be stored in organ culture for up to two weeks with reasonably good endothelial cell survival, organization and metabolic activity

31. In a clinical setting, EK donor tissue preparation up to 2 days before surgery was demonstrated to have no detrimental effect on endothelial cell survival or graft attachment

32, and international shipping of pre-cut DSAEK donors and pre-stripped DMEK donors showed an extremely low level of endothelial cell damage

33. With rare exceptions

34, eye bank pre-cut and pre-stripped donor tissues proved to match those of surgeon-dissected and surgeon-stripped tissues in terms of post-transplant endothelial cell survival, transplant dislocation rate and graft failure rate

29, 32, 35-38. Anterior lamellar graft storage poses less concerns; stromal keratocyte survival is not mandatory as infiltration with the recipient’s own keratocytes after transplant would be expected in the long term, therefore, the only requirements are maintenance of stromal architecture and clarity

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Over time, the advantages of eye bank lamellar graft preparations have become increasingly evident. Ready-to-use tissue has been shown to decrease surgical stress by reducing perioperative complexity, shortening the operating time and avoiding postponement or cancellations on the day of surgery due to errors in tissue preparation

40. On average, approximately 5% of donor DMEK preparations fail, leading to tissue waste with a range depending on the experience of the surgeon or the eye bank technician 27,

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 36, 41, 42. Furthermore, eye bank donor tissue preparation guarantees greater consistency in terms of lamellar graft thickness and endothelial cell count, since slit-lamp bio-microscopy and specular microscopy can be readily performed to evaluate tissue quality and endothelial cell count before shipping, reassuring the surgeon that the grafts they are receiving are healthy

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Moreover, now that hemi-DMEK and quarter DMEK have been demonstrated to be viable alternatives to DMEK in suitable cases

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23 , the role of the eye bank in preparing validated split donors will become even more valuable. One point to note is that given that hospitals are not equipped with the necessary equipment to preserve the split graft for a long period, surgeon-stripping of the graft would necessarily have to be accompanied with a re-thinking of an operating list in an attempt to group all the operations using the same donor within a few days. Conversely, eye banks could harvest the tissue, split it into the desired number of grafts to be delivered to different centers according to the demand, not requiring any change in the theatre list planning

For surgeons that only perform occasional transplants there are additional advantages of eye bank pre-cut and pre-stripped tissues; for pre-cut corneas for UT-DSAEK and ALK, there is no longer the need to invest in an expensive microkeratome

37 and in cases of pre-stripped corneas for DMEK there is no need to undertake the lengthy process of gaining sufficient expertise in tissue preparation, the first surgical step that often discourages surgeons from attempting this technique

36. Although there is a well-known DMEK learning curve for surgery, the same applies to tissue preparation

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43 and several studies have shown that the more experienced the eye bank technician/surgeon is, the lower the endothelial cell loss and tissue preparation failure rate

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Current advice is that surgeons who perform occasional corneal transplants should take advantage of the availability of eye bank prepared graft tissue

18 . Departments who undertake high volume corneal transplant surgeries now have the opportunity to decide in accordance with their preferences and cost evaluations, balancing longer operating theatre time and risk of graft preparation failure (which should be low in these cases), with reduced costs associated with local tissue preparation compared to pre-cut and pre-stripped eye bank corneas

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Before adopting this new practice, however, a careful evaluation on the risk of infection needs to be considered. Microbial contamination of the corneal buttons has a high prevalence that varies widely, likely related to the processes of harvesting, storage, and culture techniques

44. Although postoperative corneal graft infection rates are low despite the potential for contamination, lamellar graft preparation using aseptic technique under laminar flow is advised as it will decrease the risk when using the same donor cornea for multiple patients

44. This may limit the surgeon from performing the splitting procedure if they don’t have access to a suitably sterile environment.

If the use of the same donor cornea for more than one patient becomes routine, eye bank tissue preparation would provide the additional advantage of facilitating the shipping of different parts of the same tissue to different eye clinics, according to the specific demand. This is particularly important from a regulatory point of view as the traceability of all human tissue must be maintained, which could be much more easily guaranteed if the tissues were split and distributed by the eye banks rather than by individuals.

**Estimation of the number of cornea saved using proposed model**

To quantify the effect of using 1 cornea for multiple recipients we estimated the number of tissues that could be saved using the latest available data on the number of ALK and EK performed in 2019 from the Eye Bank Association of America (EBAA) and in 2018 from the European Eye Bank Association (EEBA). Conservatively, using one donor for two recipients (combination: 1 cornea= 1 ALK + 1 DSAEK or 1 cornea= 1 ALK + 1 DMEK) leads to a significant saving of donor tissue. Extrapolating, the number of corneas saved improves considerably when considering that one cornea can be used to perform 1 ALK and multiple DMEKs (Table 2). In percentage terms, one could expect to save between 1.5% (745) to 20.7% (10656) of corneas donated that are suitable for transplant, and in Europe between 3% (561) to 25.3% (4752)

7. In order to maximize this shift, the eye bank will need to play a crucial role in providing precut and preloaded tissue.

The model presented may be limited by the number of ALK and DMEK procedures currently undertaken, however, both these techniques are being more widely adopted so the percentage of saved cornea could be even higher in the future.

45 It is also worth noting that as the number of ALKs undertaken is much lower than DMEKs, it is possible that tissue may not be split for use immediately but will need to be stored for use at a later date. Eye banks have been focusing their research on prolonging the shelf life of tissues in different preservation media as well as banking stroma

46 to enable better planning of elective surgeries or to provide enough time to transport the tissues to potentially multiple recipients worldwide. It is worth noting that in countries where the is a paucity of good quality donor tissue, this corneal splitting procedure may already be in use. In addition, biobanking the stroma for ALK will increase the number of cornea suitable for corneal transplant, particularly tissue that is unsuitable for EK due to low endothelial cell density

46 .

**Future and alternatives**

Previously, we reported the peripheral endothelium discarded during DMEK preparation can be preserved and shipped from the theatre back to the eye bank or cell culture facility to allow isolation and expansion of the cells for potential tissue engineering applications, indicating transportation of such grafts is practically possible

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48. The peripheral endothelium has a high density of endothelial cells and cells have a higher proliferative capacity compared to cells in the central cornea

20, so this tissue could be a valuable resource of cells for expansion. We have focused on the application of corneal splitting for optical grafts but the tissue could also be split for tectonic procedures, although this application may be more difficult to manage as it usually required in urgent cases rather than scheduled operations.

**Conclusion**

Corneal transplantation has evolved considerably but maintaining adequate supply of viable tissue to provide for increasing demand remains a priority to the specialty. We believe that this is the time to re-think allocation policies in order to facilitate donor cornea splitting into multiple grafts for multiple recipients. It could be crucial to act in a timely manner as we expect an increased burden in the next 12-24 months, since it likely that we will have to live with SARS-CoV-2 for at least that long

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**Figure Legend**

**Figure 1**. Schematic representation of the possible current solution of splitting a donor cornea. In addition the peripheral limbus (light blue) could be used for a keratolimbal transplant and the peripheral endothelium discarded during DMEK preparation (green) can be preserved and shipped from the theatre back to the eye bank or cell culture facility to allow isolation and expansion of the cells for potential tissue engineering applications.