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ORIGINAL RESEARCH

Comparison of Surgical Outcomes of Graft Survival Rate Using Surgeon Cut versus Precut DSAEK Tissue

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Purpose: To compare endothelial graft outcomes after DSAEK using pre-cut tissue and surgeon cut tissue in terms of final visual outcome and graft failure at 6 and 12 months postoperatively.

Patients and Methods: This retrospective study examined patients who underwent DSAEK with CB or surgeon-prepared tissue for any etiology of endothelial dysfunction. Best-corrected visual acuity (BCVA), corneal thickness, endothelial cell count (ECC), and complications were examined before and throughout the 1-year postoperative period.

Results: Total number of cases is 98 eyes of 98 patients. Fifty-five surgeon-cut grafts were compared to 43 precut grafts. Preoperative visual acuity was >/= 20/60 in 1.8% and 0.0%, >20/60–20/200 in 21.8% and 7%, and less than 20/200 in 74.6% and 86.1% for surgeon cut and precut group respectively. Visual acuity at last follow-up was >/= 20/60 in 32.4% and 5.3%, >20/60–20/200 in 29.7% and 10.5%, and less than 20/200 in 37.8% and 84.2% for surgeon cut and precut group, respectively. At 6 months, 41 (83.7%) in the surgeon cut group and 27 (67.5%) in the precut groups completed the follow-up. Of these, 10 (24.4%) and 14 (32.6%) respectively, ended up with graft failure. The statistically significant difference in graft failure was maintained until 12 months: 37 (82.2%) in the surgeon cut group and 20 (58.8%) in the pre-cut group completed the follow-up. Of these, 11 (29.7%) and 14 (70%) labeled as failed grafts, respectively.

Conclusion: We found a higher rate of graft failure 6 to 12 months postoperatively in precut tissue grafts than in surgeon cut tissue grafts despite both tissues being provided by the same eye banks.

Keywords: DSAEK, endothelial keratoplasty, precut tissue, surgeon cut tissue

Introduction

Endothelial keratoplasty is currently considered the standard of care for the treatment of visual loss due to cornea with a primary etiology of endothelial dysfunction. Many techniques have been developed to replace diseased endothelium with a healthy donor graft. Descemet Stripping Automated Endothelial Keratoplasty (DSAEK) and descemet membrane endothelial keratoplasty (DMEK) are techniques of choice for endothelial keratoplasty. However, DSAEK is still performed more often than DMEK for many reasons, including more predictable tissue handling, fewer detachments, and lower re-bubbling rates.[1–4]

Donor tissue dissection in DSAEK can be performed in the operating room (surgeon cut) or on an eye bank (Precut). Currently, the trend is moving toward using precut donor tissue rather than surgeon cut tissue. Both techniques have similar surgical outcomes with the former being less time consuming in the operating room and more readily enabling eye bank technicians to perform specular microscopy and slit-lamp biomicroscopy to evaluate endothelial health after dissection and before shipping the tissue.[2,5,6]

Some reports have studied the effect of time required from tissue processing to transplantation on the outcome of DSAEK surgery using precut versus surgeon cut tissue and found that the outcomes were comparable.[5,7]

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In some countries, precut tissue is shipped long distances after preparation in overseas eye banks, leading to a long precut-to-surgery time.

In addition, Yamazoe et al showed that presurgical cell counts after overseas shipping were within the range typically used safely with DSAEK.[7] NAKAGAWA et al found that internationally shipped, precut donor corneas produced satisfactory clinical results, with a low rate of complications.[8]

In this study, we aimed to share our experience at a tertiary eye hospital with large number of endothelial keratoplasties performed, comparing pre-cut and surgeon cut tissues and the effect of the time needed from processing the donor graft until the time of implantation on DSAEK graft outcome. To the best of our knowledge, this is the first study carried out in the Middle East on this topic. We believe that our setting is ideal for comparison as the majority of our grafts were imported from overseas eye banks in the United States and adhered to the standards of the Eye Bank Association of America (EBAA).

