Original Article

Role of therapeutic contact lens following Descemet's stripping automated endothelial keratoplasty: A randomized control trial

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Purpose: Therapeutic contact lenses (TCL) are known to help in epithelial healing and decreasing pain after various corneal surgeries. However, literature lacks any data describing their use following Descemet's stripping automated endothelial keratoplasty (DSAEK) where intraoperative epithelial debridement is commonly performed. Here we study the efficacy and safety of TCL in patients undergoing DSAEK. **Methods:** In this prospective, randomized, controlled clinical trial. 40 eyes of 40 patients of pseudophakic bullous keratopathy undergoing DSAEK were enrolled and randomized into two groups, control (no TCL) and test (TCL). Primary outcome was time taken for epithelial healing and secondary outcomes were postoperative pain score, graft attachment, best spectacle-corrected visual acuity, and endothelial cell loss at 3 months. **Results:** Average time taken for epithelial healing was 3.35 ± 0.49 days in the test group and 4.95 ± 1.05 days in the control group ($P < 0.001$). Average pain scores in first operative week were significantly lower in the test group as compared to control ($P < 0.001$). Graft detachment occurred in eight patients in control group and two in test group ($P = 0.03$). Both rebubbling rates and average endothelial cell loss at 3 months were higher in the control group with $P = 0.07$ and 0.06 respectively. No contact lens-related adverse effects were noted during the study period. **Conclusion:** Use of TCL in DSAEK leads to faster epithelial healing and lesser postoperative pain. In addition, it may also contribute to lower rebubbling rates and endothelial cell loss.

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Descemet's stripping automated endothelial keratoplasty (DSAEK) one of the most commonly performed endothelial keratoplasty has greatly evolved over the past decade in terms of technology and surgical experience, thereby outmoding full thickness keratoplasty as the surgical procedure of choice for corneal endothelial disorders.[1-8] Fuch's endothelial corneal dystrophy and pseudophakic bullous keratopathy (PBK) remain the most common indications for performing DSAEK.[9] As the recipient corneas are hazy owing to the edema, the host corneal epithelium is usually debrided at the start of the procedure to improve surgical visualization. The epithelium heals over 4 to 8 days and a therapeutic contact lens (TCL) can be placed in order to hasten the process and improve patient comfort.[10,11]

Maintenance of a smooth epithelium is crucial for the physiological roles of cornea in refraction and biodefense.[12] TCL acts via protection of the corneal surface from shearing forces of the eyelid during normal blinking, retention of a stable ocular tear film, creation of a barrier between the tears and the cornea, and reduction of neutrophil infiltrate from the tears.[13] In the postoperative period, they facilitate epithelial healing, help in sealing wound leaks, increase patient comfort, and have the additional advantage of continuation of instilling eye drops as opposed to eye patching.[14] They have been widely used after corneal surgeries where the procedure necessitates epithelial debridement, like photorefractive keratectomy (PRK),[15] laser epithelial keratomileusis (LASEK),[16] Epi-LASIK (laser-assisted *in situ* keratomileusis), penetrating keratoplasty (PKP), lamellar keratoplasty, and pterygium surgery.[10,17]

TCL have proven their efficacy in the immediate postoperative period in terms of faster corneal epithelial healing and better patient comfort. However, correlation with postoperative anatomical outcomes and graft attachment, if any, has not been elucidated and needs further evaluation. The hypothesis of our study is that use of a TCL in the immediate postoperative period after DSAEK would lead to faster epithelial healing and better patient comfort. Reduced eye rubbing and squeezing (which are known possible contributing factors for postoperative graft dislocation and detachment) may be added advantages of using a TCL. On the other hand, there could be increased corneal hypoxia in an already compromised cornea and

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increased risk of corneal infection. There are no studies in literature weighing the above-mentioned parameters and our study intends to determine whether routine prophylactic use of a TCL is justified.

