Opportunities for More Rational Assessment of Refractive Corneal Surgery

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This issue of Refractive and Corneal Surgery contains two new, unique contributions that portend hope for a broader, more rational assessment of refractive corneal surgical procedures. The first is the guidelines promulgated by the Food and Drug Administration (FDA) concerning excimer laser corneal surgery. The second is the direct comparison of series of cases using different surgical techniques (epikeratoplasty, keratomileusis, minus power anterior chamber intraocular lenses) by individual surgeons, Joseph Colin, MD and Georges Baikoff, MD.

Assessing Laser Corneal Surgery

Like so many technological developments in ophthalmology, including intraocular lenses and radial keratotomy, development of excimer laser corneal surgery has spawned tumultuous economic and scientific competition, replete with public relations hype, overly optimistic premature disclosure of results, lawsuits, and patent interferences. Hopefully, in assessing excimer laser corneal surgery, we can avoid some of the problems that have plagued new anterior segment surgical techniques. We can avoid the high volumes of investigational techniques such as closed loop anterior chamber intraocular lenses that proliferated because of the FDA policy of allowing unrestricted use of the lenses in adjunct studies, spawning another wave in the epidemic of pseudophakic corneal edema. We can avoid the free-for-all public claims and counterclaims that characterized the development of radial keratotomy in the United States. We can avoid premature claims of success, as occurred with epikeratophakia for myopia. As of 1990, much of the confusion and litigation surrounding these procedures has subsided, each finding its place among the surgeon's resources in the management of refractive problems.

What will spare us this conundrum as we evaluate excimer laser corneal surgery? First, because the technology is complex and expensive, fewer companies offer systems for clinical use and fewer ophthalmologists are buying them. This reduces the overall incentive for intense marketing by industry and decreases the personal and financial vested interest that ophthalmologists will have in the field. Indeed, the recent amalgamation of the Visx Corporation and Taunton Technologies leaves only two companies in the United States—Summit Technology being the other—that offer excimer laser units for clinical ophthalmic surgery. One or two other companies are developing lasers for corneal surgery, but clinical units are not available. The smaller number of companies may decrease competitive pressures in the marketplace and therefore allow more emphasis on research and development in both the laboratory and the clinic.

Second, because the community of individuals with direct involvement in excimer laser corneal surgery is relatively small, there is increased potential for scientific and personal communication. One of the forums for such communication has been the International Corneal Laser Society (ICLS), which was established in November 1987 as a workshop group. This society has no officers or dues. Its biannual meetings are characterized by brisk exchanges, with presentations limited to "5 minutes and 5 slides" followed by lengthy discussion. ICLS has held five meetings, during the American Academy of Ophthalmology and the Association for Research and Vision in Ophthalmology meetings and will sponsor along with Emory University the more formal Third International Congress on Corneal Laser Surgery, in Atlanta, November 2-3, 1990.
immediately following the American Academy of Ophthalmology meeting.

Recently, the society decided to avoid establishing itself as another free standing organization with the attendant bylaws, officers, dues, meetings and attorneys, and voted to become a section of the International Society of Refractive Keratoplasty (ISRK). More about this in a subsequent issue of Refractive and Corneal Surgery. The society will continue to provide a forum for honest, down-to-earth and realistic personal and scientific assessments of excimer laser corneal surgery.

The third factor that will encourage more rational assessment of excimer laser corneal surgery is regulation by the FDA. The Ophthalmic Devices Division, with the help of the members of the Ophthalmic Devices Advisory Panel have propounded some detailed guidelines for clinical assessment of excimer laser corneal surgery. The draft FDA guidelines for clinical testing in humans is published in this issue. The FDA's insistence on more detailed assessment of the technology will provide more substantive scientific and clinical information which will allow more rapid accumulation of definitive information. The FDA's encouragement that companies and investigators establish uniform standards for testing these lasers will also accrue to the advantage of the profession, since direct comparison of different units and different techniques will then be possible, avoiding protracted confusion.