Materials and Methods

This retrospective comparative study was conducted at the King Khaled Eye Specialist Hospital (KKESH) in Riyadh, Saudi Arabia. This study was approved by our Institutional Review Board and adhered to the tenets of the Declaration of Helsinki. The electronic medical records of patients who underwent DSAEK using a surgeon cut tissue from December 2018 to April 2019, and precut tissue from December 2019 to April 2020 were reviewed to obtain the following information: the patient's age and sex, laterality, surgical procedure, ocular history, primary diagnosis, pre and postoperative UDVA and BCDVA, endothelial cell count and corneal thickness, in addition to the frequency of graft detachment, graft failure and any other complications at 1 week, and 1, 3, 6, and 12 months postoperatively. Donor tissue characteristics were obtained from the hospital eye-bank records. All patients involved in the study have signed an informed consent prior to undergoing treatment at the hospital authorizing the use of their clinical data for scientific and research purpose while maintaining their confidentiality.

Surgical Technique

Standard tissue eligibility criteria were established in accordance with EBAA and KKESH Eye Bank guidelines. For endothelial keratoplasty, a donor between the ages of 4 and 75 years, corneal tissue with an endothelial cell count (ECD) greater than 2,000 cells/mm2, and an interval between death and transplantation of not exceeding 12 days are favorable criteria.

Precutting

Precut tissues were received ready from overseas eye banks and either used on the same day or stored in the hospital eye bank until the day of surgery.

Surgeon-Cutting

Donor corneo-scleral grafts were received from overseas eye banks, intraoperatively, the donor cornea was mounted and well centered on an artificial anterior chamber, and the pressure was adjusted. The surgeon then performed a lamellar cut using a Moria ALTK manual microkeratome (Moria, Antony, France) with variable cutting head sizes depending on the corneal thickness, which was measured intraoperatively using pachymetry. The graft was marked for orientation on the stromal side using an F or S. The free cap was then re-placed, and the tissue was immediately used for DSAEK. Punch was used to cut the posterior lamellar graft to the intended diameter, which was determined based on the corneal diameter and presence of anterior synechea.

The study included patients of many surgeons at KKESH, all included surgeons had comparable level of expertise. Regardless of the type of tissue used, precut or surgeon cut, a standardized surgical technique and tissue insertion has been used. After stripping the Descemet's membrane over an area of approximately 8 mm in diameter, an anterior chamber maintainer was inserted, a 3.5–5 mm clear corneal wound was created, depending on the surgeon's chosen method of insertion, using one of the following standard techniques:

1. Pull-through technique using the modified Busin glide, as described in the literature. 10
2. Needle-Push Insertion with or without a sheet glide, as described by Richard Schulze, Jr., MD.[9]

The graft centration and orientation were confirmed, and an air bubble was injected to fill the entire anterior chamber. After maintaining the supine position and adequate air filling of the anterior chamber for graft attachment, the air-bubble was reduced to approximately 80% of the anterior chamber's volume. Postoperatively, the patients were instructed to remain in a supine position and were prescribed topical corticosteroid drops every 2 hours while awake for 1 week and then tapered according to the physician's preference.

Follow-up

All patients who underwent DSAEK were examined preoperatively and 1, 3, 6, and 12 months postoperatively. The following variables were recorded at each visit. Whenever available: UCVA or BCVA, slit-lamp examination, endothelial cell count, corneal thickness, graft detachment, air or gas injections, graft failure, and post operative complications.

Statistical Analysis

The data were entered into Microsoft Excel 2010 (Microsoft Corporation, Redmond, Washington, USA) and analyzed using SPSS v26 (IBM, USA). Categorical data were presented as frequencies and percentages. Means and standard deviations were used to summarize the continuous variables. Student *t*- t-tests or ANOVA will were used to compare the means, as appropriate. The chi-square test was used to compare the proportions. Statistical significance was defined as P<.05.

Results

The total number of cases was 98 eyes of 98 patients. 55 surgeon-cut grafts (group I) were compared with 43 pre-cut grafts (group II). Table 1 shows the demographic characteristics of the study population. The mean age was higher in group II (P = 0.030). The primary preoperative diagnosis was almost comparable between the two groups, this includes pseudophakic bullous keratopathy (PBK) (56.4% in surgeon cut group and 60.5% in precut group), failed previous DASEK graft (14.4% in surgeon cut group and 11.6% in precut group), and other less frequent causes. Cases of Fuchs endothelial dystrophy represent 9.1% in the surgeon cut group and 4.7% in the precut group.

Most surgeries performed were DASEK alone in both groups. Only four (7.2%) and three (7%) (Groups I and II, respectively) were combined surgeries in which DSAEK was combined with either cataract extraction and intraocular lens implantation or phakic intraocular lens removal (Table 2).