Methods

The study was planned as a randomized control trial. Approval for conducting the study was obtained from the Institute Ethics Committee before the commencement of the trial, which has been registered with the Clinical Trials Registry India (CTRI), National Institute of Medical Statistics (Indian Council of Medical Research) (Reference No: REF/2016/10/012434). Patients of PBK aged 18 years or above, presenting to our cornea clinic from April 2015 to June 2016, and planned for DSAEK were included in the study. Patients with preexisting glaucoma, limbal stem cell deficiency, any known posterior segment pathology, or with history of any prior ocular surgery (except cataract surgery with intraocular lens) and those not willing for follow-up were excluded from the study. A written informed consent was obtained from all patients who were enrolled in this study. The trial adhered to the tenets of the Declaration of Helsinki.

Sample size was calculated based on a difference in the time taken for reepithelization in previous studies. In one particular study by Chen *et al*.[11], the average time course of reepithelization in the bandage contact lens (BCL) and non-BCL group was 3.9 ± 1.2 days and 5.7 ± 1.8 days, respectively, amounting to a reduction of 30%. Expecting at least a 20% reduction in the time taken for epithelial healing and taking 5% alpha value and 80% power of study, the calculated sample size came out to be 16 in each group. Therefore, to have at least 16 evaluable cases in each group at the end of the study, a sample size of 20 in each group was taken.

All patients were randomized into two groups using a computer-generated randomization table, group 1 being the test group comprising patients in whom a TCL was put after completion of the surgery and group 2 being the control group comprising patients in whom a TCL was not put. The operating surgeon was informed regarding the randomization only at the end of the surgical procedure.

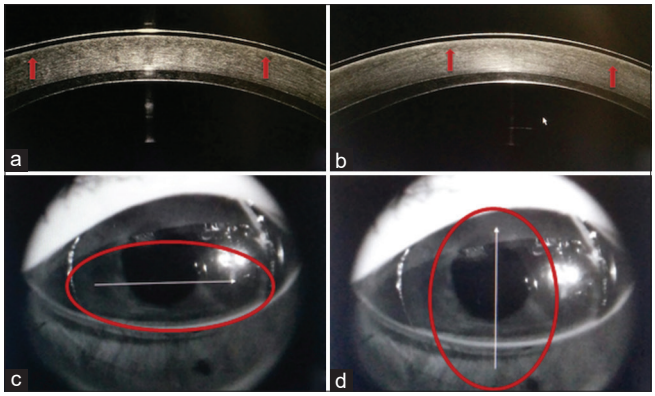

Figure 1: Spectral-domain anterior segment optical coherence tomography documentation of healing corneal epithelium under contact lens with a and b depicting OCT scans (red arrows indicating the edge of the growing epithelium) and c and d depicting respective axis of scanning over the cornea

The intervention used in the study, i.e., TCL, was a silicone hydrogel soft contact lens (Bausch + Lomb PureVision®2) made of Balafilcon-A (copolymer of silicone vinyl carbamate, N-vinyl pyrrolidone, a siloxane crosslinker, and a vinyl alanine wetting monomer). TCL was removed after complete epithelialization was noted as seen on the spectral-domain anterior segment optical coherence tomography (ASOCT).

Surgical Procedure: A donor corneoscleral button stored in cornisol medium was mounted on an artificial chamber (Moria, Antony, France) and the donor lenticule was harvested using a Carriazo Barraquer microkeratome (Moria, Antony, France) with the appropriate cutting head. Careful disassembly of the anterior chamber was done to remove the cornea-scleral rim atraumatically. All surgeries were done under peribulbar anesthesia by expert cornea surgeons. Epithelial debridement was done in the central 8 mm of host cornea to achieve better surgical visualization. The donor lenticule was trephined according to host corneal diameter and inserted using a Busin glide (Moria) through a 3.2 mm clear corneal incision. Complete air fill was maintained for 8–10 min, and the procedure was completed while leaving a half to two-thirds air fill to maintain the stability of the donor graft. The main wound was sutured with a single 10,0-monofilament nylon suture wherever deemed necessary. An occlusive eye patch was applied and patients were instructed to remain supine for next 24 h.

A standard treatment regimen, comprising e/d moxifloxacin HCl 0.5% 3 times a day, e/d prednisolone acetate 1% 6 times a day, and e/d carboxymethylcellulose sodium 0.5% 6 times a day was prescribed to all patients. Patients were strictly instructed to avoid eye rubbing and squeezing. In an event of graft detachment or dislocation in the postoperative period, a rebubbling or graft repositioning was carried out in the operation theater. Partial detachments with small fluid pockets in the graft-host interface were carefully observed for spontaneous reattachment.

