



Perry S Binder

Risk factors for post-LASIK ectasia remain ambiguous

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in London

THE primary take home message from an analysis investigating ectasia after laser refractive surgery is that eyes can have "risk factors" and not develop ectasia, according to Perry S Binder MS, MD, La Jolla, California.

Dr Binder delivered a keynote address on ectasia after lamellar refractive surgery during the XXIV Congress of the ESCRS. He analysed his personal series of more than 10,000 LASIK cases performed since October 1995 and identified eyes with any one of the following five features that are currently accepted as risk factors for ectasia after LASIK: residual bed thickness less than 250 microns; keratometry steeper than 47.5 D; age under 25 years; central corneal thickness less than 500 microns; and against-the-rule astigmatism.

Each subgroup included between 137 and 473 eyes, of which up to 20% had an enhancement. Mean follow-up durations were reasonable, exceeding eight months in all subgroups and approaching one year in some. However, there were no cases of ectasia within any of the subgroups, even among eyes that had multiple risk factors.

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"There has been a lot of interest in ectasia worldwide because it is a lose-lose situation for both patients and surgeons. However, I believe there are too many holes in available literature reports to allow risk factors to be conclusively defined. Likely, there are other variables that are not measured or that we don't know how to measure that account for this complication," said Dr Binder.

He added, "Any of the current recommendations for safe patient selection are guesswork and unproven. The best we can do is to carefully

examine patients before surgery so to rule out those having topographic abnormalities of forme fruste keratoconus or pellucid marginal corneal degeneration and to carefully evaluate flap dimensions intraoperatively, especially central flap thickness. Those strategies should reduce the number of ectasia cases, but will not completely eliminate them because there are eyes that will go on to develop ectasia in the future whether they are operated on or not."

Given the uncertainty regarding risk factors, Dr Binder also suggested that a surgeon operating on a cornea with a 500-micron central corneal thickness or other purported ectasia risk factors is not guilty of malpractice. Nevertheless, he emphasised the importance of a thorough informed consent.

Long-term review

Dr Binder's retrospective review identified 402 eyes with a central corneal thickness less than 500 microns (mean 486, range 402-500). Those eyes had a mean follow-up of 11.6 months. Mean±SD flap thickness for those eyes was 114±28 microns. The mean attempted correction was for an SE of -3.66 D, and 62 eyes had an enhancement. In addition, he had 224 eyes with a residual stromal thickness of 250 microns or less (mean 236 microns, range 102-250 microns). Mean flap thickness in these eyes was 153±26 microns, mean attempted SE correction was -7.33 D, and 43 eyes underwent enhancement.

There were 137 eyes with a K value steeper than 47.5 D (mean 47.9, maximum 50.81). That group had mean follow-up of 10.8 months, mean attempted correction of -5.26 D, and included 27 eyes that were enhanced. In the category of eyes in patients younger than 25 years old, there were 473 eyes of patients who had an average age of 23 years and a minimum age of 18. Mean follow-up was 8.3 months, mean flap thickness was 127±27 microns, mean attempted correction was -4.50 D, and 58 were enhanced.

"This subgroup also included 32 eyes that had more than one risk factor, and still there were no cases of ectasia," Dr Binder noted.

The analysis of eyes with against-the-rule astigmatism included those with less than -1.00 D SE and 1.00 D or more of plus cylinder in the horizontal meridian. A total of 259 eyes met those criteria and all had a minimum of 2 D of astigmatism. Mean follow-up was around 10 months and the eyes had mean sphere and cylinder values of -2.85 D and 2.6 D, respectively.

List of red flags growing

The five ectasia risk factors that Dr Binder used for his analysis were among the features identified in a recent study by Randleman and colleagues at Emory University in Atlanta. Those researchers used multivariate statistical techniques to analyse data from a series of 115 eyes that developed ectasia after LASIK and controls that underwent uneventful LASIK.

Other characteristics identified by Randleman and colleagues as being associated with an increased risk of ectasia included high myopia, enhancement surgery, and a posterior float greater than 0.55 microns on Orbscan. Avoiding resection of more than 18% of total cornea thickness, not cutting deeper than 50% of corneal thickness, and pre-operative coma RMS below 0.7 microns have also been suggested as safety guidelines for reducing ectasia risk.

"These recommendations represent opinion and remain unproven," Dr Binder said.

Dr Binder noted that many case reports describing eyes that developed ectasia post-LASIK are notable for their absence of intraoperative pachymetry data.

"Interestingly, among the 115 eyes with post-LASIK ectasia in the report by Randleman et al., some had none of the identified risk factors. However, only one of the eyes reported in their series of eight with no risk factors underwent intraoperative pachymetry," Dr Binder said.

The relevance of that observation is that until recently the thicknesses of flaps produced by available mechanical microkeratomes were characterised by a wide range.

"Therefore, it is likely that some eyes developing post-LASIK ectasia had thicker than expected flaps and a very thin residual stromal thickness combined with high attempted corrections that probably led to the ectasia," he said.

However, refractive surgeons should also recognise that due to the meniscus shape of flaps cut with a mechanical microkeratome, there are limitations associated with relying on intraoperative pachymetry to determine flap thickness, Dr Binder pointed out.

"The thickness at the centre of the flap is not predictive of thickness in the periphery, and peripheral readings vary more than central readings. Practically speaking, a flap that measures 160 microns at the centre can be as thick as 230 to 240 microns at its margin, which means the microkeratome has cut through more lamellae peripherally and caused greater

biomechanical weakening of the cornea," Dr Binder explained.

Historic basis of current recommendations

Historically, varying recommendations have been made regarding what represents a safe threshold for residual stromal thickness. After observing ectasia developing in 45 (2.8%) of 1,608 eyes that underwent myopic keratomileusis (MKM) but in no eyes that had keratophakia, Jose Barraquer, MD, suggested that when performing MKM, a residual stromal thickness of 300 microns represented a safe limit. He also recommended against performing MKM on eyes with a pre-operative pachymetry less than 450 microns.

"However, Barraquer's conclusions were based on a series of eyes for which there was no pre-operative or intraoperative pachymetry data or any pre-operative topography. Histopathology was consistent with keratoconus, and pre-operative keratoconus or forme fruste keratoconus was not ruled out," Dr Binder noted.

Luis Ruiz MD, developed the use of anterior lamellar keratoplasty to create a "controlled ectasia" for treating hyperopia. From his experience operating to depths up to 450 microns and with discs ranging from 4.0 to 6.0mm in diameter, Dr Ruiz concluded that very deep, small diameter incisions create ectasia, and that a residual stromal thickness below 150 microns is a major risk factor.

Subsequently, 200 microns, 250 microns, and, most recently, 300 microns have been recommended as thresholds for residual stromal thickness. Dr Binder noted he currently targets 300 microns for his residual stromal thickness. Even so, he believes residual stromal thickness is not the entire story.

"My series included more than 200 eyes with a residual stromal thickness less than 250 microns and some of those had a residual stromal thickness under 200 microns. However, none has gone on to develop ectasia. Furthermore, we know ectasia can occur in post-PRK eyes even though that surface ablation procedure leaves a residual stromal thickness that well exceeds 250 microns," Dr Binder said.

"It is likely that the final word is still out regarding a true safe limit. Depending on flap diameter and the intrinsic biomechanical stability of a given cornea, perhaps 300 microns may not be safe," he explained.

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