Refactive Surgery: Myth versus Reality

James Salz, MD

I would like to thank the Board of Directors of the International Society of Refractive Surgery(ISRS) for the honor of delivering the 1994 Barraquer Lecture. Jose Barraquer is the honorary President of ISRS. His lifelong commitment to the field of refractive surgery is legendary and many of us consider him to be the father of modern refractive surgery.

In preparing for this lecture, I reviewed some of Barraquer's early work and I was once again reminded of the genius of this kind and humble man. Although Barraquer has made numerous contributions to ophthalmology in general, and refractive surgery in particular, I would like to briefly discuss three of his original ideas that are continuing to have an impact on current refractive surgery techniques: (1) the "Law of Thickness," (2) the microkeratome, and (3) a hinged corneal flap.

The principles for the "Law of Thickness" were first announced in Barraquer's doctoral thesis in Spain in 1949 and were published in a booklet by the Spanish Barraquer Institute (personal communication, Carmen Barraquer, MD, September, 1994). With this formula, Figure 1, and others, Barraquer predicted the amount of tissue that either had to be added or subtracted from the cornea for a given optical zone diameter to change the corneal curvature to correct either hyperopia or myopia. These formulas still apply to the amount of tissue that must be removed with the second pass of the automated microkeratome of Ruiz in the automated lamellar keratoplasty (ALK) technique for correcting myopia and to the amount of corneal tissue that must be ablated from the anterior surface of the cornea by the excimer laser during photorefractive keratectomy (PRK) or from the back of the disc or the stromal bed in excimer laser keratomeileusis.

The microkeratome was developed as a modification of Castroviejo's electrokeratome between 1958 and 1964.

The first technique Barraquer attempted with the microkeratome was to resect corneal tissue under a hinged flap, which he called "autokeratoplasty with optical cut" (personal communication, Carmen Barraquer, MD, September, 1994). He abandoned this technique because of problems with the accuracy of the resected tissue and concentrated on complete removal of the corneal disc so that it could be reshaped on the cryolathe. The concept of a hinged corneal flap is enjoying a rebirth as recently described by Pallikaris of Greece and Slade of Houston. In an ingenious marriage of modern technology, laser in-situ keratomeileusis (LASIK) involves creating a hinged flap with a microkeratome and removing corneal tissue in the stromal bed with the excimer laser.

The theme for my lecture, "Refractive Surgery: Myth versus Reality," is outlined in Table 1.

### MYTH 1

Refractive surgeons are unwilling to have the surgery on themselves.

### REALITY

Refractive surgeons (and ophthalmologists in general) are undergoing refractive surgery in increasing numbers.

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Learning's recent American Society of Cataract and Refractive Surgery (ASCRS) poll illustrates the increasing acceptance of refractive surgery as a personal option. In 1993, 42% (1786 ophthalmologists) of the total ASCRS members responded to the poll. Figure 2 summarizes the responses to the question, "Would you have a radial keratotomy if 30 years old and a -4 myope?" between 1988 and 1993. In 1988 and 1989, only 10% answered "yes" compared to 41% in 1993. When asked if they had refractive surgery performed on themselves or a member of their immediate family, 180 (10%) of the responding ophthalmologists answered affirmatively.

I underwent astigmatic keratotomy on my left eye by Dr Richard Villasenor this past year. The uncorrected visual acuity in my left eye was 20/200 with a refraction of +1.50 - 3.75 x 180 = 20/20. After two pairs of arcuate incisions, performed 2 months apart, my uncorrected visual acuity is 20/30 with a refraction of +0.50 - 1.25 x 180. Figure 3 is the pre- and postoperative corneal topography and difference map on my left eye. My right eye has an uncorrected visual acuity of 20/40 due to a mild with-the-rule astigmatism that has been improving with age. I will not have surgery on that eye.

I believe that when the excimer laser is approved, we will see an increasing number of ophthalmologists selecting photorefractive keratectomy for themselves and family members.

**MYTH 2**

Refractive surgery is cosmetic surgery.

**REALITY**

Refractive surgery is functional surgery.

Deitz addressed this issue several years ago by pointing out that placing radial keratotomy incisions in the cornea hardly improved its cosmetic appearance. It is well established that the majority of patients electing to have refractive surgery do so to eliminate their dependence on glasses and contact lenses. For example, 77% of the patients in the Prospective Evaluation of Radial Keratotomy (PERK) study chose the surgery to lessen dependence on eyeglasses or contact lenses, to see better, or for occupational reasons, while only 3% did it for cosmetic purposes. A postoperative evaluation of over 100 of Arrowsmith's patients also concluded that most patients "elect radial keratotomy because they hope to improve their vision." Other anecdotal reasons listed by Arrowsmith's patients included "being able to see in the shower without glasses," "being able to find a crying infant across the room," and "being able to see during sexual relations."

**MYTH 3**

Radial keratotomy is precise and predictable.

**REALITY**

Although radial keratotomy is often adjustable, it is not predictable because multiple procedures are often required for best results and unusual responses to the procedure are not uncommon.

Many of you who are considering offering refractive keratotomy to your patients might think that refractive surgeons have a new operation that is somehow completely different from the old radial keratotomy of the PERK study. Although there is no doubt that refractive keratotomy results for groups of patients with low to moderate myopia are excellent, I would hardly say the operation has suddenly become precise and predictable for the occasional individual patient.