Outcome Measures: The primary outcome was measured as the total number of days taken for complete reepithelization of the cornea as seen using fluorescein staining (1 mg FLUO Strips, ContaCare, Vadodara, India) on slit-lamp examination in the control group and on serial spectral-domain ASOCT (RTVue 100, Optovue Inc., Fremont, USA) images in both control and test groups. CL raster, CL line, and pachymetry scans were taken with the eye in primary position, imaging the central 6 mm of the cornea. Using the pachymetry scan it was possible to scan the central cornea in all 360° axes [Fig. 1], in order to visualize any epithelial defect that may have been missed in the standard CL raster or line scans.

The secondary outcomes were measured as follows:

1. Postoperative Pain Score: It was measured using a visual analog scale which consists of a 10 cm long, color-coded scale with the phrase "no pain" and "maximum pain" at each end in which the patient was asked to indicate the degree of pain along the line, quantifying pain on a scale from 1 to 10[18]
2. Graft Attachment: It was documented as seen on slit-lamp examination and ASOCT. The number of detached grafts and those requiring rebubbling or repositioning in both groups were documented separately
3. Best Spectacle-Corrected Visual Acuity (BSCVA): It was measured using Snellen's chart (at 6 m) and converted into LogMAR units for analysis

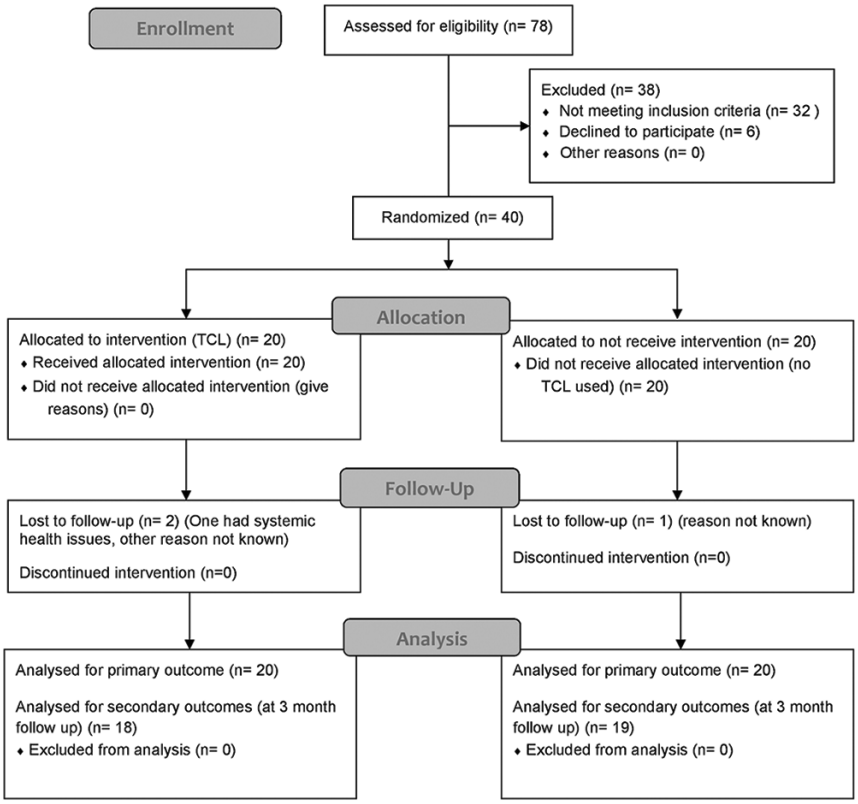

Figure 2: Consort flow diagram showing patient enrolment for the study

4. Endothelial Cell Density (ECD): It was measured at 3 months postoperatively using specular microscopy (Specular Microscope CEM-530, Nidek Co)
5. TCL Bacterial Culture and Sensitivity: All TCLs in the test group were sent for bacterial culture and sensitivity after their removal. Contact lens retention rates and any other complications were also documented separately.

