

## Validity of percentage tissue altered as a screening formula for post laser-assisted *in-situ* keratomileusis ectasia in Indian eyes

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**Purpose:** To calculate a modified percentage tissue altered (mPTA) in post laser-assisted *in-situ* keratomileusis (LASIK) eyes and to validate its role as an independent factor to evaluate ectasia in the Indian population. **Methods:** A total of 333 consecutive eyes with normal preoperative corneal topography by combined placido and scheinplflug imaging-based topography system (SIRIUS) who underwent LASIK using a microkeratome between 2011 and 2014 at a tertiary level teaching hospital in south India, were retrospectively analyzed. Preoperatively patient's refraction, flap thickness (FT), ablation depth (AD), residual stromal bed (RSB), and thinnest corneal thickness (TCT) were recorded. The formula used was  $mPTA = (FT + AD)/TCT$ . mPTA was grouped into <0.4 (low risk), 0.40 - 0.45 (moderate risk), and >0.45 (high risk). All patients were called for follow-up and underwent a topography to look for ectasia. **Results:** In total 60.1%, 29.1%, and 10.8% patients had mPTA of <0.4, 0.40 - 0.45 and >0.45, respectively. However, after a minimum follow-up of 2 years, none of the patients had any sign of ectasia. **Conclusion:** Careful selection of patients is mandatory before proceeding for LASIK. Factors like corneal thickness, RSB, degree of myopia, and AD are more important. The role of mPTA >0.4 as an independent risk factor for post LASIK ectasia is questionable in Indian eyes. Other factors or a modified formula suitable for Indian eyes needs to be investigated. A larger follow-up period is also required as ectasia has been known to develop even after 2 years.

**Key words:** LASIK, percentage tissue altered, post LASIK ectasia

Laser-assisted *in-situ* keratomileusis (LASIK) has emerged as the most common surgery for correction of refractive errors, especially myopia. The number of these surgeries has increased in recent years in developing countries, with majority of cases still being done using a microkeratome in India. PostLASIK ectasia is a known, but rare complication which can scare any refractive surgeon. It occurs when surgery is done in a weak/thin cornea or when normal cornea is weakened beyond the safety limits. Various risk factors have been described in literature like abnormal corneal topography and tomography, residual stromal bed, central corneal thickness, ectasia risk score system scores, high myopia, age, etc., Recently, the role of percentage tissue altered (PTA) has come up. *Santhiago et al.* first described it as  $PTA = (FT + AD)/CCT$ , where FT-flap thickness, AD-ablation depth, CCT-preoperative central corneal thickness. According to them,  $PTA \geq 0.4$  was the most important risk factor. They had also screened normal using placido based corneal topography.<sup>[1,2]</sup>

A few studies regarding PTA have been done, but on Brazilian and Caucasian eyes. Indian eyes have a thinner cornea as well as higher incidence of keratoconus, in comparison to Caucasians. Moreover, Asians in general, present earlier than other racial groups.<sup>[3-5]</sup>

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Since thinnest corneal thickness (TCT) is a more significant criteria than central corneal thickness to predict ectasia,<sup>[6]</sup> a modified PTA (mPTA) was calculated, where  $mPTA = (FT + AD)/TCT$ .

*Santhiago et al.* used placido-based corneal topography.<sup>[1,2]</sup> However, the accepted corneal tomography now is by SIRIUS (Costruzione Strumenti Oftalmici, Florence, Italy) or Pentacam (Oculus, Wetzlar, Germany).

This aim of this study was to calculate the mPTA in post LASIK eyes and to investigate whether it could be an independent risk factor for postLASIK ectasia in the Indian population, in eyes where preoperative screening was done using corneal tomography (SIRIUS).

## Methods

This retrospective, non-comparative study was done analyzing 333 eyes of 170 consecutive patients between 18 and 40 years of age, operated for myopia, and myopic astigmatism with normal bilateral preoperative corneal topography by combined placido and scheinplflug imaging based topography system (SIRIUS,

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V2.6) by laser in-situ keratomileusis from April 2011 to March 2014 at a tertiary level teaching eye hospital in south India. The study was approved by the institutional review board as per the tenets of the Declaration of Helsinki. Patients having history of any previous intra-ocular surgery, ocular allergy, hormonal imbalances/treatment, pregnancy were excluded from the study.