Although the PERK study has been criticized because all patients (regardless of age) received 8 incisions with only 3 optical clear zones, the PERK 1-year results can be used to illustrate variations in outcome caused by individual differences in wound healing. For example, when one studies the refractive outcome of all patients who underwent 8-incision radial keratotomy with a 3.5-millimeter clear zone plotted against patient age, significant differences in outcome are apparent for patients of similar ages. Figure 4 shows that two patients in their early 20s obtained 1.00 diopter (D) of effect
while two others obtained 4.00 D. Two patients in their mid-40s obtained a little over 2.00 D while two others achieved between 5.00 and 6.00 D of correction.

I have observed multiple examples of these “over and under responders” (Table 2). All four of these patients in their 30s had 8 American-style radial keratotomy incisions with 3.0-millimeter clear zones.

My experience is certainly not unique. I asked Werblin to share some of the “outliers” he has observed among his first 200 radial keratotomy patients operated using the Casebeer system for predictable refractive surgery (personal communication, Ted Werblin, MD, July, 1994). Tables 3 and 4 illustrate a few of these atypical results in six eyes of four patients from Werblin’s initial series of 205 eyes.11

Werblin’s report is heavily quoted in advertisements as evidence of the predictability of radial keratotomy if certain instruments and techniques are employed. What the manufacturer of the instruments is promoting is that their system is precise and predictable, not necessarily the operation. The key to modern radial keratotomy is to not overcorrect the eye so that additional surgery can be performed for residual myopia.

The idea of titrating the effect of radial keratotomy is not new. In 1986, I reported on a combined series of low to moderately myopic eyes operated on by four surgeons, where the initial surgery was a 4-incision radial keratotomy with different optical clear zones.12 Following a second surgery in 13% of the eyes, 90% were corrected to within 1.00 D of emmetropia and only 3.5% were overcorrected by 1.00 D or more.

How does the “predictable” Werblin series compare to the PERK study? Werblin’s technique had several potential advantages compared to the PERK technique: multiple optical clear zones in 0.25-millimeter steps determined by a nomogram based on thousands of previous surgeries with a similar technique (PERK—only 3 zones with 0.5-millimeter steps without a true nomogram and no previous experience with the technique); patient age considered in surgical planning (PERK ignored patient age); 4 to 16 incisions with astigmatic incisions permitted (PERK—only 8 radials); theoretically more efficient Russian-style incisions with thinner blade calibrated at 100× (PERK incisions were American style, performed with a thicker blade calibrated at about 10× under operating microscope with coin gauge); one surgeon (PERK—10 surgeons).

With all these potential advantages, the two studies had remarkably similar outcomes after only one surgery: Percentage of eyes 20/40 or better (one surgery): PERK 78%, Werblin 71%. The PERK data at 1 year was based on only one operation. Most of the Werblin patients that did not achieve 20/40 after one surgery were undercorrected so 33% of the eyes had at least one additional surgery and 10% had two or more additional surgeries.

We have made radial keratotomy results better by hoping for either a near emmetropic or myopic result after the first surgery and then adjusting the refraction with additional surgery.

These frequent secondary procedures have risk because not all of these eyes respond to secondary surgery in a predictable manner. Although not apparent from the published study, 8% of the eyes in the Werblin study are overcorrected by +1.00 D or more (cycloplegic refraction) compared to 10% of the eyes in the PERK study (personal communication, Ted Werblin, MD, May, 1994). The 5-year PERK13 results reported 17% of the eyes were then overcorrected by more than +1.00 D, increasing to 43% in the 10-year PERK study.14 This progression of the effect will no doubt also occur in Werblin’s series where the incision depth is likely deeper than that achieved in the PERK study.

**MYTH 4**

*Progressive hyperopia following radial keratotomy is not a problem if certain techniques are used.*

**REALITY**

*Progressive hyperopia following radial keratotomy is a problem requiring a solution if radial keratotomy is to survive.*

In 1985, Deitz reported that 31% of 81 eyes were 1.00 D or more hyperopic at 4 years than they were 1 year after radial keratotomy.15 In a recent follow up to the initial study, Deitz reported a long-term
Table 2
Atypical Responses to Refractive Keratotomy—Salz Series

<table>
<thead>
<tr>
<th>Age</th>
<th>Sex</th>
<th>Preoperative Spherical Equivalent Refraction (D)</th>
<th>No. of Incisions</th>
<th>Clear Zone (mm)</th>
<th>Postoperative Spherical Equivalent Refraction (D)</th>
<th>Change in Refraction (D)</th>
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</thead>
<tbody>
<tr>
<td>37</td>
<td>F</td>
<td>-7.38</td>
<td>8</td>
<td>3.0</td>
<td>+3.00</td>
<td>10.3</td>
</tr>
<tr>
<td>36</td>
<td>F</td>
<td>-6.25</td>
<td>8</td>
<td>3.0</td>
<td>-2.75</td>
<td>3.5</td>
</tr>
<tr>
<td>36</td>
<td>M</td>
<td>-9.25</td>
<td>8</td>
<td>3.0</td>
<td>Plano</td>
<td>9.2</td>
</tr>
<tr>
<td>30</td>
<td>M</td>
<td>-7.75</td>
<td>8</td>
<td>3.0</td>
<td>-3.25</td>
<td>4.4</td>
</tr>
</tbody>
</table>

Figure 3: Preoperative, postoperative, and difference computerized videokeratography on Salz’s left eye demonstrating coupling after astigmatic keratotomy.

evaluation on 225 eyes that had radial keratotomy performed with metal blades between 1979 and 1981. At 1 year, 31% of the eyes were at least 1.00 D or more hyperopic, increasing to 48% at 8.5 years. Additionally, 54% of the eyes had shifted 1.00 D or more in a hyperopic direction.

