Original Article

Ectasia after keratorefractive surgery: Analysis of risk factors and treatment outcomes in the Indian population

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Purpose: To analyze the risk factors in eyes developing ectasia following keratorefractive procedures. In addition, the study assessed visual outcomes following various treatment modalities for ectasia. **Methods:** In this retrospective study, data of patients who underwent keratorefractive procedures, presenting to the refractive services of a tertiary eye care hospital in South India between January 2016 and May 2019 was analyzed. Of these, the eyes that developed ectasia were noted and the possible risk factors were determined. Visual outcomes following treatment with corneal collagen crosslinking (CXL) with or without intracorneal ring segment implantation (ICRS) or topography-guided corneal ablation (T-PRK) were analyzed. **Results:** Forty eyes of 26 patients developed ectasia following keratorefractive procedures, with a mean interval of 73.1± 45.4 months between primary procedure and ectasia development. Of these, 14 patients had bilateral presentation. Identifiable risk factors included ablation depth >75 μm (59.25%), percentage of tissue altered (PTA) >40% (48.14%), residual stromal bed <300 μm (22.22%), mean refractive spherical equivalent >8 D (25.92%), inferior–superior (I–S) asymmetry >1.4D (7.40%), central corneal thickness (CCT) <500 μm (7.40%), Belin Ambrosio Display (BAD) >2.5 (7.40%), posterior float elevation maximum ≥18 μm (3.70%), and pellucid marginal degeneration (PMD; 3.70%). **Conclusion:** Our study shows that only 70% of the eyes demonstrated an identifiable risk factor for the development of ectasia. Ablation depth of >75 μm and the PTA >40% were the most common risk factors. Treatment following CXL with ICRS or T-PRK demonstrated significantly better visual outcomes in comparison with CXL alone.

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Ectasia post keratorefractive surgery occurs secondary to a noninflammatory biomechanical weakening of the cornea, with associated thinning and protrusion.[1] Reduction in visual acuity secondary to progressive myopia and irregular astigmatism ensue.[2-4] With a reported incidence of 0.02 to 0.6%,[5-7] the clinical presentation ranges from weeks to years following the surgery, with a peak incidence at 12 months.[8]

Identification and recognition of risk factors is an important step in preventing this dreaded complication. The aim of our study was to estimate the incidence of ectasia following keratorefractive procedures in our institute, identify the risk factors, and demonstrate the visual outcomes following different treatment strategies.

Methods

This retrospective observational study was conducted at a tertiary eye care hospital in South India. The study was approved by the ethics committee and adhered to the tenets of the Declaration of Helsinki. The data of 5813 patients (11573 eyes) presenting to us between January 2016 and May 2019 with a history of keratorefractive procedures was analyzed. After identifying cases of ectasia, the possible risk factors were studied. Refractive error corrected, age and sex, corneal tomographic features, type of procedure, and surgical parameters were analysed. Parameters considered as risk factors included anterior tomographic map irregularities (keratometry value >48 D or significant inferior–superior (I–S) asymmetry >1.4 D), thinnest corneal pachymetry <500 μm, early signs of corneal ectatic disorders including keratoconus or pellucid marginal degeneration (PMD), ablation depth >75 μm, residual stromal bed <300 μm, and PTA >40%. Visual outcomes following treatment for ectasia were analyzed.

Statistical analysis

Statistical Package for the Social Sciences (SPSS) software, version 22, was used for data entry and statistical analysis. In addition, student's *t*-test and Chi-square test were used. Statistical significance was defined as $P < 0.05$.

Results

Forty eyes of 26 patients (14 males and 12 females) developed ectasia following keratorefractive procedures, with an incidence of 0.34%. Of these, 14 patients had bilateral presentation. The mean age at primary surgery was 22.07 ± 3.66 years.