Table 1 Demographics of Patients Treated with Descemet's Stripping Automated Endothelial Keratoplasty (DSAEK)

Variable	Category	Group I N: 55 No. (%)	Group II N: 43 No. (%)	P value
Age	Mean (SD)	61.9 (20.3)	69.8 (13.3)	0.030
Gender	Male	27 (49.1)	26 (60.5)	0.262
	Female	28 (50.9)	17 (39.5)	
Laterality	OD	25 (45.5)	20 (46.5)	0.917
	OS	30 (54.5)	23 (53.5)	

Table 2 Frequency of Surgical Procedure

Surgical Procedure	Group I	Group II	P value
DSAEK	51 (92.6)	40 (93)	0.351
DSAEK + Cataract Surgery	2 (3.6)	3 (7)	
DSAEK + IOL Removal	2 (3.6)	0 (0.0)	
Total	55	43	

There was no difference in ocular co-morbidities between the groups apart for a slightly higher prevalence of glaucoma in group I, 15 (27.3%), compared to group II, 10 (23.3%). However, this difference was not statistically significant (p 0.88 value).

The mean time from death to preservation was comparable between the surgeon cut and precut tissue, while the mean time from tissue preservation to processing was significantly higher in the surgeon cut group in comparison to precut group. Both groups had comparable mean times from tissue reception to implantation. Lenticule thickness was noticeably thinner in the precut group. (Table 3).

Graft Detachment

For the 43 cases using pre-cut tissue (group II), there were 7 detachments, representing 16.3%, which was not statistically different from the 20% detachment rate in group 1 ($P = 0.637$) (Table 4).

Graft Failure

At 6 months postoperatively, 41 (83.7%) in the surgeon cut group and 27 (67.5%) in the precut groups completed the follow-up. Out of these, 10 (24.4%) and 14 (32.6%) cases ended up with graft failure, respectively. A statistically significant difference in graft failure rate was maintained for up to 12 months. At 12 months postoperatively, 37 (82.2%) cases in the surgeon cut group and 20 (58.8%) in the precut group have completed the follow-up. Out of these 11 (29.7%) and 14 (70%) cases were labeled as failed grafts, respectively (Table 5).

Additionally, different insertion techniques have been compared in relation to associated rate of graft failure in both groups and were found to be non-statistically significant (Table 6).

Table 3 Donor Tissue Characteristics in Each Group

Characteristic	Group I		Group II		p-value across groups
	Measure Mean (SD)	P value	Measure Mean (SD)	P value	
Age of donor (years)	49.1 (11.6)	0.207	52.4 (10.7)	0.543	0.199
Death to preservation (Hours)	8.7 (3.4)	0.552	8.2 (2.3)	0.067	0.586
Storage time (Days)	12.7 (4.4)	0.404	8.6 (1.5)	0.794	<0.001**
Lenticule Thickness (um)	143.5 (38.4)	0.838	87.2 (15.8)	0.329	<0.001**
Lenticule size (mm)	7.6 (0.4)	0.694	9.8 (12.6)	0.847	0.582
Duration [preparation – Transplantation] (Days)	-	-	5.6 (1.6)	0.665	-
Duration [Preservation – Processing] (Days)	9.6 (2.5)	0.470	3.1 (1.2)	0.209	<0.001**
Duration [Processing – Receiving] (Days)	-	-	3.1 (0.8)	0.164	-
Duration [Receiving – Implantation] (Days)	3.2 (2.2)	0.737	2.5 (1.7)	0.714	0.120

Notes: *Statistically significant, **Highly statistically significant.

Table 4 Graft Detachment and Bubbling

Donor Tissue	Detachment No. (%)	Re-bubbling No. (%)
Surgeon-cut (n=55)	11 (20)	9 (16.4)
Precut (n=43)	7 (16.3)	5 (11.7)
P value	0.637	0.506