This progressive flattening of the cornea with time has been observed in other radial keratotomy studies. In the PERK 10-year study, 43% of the eyes experienced a hyperopic shift of 1.00 D or more. In a study I published in 1991, 17% of 100 eyes with a follow up greater than 2 years demonstrated a reduction in minus power of 1.00 D or more. Of the 37 4-incision eyes with a greater than 2-year follow up, only 8% had a shift of this magnitude. In Werblin’s report on his initial experience with the Casebeer system, a slight but statistically signifi- cant shift of 0.22 D was noted after only 1 year. In a more recent update (Werblin TP, Stafford MG. Unpublished data), Werblin has found that 19% of patients with a 3-year follow up have experienced a shift of 1.00 D or more toward hyperopia.

In a recent letter to the editor, Casebeer postulated that by leaving an increasing amount of uncut corneal stroma in the midperipheral and peripheral cornea (Fig 5), the cornea will be more stable. His system recommends a single blade setting of 100% of the corneal thickness reading 1.5 mm temporal to the light reflex. The incisions are performed Russian style with a thin profile blade, which is supposed to produce a consistently deeper incision, especially at the optical zone, than the incisions produced with thicker blades with an American incision direction.
Table 3
Atypical Responses to Refractive Keratotomy—Werblin Series

<table>
<thead>
<tr>
<th>Patient</th>
<th>Preoperative</th>
<th>Clear Zone (mm)</th>
<th>Predicted Refraction Change (D)</th>
<th>Obtained Refraction Change (D)</th>
<th>Final Refraction (D)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Sex</td>
<td>Spherical Equivalent Refraction (D)</td>
<td>No. of Incisions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------</td>
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<td>-----------------</td>
<td>-------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>32</td>
<td>M</td>
<td>-5.75</td>
<td>8</td>
<td>3.00</td>
<td>5.50</td>
</tr>
<tr>
<td>Reoperation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>32</td>
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<td>8</td>
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<td>1.75</td>
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<tr>
<td>33</td>
<td>M</td>
<td>-3.50</td>
<td>8</td>
<td>3.00</td>
<td>3.00</td>
</tr>
<tr>
<td>51</td>
<td>M</td>
<td>-7.25</td>
<td>8</td>
<td>4.00</td>
<td>3.25</td>
</tr>
</tbody>
</table>

Figure 4: Attempted and achieved spherical equivalent correction on PERK patients 1 year after radial keratotomy with 3.5-millimeter optical clear zone and 8 incisions. (From Lynn MS, Waring GO, Sperduto RD, et al. Factors affecting outcome and predictability in the PERK study. Arch Ophthalmol. 1987;105:42-51.)

In the PERK study, although four pachymeter readings were obtained, the blade setting was based on the thinnest of the four, which was almost always the temporal measurement. This would, in most cases, be approximately the same as the reading obtained with the Casebeer system. In the PERK study, American-style incisions were performed with a thicker, presumably more inefficient blade, so these incisions should have left even more uncut tissue than Casebeer postulates in his diagram. Yet the PERK study, with a 95% follow up of patients examined by non-surgeon observers, reports an increasing incidence of hyperopic shift between 5 and 10 years.13 It is illogical to claim that you can achieve more consistent incision depth with the thinner blades of the Casebeer system, cutting Russian style, and still not expect to see the hyperopic shift documented in the PERK study where the incisions were most likely shallower.

Thornton, in the consultation section of Refractive and Corneal Surgery, stated that to avoid hyperopic shift, "one need only to avoid cutting into the limbus and into the circular ligament (the ligamentum circulare described by Frank Pollock in 1961 and years previously by Kokott)."19 I believe there is some question about the existence of this ligament. Furthermore, my personal technique and the PERK technique both avoided incisions into the limbus, yet hyperopic shift was frequently observed, as discussed earlier.

A technique that may result in a more stable cornea is to make the incisions shorter (mini radial keratotomy), as has been suggested recently by Lindstrom.20 However, it will take a few years to prove that progressive hyperopia is less frequent with shorter incisions.

MYTH 5
Bilateral simultaneous radial keratotomy is in the patient's best interest because it's convenient for both eyes to heal together.

REALITY
Although bilateral simultaneous radial keratotomy is very convenient for both patient and surgeon, it may not be in the patient's best interest because of three possible problems: infection, unusual response, and disturbing side effects.
Infection

Although the risk of infection following radial keratotomy is quite low, I believe it is not as low as some surgeons would like to believe. For example, Marmer conduced an informal survey about radial keratotomy complications and reported that infectious keratitis occurred in 2 out of 62,814 eyes. If that were true, and if 1 million radial keratotomies have been performed in the United States, there should only be about 30 cases of infectious keratitis in the entire country. The number of cases I found in preparing this paper indicates the incidence is higher than that. I have observed two cases of infectious keratitis in approximately 1000 radial keratotomies. Both were discovered during the first 3 days and recovered with no loss of vision. Lindstrom encountered one case of endophthalmitis in his first 2000 radial keratotomies (personal communication, Richard Lindstrom, MD, September, 1994).

