

# Effect of Lasik on Endothelial Cell Count in Patients Treated for Myopia

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*Pak J Ophthalmol 2010, Vol. 26 No.1*

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Received for publication  
June' 2009

**Purpose:** To compare pre and postoperative endothelial cell counts in patients undergoing laser in situ keratomeliosis (LASIK) for the treatment of myopia.

**Material and Methods:** This hospital based descriptive study was carried out in the Corneo-refractive unit of Layton Rahmatullah Benevolent Trust (LRBT) Eye Hospital, Lahore. Duration of the study was 6 months from 24-05-2005 to 24-11-2005. It took 2 months for the data collection and 4 months for the follow up. 100 eyes of 50 patients underwent LASIK. Postoperative endothelial cell counts were noted after 1 week, 1 month, 3 months and 4 months. Statistical analysis of the data was done using computer software SPSS version 10.0.

**Results:** 50 patients (100 eyes) were included in this study. 64% of the patients were female and 36% were male. Mean age was 24.54 years ranging from 20-35 years. Out of 50 patients, 29 patients (58%) had myopia between 2-5 diopters, 8 patients (16%) between 5-7 D and 13 (26%) between 8-10 D. The range of myopia was 2-10 D. Mean spherical equivalents before LASIK was -3.95 D. Mean corneal thickness before LASIK was 515  $\mu\text{m}$ .

**Conclusion:** Corneal endothelial cell count was unchanged 1 week, 1 month, 3 months and 4 months after the LASIK.

Myopia is a form of refractive error in which parallel rays of light come to a focus in front of retina. Myopia has been found to be patterned in its occurrences in different races and ethnic groups with a prevalence of 25% for Caucasian, 13% for African American and Asians have often been found to have myopia as high as 40%<sup>1</sup>. According to a local survey held from 1992-97, myopia was found three times more common than hyperopia in school children<sup>2</sup>.

Myopia can be corrected with spectacles, contact lenses, or refractive surgery. Spectacles when used in myopic patients have certain limitations because they cause image minification and "barrel" distortion along with prismatic image displacement. Contact lenses have optical benefits like image magnification, elimination of prismatic object displacement with its attendant "barrel" distortion, and the elimination of image degradation. They are cosmetically acceptable but have their own side effects such as being a constant source of infection and corneal warpage.

Refractive surgery is the latest treatment modality. In 1983, Trokel introduced a new technology to correct myopia that was photorefractive keratectomy (PRK), which involves the use of 193-nm argon fluoride excimer laser<sup>3</sup>. PRK is a procedure in which corneal epithelium is removed with the help of a knife and stroma is treated with excimer laser to reshape the cornea.

With the success achieved with PRK for the treatment of myopia, studies of more improved techniques were done. In recent times, the most exciting and prevalent method evolved for correction of refractive errors is the Laser in-situ keratomileusis (LASIK). The actual LASIK procedure involves formation of a flap with the help of a microkeratome. A hinge is left at one end of this flap and the flap is folded back to reveal stroma. Pulses from a computer-controlled laser reshape the stroma. The flap is then replaced<sup>4</sup>.

LASIK though a more complicated procedure has a good and predictable outcome, instant recovery and

stability of vision<sup>5</sup>.

LASIK is safe and effective for Myopia between -1.5 to -15.0 D<sup>6</sup>. A number of corneal surgeries have been known to be associated with a decrease in endothelial cell count postoperatively. An example is Radial Keratotomy<sup>7</sup>. Several clinical studies have demonstrated the safety, efficacy and stability of LASIK<sup>8,9</sup>.

The aim of this prospective study was to ascertain, in our set up, the available information regarding the effect of LASIK on endothelial cell count.

## MATERIAL AND METHODS

This study was conducted on 100 eyes of 50 patients selected from the Corneo-refractive unit of LRBT Eye Hospital, Lahore. The study was completed in 6 months time from 24-05-2005 to 24-11-2005. During the first 2 months all selected cases were operated. Their outcome was then assessed over the next 4 months.