The preoperative data recorded included patient's age, sex, refraction, spherical equivalent (SE), date of surgery, flap thickness (FT), ablation depth (AD), residual stromal bed (RSB), and thinnest corneal thickness (TCT). TCT was defined as the thinnest point on the corneal thickness map. All flaps were created using a microkeratome. Degree of myopia was graded by amount of SE as low (<-4 D), moderate (-4 to -6 D) and high (>-6 D) *Santiago et al.* calculated percentage tissue altered (PTA) as  $PTA = (FT + AD)/CCT$ .<sup>[1]</sup> We modified the formula using the thinnest corneal thickness rather than central corneal thickness, as it plays a larger role in the preoperative evaluation of LASIK than CCT. Therefore, modified PTA (mPTA) =  $(FT + AD)/TCT$ . mPTA <0.4, 0.40 - 0.45, and >0.45 was considered as low, moderate and high risk for ectasia respectively. All data were formulated in Microsoft excel sheet and analysis was done using SPSS Version 20. All patients were called for a follow-up visit after a minimum period of 2 years and underwent corneal tomography scan with SIRIUS to look for signs of ectasia.

A normal preoperative scan was defined as having regular pattern without any asymmetry or mild asymmetry (steeping  $\leq 0.5D$  and without any skewed radial axis) along with normal anterior (<12  $\mu$ ) and posterior (<17  $\mu$ ) elevation maps (Difference between anterior and posterior floats being <5  $\mu$ ). Post-operative ectasia was defined as increasing myopia or astigmatism (as evidenced by >2D of manifest refraction), progressive inferior steeping >3D or more, along with elevation in anterior (>15  $\mu$ ) and posterior (>20  $\mu$ ) floats.<sup>[1]</sup>

## Results

A total of 333 consecutive eyes with normal preoperative corneal topography by SIRIUS who underwent LASIK between 2011 and 2014 were retrospectively analyzed. The average age was 23.35 years, with females 1.6 times more involved in the study. The spherical equivalent ranged from - 0.625 to - 12 D with an average of - 4.95 D. 34.53%, 41.74%, 23.72% eyes had low (<-4 D), moderate (-4 to - 6 D) and high (>-6 D) degrees of myopia retrospectively. The average overall thinnest corneal thickness for the high myopia group was 543  $\mu$ .

The mean attempted laser ablation was  $123.09 \mu \pm 9.52$  (SD) and the mean planned RSB was  $334.45 \mu \pm 36.05$  (SD). 115 eyes (34.5%) had a FT of 110  $\mu$  and 218 eyes (65.5%) had a FT

of 130  $\mu$ . In eyes with FT of 110  $\mu$ , mPTA was <0.4 in 57.4% eyes ( $n = 66$ ) and  $\geq 0.4$  in 42.6% eyes ( $n = 49$ ). In eyes with FT of 130  $\mu$ , mPTA was <0.4 in 61% eyes ( $n = 133$ ) and  $\geq 0.4$  in 39% eyes ( $n = 85$ ). Overall, 60.1%, 29.1% and 10.8% eyes had mPTA of <0.4, 0.40 - 0.45, and >0.45 respectively, with 39.1% eyes having mPTA >0.4 [Table 1]. However, after a minimum follow-up of 2 years, none of the patients had any sign of ectasia, and, therefore, we did not use mPTA in follow-up cases. No drop outs were seen.

## Discussion

Most patients who develop post LASIK ectasia have identifiable risk factors or irregular topographic patterns. The presence of ectasia in patients with normal pre-operative corneal topography raises an alarm. PTA as an independent risk factor for developing post-LASIK ectasia is a new emerging concept, which was first described by *Santhiago et al.* The explanation was that the anterior 40% stroma contributes maximum strength to the cornea, which gets modified after laser refractive surgery. The flap itself does not give any significant biomechanical contribution. Its removal causes corneal weakening as the 40% threshold is crossed. According to them, PTA is more sensitive than RSB and that ectasia had occurred in corneas with normal thickness, normal RSB and even normal topography. However, a high PTA did not mean that ectasia will occur. It merely meant that these eyes carried an increased risk of ectasia. Most ectasia cases manifest in the first 18 months.<sup>[1]</sup>

We retrospectively analyzed 333 consecutive eyes of patients aged between 18 and 40 years who were operated for myopia and myopic astigmatism with normal bilateral pre-operative corneal tomography by combined Placido and Scheimpflug Imaging based topography system (SIRIUS) by laser in-situ keratomileusis from 2011 to 2014 at a tertiary level teaching eye hospital in south India and took corneal tomography scans to look for ectasia after a minimum follow up period of 2 years. We used a modified PTA (mPTA), rather than PTA where thinnest corneal thickness (TCT) was taken rather than central corneal thickness (CCT), as it is a more important criteria for LASIK. In our series, we found that about 39% cases had mPTA > 0.4 and that none of them had any sign of ectasia after the minimum defined period. Our current results proved mPTA cannot be relied on as an independent factor to predict postoperative ectasia. Hence, around 133 eyes benefitted from the procedure, without any complication; who otherwise would have been rejected for LASIK.