The first reported case of bilateral microbial keratitis after radial keratotomy was by Beldav and colleagues in 1993. The infection was from Staphylococcus aureus, cultured from both the lid margins and the cornea. This patient was noted to have bilateral ulcerative blepharitis and surgery should most definitely have been deferred. The patient was treated appropriately and 2 months after admission, spectacle-corrected visual acuities were 20/30 OD and 20/40 OS.

During a 1-month period, Szerynzy and colleagues at the Doheny Eye Institute treated four referred patients for microbial keratitis after bilateral simultaneous radial keratotomy. Two of the patients had bilateral keratitis. Of the six infected eyes, spectacle-corrected visual acuity several months after treatment was 20/20 in two, 20/30 in two, and 20/40 and 20/60 in two eyes of the same patient (Figs 6 and 7). No predisposing factors were noted in any of the cases.

Grimmett, Holland, and Krachmer described a patient who underwent bilateral simultaneous radial keratotomy and developed a Streptococcus pneumoniae keratitis in one eye (Fig 8). Despite aggressive and appropriate therapy, the patient required emergency therapeutic keratoplasty because of a persistent wound leak and progressive corneal thinning. Although the eye was saved, at 7 months postoperatively, refraction was \(-7.00 +3.00 \times 180 = 20/30\). The patient was unable to perform his usual activities because of anisometropia.

Duffy performed bilateral simultaneous radial keratotomy on a female physician. On the first postoperative day, the patient had uncorrected visual acuity of 20/20 OD, 20/40 OS and reported no discomfort. After 48 hours, she returned to work, which included duties in the intensive care unit. On the fifth postoperative day, she was evaluated because of discomfort during the previous evening. She developed bilateral hypopyon, with deep infiltrates down to Descemet's membrane in 4 of 8 incisions OD and 2 of 8 incisions OS. She was treated with aggressive topical and subconjunctival antibiotics, opening and irrigation of the involved incisions with saline and eventually with dilute povidone-iodine 5 times during the first 48 hours. Twelve hours after admission, the cultures identified Serratia marcescens. She was discharged after 6 days and eventually recovered 20/20 visual acuity in both eyes.

To quote from Duffy's case report: "The risk of bilateral suppurative keratitis leading to bilateral perforation and bilateral blindness on the rare occasion when severe bacterial keratitis develops must be heavily weighed before the benefits of simultaneous bilateral radial keratotomy to the patient are considered."

Unusual Response

Unusual responses to keratotomy surgery are possible no matter which technique or nomogram is used. By operating on one eye at a time, the surgeon has an opportunity to adjust the plan for the other eye. This is evident in Werblin's patient summarized in Table 4.

Table 5 details some of these cases. In fact, I believe the most important predictive information we have available is the result obtained in the first eye. Using this information will most assuredly minimize the number of additional operations and thus reduce the risks to the patient.

Disturbing Side Effects

Even with satisfactory postoperative uncorrected visual acuity, radial keratotomy patients may be bothered by fluctuating vision, glare, decreased contrast sensitivity making night driving difficult, or photophobia. Although only 10% of the PERK patients said they were dissatisfied with the results of the surgery, 18% (80) elected not to have the surgery on their other eye for the reasons summarized in Table 6. Glare, fluctuating vision, and successful adjustment to monovision were the most common reasons for not having the surgery when over- and undercorrections and presbyopia are excluded.

I have seen two patients in the last 6 months who had excellent results following radial keratotomy, but chose photorefractive keractectomy for their second eye because of difficulty with night driving. Both patients had uncorrected visual acuities of 20/20 following 4-incision radial keratomies in their nondominant eyes for approximately 3.00 and 4.00 D of myopia. With photorefractive keractectomy likely to be approved sometime next year, it seems prudent to make certain a patient is pleased with the results of radial keratotomy in the first eye before operating on the other eye.
There appears to be an increase in the number of surgeons performing bilateral radial keratotomy. In a recent survey of the members of the American Society of Cataract and Refractive Surgery, 22% of 1841 respondents stated that they performed bilateral, simultaneous radial keratotomy. I hope the patients consenting to bilateral surgery are truly informed about the potential for developing a serious infection, the not infrequent unusual response to the surgery, or the occasional persistence of symptomatic nighttime glare and fluctuating vision.

**MYTH 6**

Photorefractive keratotomy is quite painful and often results in hazy corneas.

**REALITY**

New techniques have practically eliminated severe postoperative pain and significant corneal haze.

**PAIN AFTER PHOTOREFRACTIVE KERATECTOMY**

When our group at Cedars-Sinai Medical Center in Los Angeles began performing photorefractive keratotomy 4 years ago, we were concerned that patient acceptance of the procedure would be adversely influenced by the severe postoperative pain. We now use the combination of a bandage contact lens and diclofenac for pain control. This was first reported by Sher and colleagues who later confirmed the efficacy of this method of pain control in a randomized, double-masked study. Other investigators have also reported a favorable experience with diclofenac for pain control following photorefractive keratectomy and radial keratotomy.

