The Expanding Field of Refractive Surgery

Refractive surgery is a very new but rapidly developing and expanding field of surgery that promises to be one of the most exciting and interesting areas in ophthalmology over the next few years.

Although there are several aspects to refractive surgery, the most controversial has been the development of radial keratotomy. This work was initiated in Japan many years ago by the brilliant Japanese academician, T. Sato, MD. Sato found that he could reduce myopia by making cuts on both the anterior and posterior surfaces of the cornea in a way generally similar to the radial keratotomy procedure of today, except that the present procedure does not involve posterior incisions. Unfortunately, in the case of Sato's patients, a significant proportion developed bullous keratopathy and blindness 20 years after the initial surgery.

More recently, the general principles of radial keratotomy were revived and modified by Fyodorov and his co-workers. Fyodorov found that simply making cuts into the anterior corneal surface permitted the sides of the cornea to bulge and the top to flatten, thereby reducing myopia. Serious controversy developed after the introduction of this procedure because there were virtually no animal experiments to document safety and efficacy, and the objectivity and completeness of followup of Fyodorov's experience was uncertain to American ophthalmologists.

The controversy, lawsuits, and other problems surrounding this procedure seemed to me to represent a low point in the morals and ethics of American ophthalmology, ie, that physicians would sue their colleagues for expressing legitimate doubts about a new procedure. Nevertheless, objective studies in which a large proportion of ophthalmologists could have confidence have been done, and many of the fears that once seemed justifiable about the radial keratotomy procedure now seem unlikely.

Although the results become relatively unpredictable above four or five diopters of correction, below that the predictability rate is fairly good, and the procedure seems safe when done carefully according to well worked out standards. Radial keratotomy represents a kind of surgery that can treat a very large number of low myopes around the world. If safety, efficacy, and the degree of correction can be predicted, this procedure will bring refractive surgery to large numbers of practicing ophthalmologists, who can easily perform this surgery if they wish.

Along the same lines, some 25 years ago in Bogota, Colombia, Barraquer began developing operations to modify corneal shape. The operations he developed were keratomileusis and keratophakia. Although the precision of the correction was uncertain and the actual incidence of complications not absolutely clear, there was no question that Barraquer could correct myopic and hyperopic optical errors within certain limitations, and that his procedures were effective.

As Barraquer developed them, however, the surgical techniques were complex. Requirements included a microkeratome with a series of suction rings, the elevation of the intraocular pressure to 65 mmHg, and the precise removal of a disk of cornea. In the original procedures, computer calculations were performed after a series of complex measurements, and then the new tissue was lathed to the precise description and sewed onto the patient's cornea. This procedure was clearly effective, but difficult for the average ophthalmic surgeon.

From the LSU Eye Center, Louisiana State University Medical Center School of Medicine, New Orleans, Louisiana.
Reprints requests: Herbert E. Kaufman, MD, LSU Eye Center, 136 South Roman Street, New Orleans, Louisiana 70111.
The development of the ability to pre-shape and preserve the donor tissue was followed by the evolution to the epikeratoplasty procedure, which does not require the microkeratome and seems to be both safe and reversible. Such newer procedures bring an exciting new era to the surgical correction of myopia, as well as hyperopia, and herald the possibility of a future in which any well trained ophthalmic surgeon can participate in this kind of refractive surgery.

Today, investigators are turning their attention to the correction of astigmatism, in addition to refractive error. Earlier methods—relaxing incisions or wedge resections—were employed for post-penetrating keratoplasty astigmatism, but their results were only approximate. Trapezoidal astigmatic keratotomy, a new pattern of incisions for the correction of astigmatism, has been developed by Ruiz. Present development of this procedure is focused on quantitating the results; however, the precision and reproducibility of the corrections are not yet absolutely clear.

Similarly, toric epikeratoplasty lenses are being developed; these can be sewn on the eye to precisely correct astigmatism independent of possible variations in patient healing. This technique is experimental, however, and although it is exciting and appears to be working, it is too early to be certain of its ultimate utility.

Finally, for the future, there is the possibility of using alloplastic implants and inclusions in the cornea. This would be particularly valuable in that the surgery might be simpler, donor tissue might not be required, and precise corrections may be obtainable. At present, the field is somewhat restricted. Experimental studies on plastic implants have sometimes shown corneal clouding and complications many months, or even a year or more, after the implantation. Animals need to be followed for a very long time to ensure the safety of these implants.

