Another Surprise From Radial Keratotomy

Radial keratotomy has a penchant for surprises. The first major surprise staggered Japanese surgeons in the 1960s when corneal edema appeared 20 years after the anterior-posterior keratotomy of Sato. Universal ignorance about the function of the corneal endothelium in the 1940s and early 1950s prevented them from foreseeing this devastating complication.

A second unanticipated factor emerged gradually in the 1970s and 1980s: most of the central corneal flattening occurs from the first few incisions. As a result, the number of incisions commonly used has fallen from 32 to four. Our general ignorance of corneal biomechanics was at fault here.

A third unexpected phenomenon has now surprised refractive surgeons; radial keratotomy has a continued effect over many years in approximately one of five patients.

First described by Deitz and Sanders as a change in refraction of +1.00 diopter or more in 31% of cases,1,2 this phenomenon has been confirmed during 4 to 5 years of follow-up by the Prospective Evaluation of Radial Keratotomy (PERK) study (23%) Arrowsmith and Marks (22%),3 Neumann et al (26%),4 Ivanova and Fyodorov over a 12-year follow-up (paper presented at Second International Cataract, Implant, Microsurgical and Refractive Keratoplasty Meeting, Nagoya, Japan, July 1 to 3, 1988), and by Sawelson and Marks in this issue of Refractive and Corneal Surgery (pages 8-20, see Table 7). This unsettling circumstance raises a number of questions.

What Should We Call This Phenomenon?
The original appellation “progressive hyperopia” is inappropriate because it suggests that only hyperopes are affected; an undercorrected person whose postoperative refraction gradually changes from −3.00 to −1.50 D is not experiencing “progressive hyperopia.” A similar, more acceptable designation is “a change in the hyperopic direction.” The PERK investigators described it as “a decrease in minus power,” which is certainly appropriate for the individual with myopia and is technically correct—albeit a bit misleading—for the hyperope whose refraction changes from a +1.00 to +2.50 D. I like the term “a continued effect of the surgery,” because it signifies what is happening without reference to a specific refractive error.

Was A Continued Effect of Radial Keratotomy Anticipated?
Not at all. Indeed, in the late 1970s and early 1980s, some ophthalmic gurus predicted that the cornea had memory and would return to its original shape. Others assumed that when wound healing was complete, the cornea would lock into a new shape. No one mentioned a continued effect of the surgery over years.

How Clinically Meaningful Is the Continued Effect?
A change of 1 D or more is certainly meaningful; most individuals under normal circumstances would buy new spectacles or contact lenses to adjust. The reported range of changes is from 1 to 4 D between approximately 1 and 5 years after surgery. This is particularly meaningful if the individual is emmetropic or hyperopic soon after surgery and becomes increasingly hyperopic, experiencing earlier symptomatic presbyopia and more difficulty with distance vision. Deitz reported at the meeting of the International Society of Refractive Keratoplasty in November 1988 a series of individual cases with continued effect of the surgery during 7 years. One was a 40-year-old woman with the following spherical equivalent refractions: preoperative, −7.75 D; 6 months, plano; 1 year, +.50 D; 3 years, +1.50 D; 5 years, +2.25 D; 7 years, +3.25 D. That’s clinically meaningful. Of course, if the person is undercorrected, the continued effect is a boon—as long as they don’t pass emmetropia.

Who Is Affected?
Studies report the phenomenon in 13% to 31% of the cases. The problem is, there is no way before surgery to distinguish those who will show a continued effect from those who stabilize. Multiple regression analysis in the Deitz and Sanders studies failed to correlate the phenomenon with patient age, the amount of preoperative myopia, the number of incisions, the diameter of the clear zone, or the depth...
of the incision. Sawelson and Marks and the PERK investigators found that eyes with longer and deeper incisions have greater tendency for more prolonged change.

When Will the Continued Effect Stop?

No one knows. After the phenomenon was described and verified, there was a general assumption that it was somehow related to the slow wound healing of the unsutured corneal incisions, so that when the incisions finally healed, corneal curvature would stabilize. This was projected to be around 4 to 5 years after surgery, since that is when the feathering and remodeling of the scars disappear and when the epithelial plug seems to be expelled from most of the wounds. Sawelson and Marks suggest stability at 3 years, but do not provide clear evidence for this opinion. Neumann et al found the same average change between 1 and 3 years (+0.27D) and 3 to 5 years (+0.30D). The unpublished observations of Deitz that describe changes at 7 years, and of Fyodorov up to 12 years, document that the effect may continue for many years.

How Does the Phenomenon Affect Clinical Practice?

First, all patients considering radial keratotomy must understand that they have roughly a one in five chance of experiencing a progressively unstable refractive error for some years after surgery, a fact that makes the outcome even more unpredictable. Second, this is a good basis for the practice of many surgeons who try to leave patients slightly undercorrected. Third, the phenomenon cries out for further study and documentation, particularly by authors such as Sawelson and Marks, who have commendably and consistently reported findings over 4 to 5 years after surgery. Finally, this surprise is another stern reminder for refractive surgeons to eschew sweeping exaggeration of early good results. Rather, a cautious, critical attitude must persist for years in evaluating any new refractive surgical procedure.

A similar surprise scuttled the high hopes for myopic epikeratoplasty when investigators found a progressive loss of the effect of the surgery over a period of years. This was one of the major reasons for the Food and Drug Administration Ophthalmic Advisory panel's recommending that myopic epikeratoplasty be retained on core study and for Allergen Medical Optics' decision to stop study of human myopic lenticules.

Surprises will continue to occur in all fields of refractive surgery; they will be detected earliest when these procedures are evaluated in formal prospective clinical trials with honest, prompt reporting of unanticipated findings based on many years of long-term follow-up.

References

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