**HAZE AFTER PHOTOREFRACTIVE KERATECTOMY**

Although early transient mild corneal haze following photorefractive keratectomy is common, significant symptomatic haze rarely persists following photorefractive keratectomy for low and moderate myopia. For example, in the national VISX phase III clinical trial, of 586 eyes with a 2-year follow up, 7% of the eyes had greater than +1 haze at 1 month, 2% at 1 year, and 0.6% at 2 years (personal communication, Donald Sanders, MD, September, 1994). The haze grading system is as follows: 0 = clear cornea; 0.5 = haze barely detectable; 1.0 = mild haze not affecting refraction; 1.5 = mild effect on refraction; 2.0 = moderate haze, refraction

<table>
<thead>
<tr>
<th>Age</th>
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<th>Preoperative Spherical Equivalent Refraction</th>
<th>No. of Incisions</th>
<th>Clear Zone (mm)</th>
<th>Predicted Refractive Change</th>
<th>Obtained Refractive Change</th>
<th>Spherical Equivalent Refraction 2 Yrs. Later</th>
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<td>3.37 (mono)</td>
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<tr>
<td></td>
<td></td>
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<td>4</td>
<td>3.25</td>
<td>5.75 (based on left eye above)</td>
<td>7.75</td>
<td>+1.25</td>
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<table>
<thead>
<tr>
<th>Patient</th>
<th>Age</th>
<th>Eye</th>
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<th>Clear Zone (mm)</th>
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<th>Initial Spherical Equivalent Result (D)</th>
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<td></td>
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<td>-10.50</td>
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<td>4</td>
<td>-1.50</td>
<td>-0.50 (7 yrs.)</td>
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<td>+3.00</td>
<td>-0.50</td>
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<tr>
<td></td>
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<td>4</td>
<td>+0.50</td>
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<td>3.0</td>
<td>8</td>
<td>Recoeperation + 4</td>
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Table 6
Reasons for Not Having Radial Keratotomy on Fellow Eye—PERK Study

<table>
<thead>
<tr>
<th>Reason</th>
<th>% of 80 Patients</th>
</tr>
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<tr>
<td>Under- or overcorrected</td>
<td>36</td>
</tr>
<tr>
<td>Glare</td>
<td>26</td>
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<tr>
<td>Problems of presbyopia</td>
<td>18</td>
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<tr>
<td>Fluctuating vision</td>
<td>18</td>
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<tr>
<td>Monovision acceptable</td>
<td>10</td>
</tr>
<tr>
<td>Contact lens on second eye acceptable</td>
<td>8</td>
</tr>
<tr>
<td>Waiting for further results</td>
<td>11</td>
</tr>
<tr>
<td>Other</td>
<td>7</td>
</tr>
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</table>

possible but difficult; 3.0 = easily detectable, affects refraction.

I believe the myth about corneal haze and photorefractive keratotomy at least partially arose early in the VISX study when nitrogen flow was blown across the cornea to remove the ablation plume because it was felt that it might interfere with the quality of the laser beam. This nitrogen flow had a dehydrating effect on the cornea and has been correlated with increased haze in the early postoperative period when compared with eyes treated without the nitrogen flow. Nitrogen flow has also been shown to be associated with less refractive accuracy and delayed recovery of visual acuity. The Summit national phase III FDA trial also reveals a very low incidence of significant late corneal haze with only 2.6% of 585 eyes graded as having moderate haze at 1 year. It is also encouraging to note that significant corneal haze usually tends to clear with time. Figure 9 shows an eye following photorefractive keratotomy after radial keratotomy with grade 2 corneal haze at 1 year and Figure 10 shows almost complete clearing of the haze by 2 years.

MYTH 7
Photorefractive keratotomy is better than photorefractive keratotomy or photorefractive keratotomy is better than radial keratotomy.

REALITY
Both procedures produce comparable short-term results in properly selected patients. Although each procedure has advantages and disadvantages, photorefractive keratotomy will be selected by most patients. Incisional surgery will survive because it will be less expensive and may be preferable for certain refractive errors.

I compare here both photorefractive keratotomy and radial keratotomy in six areas: efficacy, stability, safety, side effects, economics, and future developments.

Efficacy
Hong analyzed my personal photorefractive keratotomy and radial keratotomy results over the past 3 years. This study analyzed the results obtained on 117 eyes of 81 radial keratotomy patients with a follow up of 1 to 36 months and 103 eyes of 76 photorefractive keratotomy patients with a follow up of 6 to 36 months. The results are based on the most recent examination. The details of the radial keratotomy and photorefractive keratotomies have been previously published. Table 7 summarizes the results of both procedures according to the degree of preoperative myopia.

Eyes with low and moderate myopia obtained comparable results from the two procedures, but approximately 20% of the eyes that had radial keratotomy required additional surgery compared to only one of the eyes in the photorefractive keratotomy group.

This recent analysis of my radial keratotomy patients, with over 90% of eyes with low and moderate myopia obtaining at least 20/40 uncorrected visual acuity with accuracy within 1.00 D of emmetropia is generally similar to the PERK and Werblin results discussed earlier and to recent reports on the Casebeer and Genesis systems and Lindstrom's mini radial keratotomy technique (Tables 8 and 9). My photorefractive keratotomy re...
Table 7
Comparison of Results of Radial Keratotomy (RK) at 1 to 36 mos. and Photorefractive Keratectomy (PRK) at 6 to 36 mos. After Surgery