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Preoperative data was further analyzed for 27 eyes, wherein complete records were available. Table 1 represents the preoperative and intraoperative patient data for this subset. The choice of surgical procedures included microkeratome laser *in situ* keratomileusis (LASIK) in 17 eyes (42.5%), femtosecond LASIK in 5 eyes (12.5%), small incision lenticule extraction (SMILE) in 2 eyes (5%), and transepithelial photorefractive keratectomy (PRK) in 3 eyes (7.5%). The mean duration of clinical presentation of ectasia from the time of surgery was 73.1 ± 45.4 months, with a minimum interval of 10 months and maximum interval of 12.2 years. Of the remaining 13 eyes (32.5%), no preoperative data was available as they were operated elsewhere and presented to our institute following the development of ectasia.

Table 2 demonstrates the risk factors for the development of ectasia in the same subset. Ablation depth of >75 µm (59.25% eyes) and percentage of tissue altered (PTA) >40% (48.14% eyes) were the most common risk factors. No identifiable risk factor was demonstrated in eight eyes (29.62%). Fig. 1a demonstrates the preoperative corneal tomography of a 27-year-old, showing with the rule astigmatism, regular pachymetry distribution, no abnormal float elevation, and a normal Belin Ambrosio Display (BAD) map [Fig. 1b]. She underwent femtosecond-assisted LASIK correction for a refractive error of −2.75D sphere with −1.25D cylinder * 140°. Fig. 1c demonstrates corneal ectasia at the 3-year follow-up visit.

Table 1: Preoperative and intraoperative parameters (*n*=27)

Parameter	Mean±SD
Preoperative CDVA (Log MAR)	0.07±0.02
Mean refractive spherical equivalent (D)	6.24±2.85
Maximum keratometry (D)	45.16±2.09
I–S asymmetry (D)	0.6±0.6
Posterior float elevation maximum (5 mm zone)	10.6±4.3
CCT (µm)	531.6±25.9
BAD	2.06±1.08
Residual stromal bed (µm)	323.6±34.8
Ablation depth (µm)	91.1±32.4
Flap thickness (µm)	112.2±26.5
PTA (%)	38.15±7.20

Preop=Preoperative, SD=Standard deviation, CDVA=Corrected distance visual acuity, D=Diopters, I–S=Inferior–superior, CCT=Central corneal thickness, BAD=Belin Ambrosio Display, PTA=Percentage of tissue altered

Table 2: Risk factors for ectasia post keratorefractive surgery

Risk factor	Number of eyes (%)
MRSE >8 D	7 (25.92)
Maximum keratometry >48 D	2 (7.40)
I–S asymmetry >1.4D	1 (3.70)
Posterior float elevation maximum ≥18 µm	2 (7.40)
Central corneal thickness <500 µm	2 (7.40)
BAD >2.5	3 (11.11)
Ablation depth >75 µm	16 (59.25)
Residual stromal bed <300 µm	6 (22.22)
PTA >40%	13 (48.14)
PMD	1 (3.70)
Pregnancy	1 (3.70)
Enhancement procedure	1 (3.70)
Nil	8 (29.62%)
Total number of eyes	27 (100%)

MRSE=Mean refractive spherical equivalent, D=Diopters, I-S=Inferior-superior, BAD=Belin Ambrosio Display, PTA=Percentage of tissue altered, PMD=Pellucid marginal degeneration

