The efficacy of radial keratotomy

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The efficacy of radial keratotomy

Abstract
Many people have questions on the effectiveness of the surgical procedure to correct myopia called radial keratotomy. This paper examines the available literature to help to understand the process and the outcome of this new procedure. The literature cited substantiates that results are best on patients with 3 diopters or less of myopia and that many complications are known to exist.

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THE EFFICACY of RADIAL KERATOTOMY

THESIS BY:
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SUBMITTED TO THE FACULTY OF
PACIFIC UNIVERSITY COLLEGE OF OPTOMETRY
FOR THE PARTIAL FULLFILLMENT OF THE REQUIREMENTS FOR THE
DEGREE: DOCTOR OF OPTOMETRY

SPRING 1986
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ABSTRACT

Many people have questions on the effectiveness of the surgical procedure to correct myopia called radial keratotomy. This paper examines the available literature to help to understand the process and the outcome of this new procedure. The literature cited substantiates that results are best on patients with 3 diopters or less of myopia and that many complications are known to exist.

KEY WORDS: radial keratotomy, myopia, astigmatism, spherical equivalent, visual acuity, keratometry, epithelium, endothelium
HISTORICAL PERSPECTIVE

Since the late 19th century ophthalmic surgeons have attempted to correct myopia and astigmatism by making incisions in the cornea to change its shape.\textsuperscript{1} In 1869, Snellen described methods for the correction of astigmatism and discussed the possibility of altering corneal curvature.\textsuperscript{2} In 1894, Bates attempted the first surgical alteration of the cornea to correct for astigmatism by employing a method of unsutured wedge resections.\textsuperscript{3}

The technique of radial keratotomy is designed to correct myopia through the use of anterior corneal incisions extending from the extra-pupillary area to the limbus. This causes a relative flattening of the central cornea due to a bulging in the weakened peripheral cornea. These curvature changes result in a decrease in myopia; although the decrease in myopia obtained does not usually correlate with corneal curvature changes, and the exact mechanism of myopia reduction is not understood.\textsuperscript{19,36}

Modern radial keratotomy has evolved through a number of stages, the first beginning with Sato\textsuperscript{4} in Japan. After examining two cases of keratoconus where Decemet's membrane had ruptured with accompanying loss of acuity and corneal shape change, Sato theorized that incisions made deliberately in the posterior corneal surface would be beneficial in the treatment of keratoconus. Sato also believed posterior corneal incisions could be applied to other problems in addition to keratoconus. He used the technique to correct corneal staphyloma and various other diseases of the iris and lens. In 1943, he began correcting astigmatism using posterior incisions, and after 1945 began using both anterior and posterior incisions to correct myopia.\textsuperscript{4}

The fact that Sato's operation met with poor surgical results and disastrous postoperative sequelae is well known.\textsuperscript{5-7} The occurrence of bullous keratopathy caused by the operation was first reported by Inoue in 1965.\textsuperscript{7} Since then approximately 75 percent of the original 681 eyes operated on for myopia between 1951 and 1959 have developed bullous keratopathy.\textsuperscript{5} Corneal transplant has been, for the most part, unsuccessful in treating these patients. Although there is no statistical data to support it, Akiyama, et al\textsuperscript{6} states that it is thought that Sato's anterior radial keratotomy, in which corneal shape was altered by external incision of Decemet's membrane, did not produce the desired effect. Some author's\textsuperscript{2,8,9} feel that the development of bullous keratopathy in Sato's patients was the result of the destruction of endothelial cells by the posterior incisions, and that there is no such risk in today's anterior keratotomy procedure. However, progressive endothelial cell loss has been reported with anterior radial keratotomy in both human and animal studies,\textsuperscript{10-15} and the long term effects of this procedure on corneal integrity is not yet known.

Others attempted to duplicate and improve on Sato's work, most notably Belyaev, Kio-tin, and Yenaliev.\textsuperscript{16} The first real improvement in technique came with the work of Fyodorov and Durnev in
1979. Using only anterior incisions of the cornea, they demonstrated that changes in refraction could be obtained in both human and animal subjects. This work led to the present surgical procedure used to correct myopia and astigmatism.

