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## Contralateral Eye Comparison on Changes in Visual Field Following Laser *in situ* Keratomileusis vs Photorefractive Keratectomy for Myopia: A Randomized Clinical Trial

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**Abstract:** Study purpose was to compare the changes of Visual Field (VF) during laser *in situ* Keratomileusis (LASIK) VS photorefractive keratectomy (PRK). This randomized, double blind, study involved 54 eyes of 27 Myopia patients who underwent LASIK or PRK procedures for contralateral eyes in each patient. Using Humphrey 30-2 SITA standard, the Mean Defect (MD) and Pattern Standard Deviation (PSD) were evaluated preoperatively and three months after surgery. At the same examination optical zone size, papillary and corneal diameters were also evaluated. There was no clinically significant difference in PSD and MD measurements between treated eyes with LASIK or PRK in any zone pre and postoperatively. VF may not be affected by corneal changes induced by LASIK or PRK three months after surgery.

**Key words:** Laser *in situ* keratomileusis, photorefractive keratectomy, LASIK, PRK, complication

### INTRODUCTION

A variety of surgical techniques have been developed to correct the refractive error by producing a change in the curvature of cornea. Due to some complications after PRK, laser *in situ* keratomileusis (LASIK) was introduced and became a popular modality in the 2000s with claimed advantages over PRK (Shortt *et al.*, 2006). Consequently, excimer laser superficial keratectomy techniques such as photorefractive keratectomy (PRK), laser subepithelial keratectomy (LASEK) and epithelial laser *in situ* keratomileusis (Epi-LASIK) started to gain popularity in recent years to correct myopia to refrain from possible complications of LASIK such as corneal ectasia (Taneri *et al.*, 2004). Laser *in situ* keratomileusis (LASIK) and photorefractive keratectomy (PRK) are two current techniques producing the required change in the anterior corneal surface. Refractive surgery by means of excimer laser has become the most popular method, with a dramatic rise in the number of procedures performed since its inception. Recent studies show that despite a high success rate of the procedures, LASIK is not without complications. This includes secondary glaucoma; an uncommon but very challengeable complication which is reported in some case series. Using ocular ring during LASIK raises intraocular pressure (IOP) up to 65 mmHg. It may affect the visual field and give rise

to secondary glaucoma. So, it seems that patients after PRK may have lower prevalence of secondary glaucoma. There has been always a challenge to compare these two methods for efficacy and complications and there are comparison studies of efficacy and complications of these methods (Belfort *et al.*, 2008; Ciolino and Belin, 2006; Gamaly *et al.*, 2007; Miyai *et al.*, 2008). Also, there are studies comparing long-term efficacy of LASIK and PRK showing slight differences as well as similar safety (Alio *et al.*, 2009). But to the best of our knowledge, paired randomized clinical trials to compare the two methods on same patients are rarely available. This is while individual based random allocation of eyes to compare surgical methods provides better control of confounders as well as higher statistical power. We compared the effects of LASIK and PRK conducted on contra lateral eyes of myopic patients on IOP and visual field 12 weeks postoperatively.

### MATERIALS AND METHODS

Study was conducted in 2006 in Nikookari University Hospital in Tabriz, Iran. Patients needing surgical treatment due to myopia in both eyes were asked to participate a randomized clinical trial. Contralateral eyes in each patient were subject to random allocation through which, LASIK surgery was done on one eye and PRK was done for the other eye of same patient. Randomization

was performed by a sealed envelope method immediately before starting surgery on each eye of a patient. Post operatively all patients were reevaluated by full ophthalmologic examination and perimetry at 12 weeks. Although, the surgeon naturally can't be blinded but the evaluator and statistician were blinded to the surgery method.

Due to unavailability of appropriate information for sample size calculation in literature and as an exploratory clinical trial, the best estimation of effect size was not achievable; so instead we used a reasonable estimation of effect size to fulfill an alpha value of 0.05 and 80% power of study. Of 105 eligible patients, 27 (54 eyes) agreed to participate and gave their informed consent for this study, which took place from December 2006 to October 2007.