In a previous editorial, I made a plea for establishing uniform standards for reporting results of refractive corneal surgical procedures: excimer laser corneal surgery is a perfect place to employ these "bare minimum" standards. Reports should include a measure of the relationship of refraction and visual acuity, such as the visual function score. This approach benefits everyone: investigators, patients, manufacturers, insurance companies and government agencies. The only people who lose are those who wish to obfuscate their results by creating different patterns or categories of reporting in order to make their instruments and procedures look better than they really are. Of course, whenever there is government regulation and intervention, the specters of bureaucratic delay, unnecessary complexity, nit picking over irrelevant details, and constraint of business sales and surgical volume all emerge. However, the Ophthalmic Devices Division actively seeks communication, preplanning input and periodic assessment from both industry and ophthalmic practitioners, so that our destiny is to some degree in our own hands.

Unfortunately, refractive surgery has always been tagged with an aura of excessive entrepreneurship. Here, at last, is an opportunity for everyone involved in the field of excimer laser surgery to dispel this image and to bring honest, forthright, rational and scientifically and medically responsible methods to the assessment of this potentially beneficial and lucrative technology.

Comparing Reative Surgical Procedures

One of the major problems in evaluating refractive surgical procedures is the lack of direct comparative information. There have been no prospective randomized clinical trials comparing different refractive surgical procedures, so the ophthalmic community is left with the challenge of comparing results from disparate studies done by different surgeons and presented in a way that makes direct comparison difficult.

In this issue, two surgeons report their personal experience with consecutive series of cases using different techniques; Colin comparing myopic epikeratoplasty, myopic keratomileusis and minus power anterior chamber intraocular lenses in phakic eyes, and Baikoff comparing myopic epikeratoplasty with minus power anterior chamber intraocular lenses in phakic eyes. Each study is retrospective and lacks the direct comparative rigor that would characterize a formal prospective trial. Nevertheless, the comparative information generated by one surgeon allows a more direct comparison of the results than that achieved by comparing reports from different centers with different techniques. The need for such comparative studies is pressing, as the number of refractive corneal surgical techniques increases.

Rational Assessment and Caution: IOLs and Corneal Endothelial Damage

As Fechner emphasizes in his editorial comment, the specter of corneal endothelial cell damage from the anterior chamber intraocular lenses is an ominous one. In fact, reports from Baikoff and colleagues, Colin and colleagues, and Saragossi and colleagues at the meetings of the American Society of Cataract and Refractive Surgery, the French Society of Ophthalmology, and the International Congress of Eye Research forthrightly report the discouraging findings of a rim of endothelial cell damage in the paracentral and peripheral cornea overlying the outer edge of the anterior chamber intraocular lens optic. Presumably, there has been contact between the implant and the cornea, either from eye rubbing or during specular microscopy, that has induced endothelial cell damage with increased density and increased cell size. The cell loss is highly variable from one patient to another and from one area of a cornea to another. The majority of implanted eyes is affected, and elective explantation of some lenses has occurred. Implantation of the present model of the intraocular lens has apparently stopped, and investigation of new designs with less vault and less thick optic edge, as well as more stringent case selection limited to patients with deep anterior chamber, are underway. Apparently, no frank corneal edema has
Guest Editorial

Intraocular Lenses for the Correction of Myopia in Phakic Eyes: Short-Term Success and Long-Term Caution

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The guest editorialist enjoys a freedom not available to authors and editors; he is free to profess his personal point of view and biases. In that vein, I confess that during the majority of my professional career, I considered myopia neither a disease nor a blemish, since it is correctable with glasses or contact lenses. However, in 1986, I became involved with attempts to correct high myopia by the implantation of concave intraocular lenses into the phakic eye. This experience fostered my humane attachment to many myopic patients and taught me a worthwhile lesson: Individuals with myopia of 10 diopters or more, if they are contact lens intolerant, are often deeply unhappy human beings, conscious of their impediment in both their occupational life and their personal environment. They consider themselves members of a rejected minority whose visual handicap is little appreciated by their fellow men. The degree to which they suffer becomes obvious once they experience a cure, as expressed in a typical letter, “Every morning when I open my eyes, I feel reborn, that my real life started just now.” In other words, I think myopia is a disease because it is a physical state causing deep unhappiness. It is certainly a legitimate ethical aim of the ophthalmic profession to attempt a cure for myopia, provided it can be done safely with a reasonable degree of risk.

This issue of Refractive and Corneal Surgery contains two reports on this subject, one by Colin and colleagues and the other by Baikoff and Joly. The authors compare three important surgical methods of treating myopia: epikeratoplasty, keratoconus, and corneal collagen cross-linking.

REFERENCES

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