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Risk Profiles of Ectasia after Keratorefractive Surgery

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Abstract

Purpose: To identify and evaluate the risk factors of iatrogenic ectasia after refractive surgery.

Methods: We reviewed recently published papers that identified various risk factors associated with ectasia after LASIK, PRK, SMILE and other refractive surgical procedures. We also attempted to evaluate the relative contributions of these factors to the development of ectasia following refractive surgery.

Results: Forme fruste keratoconus, genetic predisposition to keratoconus, low residual stromal bed thickness (through high myopia, thin preoperative cornea, or thick LASIK flap), and irregular corneal topography have been identified as risk factors for keratectasia development after refractive surgical procedures. A newly proposed metric, percent tissue altered (PTA) has been reported to be a robust indicator for ectasia risk calculation, where PTA > 40% has been proposed to be cut-off value with maximized sensitivity and specificity. Several cases of keratectasia have also been reported 6 to 12 months following minimally invasive SMILE procedure. Other risk factors associated with iatrogenic ectasia include eye rubbing, young age, and pregnancy.

Conclusion: Ectasia after refractive surgery is a relatively rare complication which can lead to sight threatening complications if not detected and treated in time. It is important to continue our quest to improve our methods of identifying absolute and relative risk factors of ectasia and their cut-off values following various keratorefractive surgical procedures.

Keywords

Ectasia; keratorefractive surgery; risk profiles

I. Introduction

Corneal ectasia is defined as a progressive thinning, bulging or distortion of the cornea [1]. Generally an irreversible disorder, it can significantly impact the uncorrected as well spectacle corrected visual acuities. Theoretically, there are three main scenarios where ectasia could develop following keratorefractive surgery: (I) when a cornea that is already predisposed to manifesting ectasia undergoes surgery, (II) when a clinically stable, but

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preoperatively weak cornea undergoes surgery, and (III) when a relatively normal cornea becomes weakened below a safe threshold, making the cornea biomechanically instable [2].

The phenomenon of post-LASIK ectasia was first reported by Seiler et al. in 1998 [3-4] where progressive thinning and the steepening of the cornea along with decrease in uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) were observed. Corneal ectasia has been observed to occur as early as 1 week and as late as several years post-LASIK. Approximately 50% of the cases occur within the first year, and up to 80% of the cases have been reported to show up within the first two years of surgery [5]. The reported incidence of ectasia is between 0.02% and 0.6% [6-8]. Some of the keratectasia cases that occur have a genetic predisposition. LASIK may hasten ectasia symptoms in such predisposed patients [9]. One report estimated that 4% occur after photorefractive keratectomy (PRK), while 96% cases occur after LASIK [5].

Dawson DG et al [10] reported that PRK, advanced surface ablation (ASA) and sub-Bowman's keratomileusis (SBK) are biomechanically safer than conventional LASIK with respect to keratectasia development risk post-surgery. These findings were based on comparative histologic, ultrastructural, and the cohesive tensile strength testing studies of normal, keratoconus, uncomplicated-LASIK, -SBK, -PRK,- ASA, and post-LASIK and post-PRK ectasia specimens.

II. Absolute Risk factors

Absolute risk factors for ectasia after refractive surgical procedures include:

Forme fruste keratoconus and Keratoconus

Patients with forme fruste keratoconus have a high risk for developing iatrogenic ectasia after LASIK [11-13]. In a study done by Brenner LF et al [14], 75.3% of the patients who presented with post-LASIK ectasia had signs of forme fruste keratoconus. In a study by Tatar MG et al [15], 21.4% of the iatrogenic ectatic cases had forme fruste keratoconus. Reznik J et al [16] reported a case of 25-year old man who developed unilateral inferior keratectasia in the right eye five years after he underwent PRK. This patient had forme fruste keratoconus in the right eye with an inferior superior ration of 4. Kymionis et al [17] also reported a case of corneal ectasia after LASIK with uncomplicated PRK in the fellow eye. However, there also have been few reports whereby no ectatic cases have been reported after LASIK in patients with preoperative keratoconus. Khakshoor et al [18] reported significant visual improvement ($P < 0.001$) with no signs of ectasia and keratoconus progression in patients with mild to moderate keratoconus (residual CCT ≥ 400 μm, age > 40 years) after PRK. Jampaulo et al [19] also did not report ectasia in keratoconus patient (FFK in OD, and inferior corneal steepening in OS) who had undergone LASIK procedure even when they followed up the patient 7 years post-surgery.