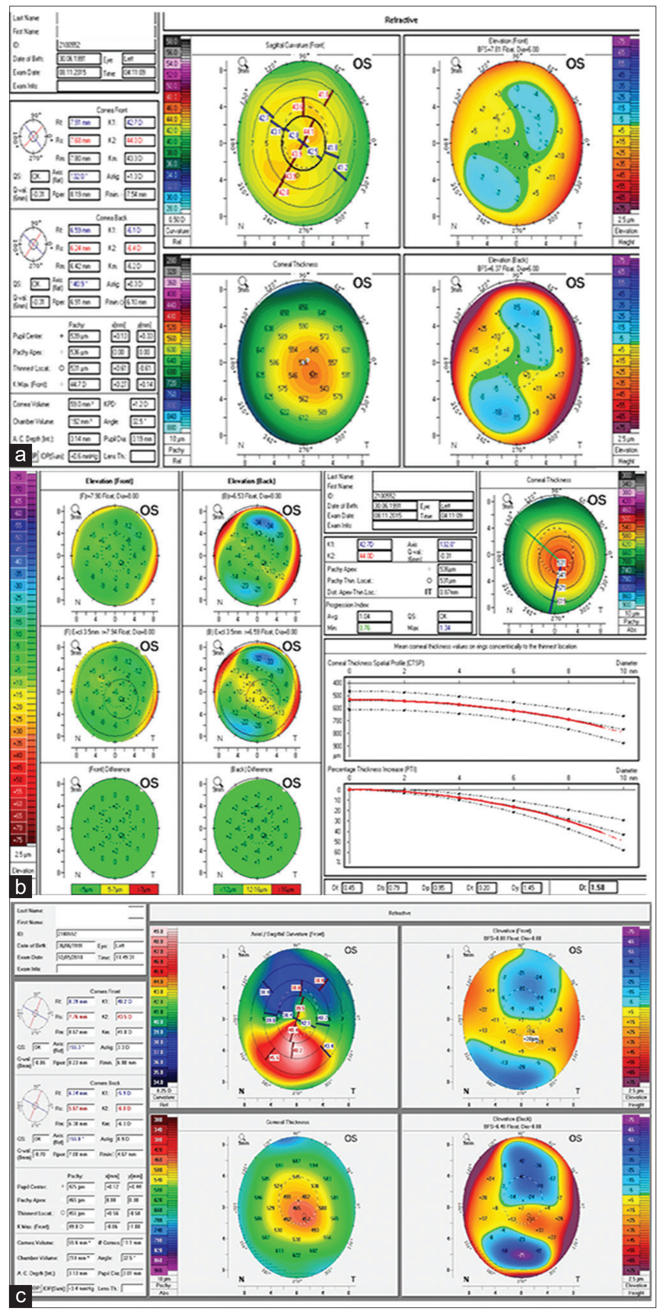

Figure 1: Preoperative corneal tomography (a) and Belin Ambrosio Display (b) of a 27-year-old who underwent femtosecond-assisted LASIK correction for a refractive error of −2.75D sphere with −1.25D cylinder *140 degrees (c) demonstrates corneal ectasia at the 3-year follow-up visit

Table 3: Visual and topographical outcomes following treatment

Parameter		CXL only	Topoguided PRK + CXL	ICRS + CXL	No follow-up
Number of eyes (%)		24 (60)	6 (15)	6 (15)	4 (10)
BSCVA	Preop	0.11±0.19	0.05±0.0	0.57±0.14	
	Postop	0.09±0.16	0.04±0.04	0.15±0.15	
	P	0.057		0.03	
Refractive cylinder	Preop	−2.04±1.49	−1.00±0.20	−4.25±1.28	
	Postop	−2.00±1.42	−0.50±0.40	−1.91±0.96	
	P	0.45		0.008	
MRSE	Preop	−2.96±2.56	−1.24±0.26	−4.08±1.85	
	Postop	−2.60±2.3	−0.76±0.47	−2.95±1.06	
	P	0.10		0.05	
K Max	Preop	49.9±5.1	48.3±3.2	56.6±4.48	
	Postop	49.7±4.32	44.7±1.10	49.9±1.92	
	P	0.15		0.02	
I-S asymmetry	Preop	6.3±3.9	5.4±2.1	5.0±3.0	
	Postop	5.3±3.3	1.4±0.6	3.2±1.7	
	P	0.08		0.03	

BCSVA=Best-corrected spectacle visual acuity, MRSE=Mean refractive spherical equivalent, K max=Maximum keratometry; I-S=Inferior-superior, Preop=Preoperative, Postop=Postoperative, CXL=Corneal collagen crosslinking, PRK=Photorefractive keratectomy, ICRS=Intracorneal ring segments

The patients underwent treatment with corneal collagen cross-linking (CXL) alone (24 eyes) or in combination with topography-guided PRK (6 eyes) or intracorneal ring segment (ICRS) insertion (6 eyes). Four eyes were lost to follow-up. Table 3 demonstrates the clinical outcomes following treatment. The concomitant use of intracorneal ring segments or topo-guided corneal regularization resulted in significantly greater keratometry flattening, corneal regularization, and reduction in mean refractive spherical equivalent in comparison with CXL alone.