Fyodorov's basic procedure is currently used by most surgeons and incorporates several improvements over earlier techniques. An operating microscope is used to provide magnification, increased illumination and more precise optics. Blade depth is set in reference to corneal pachometry, and the optical zone size is not an arbitrary 6mm, but is varied in size from 3mm to 6mm depending on certain variables. These variables include: degree of spectacle myopia, amount of corneal curvature, corneal diameter, corneal rigidity, pachometry measurements, intraocular pressure, and number of incisions. Using a nomogram which takes into account the above factors and allows the surgeon to determine a set of preoperative variables, up to 14 diopters of myopia has been corrected with Fyodorov's technique. The maximum correction obtained previously with the Sato procedure was 3.5 diopters.

Bores performed the first radial keratotomy operation in the United States in 1978. Since then increasing numbers of both surgeons and individuals with myopia have become interested in the procedure. At that time there was little scientific information available about the surgery and in December 1979, the first article in English appeared in an ophthalmologic journal and claimed the procedure was safe and effective. Since that time, numerous other studies have questioned the long and short term safety, predictability, and ethics involved in such a procedure. At present radial keratotomy is creating much discord within the ophthalmological community.

PROCEDURE

At the time Bores introduced radial keratotomy into the United States in 1970 there was little scientific information available about the procedure, and there were large variations in the techniques used and the results obtained among the practitioners performing the surgery. Typically, radial keratotomy was performed by attaching razor blade fragments to a blade holder and hand adjusting the depth of the blades using a depth gauge block. The optical zones were made from the limbus to the optical center.

On the average, these techniques were only able to correct up to 3.0 diopters of myopia with poor predictability. A large number of patients suffered from post operative glare and photophobia. In the next two years variations in surgical techniques were tried, some with disastrous results. It has subsequently been demonstrated that some of the techniques produced unpredictable and shallow incisions, that 24 and 32 incisions are not better than 16 incisions, and that the refractive change produced by eight and 16 incisions is not linear.
More recently, the mean correction achieved has increased to an average of approximately 5.0 diopters through the limitation of the optical zone to a minimum size of 3.0mm, the use of micrometer controlled diamond blades, the elimination of incisions through the limbus, and a decreased number of incisions to 16 or less. Although there is still no standardized procedure for performing radial keratotomy, most surgeons are currently achieving similar results using different techniques. Taking into account these surgeon specific variations, the basic procedure of radial keratotomy will be described.

Various authors differ in their selection criteria of candidates for radial keratotomy. Some do not discuss the selection procedure other than the candidate having some degree of myopia and no active pathology. However, most practitioners require candidates for the procedure to satisfy the following criteria: [1] Be at least 18 or 21 years of age; [2] Have a minimum degree of myopia of between 0.87 to 1.50 diopters, as determined by the spherical equivalent of a cycloplegic refraction; [3] Have myopia which is not progressive; [4] Have a best correctable acuity in each eye of at least 20/50. In addition, most require candidates who are contact lens wearers to remove their lenses two weeks prior to surgery and demonstrate refractive and keratometric stability. In addition to above, one author requires candidates to have an intraocular pressure of at least 9.0mm Hg, and demonstrate either a specific job requirement and/or psychological need for the surgery.

After a candidate has been accepted for the radial keratotomy procedure, a preoperative evaluation is performed. This typically includes: slit lamp examination, cycloplegic refraction, keratometry with a calibrated instrument, applanation and Maklakov tonometry, anterior segment photography, and ultrasonic pachometry. Endothelial cell counts are not routinely done at present by the majority of surgeons performing radial keratotomy, and very few of the more recent studies include this information.

During the next phase of the procedure a determination of the operative parameters is made, usually by solution of the equations described by Fyodorov. These equations require that the amount of myopia to be corrected, a scleral rigidity factor, as determined by Maklakov tonometry, and mean corneal radius of curvature known. Based on these equations the surgeon determines the optical zone size, the number of incisions and the depth of the incisions to be used. Solutions to the equations are determined graphically using a series of nomagrams based on the use of either 8 or 16 incisions. Initially, 16 incisions were used when the spherical equivalent of the refractive error exceeded 4 diopters. More recently, studies indicate that eight incisions are safer and as effective in correcting simple myopia as and an eight incision technique is most often found in the current literature.

Adjustments to the surgical parameters determined graphically can be made based on intraocular pressure, age of the patient, and magnitude of the desired keratometric effect. In general,
higher intraocular pressure, higher keratometry readings, and older age correlate clinically with a greater reduction in myopia for the same surgical procedure. An attempt is usually made to correct for astigmatism when cylinder power is 1.00-1.50 diopters or greater, or if there is a large reduction in acuity due to the astigmatic component of refractive error.