Other Genetic factors

Several other ectatic corneal conditions, which can be identified by corneal topography, such as pellucid marginal degeneration are contraindications for LASIK. Sometimes, the genetic predisposition for ectasia can be discovered postoperatively by performing corneal topography on siblings. Navas et al [20] reported a case of 35-year old man who developed bilateral corneal ectasia 2 weeks after he underwent PRK procedure. He had asymmetric bowtie topographical pattern and his sister had had topographic and clinical signs of keratoconus.

III. Relative Risk factors

Some of the relative risk factors for the development of keratectasia after various refractive surgery procedures are:

Low residual stromal bed thickness

- High myopia

  In a retrospective review evaluating the long-term incidences of corneal ectasia in patients who had undergone myopic LASIK correction, Spaeda et al [21] looked at a total of 4027 eyes where they observed that 0.63% patients developed ectasia. The ectasia cases were identified by characteristic corneal thinning with steepening on the center of the treated area, along with posterior bulge in the tomographic evaluation. The authors noted that RSB was the most important factor in the development of ectasia in their experience.

  Peinado et al [22] reported a case of 25-year old man who developed corneal ectasia after myopic LASIK five years after surgery. The patient did not have an extremely reduced CCT and RSB, instead the values of corneal hysteresis (CH) and resistance factor (CRF) were significantly smaller compared to the healthy post-LASIK eyes.

  Twa et al [23] reported their study on the characteristics of corneal ectasia after LASIK for myopia. They reported the postoperative characteristics of corneal ectasia as myopic refractive error with increased astigmatism, worse SCVA, thin corneas, greater residual myopia, and increased corneal toricity with topographic abnormality and progressive corneal thinning.

- Thin corneal pachymetry

  LASIK procedure in thin corneas (< 500 μm) appear to be safe as reported by Kymionis et al [24], Kremer et al [25] and Djodeyre et al [26]. However, it is to be noted that all corneas with the same thickness do not necessarily have the same strength [27]. Padmanachan et al [28] reported a case of a patient who went on to develop keratectasia even though she had an RSB thickness of 327 microns, which is well above the minimum recommended thickness of 250 microns.

- Thick LASIK flap

  LASIK contributes to the risk of developing ectasia because it reduces the biomechanical integrity of the cornea as its effective thickness is reduced after flap creation. The anterior 40% of the cornea has been observed to demonstrate greater tensile strength than the posterior 60% of the cornea in a healthy, untouched cornea. A thicker flap creation isolates the obliquely running anterior stromal layers in the flap leaving behind an inherently weaker corneal stroma [29]. A greater kearatocyte density has also been found in the anterior 10% of the stroma [30], which contributes to its greater tensile strength compared to the posterior part.

However, a report by Randleman et al [31] stated that excessively thick flap may not be a major contributing factor to the pathogenesis of post-LASIK ectasia. The authors measured and compared the central flap thickness of 50 eyes who developed post-LASIK ectasia with the estimated flap thickness values (based on the mean published values for each device used for flap creation), as well as performed confocal microscopic analysis using the Confoscan 3 device to measure the central flap thickness in the ectatic eyes. They found no significant differences between the measured and estimated flap thickness, the RSB thickness or flap thickness between eyes developing ectasia with normal corneal topographies and eyes with abnormal corneal topographies.

Corneal topographical irregularity

Reports by several authors have placed irregular corneal topography as an important risk factor for the likelihood of ectasia development after refractive surgeries. Randleman et al [32] reported corneal topographic irregularity in 50% of the patients in ectasia. Randleman also found high risk of corneal ectasia in patients with preoperative irregularities of the cornea such as superior or inferior skewed steepening, and asymmetric bowtie patterns. Guilbert E et al [33] reported a case of unilateral ectasia post-LASIK in a patient with abnormal topography but normal tomography. The patient had developed the unilateral ectasia in the right eye five years and 5 months post the LASIK procedure. Typically, tomography is a very sensitive technique for detecting ectasia, however, in the case of this patient, the posterior elevation and the pachymetry map were both normal. Only the Placido map of the anterior corneal curvature was sensitive enough to show an asymmetry with 1.8 D of steepening when evaluated from upper left to lower right meridians, with a skewing of the steepest radial axes.