The inclusion criteria were as; age between 20-40 years, best corrected visual acuity = 20/30, stable refraction at least 12 months prior to surgery, myopia between -1.5 to -6.00 diopters and astigmatism less than -4.0 diopters. The exclusion criteria were as; older than 40 years of age, chronic eye disease, amblyopia, KCN, history of glaucoma, ocular surgery, IOP greater than 22, lens opacities, diabetes mellitus, diseases of the immune system, abnormal retinal and optic disc, pachymetry under 500  $\mu\text{m}$ , unstable refraction, dry eye, media opacity false positive and negative error greater than 15%.

**PRK procedure:** After prep and drape, 0.5% Tetracaine eye drops were instilled-one drop 5 min before operation, second drop at the beginning of cleaning the periocular skin and another drop after the patient was positioned on the operating table. An optical zone marker 1 mm larger than the desired treatment zone was centered on the cornea and 20% alcohol was applied in the well of the instrument for 20 sec. Then it was wiped by microsurgical sponge and rinsed with BSS solution. The epithelium was removed using an epithelial peeler. The laser treatment was performed using the Nidek EC 5000 excimer laser with 6.5 mm optical zone and a 75 mm transition zone. The eye was washed using BSS solution. A bandage contact lens was placed on the cornea. Treatment with ciproflaxacin was started after the completion of surgery and used 6 times per day until the bandage lens was removed. Topical steroids were used 4 times per day for 10-14 days then changed to fluorometolon eye drops and was continued until 3 months post operatively. Sterile ophthalmic solution of 0.1% diclofenac 3 time daily was administered for 2 days. Patients were visited on days 2 and 5 days after surgery.

**LASIK procedure:** Laser *in situ* keratomileusis was performed using the moria microkeratome to create cornea

flap and 193 nm argon-fluoride excimer laser (Nidek EC-5000). The suction ring was centered around the limbus and was applied with 65 mmHg. The microkeratome was advanced across the cornea and stopped by an automatic stopper. The suction pump was deactivated and the ring and microkeratome were removed. The corneal flap was reflected superiorly using blunt smooth spatula. Laser ablation was done using optical zone size of 6.0 to 6.5 mm. The surfaces of the stromal bed and flap were moistened with BSS and the flap was folded back on the cornea with a cannula and the interface was irrigated then gently massaged using the same cannula or microsurgical sponge. After completion of surgery topical Betamethason and ciproflxacin were prescribed 4 times daily for 2 weeks.

**Visual field testing:** The Humphrey automated static perimetry was performed, with Swedish Interactive Threshold Algorithm (SITA) standard strategy in central of 30-II before doing PRK or LASIK and three months post operation. SITA fast reduces testing time, is preferred where patient is tired and can be recommended for routine visual field assessment.

Data were entered into the computer and analyzed using SPSS statistical software package. Nonparametric tests for paired data were mainly used to analyze the data. Two-sided p-values were calculated and a p value lower than 0.05 was considered as statistically significant. Local ethics committee of Tabriz University of medical sciences has approved this research with the approval code of fo-854.

## RESULTS

Ten (37%) of 27 subjects were males and 17 patients were female. Mean (Standard deviation) of age of patients was 29.48(9.2) years.

Average mean difference (MD) without considering the operation type was -2.97( $\pm$ 2.52) before the operation and it was calculated to be -2.35( $\pm$ 2.27) after three months. The change was statistically significant using Wilcoxon signed-rank test ( $p < 0.05$ ).

Average Mean Difference (MD) in PRK group was -3.08( $\pm$ 2.76) before the operation and it was calculated to be -2.15( $\pm$ 2.26) after three months (PV = 0.06). Average Mean Difference (MD) in LASIK group was -2.77( $\pm$ 2.32) before the operation and it was calculated to be -2.55 ( $\pm$ 2.316) after three months. The difference was not statistically significant.