Statistical Analysis: It was performed using SPSS Version 17 (SPSS Inc. Chicago, IL, USA). The analyses of outcome variables with continuous data were done as mean (with standard deviation) and median (with the range) using two-sample unpaired t-test and two samples Mann–Whitney/Wilcoxon Rank sum test. Comparison of various parameters in the same group at different observation period for continuous data was done using two-sample paired t-test and Wilcoxon signed-rank test. The categorical data was analyzed using Pearson's Chi-square test or Fisher's exact test. *P* value < 0.05 was considered as statistically significant.

Results

A total of 78 patients were assessed for eligibility, out of which 38 either did not meet the proposed criteria or refused participation in the study [Fig. 2]. The remaining 40 patients (40 eyes) were randomized as mentioned above. One patient in the control group and two patients in the test group were lost to follow-up (one owing to health issues, reasons for other two not known) (Drop-out rate = 7.5%)

Baseline Patient and Donor Characteristics: Mean age in the control group was 65.35 + 9.52 years and mean age in the test group was 62.05 + 11.13 years ($P = 0.33$). There were 10 males and 10 females each in the control group, while there were 14 males and 6 females in the test group ($P = 0.32$). Six out of 20 patients in the control group and four out of 20 patients in the test group had diabetes mellitus ($P = 0.72$).

Baseline patient preoperative parameters, donor cornea parameters, and relevant intraoperative parameters are summarized in Table 1. There was no statistically significant difference in any of the above-mentioned parameters in both the groups.

Primary outcome measure

The average time taken for complete epithelial healing was significantly lesser in the test group (3.35 ± 0.49 days) as compared to control group (4.95 ± 1.05 days) ($P < 0.001$). Time taken for complete reepithelization was 3–4 days in the test group as opposed to 4–8 days in the control group, with two patients showing complete reepithelization at day 7 and day 8, respectively [Figs. 3-5]. The number of days taken for complete reepithelization as measured by fluorescein staining and ASOCT were similar in all 20 patients in the control group.

Secondary outcome measures

1. These are summarized in Table 2. Average postoperative pain scores were significantly lesser in the test group in the first postoperative week as compared to the control group ($P < 0.001$). At 1-month and 3-month follow-up, the pain scores were still lesser in the test group, but the difference was not statistically significant
2. Graft Attachment and Rebubbling Rates: On the first

Table 1: Preoperative patient parameters, donor parameters, and intraoperative parameters in both the groups

Category	Parameters	Mean/S.D		*P*
		Control Group	Test Group	
Baseline Patient Parameters	Best-corrected LogMAR Visual Acuity	2.07/0.55	1.77/0.48	0.08
	Intraocular Pressure (mm Hg)	14.40/2.56	15.05/3.20	0.48
	Central Corneal Thickness (μm)	769.55/89.22	783.65/154.43	0.73
	Time between Diagnosis and Surgery (months)	9.95/3.98	8.30/2.87	0.14
	Time between Cataract Surgery and DSAEK (months)	61.11/64.70	42.95/59.90	0.37
Preoperative Host Biometric and Tear Film Parameters	Axial Length (mm)	23.73/1.67	23.49/1.42	0.63
	Anterior Chamber Depth (mm)	3.79/0.85	3.39/0.75	0.25
	Average Keratometry (D)	43.85/2.64	42.91/2.40	0.25
	Schirmer's Test (mm)	22.55/4.51	23.00/4.61	0.76
	Tear-film Break-up Time (sec)	3.30/2.66	2.45/2.11	0.27
Donor Cornea Parameters	Donor Age (years)	39.05/11.82	34.80/14.99	0.33
	Donor Endothelial Cell Density (per mm^2)	2430.12/241.57	2380.28/233.37	0.54
	Death to Preservation Time (h)	5.39/3.43	6.95/3.81	0.18
	Death to Surgery Time (h)	46.00/23.46	56.20/28.41	0.22
Intraoperative Parameters	Donor Lenticule Thickness (μm)	170.50/35.61	168.67/39.65	0.88
	Donor Graft Size (mm)	7.48/0.29	7.50/0.36	0.81
	Operating Time (min)	44.50/4.26	43.50/5.64	0.53