The inclusion criteria were:

Age between 20-35 years.

Best corrected visual acuity of 6/9 or better.

No more than 0.50 D change in refractive error for at least 1 year before LASIK surgery.

The exclusion criteria were:

Patients with keratoconus, corneal ectasias and other diseases causing corneal scarring.

Patients having cataract, glaucoma, retinal disease or any systemic disease.

Informed consent was taken and a detailed history was then taken covering all important aspects.

Complete ocular examination was done including VA, refraction, slit lamp examination, keratometry, corneal topography, pachymetry, pupil size and applanation tonometry. Slit lamp examination of anterior segment was done to look for pre-existing corneal disease. Dilated fundus examination was also done to look for any retinal disease. Keratometry and corneal topography were performed on every patient pre-operatively, to reveal sub clinical keratoconus, a contraindication for refractive surgery. For refractive error over 5 D, back vertex distance was measured in order to evaluate the refractive power of the cornea.

In all cases specular microscopy was performed before operation and on each visit postoperatively. The Konan Noncon Robo (SP 6000) specular microscope was used. It is a non-contact, specular microscope which counts the endothelial cells/mm<sup>2</sup> in the centre of the cornea.

The endothelial cell density was measured by variable frame method and sampling error was reduced by analyzing as many cells as possible (100-150 cells/frame). Bilateral LASIK was then performed on all patients using Excimer laser SUMMIT Technology Ireland B.V. Model (INFINITY LS KYNAR).

The patient was positioned on the excimer laser table. Laser calibration and programming was done. The operative eye was draped and other was patched. A lid speculum was applied and a topical anaesthetic (0.5% proparacaine) instilled. A corneal marker was used to mark the peripheral cornea. The Hansatome 8.5 mm suction ring (Bausch & Lomb Surgical, Irvine, CA, U.S.A) was positioned on the eye and suction applied. Intraocular pressure of greater than 65 mm Hg was confirmed to obtain a resection that is uniform and regular and has an appropriate diameter. The Hansatome microkeratome blade with a 160 um depth plate was then advanced to create a nasally hinged flap. Suction was then released (after a total duration of less than 30 second for all eyes), and the microkeratome blade and suction ring were removed from the surgical field. Smooth tipped forceps were used to fold back the flap onto nasal conjunctiva. The patient was then properly aligned under the laser down tube and asked to fixate at green fixation light. The eye was moved into position such that the incoming beam was centred on the patient's entrance pupil. Excimer laser was then used to ablate the corneal stroma.

All ablations were performed with a laser pulse rate of 6 to 10 Hz and energy of 160 mJ/cm<sup>2</sup> using aspheric multizone treatments. The interface was then irrigated with 2-3 ml balanced saline solution in a 5 ml syringe. The corneal flap was then replaced and allowed to settle for 30 seconds. Moist merocel sponges were then used to gently reposition the flap to its original position using the corneal markings. 0.3 % topical ofloxacin, 0.1% diclofenac sodium, and 0.1% fluoromethalone were instilled in the eye and the eyelid speculum was removed. The patients were then examined on 1<sup>st</sup> post-op day, then at 1 week, 1 month, 3 months and 4 months. Non contact specular microscopy was then performed to check the endothelial cell count which was compared with that of the preoperative value.

Data was analyzed with the help of computer software SPSS Version 10.0. Descriptive statistics were calculated. The means and standard deviations were calculated for age and endothelial cell count (ECC).

The mean  $\pm$  SD of ECC at each visits i.e. preoperatively and postoperative was calculated. The preoperative ECC was compared with postoperative ECC on the follow up visits by using paired “t” test.  $P < 0.05$  was taken as significant.