*Santhiago et al.* evaluated 204 Brazilian eyes post-LASIK (30 ectatic, 174 normal eyes). The ectatic group had PTA > 0.4 in 97% eyes, and hence, he suggested that PTA was an important predictor for post-LASIK ectasia. However, he screened "normals" by placido based corneal topography.<sup>[1]</sup> Nowadays,

**Table 1: Percentage of mPTA**

| Risk of ectasia | mPTA        | Number of eyes with FT=110 $\mu$ | Number of eyes with FT=130 $\mu$ | Total number (%) |
|-----------------|-------------|----------------------------------|----------------------------------|------------------|
| Low             | <0.4        | 66                               | 133                              | 200 (60.1%)      |
| Moderate        | 0.40 - 0.45 | 41                               | 56                               | 97 (29.1%)       |
| High            | >0.45       | 8                                | 29                               | 36 (10.8%)       |
| Total           |             | 115                              | 218                              | 333              |

m-PTA-Modified-Percentage Tissue Altered, FT-Flap Thickness

newer methods like Corneal tomography are available, which take into account both the anterior and posterior elevation indices. This makes a better preoperative screening possible. Hence, the risk of post-operative ectasia decreases further.

Saad *et al.* also calculated PTA in post-LASIK American eyes and did not find any ectatic eye over a mean follow-up of 30 months. However, he used various topographers, thereby lacking a uniform topography tool. Moreover, some of these topographers were curvature based, further adding to varying results.<sup>[7]</sup> Our study used a single corneal tomography device (SIRIUS), thereby maintaining a uniformity of the scans and results.

Chan *et al.* also compared the accuracy of PTA along with ectasia risk score system (ERSS) and screening corneal objective risk of ectasia (SCORE) to identify post LASIK ectasia. They concluded that the PTA is a less accurate predictor of post LASIK ectasia, which has also been validated in our study.<sup>[8]</sup>

Indian corneas have been known to be thinner. They also have a higher incidence of keratoconus, in comparison to Caucasians. Moreover, Asians in general, present with ectasia earlier than other racial groups.<sup>[3-5]</sup> Hence, the corneal data in Brazilians and Caucasians cannot be relied on to comment on Indian eyes, as they can behave differently. We believe ours to be the first study to evaluate the role of mPTA in Indian eyes.

Our strength in the study is that we have a good sample size and follow up period. Our study is limited as it is retrospective and also that ectasia cases have even been reported after 2 years. Another limitation of the study is that anterior segment optical coherence tomography (AS-OCT) was not done in the postoperative period to see the actual flap thickness, where accuracy of the flap is an important factor in microkeratome LASIK.<sup>[9]</sup>

With recent advances in technology, it is possible to make flaps more predictable with the use of femtosecond laser. The flap architecture using a microkeratome is that of meniscus and with femtosecond laser a planar one.<sup>[10,11]</sup> Moreover, with the use of femtosecond laser the flap construction error reduces from 24  $\mu$ (microkeratome) to 6  $\mu$ .<sup>[10]</sup> This makes the flaps more predictable and, hence, the PTA more accurate.<sup>[9-12]</sup>

## Conclusion

Careful selection of patients is mandatory before proceeding for LASIK. Factors like corneal thickness, residual stromal bed, degree of myopia and ablation depth are more important. Our study shows that the role of mPTA >0.4 as an independent risk factor for postLASIK ectasia is questionable in Indian eyes. A larger prospective study is warranted to further validate the role of mPTA in Indian eyes. Further, other factors or a modified

formula suitable for Indian eyes needs to be investigated. With the advent of corneal tomographers like SIRIUS and Oculus Pentacam, preoperative screening is much better and this further improves the screening before LASIK.

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## Conflicts of interest

There are no conflicts of interest.

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