<table>
<thead>
<tr>
<th>Results</th>
<th>Low Myopia (D)</th>
<th>Moderate Myopia (D)</th>
<th>High Myopia (D)</th>
<th>Overall (D)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>RK (N=37 eyes)</td>
<td>PRK (N=38 eyes)</td>
<td>RK (N=56 eyes)</td>
<td>PRK (N=57 eyes)</td>
</tr>
<tr>
<td>Uncorrected Visual Acuity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20/20</td>
<td>15 (41)</td>
<td>18 (50)</td>
<td>17 (30)</td>
<td>19 (33)</td>
</tr>
<tr>
<td>20/40 or better</td>
<td>34 (91)</td>
<td>34 (94)</td>
<td>50 (69)</td>
<td>46 (60)</td>
</tr>
<tr>
<td>Refractive Outcome</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>±0.50 D</td>
<td>26 (70)</td>
<td>31 (86)</td>
<td>35 (63)</td>
<td>30 (53)</td>
</tr>
<tr>
<td>±1.00 D</td>
<td>35 (94)</td>
<td>36 (100)</td>
<td>53 (95)</td>
<td>47 (83)</td>
</tr>
<tr>
<td>Greater than</td>
<td>1 (3)</td>
<td>0 (0)</td>
<td>3 (5)</td>
<td>9 (16)</td>
</tr>
<tr>
<td>-1.00 D</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Greater than</td>
<td>1 (3)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>+1.00 D</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reoperations</td>
<td>7 (18)</td>
<td>0 (0)</td>
<td>12 (21)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Loss of spectacle-corrected visual acuity (2 or more lines)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1 (2)</td>
</tr>
</tbody>
</table>

Figure 7: Slit-lamp microscope photograph of the other eye of patient described in Figure 6. Spectacle-corrected visual acuity of 20/60.

Figure 8: Slit-lamp microscope photograph of eye with Streptococcus pneumoniae infectious keratitis 3 days following bilateral simultaneous radial keratotomy. (Courtesy of Drs Grimmelt, Holland, and Krachmer.)

Results are also in general agreement with reports in the literature by McDonald, Seiler, and our group at Cedars-Sinai. Figures 11 and 12 are scattergrams of the attempted versus achieved corrections (spherical equivalent) results of radial keratotomy and photorefractive keratectomy in my personal series.

A particularly impressive photorefractive keratotomy series was recently reported by Talley et al. These investigators used a VISX 2015 excimer laser on 91 eyes of 91 patients with preoperative myopia of 1.00 to 7.50 D and no more than 1.00 D of astigmatism. At 1 year, uncorrected visual acuity of 20/40 or
Table 8
Comparison of Results (% of Eyes) of Prospective Refractive Keratotomy Studies

<table>
<thead>
<tr>
<th>Results</th>
<th>PERK⁹</th>
<th>Casebeer³⁰</th>
<th>Genesis³⁰</th>
</tr>
</thead>
<tbody>
<tr>
<td>20/20 (after reoperations)</td>
<td>60</td>
<td>54</td>
<td>52</td>
</tr>
<tr>
<td>20/40 (after reoperations)</td>
<td>88</td>
<td>93</td>
<td>95</td>
</tr>
<tr>
<td>± 1.00 D of emmetropia</td>
<td>41</td>
<td>89</td>
<td>85</td>
</tr>
<tr>
<td>Greater than +1.00 D</td>
<td>17</td>
<td>2</td>
<td>1.3</td>
</tr>
<tr>
<td>Reoperations</td>
<td>12</td>
<td>30</td>
<td>23</td>
</tr>
<tr>
<td>More than 1 reoperation</td>
<td>0</td>
<td>14</td>
<td>1</td>
</tr>
</tbody>
</table>

Figure 9: Slit-lamp microscope photograph of eye with grade 2.5 haze 1 year after excimer laser phototherapeutic keratectomy after radial keratotomy.

better was achieved in 98% of the eyes and 93% were corrected within 1.00 D of that attempted with only one procedure. The authors postulate that these superior results may have been due to the larger ablation diameters used and possibly the increased experience of the surgeons.

In comparing the efficacy of the two procedures, it is important to remember that the amount of correction that can be obtained with radial keratotomy is age dependent¹⁰ while photorefractive keratectomy is not. For example, I recently performed photorefractive keratectomy with astigmatic correction (elliptical program) on the more myopic right eye of a 27-year-old patient with anisometropia. Her refractive error was OD −9.50 −2.50 × 165 =20/40, OS −2.50 =20/20. Six months later, her uncorrected vision in the operated eye was 20/50 with a refraction of +0.75 −0.50 × 165. Refractive keratotomy would have been an inappropriate procedure for this patient.

There are also times when incisional surgery may be the more appropriate procedure. For example, the astigmatism in my left eye (+1.50 −3.75 × 180) was best approached with incisional surgery, specifically arcuate incisions that cause flattening of the meridian of the incisions and steepening of the opposite meridian (coupling) as seen in the videokeratographs in Figure 3. This coupling effect is difficult to accomplish with current laser technology. I also recently performed a 2-incision radial keratotomy as suggested by Suarez de Caracas, Venezuela, at the ISRK Symposium (Chicago, November 1993), for a 40-year-old patient with mild myopic astigmatism (−0.50 −1.50 × 170) (Fig 12). Two incisions with a 4.75-millimeter clear zone (Fig 13) in the 70-degree meridian produced an emmetropic result the next day, at 1 week (Fig 14), and at 6 months.

