Femtosecond laser enabled keratoplasty for advanced keratoconus

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Purpose: To assess the efficacy and advantages of femtosecond laser enabled keratoplasty (FLEK) over conventional penetrating keratoplasty (PKP) in advanced keratoconus. **Materials and Methods:** Detailed review of literature of published randomized controlled trials of operative techniques in PKP and FLEK. **Results:** Fifteen studies were identified, analyzed, and compared with our outcome. FLEK was found to have better outcome in view of better and earlier stabilization uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), and better refractive outcomes with low astigmatism as compared with conventional PKP. Wound healing also was noticed to be earlier, enabling early suture removal in FLEK. **Conclusions:** Studies relating to FLEK have shown better results than conventional PKP, however further studies are needed to assess the safety and intraoperative complications of the procedure.

Key words: Femtosecond enabled keratoplasty, keratoconus, penetrating keratoplasty

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Corneal transplantation continues to move in new directions in the arena of full-thickness penetrating keratoplasty (PKP) and partial-thickness lamellar keratoplasty. Lamellar keratoplasty or selective tissue corneal transplantation involves only the diseased portion of the recipient cornea being replaced with similar healthy tissue, whereas in PKP, the entire recipient cornea within the circular trephination area is replaced with full thickness donor corneal tissue.

A manual PKP wound is usually vertical, and variations from this type of wound construction are not easily possible in the manual PKP technique. Since PKP was first performed more than a century ago, advances in instrumentation have resulted in improved patient outcomes. Manual trephination has evolved to current state-of-the-art vacuum trephines such as the Hanna trephine, which reliably provide smooth circular incisions. However, potential problems may occur with these instruments, including damage to intraocular structures and incomplete/oblique cuts. This may influence final visual outcome as regularity of the donor-host junction may be compromised, leading to both regular and irregular astigmatism. Anteroposterior and rotational misalignment of the donor and host corneal surfaces, excess and uneven suture tension, and slow and asymmetric postoperative wound healing are some of the causes of optical distortion.[1]

The advent of the state-of-the-art femtosecond laser technology as an ocular surgical tool offers potential for more finite control and precision in corneal surgery. The femtosecond laser has enabled these newer shapes of wound construction for femtosecond laser-enabled keratoplasty (FLEK). Variations from a vertical wound in PKP include top hat, mushroom, zigzag, Christmas tree, and other configurations [Fig. 1].[2] Some of these wound shapes were initially described by Barraquer in 1951.[3] Recently, there has been a newfound interest in these new wound shapes. These newer wound constructions in PKP have been associated with better wound integrity, presumed faster donor-recipient junction wound healing, earlier suture removal, less surgically induced corneal astigmatism, and earlier visual rehabilitation.

Steinert *et al*., in their laboratory investigations showed that wound leakage occurred at 38.11 and 240.69 mmHg on the traditional and shaped PKP groups, respectively.[4] Ignacio *et al*., demonstrated that PKP incisions created by the femtosecond laser in a top-hat shape led to a seven-fold increase in resistance to wound leakage and possibly less astigmatism.[4,5]

Sizing of the donor corneal tissue has been a matter of debate since the time of inception of PKP.

An increase in postoperative astigmatism in oversized donor

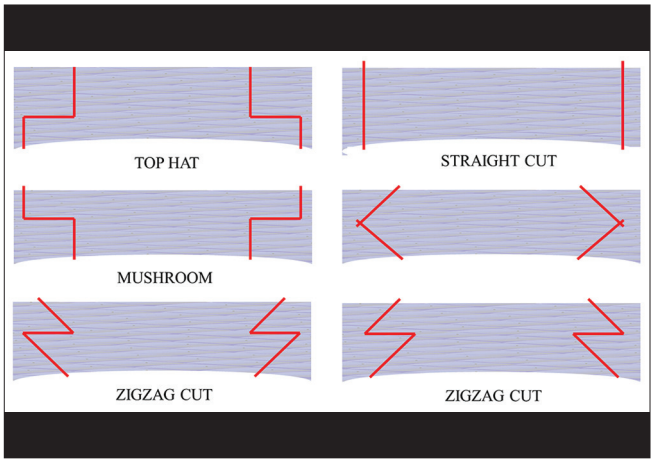

Figure 1: Various patterns of femtosecond laser cuts

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groups was demonstrated by Perry and Foulks;[6] however, the opposite was reported by Wilson and Bourne.[7]