A KISA% index (quantifying the topographic features of patients with clinical keratoconus, and initially derived as, KISA% = (K) × (I-S) × (AST) × (SRAX) × 100, where K-value = expression of central corneal steepening; I-S value = expression of inferior-superior dioptric asymmetry; AST index = quantification of degree of regular corneal astigmatism; SRAX (skewed radial axis) index = expression of irregular astigmatism occurring in keratoconus [34]) of 128.4 was calculated in the right eye while the normal left had only 5.6 KISA% index. Spaeda et al [21] reported 34.8% patients with topographic irregularities who later went on to develop ectasia after LASIK. Conversely, Wang et al [35] have reported a case of bilateral corneal ectasia who had normal preoperative topography, and LASIK in only one eye.

High percentage of tissue altered (PTA)

Santhiago et al [2] proposed a metric for calculating the ectasia risk in patients who are undergoing to undergo LASIK procedure. This metric can be expressed in terms of the following equation:

$$PTA = (FT + AD) / CCT$$

where PTA = percent of tissue altered
FT = flap thickness
AD = ablation depth, and
CCT = central corneal thickness

Santhiago et al have reported that in eyes with normal topography, PTA > 40% was observed to present higher prevalence, higher odds ratio, and higher predictive capabilities of ectasia risk than RSB, CCT, high myopia, ablation depth, moderate to high ERSS or age (Table 1) [36]. They found the mean PTA in affected eyes (n=30) to be 45.1% ± 3.9%, which they compared with the mean PTA of 31.9% ± 5.8% in 174 control eyes that came through LASIK without any problems [36]. The subjects who were found to develop ectasia in the study would have ordinarily been considered as low risk subjects had they been assessed solely with other measurements such as RSB or CCT.

SMILE

Small Incision Lenticule Extraction (SMILE) is a minimally invasive surgical procedure that utilizes the carving of intrastromal lenticules to achieve the desired refractive correction. The flapless lenticule extraction procedure is thought to cause reduced disruption of peripheral collagen fibers as compared to LASIK, thus maintaining the biomechanical integrity of the corneal layers. However, it is still not immune to the risk of keratectasia development after the procedure. Sachdev G et al [37] reported a case of unilateral corneal ectasia in a 26-year old patient who had normal preoperative corneal topography and thickness, 12 months after the procedure. The early signs of corneal ectasia on the left eye were determined from the corneal topography images, which showed worsened condition 18-month post-surgery. Wang Y et al [38] have reported another case of corneal ectasia development 6.5 months after SMILE procedure, diagnosed based on anterior and posterior surface keratometry of 38.4/39.5 D and −6.3/−8.6 D respectively in the right eye, and 38.6/40.8 D and −7.1/−6.6 D respectively in the left eye. The trends of post-surgery decrease of corneal thickness with gradual increase in keratometry were observed during the 13-month follow-up.

Eye rubbing

Eye rubbing has been implicated as an important factor in the development of keratoconus. One study reported a statistical difference between the normal and keratoconus subjects who rubbed eyes, 89% of the patients with keratoconus rubbed eyes versus 39% of the control subjects [39]. Another 48-year, retrospective, clinical, and epidemiological study of keratoconus reported that 25% of the patients had a history of rubbing their eyes excessively before they were diagnosed with keratoconus [40]. Rubbing eyes, could therefore be, one of the contributing factors towards the development of keratoconus, owing to the biomechanical, mechanical and biochemical changes that could result from rubbing.

Young age

According to the Randleman Ectasia Risk Scoring System (ERSS) [5], young age is significant risk factor for the development of iatrogenic corneal ectasia. Tatar et al [15] reported 33% of the patients younger than 30 years in their study of keratoconus cases. Spaeda et al [21] reported 17.4% of cases of post-LASIK ectasia to be patients younger than 30 years. However, Binder and Trattler [41] have reported no findings of ectasia in 150 eyes in subjects of 21-29 years of age.

Pregnancy

Pregnancy has been associated with post-LASIK corneal ectasia in a small number of patients, possibly due to hormone induced-change in the biomechanical stability of the body's connective tissues. Hafezi et al [42] reported 5 cases of pregnant LASIK patients who experienced decreased vision during pregnancy associated with progressive ectasia. The patients were subsequently treated with collagen crosslinking to prevent further progression. Hormonal changes during pregnancy, in theory, can lead to reduced stiffness and increased extensibility of the connective tissues of the body. Cornea is also comprised of dense fibrous connective tissue, which could explain the progressive ectasia seen in these pregnant LASIK patients.