Radial keratotomy is normally performed on an out-patient basis, and the nondominant eye is usually the first to be operated on. Before surgery a wide spectrum antibiotic is administered as a prophylactic measure, and the patient placed on the operating table in a supine position. A topical anesthetic of 0.5% tetracaine hydrochloride or 0.5% proparacaine is applied to the eye to be operated on and a diazepam {Valium} sedative is given if necessary. A lid speculum is inserted into the operative eye and the corneal reflection of the operating microscope filament is used to estimate the intersection of the visual axis of the cornea. The corneal light reflex is assumed to be 0.3-0.4mm above the patient's visual axis. Using this reference a dull marking trephine of the appropriate diameter is used to make a circular corneal epithelial impression with the visual axis at the center. The probe tip of an ultrasonic pachometer is then placed perpendicularly to the cornea at the 3, 6, 9, and 12 o'clock meridians just outside the trephine mark and the corneal thickness is measured. Readings are taken at each site until two or three are identical, and these measurements are used to set the depth of the blade on the micrometer diamond knife. This is then verified using a Kremer blade gauge or a Bores gauge block under the highest power of the operating microscope. The blade is set to obtain 90%-95% corneal incision depth at the most central portion of the incisions.

The radial cuts are made by gently plunging the tip of the cutting blade perpendicularly into the cornea at the edge of the marked optic zone and cutting to the limbal corneal vascular arcade. After holding the blade in place for a few seconds to insure maximum depth, it is pulled toward the limbus in a single, slow, smooth movement while the knife handle is maintained perpendicular to the corneal surface. Each incision is made equidistant around the cornea usually starting at the 9 o'clock meridian and ending at the 12 o'clock meridian. Single or double pronged forceps are used to grasp the globe at the limbus 180 degrees away from the direction of the incision being made. Each incision is irrigated with a balanced salt solution and its uniformity checked with a depth gauge or by direct inspection using an incision spreader. A cycloplegic agent [atropine, homatropine, or cyclopentolate] and topical antibiotic is instilled, and a pressure patch is applied at the discretion of the surgeon. In general, a recent study finds a 38% increase in corneal perforation following redeepening incisions with no significant increase in corneal flattening for any optic zone diameter.34

Patients undergo postoperative examinations at frequent intervals. A typical schedule of follow up exams is: 24 hours, four days, two weeks, one month, three months, six months, one year, and yearly intervals thereafter. Each examination begins with a subjective evaluation designed to measure symptoms of fluctuating vision, glare, light sensitivity, and lines around lights at night. Also measured
is uncorrected distance acuity, manifest refraction, best corrected visual acuity, keratometry and slit lamp examination. A cycloplegic refraction is normally performed approximately six months after surgery.

RESULTS

Although a number of studies have reported the efficacy of radial keratotomy, most reports were based on results obtained no more than one year after surgery. Longer term data now available indicates significant visual and refractive changes occur after the procedure. The results reported on radial keratotomy have tended to rely on the spherical equivalent before surgery compared to visual acuity postoperatively. [see Table 1, Figures 1 and 2.]

Cowden\textsuperscript{54} found an overcorrection at one year, 35% [54 eyes] were either emmetropic up to 1.0 D hyperopic, 15% [24 eyes] were 1.1 to 2.0 D hyperopic, 4% [7 eyes] were 2.1 to 4.0 D hyperopic, and 1% [2 eyes] were more than 4.0 D hyperopic.

Sawelson and Marks\textsuperscript{33} reported an average \( SE \) of -1.14 diopters after one year, and average \( SE \) of -0.85 diopters after two year postoperatively. [See Figure 3]. The best-corrected visual acuity of 20/25 was found in 98% [276] of the eyes, and a best-corrected visual acuity of 20/50 in one eye, and two eyes showed more than one line drop in Snellen chart.

In another recently released study, Deitz and Sanders\textsuperscript{46} have shown a clear trend toward increasing hyperopia being demonstrated in the third and fourth postoperative years. [See Figure 4.] A mean \( SE \) at one year of +0.11 D [\( +/- \) 0.21] was found, as compared to a mean \( SE \) of +0.64 D [\( +/- \) 0.23] at four years postoperatively.

Nuemann\textsuperscript{69} confirmed the results of Deitz and Sanders study: a change in \( SE \) and keratometry reading exceeding 0.5 D was present one year postoperatively in 11% to 24% of eyes, depending on the degree of preoperative myopia.

