Alloplastic Intracorneal Lenses

In the 1989 Lans Distinguished Refractive Surgery Lecture, Werblin discusses the developments of lamellar refractive surgery during the last ten years and speculates about the future. Of course, the aim of refractive surgeons is to develop procedures that are completely safe and guarantee all patients 20/40 or better uncorrected visual acuity. Werblin rightly emphasizes the relative accuracy of the refractive results of the currently available lamellar procedures. It seems unlikely that refractive surgery will achieve the required safety and accuracy in the near future. In the meantime it is reasonable to compare the results of any form of refractive surgery with the most frequently performed refractive surgical procedure, the implantation of an intraocular lens. The standard deviation of the refraction after this procedure is less than plus or minus 1 diopter.

Basically, there are three ways of changing the ocular refraction by operating on the cornea:

1. Altering the anterior corneal curvature—as in radial keratotomy, epikeratoplasty, and keratomileusis—such that small changes in corneal radius result in relatively large changes in dioptric power;

2. Altering the power of the cornea by inserting an intracorneal lenticule that has a refractive index substantially higher than the refractive index of the corneal stroma; and

3. Combining 1 and 2.

José Barraque developed keratophakia and keratomileusis techniques that change the anterior corneal curvature and are effective in reducing hyperopia and myopia, but that are technically complex. The standard deviation of the refraction after these procedures is more than plus or minus 2 dioplers. Epikeratoplasty also changes the anterior corneal curvature, but it cannot yet achieve the predictability of an intraocular lens, especially in myopic patients. This does not mean that there are no indications for keratomileusis or epikeratoplasty, but emphasizes that our research should aim at improving the results.

About 30 years ago, impermeable alloplastic intracorneal lenses were investigated for the evaluation of corneal and transport mechanisms and the treatment of corneal edema. Chocey and Dohlman used water impermeable corneal inlays to block the fluid movement across the corneal stroma in patients with bullous keratopathy, but were abandoned because of high extrusion rate secondary to aseptic nutritional necrosis of the anterior cornea. In recent years, Choyce implanted smaller, water impermeable, polysulfone lenses with high refractive index in humans for the correction of refractive errors. In doing so, he did not alter the anterior corneal curvature but altered the power of the cornea. In uncomplicated cases, the accuracy was excellent and stable, and many of his patients have maintained clear corneas over the years. However, stromal opacification developed in front of a number of the lenses, most likely because the metabolic demands of the cornea were not met.

Similar complications were found in cats and dogs with water impermeable intracorneal lenses implanted for refractive purposes.

Since Krawicz's original experiments in the early 1960's, hydrogel intracorneal lenses have been extensively investigated in the laboratory and the results appear promising. They are well tolerated by both the non-human primate cornea and by the human cornea. Because their refractive index approximates the refractive index of the corneal stroma, the lenticules must change the anterior corneal curvature in order to obtain a change in refraction. Hydrogels implanted in a freehand pocket dissection do not change the anterior corneal curvature, because the collagen fibrils remain anchored across the anterior cornea, and therefore the more complex lamellar keratectomy with a microkeratome is required. This is unfortunate, because the microkeratome is expensive and more complex to use, not being routinely used by the general ophthalmic surgeon. The microkeratome produces a smooth cut superior to that of a freehand lamellar keratectomy, and is the instrument that should be used for this procedure.
Intracorneal lenses have a number of advantages. The supply is limitless, as opposed to procedures such as epikeratoplasty using human donor material. The lenticules can be created with great refractive accuracy, as are contact lenses; this has the potential to decrease some of the poor predictability that characterizes current methods of refractive surgery. Wound healing does not play a major role in determining the refractive outcome, which should also increase the predictability of the procedure. The lenticules can be removed from their lamellar bed and replaced by another lenticule, so that the operation is potentially reversible and modifiable, although no laboratory or human data have been published to document the safety, effectiveness, and predictability of repeated surgery.

Currently underway are two commercially sponsored trials in humans of hydrogel intracorneal lenses for aphakia and myopia, under the auspices of the United States Food and Drug Administration, which regulates intracorneal lenses as devices. We look forward to the results of these trials in the hope that they may allow us to take advantage of this unique type of refractive corneal surgery.

References

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