Discussion

Reduction in biomechanical strength following keratorefractive procedures may result in ectasia in eyes with subtle tomographical abnormalities or those yet to manifest these features. Additionally, deeper ablation profiles may result in loss of biomechanical integrity beyond the safety threshold in an otherwise normal cornea.[9-11] Therefore, it is imperative to gain a comprehensive understanding of the possible risk factors, to aid in preoperative decision making.

Deep ablation and an increased PTA were the most common risk factors in our cohort. Higher dioptric correction entails deeper ablation with myopia >8 D as an established risk factor for ectasia development.[12] Preoperative refractive errors >8 D and an ablation depth >75 μm were demonstrated in 7 and 16 eyes, respectively. Tartar and coworkers demonstrated deep stromal ablation as the most common risk factor (23.8%), wherein a myopic error of >8D was noted in 19.04% eyes.[13]

However, isolated myopia without topographical abnormalities has a lower risk of ectasia development vis-à-vis increase in the PTA.[10,14] In our study, 48.14% of the patients demonstrated a PTA >40%.

Preoperative corneal pachymetry <500 μm and a residual stromal bed <300 μm are other risk factors for ectasia development.[15] Bohac and colleagues demonstrated a preoperative corneal thickness <500 μm as the most common risk factor in their cohort.[16]

Keratorefractive surgeries in eyes with preexisting abnormalities like forme fruste keratoconus (FFKC) and PMD results in further loss of biomechanical integrity, and ectasia ensues.[17,18] Brenner and coworkers demonstrated FFKC in 58 of the 77 eyes (75.3%) with ectasia.[19] Ambrosio and Wilson[20] reported post LASIK ectasia in 2 patients with early PMD. Epithelial thickness mapping with localized thinning at the area of the cone is a useful diagnostic modality for the early detection of ectasia.[21]

One patient in our cohort developed bilateral ectasia post SMILE. Preoperative tomography demonstrated steep corneas with a maximum keratometry >49D, early posterior float elevation in one eye and a high spherical equivalent of 9.25D in the other eye. Although, the biomechanical superiority of SMILE over LASIK is attributed to stromal tissue removal at the deeper layers,[22] the risk factors for ectasia should be applied uniformly to both procedures nonetheless.

Eight eyes in our cohort demonstrated no identifiable risk factors for the development of ectasia. Thus, a deeper knowledge of the ectasia development process and initial inciting factors is necessary to develop a better understanding for selecting patients that could safely undergo keratorefractive procedures.

Management and subsequent visual recovery of eyes with keratectasia is crucial. Corneal collagen cross-linking allows the arrest of the disease process by strengthening the remaining anterior and central stroma.[23,24] However, it does not allow a significant reduction in spherical equivalent and keratometry or improvement in visual acuity.[25]

Kymionis and coworkers reported significant improvement in corrected and unaided visual acuity using simultaneous customized topography-guided surface ablation with collagen cross-linking.[26] Similar results were demonstrated in our study with an improvement in CDVA from Log MAR 0.10 ± 0.01 to 0.07 ± 0.03. The use of intracorneal ring segment implants (Intacs and KeraRings) significantly reduces coma-like aberrations and astigmatism in ectatic irregular corneas.[27] There was a significant improvement in mean CDVA from Log MAR 0.57 ± 0.14 to 0.09 ± 0.02 and also a significant reduction in cylindrical error ($P < 0.05$) in our study. Longer follow-up may be needed following the management of ectasia to assess stability and long term visual outcomes in these patients.

Conclusion

Our study demonstrates the risk factors for development of ectasia following refractive surgery in the Indian population, which could play a major role in cautiously analyzing and choosing ideal candidates for LVC. Moreover, the study provides data on the various management options that would be crucial for the recovery of vision in patients who have had this rare but dreaded complication post laser vision correction.

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Conflicts of interest

There are no conflicts of interest.

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