Average Pattern Standard Deviation (PSD) without considering the operation type was 2.47 ( $\pm$ 1.38) before the operation and it was calculated to 2.19 ( $\pm$ 1.13) after three months. The difference was not statistically significant.

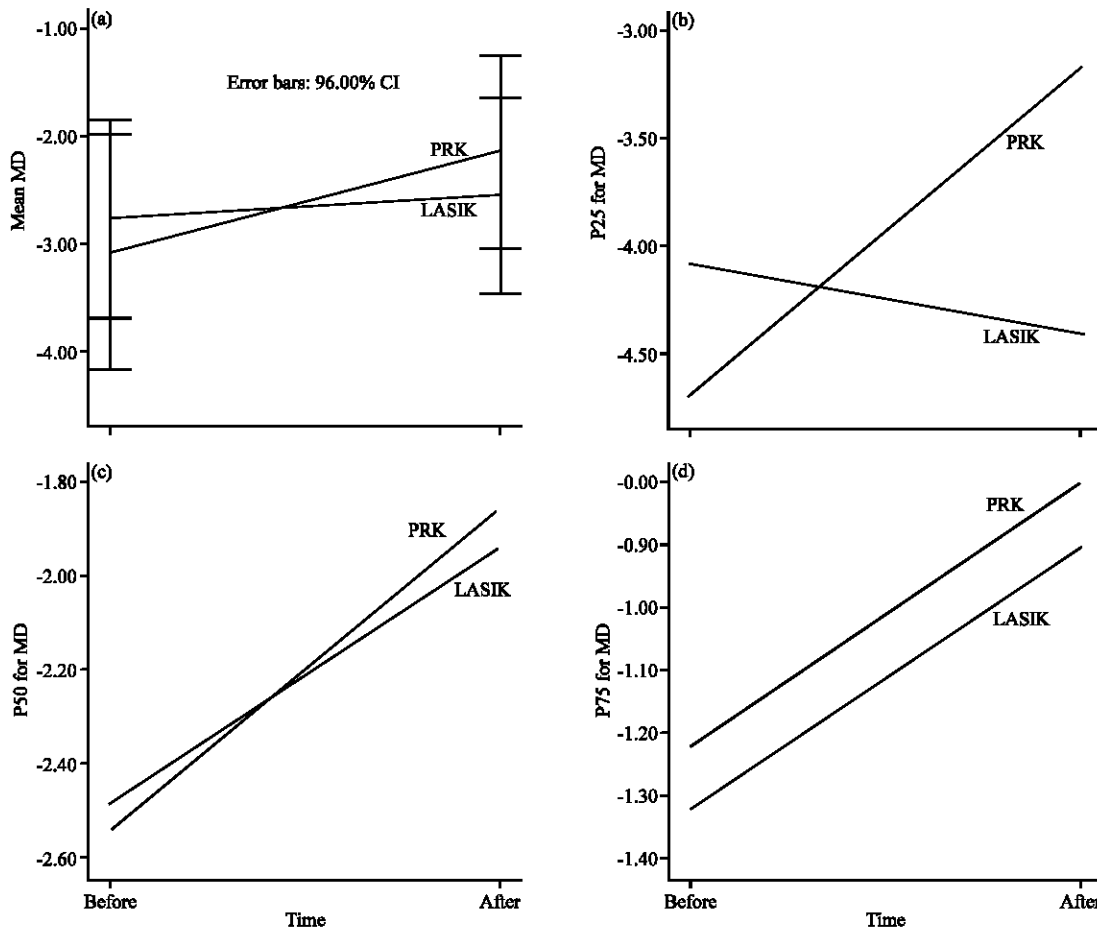


Fig. 1: The changing pattern of mean, median, 25 and 50 percentiles of MD compared between groups. (a) Mean (95%) CI of MD, (b) First quartile of MD, (c) Median of MD and (d) Third quartile of MD

Average Pattern Standard Deviation (PSD) in PRK group was 2.52 ( $\pm 1.6$ ) before the operation and it was calculated to be 2.12 ( $\pm 1.06$ ) after three months ( $PV = 0.07$ ). Average Pattern Standard Deviation (PSD) in LASIK group was 2.42 ( $\pm 1.16$ ) before the operation and it was calculated to be 2.26 ( $\pm 1.21$ ) after three months. The difference was not statistically significant.