## RESULTS

A sample of fifty patients (100 eyes) was taken from the Corneo-refractive unit of LRBT Eye Hospital, Lahore. A single surgeon carried out all surgeries. All patients were followed up for the period of 4 months. Follow up was excellent and only 3 patients did not turn up for the last follow up visit. Mean age of the patients was 24.54 years. Thirty nine patients (78%) were from 20 to 25 years of age and eleven patients (22%) were from 26 to 35 years (Table 1). The majority of the patients were female (Fig. 2). The range of myopia was between 2-10 D (Table 2). 58% of the patients had myopia between 2-5 D, 16% between 6-7 D and 26% between 8-10 D. Mean spherical equivalent before LASIK was  $-3.95$  D. Mean corneal thickness before LASIK was  $515 \mu\text{m}$ . Mean endothelial cell count before and after LASIK is shown in Table 3. Figure 3 is the graphical representation of the same data. Pre LASIK mean endothelial cell count was  $2464.76 \pm 109.64$ . At four months post LASIK it was found to be  $2435.78 \pm 113.79$ . There is a less than 1% loss in endothelial cell count before and 4 months after LASIK which is clinically and statistically insignificant ( $P=0.1$ ). No significant complication was noted. A few patients complained of mild pain for 1-2 days after the procedure.

## DISCUSSION

Few studies have been done to evaluate the effect of LASIK on corneal endothelium in which the ablation is in mid stroma. Pallikaris and Siganos have reported a decrease of 8.67% in endothelial cell count 12 months after LASIK in their study of 10 eyes<sup>10</sup>. They did not perform morphometric analysis. This decrease was considered insignificant. The results of the study however show a decrease of less than 1% up to 3 months after laser. Decrease at 6 months is a little more than 1%. This may be due to the younger age of patients in study. Perez-Santonja et al reported a significant increase in cell density; decrease in coefficient of variation along with a significant increase in hexagonality<sup>11</sup>. Study included 45 eyes and follow up was one year. They also suggest that the cessation of contact lens wear may be responsible for positive modifications of cell density and morpho-

metric indices. Because of the inability of the corneal endothelium to regenerate, only a migration of endothelial cells from the peripheral to the central cornea could explain such modifications. The decline in peripheral cell density reported after PRK also supports this hypothesis.

**Table 1:** Age and Gender Distribution

Age (Years)	No of Patients n (%)	Male	Female
20-22	14 (28)	4	10
23-25	25 (50)	11	14
26-30	6 (12)	2	4
31-35	5 (10)	2	3

**Table 2:** Refractive Status of Patients

Refractive Error (Dioptres)	No. of Patients N (%)
2-5	29 (58)
6-7	8 (16)

**Table 3:** Mean Endothelial Cell Count with Standard Deviation (Pre and Post LASIK)

	Mean Endothelial Cell Count $\pm$ Standard Deviation
Pre LASIK	2464.76 $\pm$ 109.64
1 Week	2456.24 $\pm$ 117.47 ( $P=0.100$ )
1 Month	2453.84 $\pm$ 110.91 ( $P=0.102$ )
3 Months	2453.32 $\pm$ 106.63 ( $P=0.115$ )
4 Months	2435.78 $\pm$ 113.79 ( $P=0.074$ )

In another similar study Perez-Santonja et al studied same parameters in 33 eyes of 19 patients who underwent LASIK to correct myopia of 8.25 to 18.5 D and reported no detrimental changes to endothelium at 3 and 6 months<sup>12</sup>. In fact they also showed improvements in endothelial cell count and coefficient of variation. They also ascribed their changes to cessation of contact lens wear. Jones et al in a prospective study of 98 eyes undergoing LASIK for the correction of 2.75-14.5 dioptres of myopia found no significant change in endothelial cell density or coefficient of variation.<sup>13</sup>They, however, observed 1%

decrease in hexagonal cell at 3 months which they consider insignificant. They further reported that contact lens wear did not predispose the cornea to further endothelial damage by LASIK.