Table 5 Postoperative Assessment of Primary and Secondary Outcome Measures

Variable	Category	Group I No. (%)	Group II No. (%)	P value
Six month follow up assessment				
Tissue Detachment	Yes	1 (1.8)	2 (7.4)	0.329
	No	40 (72.7)	25 (92.6)	
Graft Failure	Yes	10 (24.4)	14 (32.6)	0.020
	No	31 (75.6)	13 (48.1)	
BCVA	[≥20/60]	1 (1.9)	3 (7.5)	0.003
	[<20/60 – 20/200]	12 (22.2)	0 (0.0)	
	[<20/200 – 20/400]	3 (5.6)	7 (17.5)	
	[<20/400]	38 (70.4)	30 (7.5)	
Twelfth month follow up assessment				
Tissue Detachment	Yes	0 (0.0)	1 (5.0)	0.170
	No	37 (100)	19 (95)	
Graft Failure	Yes	11 (29.7)	14 (70)	0.008
	No	26 (70.3)	6 (30)	
BCVA	[≥20/60]	12 (32.4)	1 (5.3)	<0.0001
	[<20/60 – 20/200]	11 (29.7)	2 (10.5)	
	[<20/200 – 20/400]	6 (16.2)	3 (15.8)	
	[<20/400]	8 (21.6)	13 (68.4)	

Visual Outcome

Preoperative best corrected visual acuity was 20/60 or better in 1.8% and 0.0%, between 20/60 and 20/200 in 21.8% and 7%, and less than 20/200 in 74.6% and 86.1% of surgeon cut and precut groups, respectively.

The best corrected visual acuity at last follow-up was 20/60 or better in 32.4% and 5.3%, between 20/60 and 20/200 in 29.7% and 10.5%, and less than 20/200 in 37.8% and 84.2% for surgeon-cut and precut group, respectively.

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Table 6 Insertion Technique and Graft Failure

Month 3	**Group I**	**Group II**	**P value**
Modified Busin glide	5 (21.70)	5 (50)	0.729
Sheet glide + 30 gauge needle	3 (37.5)	4 (80)	
30 gauge needle	3 (42.9)	2 (100)	
Taco folding	1 (100)	0 (0.0)	
Total	12	11	
Month 12			
Modified Busin glide	5 (23.8)	9 (60)	0.292
Sheet glide + 30 gauge needle	5 (71.4)	2 (100)	
30 gauge needle	1 (100)	0 (0.0)	
Taco folding	0 (0.0)	0 (0.0)	
Total	11	11	

Abbreviations: DSAEK, Descemet stripping automated endothelial keratoplasty; DMEK, Descemet Membrane Endothelial Keratoplasty; EBAA, Eye Bank Association of America.

Discussion

The percentage of endothelial keratoplasties among all keratoplasties performed has grown significantly over the past decade. With a better understanding of different corneal pathologies and advancements in corneal tissue processing techniques, DSAEK has become the preferred surgical option for many corneal surgeons.[10,11] The better utilization of operative room time and surgical efficiency, in addition to the lower risk of tissue loss due to inadvertent perforation have been some of the main reasons why many surgeons switch to precut DSAEK tissue.

Many countries, including Saudi Arabia, have used imported corneas for different types of keratoplasty to meet surgical demands.

Few published studies have compared the outcomes of DSAEK with surgeon cut versus precut tissue and found that they were comparable.[1,7]

In this study, we aimed to share our own experience and compare the outcomes of using surgeon cut corneas with those of precut tissues in patients up to 12 months after DSAEK. We included patients through a retrospective review of our charts, and we had an almost evenly distributed number of patients among the precut and surgeon cut groups, who shared similar demographic characteristics. This helped to eliminate potential sources of bias. In our study, we found a statistically significant difference in graft survival between surgeon cut and precut DSAEK tissues at 6 and 12 months, with the latter showing a higher percentage of graft failure.

Regarding BCDVA at 6 months and 1 year of follow-up, there was also a statistically significant difference between the groups, with a higher percentage of patients who achieved vision better than 20/60 in the surgeon cut group than in the precut group, which is explained by the higher number of graft failures in the latter group. Nevertheless, the poor visual outcome in our study could be attributed to the fact that the majority of our cases are PBK, which is known to have a reduced BCDVA due to many reasons such as the persistent stromal haze due to choronicity.[12]

We attempted to understand the difference in graft survival between surgeon cut and precut tissues by analyzing the differences in donor characteristics, underlying pathology, and postoperative course.

We also attempted to limit the confounding factors as much as possible by unifying the tissue criteria of the imported corneas, supplying overseas eye banks, and using them in cases with comparable corneal pathologies. The main difference was the duration from cutting in the operating room by the surgeon or at the original eye-bank a few days before shipment.