Ectasia without any apparent risk factors

Although several risk factors have been identified for the likelihood of ectasia development after keratorefractive surgeries, some cases have been reported to develop in an enigmatic way, without the presence of any of these risk factors. Some authors have proposed issues such as optical treatment diameter, percentage of ablated tissue, and corneal warpage as risk factors. Yet others have considered a low hysteresis (where normal value is between 8 mm Hg and 12 mm Hg) measured with the ocular response analyzer as a predictive index of a preectatic condition. In a report by Saad and Gatinel [43], a patient developed ectasia 2 years post LASIK who had 0 score in the ERSS in both eyes. In a study by Tatar et al [15], 9 patients developed ectasia without any apparent risk factors.

IV. Conclusion: Risk profiles for various keratorefractive procedures

Corneal ectasia is a rare but sight threatening, and generally irreversible complication after keratorefractive surgical procedures. Keratoconus and genetic predisposition to keratoconus are major risk factors for iatrogenic corneal ectasia.

The most popular currently available nomogram is the Randleman Ectasia Risk Scoring System (ERSS) (Table 2) [5]. A recently developed metric is PTA by Santhiago et al. [2] which considers the relationships between flap thickness, ablation depth and corneal thickness simultaneously in one metric. It should be noted however, that PTA is more of an indicator than an actual screening method for corneal ectasia risk.

The onset of ectasia can be missed, for instance, by mistaking increased myopia for cataractous changes. In such scenarios, taking preoperative and postoperative topographic difference maps can be helpful in tracking the topographic changes that may indicate the onset of ectasia. In cases in which LASIK poses a risk or ectasia, consideration should be given for other procedures or for observation instead of LASIK surgery.

In a recent report by Mattila et al [44], a keratoconus patient who had undergone the SMILE developed bilateral ectasia. Although SMILE is supposed to have advantage of preserving the integrity of most of the anterior stromal lamellae, this principle is more applicable to normal corneas, and not to the keratoconic corneas, where the structure of the corneal stroma is pathological.

PRK is often utilized for predominantly thin, high-risk corneas as opposed to LASIK. However, even though the likelihood of ectasia is lower after PRK than after LASIK, it should be noted that it is not always safe to do PRK on thin corneas. The onset of post-PRK ectasia is often late, which may lead to late diagnosis. Preoperative and postoperative topographies, particularly the topographic difference maps, are useful in making the diagnosis and in tracking the response to treatment such as crosslinking.

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Key Points:

- Corneal ectasia is a rare but sight threatening, generally irreversible complication after various keratorefractive surgical procedures.
- Keratoconus and genetic predisposition to keratoconus are definite risk factors for iatrogenic corneal ectasia.
- Low RSB, corneal topographical irregularity, high PTA, SMILE, eye rubbing, young age and pregnancy are relative risk factors for iatrogenic ectasia.
- Some cases of corneal ectasia can even develop without the presence of any assumed risk factors.

Table 1.

Santhiago's Receiver Operating Characteristic (ROC) Table for Percent tissue Altered (PTA) values related to post-LASIK ectasia risk for a study population of 30 eyes with bilateral normal preoperative Placido based corneal topography that developed ectasia after LASIK, and 174 eyes with uncomplicated LASIK and at least 3 years of postoperative follow-up [35].

Cut-off Percent Tissue Altered Value (%)	Sensitivity (%)	Specificity (%)
48	27	100
47	33	100
46	33	98
45	53	97
44	63	96
43	77	94
42	87	91
41	90	91
40	**97**	**89**
39	97	87
38	97	83
37	97	82
36	97	79
35	100	72
34	100	64

The results of this table are derived from receiver operating characteristic (ROC) curve, and revealed a cut-off of 40% as the value with the maximized sum of sensitivity and specificity; PTA= Percent Tissue Altered (Flap Thickness + ablation Depth)/ Central Corneal Thickness.

Table 2.

Randleman et al. Ectasia Risk Score System (ERSS) [5].

Risk Factors (in order of significance)	**Score**				
	0 (low risk)	**1 (low risk)**	**2 (low risk)**	**3 (moderate risk)**	**4 (high risk)**
Preop topography	Symmetrical bowtie	Asymmetric bowtie (asymmetric steepening in any direction less than 1.0 D)		Inferior steepening; skewed radial axis (significant skewed radial axis with or without inferior steepening, I-S value less than 1.4 D)	Keratoconus; pellucid marginal degeneration; forme fruste keratoconus with I-S value of 1.4 or more
Residual stromal bed (RSB) thickness (μm)	>300	280-299	260-279	240-259	<240
Age	>30	26-29	22-25	18-21	
Preop corneal thickness (μm)	>510		481-510	451-480	<450
Preop spherical equivalent manifest refraction (D)	−8 or less	> −8 to −10	> −10 to −12	> −12 to −14	> −14