In conventional PKP, when the donor corneal tissue is punched from the endothelial surface, it produces a graft with an anterior diameter 0.2-0.3 mm smaller than would be obtained after trephination from the epithelial side of the tissue as a result of a flattening of the donor tissue when punching from the posterior surface.[8,9]

Studies have reported that larger size donor trephination in PKP for keratoconus produces an increase in corneal curvature, and hence postoperative myopic refraction than when same size donor trephines are used.[10]

Femtosecond laser technology produces precise and reproducible incisions of donor and recipient corneas through computer-guided pulsed laser. The laser allows for patterns and angles of incisions that are not achievable with conventional trephines. Femtosecond laser cut provides accurate 'trephination' of the donor and recipient buttons and do not cause the disparity that is produced by the manual trephines.

Thirty-five cases of advanced keratoconus who underwent femtosecond laser enabled PKP were assessed at 1, 3, 6, and 10 months postoperatively in our study. Patients requiring PKP were recruited from the cornea clinic at Narayana Nethralaya, Bangalore. After informed consent was obtained, patients underwent surgery as follows. The Wavelight femtosecond laser (Wavelight FS 200, Alcon) was used to trephine both recipient and donor corneas. This was a prototype machine with a repetition rate of 200 kHz, and it was programmed to deliver pulses in a raster pattern, to create a mushroom-shaped cut aiming to achieve a straight, smooth perpendicular, and horizontal trephination. Laser settings used were as follows: Energy 1.9 mJ; outer diameter of 8.5 mm, inner diameter of 7.5 mm, anterior vertical cut of 350 μm, posterior vertical cut of 650 μm,and spot spacing of 4 μm.

A donor corneoscleral rim was first placed on a Katena artificial anterior chamber. This was then trephined by the laser, commencing from the anterior chamber and progressing anteriorly until the epithelium was breached. Remaining tissue bridges were severed with Sinskey hook and the donor button was set aside. The recipient cornea was then trephined in a similar manner. In all cases, the recepient was trephined to the same diameter as that of the donor cornea.

The donor button was then placed on the recipient eye and sutured in place with eight interrupted 10-0 nylon sutures. Postoperatively, patients were commenced on G PredForte (Allergan; Irvine, California, USA) G Vigamox (Alcon; Fort Worth, Texas, USA) both instilled one drop 3 hourly.

In our experience with FLEK, same size donor and recipient was used in all the cases with good results. The mean preoperative spherical equivalent (SE) was 9.2 D and postoperative SE was 2.23 D at 1 month [Fig. 2]. There was a further improvement at 3 months when it was found to be 1.97 D, only to marginally increase to 2.01 D at 6 months and to stabilize at 2.12 D at 10 months.

Farid *et al*., in their study comparing FLEK and conventional PKP found lower average astigmatism in the FLEK group as compared to the conventional PKP group (3 D vs. 4.5 D) and they also found that the astigmatism reduced significantly at 1, 3, and 6 months in the FLEK group while no such downward trend in astigmatism was noticed in the conventional PKP group.[1]

In our study, the mean preoperative astigmatism was found to be −7.38 D. We found considerable reduction in the mean residual astigmatism postoperatively at the following intervals of time: −2.32, −1.53, −1.58, and −1.57 D at 1, 3, 6, and 10 months, respectively.