However, whether such implants are in the class of HEMA implants, which have a refractive index nearly the same as the cornea and require a change in corneal shape, or whether they might be substances such as the polysulfones, which have a high refractive index and can incorporate significant refractive changes without much change in the corneal shape, this is an area that has great potential and certainly needs to be explored.

In all, the era of refractive surgery has arrived. It is an era that will not be limited to only a few specialized ophthalmologists, but one in which all ophthalmic surgeons may participate if they wish. It is with this bright view of the future that we initiate this new journal.

Herbert E. Kaufman, MD
President, International Society of Refractive Keratoplasty

Journal of Refractive Surgery

Prednisolone acetate in a combination. Poly-Pred® (prednisolone acetate, neomycin sulfate, polymyxin B sulfate)

Liquidfilm® sterile ophthalmic suspension

INDICATIONS AND USAGE: A steroid/anti-infective combination is indicated for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where bacterial infection or a risk of bacterial ocular infection exists.

Ocular steroids are indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe where the inherent risk of steroid use in certain infective conjunctivitides is accepted to offset a potential for enhancing ocular inflammation. They are also indicated in chronic anterior uveitis and corneal injury from chemical radiation, thermal burns, or penetration of foreign bodies.

The use of a combination drug with an anti-infective component is indicated where the risk of infection is high or where there is an expectation that potentially dangerous numbers of bacteria will be present in the eye.

The particular anti-infective drugs in this product are active against the following common bacterial eye pathogens: Staphylococcus aureus; Escherichia coli; Hemophilus influenzae; Klebsiella Enterobacter species; Neisseria species; and Pseudomonas aeruginosa.

The product does not provide adequate coverage against: Serratia marcescens; Streptococci including Streptococcus pneumoniae.

CONTRAINDICATIONS: Epithelial herpetic simplex keratitis (idiotic keratitis), vaccinia, varicella, and many other viral diseases of the cornea and conjunctiva. Mycobacterial infection of the eye. Fungal diseases of the ocular structures. Hypersensitivity to a component of the medication. (Hypersensitivity to the antibiotic component occurs at a higher rate than for other components.)

The use of these combinations is always contraindicated after uncomplicated removal of a corneal foreign body.

WARNINGS: Prolonged use may result in glaucoma, with damage to the optic nerve. Defects in visual acuity and fields of vision, and posterior subcapsular cataract formation. Prolonged use may suppress the host response and thus increase the hazard of secondary ocular infections. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids in acute purulent conditions of the eye. Steroids may mask infection or enhance existing infection. If these products are used for 10 days or longer, intracocular pressure should be routinely monitored even though it may be difficult in children and uncooperative patients.

Employment of a steroid medication in the treatment of herpetic simplex requires great caution.

There exists a potential for neomycin sulfate to cause cutaneous sensitization. The exact incidence of this reaction is unknown.

PRECAUTIONS: The initial prescription and renewal of the medication order beyond 20 milliliters should be made by a physician only after examination of the patient with the aid of magnification, such as slit lamp biomicroscopy, and, where appropriate, fluorescein staining. The possibility of persistent fungal infections of the cornea should be considered after prolonged steroid dosing.

ADVERSE REACTIONS: Adverse reactions have occurred with steroid/anti-infective combination drugs which can be attributed to the steroid component, the anti-infective component, or the combination. Exact incidence figures are not available since no denominator of treated patients is available.

Reactions occurring most often from the presence of the anti-infective ingredients are allergic sensitizations. The reactions due to the steroid component in decreasing order of frequency are: elevation of intraocular pressure (IOP) with possible development of glaucoma, and infrequent optic nerve damage; posterior subcapsular cataract formation; and delayed wound healing.

Secondary infection: The development of secondary infection has occurred after use of combinations containing steroids and antimicrobials. Fungal infections of the cornea are particularly prone to develop coincidentally with long-term applications of steroid. The possibility of fungal invasion must be considered in any persistent corneal ulceration where steroid treatment has been used.

Allergan Pharmaceuticals, Inc.
Irvine, California 92713, U.S.A.