Another advantage for photorefractive keratectomy, especially for low and moderate myopia, is the high percentage of satisfactory results from only one procedure. Table 7 shows that although the low and moderate myopic eyes achieved comparable results, 20% of the radial keratotomy patients required additional surgery compared to only 2% of the photorefractive keratectomy patients. In the Talley photorefractive keratectomy report,⁴⁰ 98% of the eyes obtained an uncorrected visual acuity of 20/40 or better with a single procedure compared to 99% in the Werblin refractive keratotomy series¹⁰ with a reoperation rate of 33%.
### Table 9
Comparison of Results of Refractive Keratotomy Techniques for 6.00 D or Less of Myopia (Study Design)

<table>
<thead>
<tr>
<th></th>
<th>Lindstrom Mini RK&lt;sup&gt;20&lt;/sup&gt; (Retrospective)</th>
<th>Saiz American&lt;sup&gt;35&lt;/sup&gt; (Retrospective)</th>
<th>Casebeer Russian&lt;sup&gt;38&lt;/sup&gt; (Prospective)</th>
<th>Genesis Combined&lt;sup&gt;39&lt;/sup&gt; (Prospective)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of surgeons</td>
<td>1</td>
<td>1</td>
<td>18</td>
<td>9</td>
</tr>
<tr>
<td>Number of eyes</td>
<td>100</td>
<td>87</td>
<td>508</td>
<td>336</td>
</tr>
<tr>
<td>Outcome (% of eyes)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uncorrected VA 20/40 or better</td>
<td>100</td>
<td>93</td>
<td>94</td>
<td>96</td>
</tr>
<tr>
<td>± 1.00 D</td>
<td>98</td>
<td>94</td>
<td>90</td>
<td>93</td>
</tr>
<tr>
<td>Greater than + 1.00 D</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>1.3</td>
</tr>
<tr>
<td>Reoperations</td>
<td>6</td>
<td>20</td>
<td>38</td>
<td>20</td>
</tr>
</tbody>
</table>

Figure 11: Attempted versus achieved correction (spherical equivalent refraction) on Saiz’s radial keratotomy patients as of last examination.

Figure 12: Attempted versus achieved correction (spherical equivalent refraction) on Saiz’s excimer laser photorefractive keratotomy patients as of last examination.

### Table 10
Comparison of Radial Keratotomy and Photorefractive Keratotomy

<table>
<thead>
<tr>
<th></th>
<th>Radial Keratotomy</th>
<th>Excimer Laser PRK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy (−1.00 to −6.00 D)</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Efficacy (−6.00 to −10.00 D)</td>
<td>−</td>
<td>+</td>
</tr>
<tr>
<td>Stability—short term</td>
<td>+</td>
<td>−</td>
</tr>
<tr>
<td>Stability—long term</td>
<td>+</td>
<td>−</td>
</tr>
<tr>
<td>Side effects</td>
<td>−</td>
<td>+</td>
</tr>
<tr>
<td>Economic factors</td>
<td>+</td>
<td>−</td>
</tr>
<tr>
<td>Future developments</td>
<td>−</td>
<td>+</td>
</tr>
</tbody>
</table>

*+ = advantage for the procedure
− = disadvantage for the procedure

### Stability

Earlier in this paper, we discussed the stability of radial keratotomy and pointed out that a significant percentage of radial keratotomy patients experience a continued flattening of the cornea, the so-called progressive hyperopic shift. The incidence of this shift, defined as a refractive change of 1.00 D or more in a hyperopic direction, in several published studies is as follows: PERK at 5 years,<sup>13</sup> 22%; PERK at 10 years,<sup>14</sup> 43%; Saiz, 1 to 10 years,<sup>17</sup> 17%; Deitz, 5 to 12 years,<sup>16</sup> 54%; and Werblin, 1 to 3 years,<sup>11</sup> 19%. Although long-term follow up of photorefractive keratotomy patients is not yet available, preliminary reports indicate the procedure appears to stabilize between 6 and 12 months for the low myopes treated with the VISX laser. The mean postoperative spherical equivalent in the VISX phase III study was −0.40 D at 6 months and −0.50 D at 2 years.
(personal communication, Donald Sanders, MD). The mean spherical equivalent in the Cedars-Sinai study with the VISX Twenty/Twenty at 3 months was −0.60 D at 3 months and −0.50 D at 3 years. The Summit excimer laser has a different early regression profile. In general, the eyes are usually mildly hyperopic for the first few months and slowly regress toward emmetropia, stabilizing between 18 and 24 months.

Safety

The only vision-threatening complications encountered in my patients summarized in Table 7 were an early postoperative keratitis in a radial keratotomy patient, which cleared without sequelae, and a grade 2 corneal haze in a photorefractive keratectomy eye, which gradually improved to grade 1 over a 2-year period.

Published studies on radial keratotomy and photorefractive keratectomy support the safety of both procedures. The only vision-threatening complication encountered in the PERK study was delayed bacterial keratitis in 3 eyes. Neither the Salz nor Werblin studies discussed earlier reported vision-threatening complications. The Summit and VISX photorefractive keratectomy phase III FDA trials reported no vision-threatening complications.

Another measure of the safety of a refractive surgical procedure is an analysis of the percentage of eyes that lose two or more lines of spectacle-corrected visual acuity. Although 3% of the eyes in the PERK study at 5 years lost two or more lines of spectacle-corrected visual acuity, only one eye had a spectacle-corrected visual acuity worse than 20/40 and that was secondary to a cataract presumably unrelated to the surgery. In the 2-year analysis of the VISX phase III trial, only 4 eyes (0.7%) out of 586 lost two or more lines of spectacle-corrected visual acuity and none was worse than 20/30 (personal communication, Donald Sanders, MD). The Summit results revealed a similar low incidence of loss of spectacle-corrected visual acuity of only 2% of 585 eyes at 1 year.