Studies have shown that significantly more eyes reached a BCVA of 20/40 at month 1 and 3 in those who have undergone FLEK than conventional PKP.[1] Price *et al*., reported a mean BCVA of 20/50 by month 3 with only 65% achieving 20/40.[11]

In our experience, the mean uncorrected and best corrected visual acuity (UCVA and BCVA) [Fig. 3] preoperatively was 0.05 and 0.27 log Mar units, respectively. The UCVA more or less remained stable at follow-up visits at 0.32 (1 month), 0.34 (3 months), and 0.35 (6 and 10 months). However, the

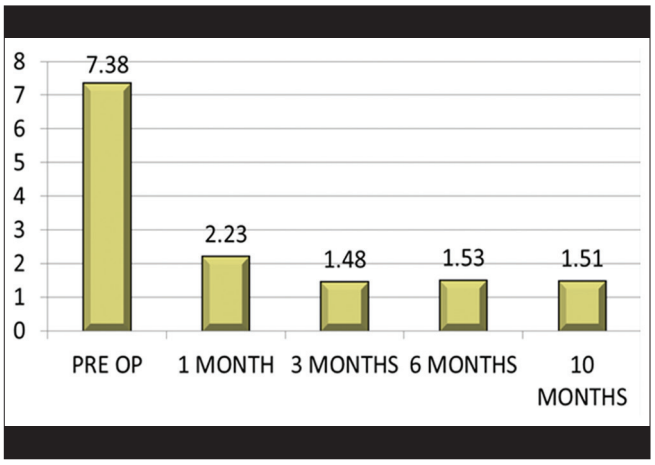

Figure 2: Preoperative and postoperative spherical equivalent in patients who have undergone FLEK at 1, 3, 6, and 10 months

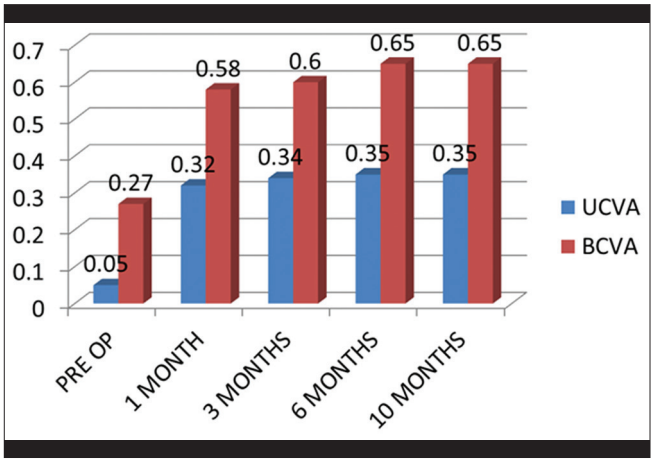

Figure 3: Preoperative and postoperative uncorrected and best corrected visual acuity in patients who have undergone FLEK at 1, 3, 6, and 10 months

BCVA improved to 0.65 at 6 months which remained stable thereafter. There was early stabilization of UCVA and BCVA by 3 months.

Buratto and Böhm have performed PKP using the IntraLase laser (AMO; Santa Ana, California, USA).[12] Using proprietary Intralase Enabled Keratoplasty software, top hat and mushroom donor configurations were created and surgery was performed for indications including keratoconus and bullous keratopathy. Visual results were good, with patients achieving BCVA between 20/20 and 20/60 at 3 months. Mean refractive astigmatism was 2.9 D at 3 months, which appeared quite similar to our results. Although it is likely that other factors such as suture techniques influence this significantly, the precision of femtosecond laser trephinations may also contribute to this observation.

Out of 35 patients in our study, two patients developed raised intraocular pressure due to steroid response. One patient had an incomplete laser cut in one quadrant, which had to be completed with scissors. Three patients had aqueous humor leak immediately after femtosecond laser cut.

Discussion

With the use of proprietary software, femtosecond lasers are currently able to create precise corneal incisions in almost any plane while minimally distorting corneal tissue.