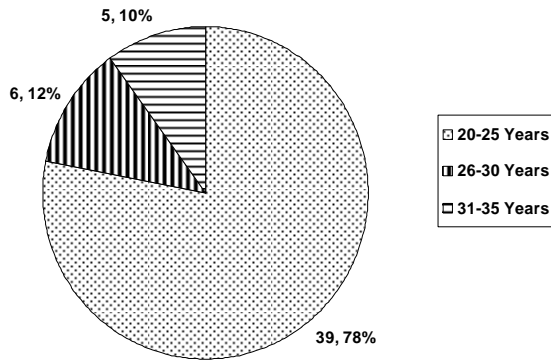


Fig. 1: Age Distribution n=50

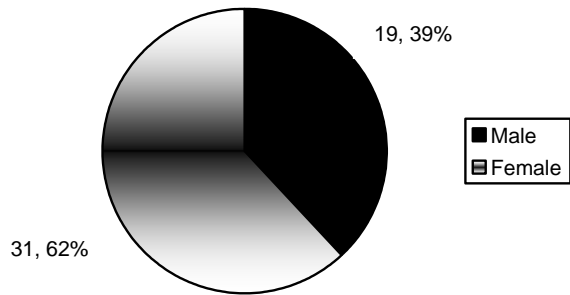


Fig. 2: Gender Distribution n=50

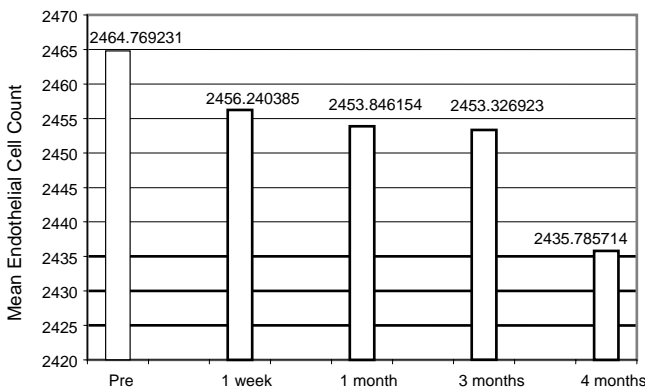


Fig. 3: Comparison of Mean Endothelial Cell Count (Pre and Post LASIK)

A study by Kim et al is different from other studies mentioned so far<sup>14</sup>. They studied human corneal endothelial changes immediately after LASIK (within 15 minutes) both by slit lamp examination and non contact specular microscopy. They revealed acute morphologic changes in the corneal endothelium that rapidly resolved. The authors believe that these changes may represent transient and reversible endothelial cell edema.

Various mechanisms of endothelial cell injury after excimer laser ablation of the cornea have been proposed including mechanical trauma caused by shock waves, ultraviolet exposure and thermal damage<sup>15,16</sup>. Kim et al suggested that in addition to these factors, increased intraocular pressure induced by the suction ring may also contribute to this damage.

A case has been reported in literature where endothelial decompensation occurred after LASIK in a patient having Fuchs' endothelial dystrophy<sup>17</sup>. This patient had endothelial dysfunction without edema in one eye and with edema in the other eye. Both eyes decompensated to different extents after the surgery. The eye without edema developed persistent edema after surgery whereas the eye that already had edema decompensated completely after surgery requiring penetrating keratoplasty. The immediate increase in corneal edema the day after surgery clearly shows a relation between LASIK and endothelial damage. Any of the factors already described may be responsible for this effect.

In my study carried out at LRBT there was no significant loss of endothelial cells at 1week, 1 month, 3 months and 4 months post LASIK. I did not have the facility of morphometric analysis i.e. the coefficient of variation (CV) and hexagonality. My results are, however, comparable to the international studies so far as the endothelial cell count is concerned. A difference exists regarding the age groups between my study and the studies carried out in the developed countries. Age range in these studies is up to 55 years whereas we did not perform the procedure in patients more than 35 years old.

Based on the studies so far although it is safe to assume that LASIK is unlikely to cause endothelial damage at least in healthy eyes but at the same time the case reported above emphasises the care refractive surgeons must exercise in selecting the patients for refractive surgery. Long-term follow-up studies are needed to confirm endothelial safety at 5 and 10 years.

## CONCLUSION

There is no clinically or statistically significant loss of endothelial cell count up to four months after laser in situ keratomileusis used for the correction of myopia.

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