Side Effects

The most common side effects reported in the PERK study were fluctuating vision and glare.
Schanzlin et al. studied 63 PERK patients at 1 year and found 44% had a 0.50 D of diurnal fluctuation and 9% had a fluctuation greater than 1.00 D between morning and evening.

In regard to glare, 37% of the PERK patients complained of glare, halos, radiating lines, or discomfort in bright light before they had surgery. After surgery, 52% had these complaints (p<.01), but only three patients felt these symptoms interfered with night driving and refused surgery on their second eye.

In the VISX phase III study, glare testing was performed on over 150 cases with the brightness acuity tester. At 6 months, 3.6% were abnormal, decreasing to 1.5% at 1 year and 0.6% at 2 years. In a patient survey about sensitivity to bright lights, 20% responded positively preoperatively, compared to 27% at 1 year and 25% at 2 years. When asked about difficulty with night vision, 26% responded often or always preoperatively compared to 40% and 43% at 1 and 2 years, respectively. Difficulty with night vision was correlated with smaller ablation zone diameters, with 48% of the patients with a 5.0-millimeter zone having difficulty often or always compared to only 28% with a 5.5-millimeter zone (26% preoperatively). Probably the best indicator of how troublesome these side effects really are is the patient's overall satisfaction with the procedure. At 1 year, 56% of the VISX photorefractive keratectomy patients were very satisfied, 37% were moderately satisfied, and 7% were not satisfied. In the PERK study at 1 year, 90% of the patients were satisfied.

I believe PRK has an advantage because sensitivity to bright light is less common, diurnal fluctuation of vision is rare, and difficulty with night vision is likely to be even less of a problem with the larger ablation diameters currently in use.

**Economic Factors**

**Surgeon's Perspective.** A surgeon can purchase radial keratotomy instrumentation for perhaps $20,000 to $50,000, take a weekend course, and begin performing radial keratotomy, often in an office operating room. If the same surgeon wants to perform photorefractive keratectomy in the office, an excimer laser can be purchased for approximately $500,000. After 1 year, a service contract will be about $50,000 per year. Access to excimer lasers will be available through hospitals, universities, multispecialty groups, ophthalmology groups, networks of individual ophthalmologists, local commercial laser centers, national commercial laser centers, and mobile lasers.

**Patient's Perspective.** The typical radial keratotomy patient in a large metropolitan area pays anywhere from $1000 to $1500 per eye. This fee typically includes the preoperative examination, 3- to 6-month postoperative examinations, use of the operating room, and additional surgery as necessary.

The cost for photorefractive keratectomy at United States test sites is typically around $2000 per eye, with about half the fee for the surgeon and half for the facility. Although these charges will most likely decrease with the increased availability of lasers and surgeons, there is a definite lower limit because of fixed expenses. These include debt service for the laser purchase, significant maintenance fees (typically 10% of laser purchase price after first year), and a royalty fee per eye (estimated to be anywhere from $100 to $250).

From either the surgeon's or patient's perspective, radial keratotomy has, and will continue to have, a significant economic advantage over photorefractive keratectomy.
Future Developments

Although there have been significant improvements in radial keratotomy instrumentation, technique, and surgical planning over the past 15 years, it is unlikely that there will be a major breakthrough that will dramatically improve the procedure. Photorefractive keratectomy, on the other hand, is still in the early phase of its development. Although the results of the US FDA clinical trials are already quite respectable compared to advanced radial keratotomy techniques, we should remember that these reported results were obtained with lasers and techniques that were already 5 years old. By simply enlarging the ablation zone from 5 to 6 mm, the current practice both in the continuing US studies and abroad, significantly better results have already been reported and presented at recent meetings.

Although the excimer laser has been used primarily for the correction of myopia and myopic astigmatism, other applications are on the horizon. Figure 15 is a videokeratograph of a 3.00 D hyperopic ablation at 1 year in one of the blind eye patients in the VISX phase I FDA hyperopic trial. Hyperopic corrections have been performed successfully in Germany for the past 2 years. Incisional surgery for hyperopia (hexagonal keratotomy) has been associated with an unacceptable incidence of complications. In the area of future developments, both photorefractive keratectomy in particular and corneal laser surgery in general have a decided advantage over radial keratotomy. The advantages and disadvantages of radial keratotomy and photorefractive keratectomy are tabulated in Table 10.

Both radial keratotomy and photorefractive keratectomy are currently in use throughout the world for the correction of myopia and myopic astigmatism with success and a high percentage of satisfied patients. As photorefractive keratectomy becomes more available, it will probably be the method of choice for the majority of myopic patients. Incisional surgery will survive because it will be more appropriate for certain refractive errors, it may be used to reduce residual refractive errors following photorefractive keratectomy, and it may be selected by some patients and surgeons for economic reasons as it is likely to be significantly less expensive than corneal laser surgery.

I would like to thank the ISRS Board for the honor of selecting me to deliver the 1994 Barraquer Lecture and Dr Carmen Barraquer for supplying me with information about her father’s many contributions. An early myth about refractive surgery was that it was only performed by “buccaneer surgeons” solely for profit. Thousands of scientific articles in peer-reviewed journals and hundreds of presentations at scientific meetings all over the world attest to the reality that refractive surgery has become an accepted and respected subspecialty of ophthalmology.

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