The FLEK edges provide a smooth anterior transition between donor and host, which allows for a watertight wound seal. Same sized donor and graft improved natural alignment intrinsically and produces less optical distortion that, combined with a watertight seal and less suture tension, results in lesser amount of induced astigmatism. Further, there may be a rapid resolution of wound edema in the femtosecond group owing to less tissue manipulation and trauma as compared with conventional trephination.[1] We noticed a similar trend in our study where there was early stabilization of BCVA, low astigmatism, and minimal wound edema on the 1st postoperative day with a better UCVA as compared to conventional PKP.

Fibrosis along incisions and suture tracks indicating wound healing, was evident by 3 months in all patients and appeared stronger than typically seen after standard PKP in patients of similar age and diagnoses.[13] In our experience, anterior segment optical coherence tomography (AS-OCT) images taken at 3 months postsurgery showed good fibrosis along the graft host junction [Fig. 4].

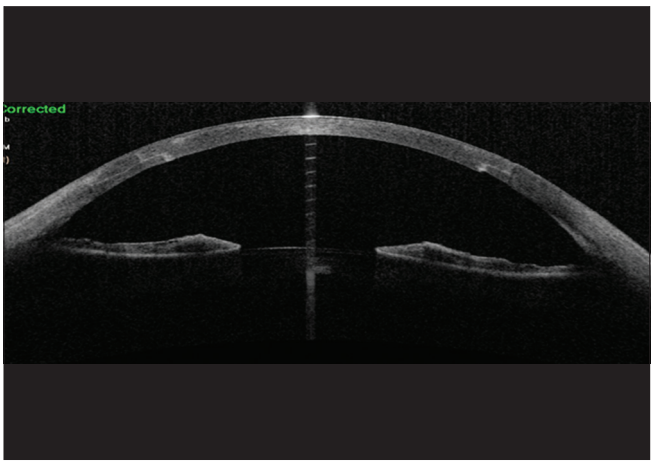

Figure 4: AS-OCT image of a patient who has undergone FLEK at 3 months postop showing good scarring and approximation at the interface

Busin first described the novel wound configuration described as "top hat" for PKP, theoretically providing better resistance against leakage attributable to the self-sealing posterior lip.[14] Sutures therefore would not need to be as tight, which might reduce initial suture-induced astigmatism. Incision healing might be stronger attributable to increased wound surface area. Complete suture removal has been reported as early as the 3rd postoperative month, potentially permitting rapid visual rehabilitation as compared with traditional PKP.

Steinert *et al*., recently described a series of patients who underwent FLEK, a low mean cylindrical refractive error of 1.97 D was achieved in seven patients at 3 months.[4] Wound integrity of one patient was maintained even with early suture breakage and complete removal at 3 months.

Price in his study showed that when the donor and recipient posterior diameters were sized the same, the posterior brim, was observed to buckle with suture placement.[11] However, by the 3rd month, all cases exhibited good apposition of posterior donor and recipient tissue with no evidence of posterior buckling. When the donor posterior diameter was undersized relative to the recipient, although the posterior donor tissue was well-opposed to the recipient, a slight gap developed between the posterior rim of the donor and recipient as the wound healed and suture tension relaxed. We would advocate using same diameter of the donor and recipient graft as this has shown to provide good visual as well as biomechanical outcome.

Conclusion

Long-term benefits of femtosecond laser keratoplasty and cost-to-benefit ratio for patients needing corneal transplantation remain to be determined. Potential risks with greater donor manipulation and risks of perforation with hypotony and choroidal hemorrhage during transport from laser suite to the operating room remain theoretical at this point. Femtosecond laser reliably trephines donor corneas and recipient beds for PKP, providing good visual outcomes. Better optimization of laser parameters for different degrees of corneal opacity and edema would increase ease of surgery and possibly improve outcomes. Although both conventional and alternate trephine profiles such as mushroom pattern, top hat, and zigzag configurations seem to provide good results with low astigmatism, further studies with new trephine patterns may better define the advantages associated with femtosecond laser assisted PKP.

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