In a study by Terry et al. It was found that longer precut resection to surgery times were weakly correlated with greater cell loss at 6 months, but this weak correlation was not statistically significant at the 1-year visit. They also found a trend towards greater cell loss with longer death to surgery times, but this correlation was not statistically significant at a level of 0.05 at 6 months or at 1 year.[13] In our study, the mean duration from death to surgery was almost equal between the two groups. However, the average time from tissue processing to implantation in the pre-cut group was 133.9 hours (SD 37.5) which is a noticeably long interval in comparison to other studies with overseas transportation, 53.5 ± 6 6.6 hours (range, 32.7–79.2 hours)[5] and the mean precut-to-DSAEK time was 61.8 ±15.2 hours (range, 29–79 hours).[8]

We also examined other factors that may contribute to graft failure and compared the groups. One of these factors was the rate of graft detachment, which was commonly encountered in the first postoperative week and was comparable between groups. Given that the rate of detachment was similar between the two groups, we do not think there were any iatrogenic factors implicated. Although the precut tissue lenticule thickness was less than that the surgeon cut lenaicules, this failed to explain the difference in visual outcome or better graft survival. Another possible contributing factor for the higher rate of graft failure in the precut group is the effect of overseas transportation on endothelial cells. Yamazoe et al reported a significant decrease in ECD caused by transportation. Nonetheless, the pre-surgical cell counts after overseas shipping were within the range typically used safely for DSAEK. These findings were also supported by a study conducted by Nakagawa et al, who concluded that internationally shipped precut donor corneas produced satisfactory clinical results with a low rate of complications. Both the studies were conducted in Japan.[5,8]

In our study, the mean endothelial cell count after cutting was 2967.4 cells per square millimeter, well within the range commonly accepted for DSAEK. However, this number was measured by the original eye bank before shipping the tissues and was not rechecked at our hospital prior to implantation. This makes it impossible to determine the effects of overseas transportation to our country on endothelial cell count; however, the effect of overseas transportation on endothelial cell density was evaluated by Yamazoe et al and measured before the surgery, they concluded that the ECD was within the range of commonly used for DSAEK, and they suggest that the influence of precutting and long-distance transportation on endothelial cell loss is not significant.[5] The incidence of graft failure in the precut group in our study was higher than that in the surgeon cut group; however, both tissues were transported from the same eye bank and via the same route.

The overall primary graft failure in our study was 24%, which adequately falls within the range of the previously published studies >1% to 36%.[1,8,14,15] We would like to emphasize that most of the cases referred to our tertiary center have complex anterior segment pathology and delayed presentation, which may contribute to higher rates of graft failure.

Our study also had a few other limitations, including the lack of cell density measurements before implantation. We relied on measurements performed in the original eye banks before shipment. In addition, some of our patients were lost to follow-up, which could be attributed to the fact that most of our patients were from remote areas in the Kingdom, which complicates the logistics of follow-up.

These limitations are partly related to the retrospective nature of the study and highlight the importance of conducting a prospective study that more accurately addresses the differences between pre-cut and surgeon cut DSAEK tissues, particularly those imported overseas. However, our study has suggested indicators starting from the common anterior segment pathology and similarity between them, as well as the identical source and route of corneas used and despite having multiple surgeons included in our study, the standardized tissue preparation technique between the two groups led to strong evidence that delayed processing to implantation is a potential source for graft failure.

Additionally, the short follow-up time of one year or less and the difference in follow-up duration among both groups may not represent the full picture. Also, an important predictor of graft failure that is the post processing endothelial cell count, which was not measured in surgeon cut group precluding thorough comparison. However, it has been reported in the literature a comparable mean endothelial cell count as well as the endothelial cell loss in surgeon cut and precut tissues.[1,16,17]

Conclusion

We found that the graft failure rate was higher in the Pre-cut tissue group in comparison to the surgeon cut group up to one year postoperatively. We hypothesize that this could be attributed to the longer duration from tissue processing to

implantation in that group, especially in the absence of significant difference in other confounding factors such as primary diagnosis, surgical technique, graft detachment, ocular history, and death to preservation time.

Our study raises the question of whether a shorter duration from tissue processing to implantation is an important factor for reducing the rate of graft failure.

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Disclosure

The authors report no conflicts of interest in this work.

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