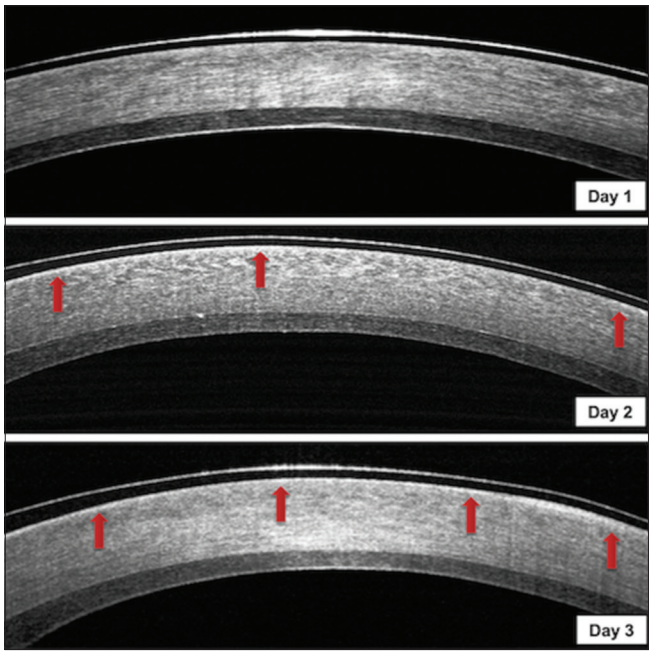

Figure 3: Serial representative spectral-domain anterior segment optical coherence tomography photographs showing complete epithelial healing at day 3 in a patient in the test group

postoperative day, eight grafts in the control group were detached as compared to two grafts in the test group, the difference being statistically significant ($P = 0.03$). Out of these, there were three grafts in the control group which required rebubbling as opposed to none in the test group ($P = 0.07$). One patient in the control group required graft repositioning at day 3 and day 7, while none of the patients had a detached graft in the test group on and after postoperative day 2

3. There was a trend toward a better BSCVA in the test group, with the difference reaching statistical significance difference at day 7 ($P = 0.05$), which was annulled thereafter
4. The average ECD as measured by specular microscopy at 3 months was comparable in both the groups ($P = 0.20$). The percentage less loss was lesser in the test group (18.59%) as compared to the control group (22.09%), although the results were just short of reaching statistical significance ($P = 0.06$)
5. All the TCL sent for bacterial culture and sensitivity after removal had negative culture reports (no growth noted up to 48 h of incubation). There was a 100% retention rate with no event of spontaneous misplacement of the contact lens in any of the cases in the test group. No evidence of corneal infiltrates as seen on slit-lamp examination was noted in any of the patients in the test group
6. Average central corneal thickness (CCT) was significantly lesser in the first 3 postoperative days in the test group as compared to the control group ($P < 0.05$); however, there was no statistically significant difference between the two groups at subsequent follow-ups.

Discussion

DSAEK is the surgical procedure of choice for any visually disabling endothelial dysfunction, the most common indications being Fuch's endothelial dystrophy and pseudophakic bullous keratopathy.[9] Early treatment in these cases generally produces a much rapid corneal clearing and visual recovery as compared to those with longstanding corneal edema or bullous changes.[19] A large proportion of surgeries being done in developing countries like ours belongs to the latter category, owing to the huge disparity in demand and supply of the donor corneal tissue, and also in part to the late presentation of patients to a tertiary care center. These eyes have relatively higher preoperative central corneal and epithelial thickness and significant corneal haze owing to the epithelial edema which necessitates epithelial debridement at the time of surgery, resulting in

Table 2: Comparison of postoperative parameters between the two groups

Parameter	Follow-up Day	Mean/S.D		*P*
		Control Group	Test Group	
Postoperative Pain Scores	Day 1	7.70/0.80	5.90/1.29	<0.001
	Day 2	7.30/0.73	4.85/1.31	<0.001
	Day 3	5.60/1.14	3.75/1.12	<0.001
	Day 7	3.45/0.76	2.15/0.93	<0.001
	Day 30	1.50/0.61	1.35/0.81	0.51
	Day 90	1.58/1.17	1.26/0.65	0.31
Average Log MAR Visual Acuity	Day 1	2.41/0.72	2.11/0.75	0.21
	Day 7	1.57/0.51	1.26/0.48	0.05
	Day 30	0.99/0.57	0.87/0.35	0.41
	Day 90	0.84/0.83	0.55/0.57	0.22
Average Intraocular Pressure (mmHg)	Day 1	19.95/9.64	18.25/4.82	0.49
	Day 90	15.74/3.11	15.63/2.77	0.84
Average Central Corneal Thickness (μm)	Day 1	880.35/164.23	772.74/117.50	0.03
	Day 2	847.00/171.60	739.74/112.58	0.03
	Day 3	819.65/171.64	719.25/110.61	0.04
	Day 7	727.60/132.92	676.40/105.38	0.19
	Day 90	655.16/169.27	605.61/112.21	0.30
Endothelial Cell Density (cells/mm^2)	Day 90	1734.38/157.836	1821.87/191.387	0.20
Endothelial Cell Loss (percentage)	Day 90	22.09/3.07	18.59/7.21	0.06