The changing pattern of mean and median, 25 and 75 percentiles of MD compared between groups is given in Fig. 1a-d.

### DISCUSSION

LASIK and PRK are the two most popular refractive surgery methods. Using the suction ring in LASIK increases intraocular pressure up to 65 mmHg. This may affect the blood supply from central retinal artery and cause damage to optic nerve and NFL (Harris *et al.*, 1996). Dislocation of lamina cribrosa is observed after suddenly

increased intraocular pressure in animal studies (Coleman *et al.*, 1991; Levy and Crapps, 1984; Zeimer and Ogura, 1989). PRK is different in the fact that suction ring is not used to cause increased intraocular pressure.

In the present study the visual field was compared after PRK and LASIK. Conducting the procedure on both eyes of the same patients was the key point in this study to efficiently control individual factors like pupil size, optical aberration and lenticular aberration. We didn't find a significant decreased sensitivity in 30-degree central visual field between PRK and LASIK. Brown *et al.* (2005) found no significant change in the MS in the central 15-degree visual field; while between 15 and 30 degrees, they found a statistically significant decrease of  $-0.82 \text{ dB} \pm 1.40$  (SD). They discussed that MS didn't change in the central 15-degree visual field because OZ diameter is not important when considering light passing through the central cornea and the change in the central 30-degree visual field is due to spherical aberration by OZ

(Brown *et al.*, 2005). In present study there was a negative correlation between OZ and MS. Larger OZ affects the MS caused by aberration in operated eye. Another study conducted on fifty-one patients scheduled for routine, bilateral, myopic LASIK. Patients served as their own control and received brimonidine in one eye and placebo in their fellow eye. No statistically significant change was found in any of the visual field parameters measured in either the placebo or brimonidine group postoperatively (McCarty *et al.*, 2003). Like our study they studied the peripheral visual field and concluded that LASIK does not affect the structure or function of the parameters of the optic nerve. Similarly in another study on 37 myopic patients 30-degree visual field was evaluated and observed that LASIK doesn't affect visual field and using microkeratome doesn't harm optic nerve (Ozdamar *et al.*, 2004). The theoretical analysis of peripheral image quality in a study by Montes-micro showed that when light passes through and part of the transitional or unablated areas, sensitivity depression in 40-degree field in temporal and nasal regions is observed for PRK group. This is thought to be due to light scattering and failure to detect the light passing through polyfocal iris areas (Montes-Mico and Charman, 2002). Another similar study showed that increased pupil diameter decreases image quality and increased OZ and blend zone improves image quality (Charman *et al.*, 2002). Considering findings from different studies, decreased peripheral field sensitivity after PRK and LASIK may be due to ablation related optical factors and not because of NFL and optic nerve involvement.

In present study, PRK and LASIK were done on pair of eyes in each patient. No significant 30-degree visual field difference was found in MD and PSD before and after the operation. Even a little improvement in visual field was observed after surgery. This interesting effect is also reported before our study specially in 20-30-degree field being considered as a learning effect (Werner *et al.*, 1990). This may even lead to masking operation effects. Also in the present study visual field was a bit less impaired after PRK compared to LASIK. This may be because of better image quality in PRK lacking the flap problems as in LASIK.

To the best of our knowledge although present research like most other published studies may suffer lower power due to small sample size, but it is one of the first paired eye randomized clinical trials (Gamaly *et al.*, 2007; Pirouzian *et al.*, 2004). This methodology improves power even for small sample size and provides better control on known and unknown confounders.

## CONCLUSION

The present study showed that LASIK or PRK may not significantly affect the visual field. The findings of this study doesn't support any priority between LASIK and PRK methods but it encourages future larger scale clinical trials randomized for paired eyes. The authors also recommend researchers to pay more attention on patient training in order to decrease the learning effect and masking.

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