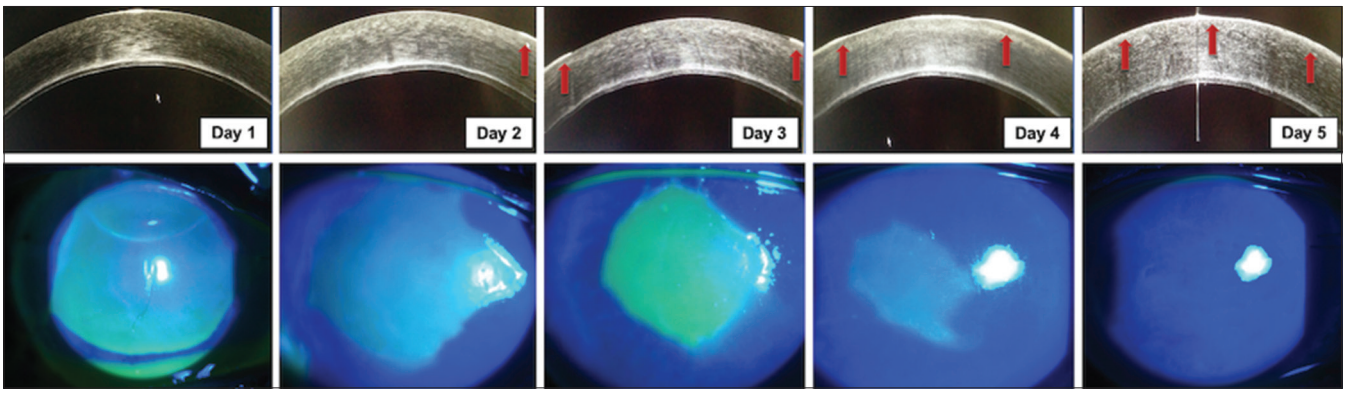

Figure 4: Serial representative spectral-domain anterior segment optical coherence tomography photographs showing complete epithelial healing at day 5 in a patient in the control group, along with respective slit-lamp clinical photographs with fluorescein staining under cobalt blue filter

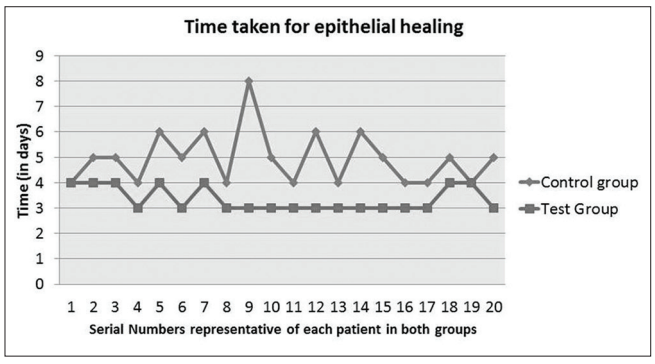

Figure 5: Graphical representation of time taken for epithelial healing in each respective patient in the control group and test group

a large central epithelial defect postoperatively. The same is evident with the higher average preoperative CCT in our study (776.60 ± 124.69 μm) compared to some of the available data from Western countries.[20,21]

The necessity of an intact corneal epithelium, for its anatomical and optical functions, cannot be stressed more. Its role as an effective mechanical barrier in protecting the eye against potential microbial pathogens is magnified in the early postoperative period following any intraocular surgery. This barrier also prevents alterations in net fluid transport from the corneal stroma and helps in corneal deturgescence,[22] which may be of special consequence following DSAEK. The other key role of the corneal epithelium is the formation of a smooth refractive surface via interaction with tear film, which is extremely important for optimal visual function.

In a prospective observational case series by Pang *et al.*, corneal epithelial healing was evaluated under a TCL by using spectral-domain ASOCT in patients who underwent

Epi-LASIK, DSAEK, and DALK.[17] Corneal epithelium was removed in all cases, and all eyes had complete epithelial healing with TCL in-situ by the third postoperative day. Similarly, Chen *et al*. in 2014 studied corneal epithelial healing by ASOCT with a contact lens *in situ* in patients undergoing pterygium excision and conjunctival autografting.[11] The average time course of reepithelialization in the contact lens and control group was 3.96 ± 1.2 days and 5.76 ± 1.8 days, respectively, ($P = 0.001$) with lower pain levels in the contact lens group at each point in time ($P < 0.05$). The results in our study are consistent with the previously reported data, with complete reepithelization noted in 3.35 ± 0.49 days in the test group as compared to 4.95 ± 1.05 days in the control group, along with the significantly lower average pain scores in the first postoperative week in the test group.

A recently published study in 2016 by Shimazaki *et al*. showed no significant benefits of bandage contact lens (BCL) application in terms of promoting epithelialization and alleviating pain following corneal transplantation.[23] However, there are some essential differences in the methodology of the study. First, the sample population included cases of PKP or deep anterior lamellar keratoplasty (DALK) in which the host corneal epithelium has to grow over the donor graft. Second, they used Breath-O® (BCL) which is hydrophilic lens comprising vinyl pyrrolidone and methyl methacrylate polymer with 78% water content and oxygen transmissibility (Dk/L) value of 48 × 10−11(cm^2/s) as compared to the silicone hydrogel lenses (balafilcon A) with high-Dk value and oxygen transmissibility (Dk/L) value of 101 × 10 − 11(cm^2/s) used in our study. Last but not the least, their sample size for studying epithelial defects was much smaller (five patients in the BCL group and four patients in the control group) in comparison to our study.

Donor tissue dislocation and graft detachment have been one of the biggest challenges of DSAEK since its onset. In our study, we had an overall graft detachment rate of 25% (10 out of 40 grafts) and the rebubbling rate was 7.5% (3 out of 40 grafts). Graft attachment rates were significantly better in the test group in our study with 90% grafts attached all around in patients with TCL *in situ* as opposed to 60% in patients without TCL ($P = 0.03$). This may be attributed to better patient comfort in the test group which further decreases the possibility of hard squeezing and rubbing of the eyes by the patient, which is known risk factor in graft dislocation in the early postoperative period.[3] Another factor that may play a role is reduction of microleaks by the use of TCL, though further research is required in this regard. However, due to a relatively smaller sample size, the difference in rebubbling rates due to chance cannot be completely ruled out.

The average endothelial cell density as measured by specular microscopy at 3 months was 1903.47 ± 158.49 per sq. mm with a mean percentage less loss of 20.84% which is comparable to the previously reported percentage cell loss by Terry *et al*.[24] and Busin *et al*.[8] The percentage cell loss was 22.09 ± 3.07% in the control group and 18.59 ± 7.21% in the test group, the difference just short of reaching statistical significance. Higher rebubbling rates and, thus, more manipulation of the donor graft tissue in the control group lends credit to this observation of higher endothelial cell loss in the control group.

The CCT on the first three postoperative days was significantly lesser in the TCL group ($P < 0.05$), which may be explained by the faster and more regular corneal epithelial healing in the TCL group which further helped in in corneal deturgescence. Faster formation of a regular and smooth anterior corneal surface may also expound our observation regarding better visual acuity on postoperative day 7 in the TCL group; however, BCVA at 3 months was comparable in both the groups.

Conclusion

In summary, the results of this RCT indicate that TCL is efficacious in the immediate postoperative period after DSAEK as its use resulted in faster epithelial healing, lower pain scores, and better patient comfort with possible contribution to better graft attachment rates, lower rates of rebubbling, and lesser endothelial cell loss. No contact lens-related adverse effects were noted during the study period and, hence, it can be safely used in the immediate postoperative period following DSAEK in cases of PBK where epithelial debridement is done till the reepithelization is complete.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest

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