The PERK study's\textsuperscript{19} results show that between six months and one year postoperatively there is a significant increase in hyperopia. [See Figure 5.] Cycloplegic \( SE \) at one year was, in the lower group +0.14 D, middle -0.33 D, and -1.19 D in the higher group. Between baseline and one year postoperatively, 12.7% lost 3 to 7 letters on a Snellen chart, 0.7% lost 8 to 11 letters, 24.1% gained 3 to 7 letters, and 1.7% gained 8 to 11 letters.

KERATOMETRY

In general, it has been found that there is a linear relationship between the change in keratometric power and the change in refraction between baseline and one year. Most studies state that this change is usually smaller in keratometry as compared to refraction.
Rowsey, et al\textsuperscript{29} examined the keratometric data of patients undergoing radial keratotomy by the corneascope and Humphrey keratometer. They found the central cornea routinely flattens more than the periperal cornea producing an apparent knee of altered refractive change.

Deitz, et al\textsuperscript{27} found the average keratometry measurements differed by 0.5 D in 72\% of the eyes six months postoperatively and 1.0 D in 85\% of the eyes one year postoperatively. Deitz and Sanders\textsuperscript{46} in their four year study found that changes in keratometry paralleled refractive changes, but were smaller in magnitude. The mean average keratometry was 39.80 D [+-0.22] at one year following surgery, and 39.20 D [+-0.25] at four years postoperatively. Corneas at four years postoperatively were found to be flattened by 0.5 D or more in 42 cases [52.5\%]; they remained within 0.5 D in 35 cases [43.8\%]; and they steepened by 0.5 D or more in 3 cases [3.7\%]. Thirteen cases [16.3\%] flattened by 1.0 D and the remaining 67 cases [83.8\%] were within 1.0 D of the one year postoperative keratometry at four years.

Arrowsmith and Marks\textsuperscript{58} found a mean keratometric change of -3.29 D at six months and -3.64 D at twelve months, whereas Cowden's study\textsuperscript{54} revealed a change of +1.00 to -3.87 D with a mean change of -1.41 D six months postoperatively.

In the PERK study, it was found that in the middle and higher groups the change in refraction is, on the average, greater than the change in keratometric power by 0.54 and 0.97 diopters, respectively. In the lower group the change in refraction varies, on the average from 0.58 diopters more to 0.30 diopters less than the change in keratometric power.\textsuperscript{19}

In a recently released update of the PERK study, Schanzlin, et al\textsuperscript{65} writes that the cornea becomes steeper from morning to evening at both three months and one year for many patients. A morning to evening change of 0.50 and 1.25 diopters occurred in 37\% of the eyes at three months with the average change of all operated eyes being 0.40 diopters. The one year results showed a similar change with the average change being 0.43 diopters.

**ASTIGMATISM**

Radial keratotomy was originally done to correct astigmatism and keratoconus. The results varied with all sorts of different procedures being tried; varying the number and location of incisions, as well as the size of the optic zone and the direction of the incision [radial and perpendicular incisions].

Properative cylinder protocol varied with studies from a low of less than 1.50 D refractive cylinder in the PERK study\textsuperscript{19} to a high of less than 4.25 D in Cowden's study.\textsuperscript{54} Very little literature documents the astigmatic error of eyes after radial keratotomy.

The PERK study, one year postoperatively, revealed increases of more than 0.25 diopter of astigmatism in 33.6\% of the eyes, while 11.7\% of the eyes showed a decrease of more than 0.25
diopters. The study showed a range of change in astigmatism from a decrease of 1.25 diopters to an increase of 2.25 diopters. Sawelson and Marks's preoperative cylinder measurements ranged from 0 to 3.5 D, with a mean of 0.72 D. One year after surgery, there was a drop in average cylinder of 0.1 D, with a range of decrease from 2.50 D to an increase of 2.25 D. The two year results revealed a drop in average cylinder compared to preoperative cylinder of 0.13 D, with a range of a drop from 2.75 D to an increase of 2.00 D. In 50% of the eyes the refractive cylinder was reduced, in 18% there was no change in cylinder, and in 32% of the eyes there was a worsening of the cylinder refractive error or surgically induced astigmatism.

Arrowsmith and Marks did not report any specific preoperative protocol for astigmatism. Their postoperative results show a range of reduction in cylinder power from a reduction of 4.0 D to an increase of 3.75 D. [see figure 6.]

Cowden reported an average change of axis of 6.24 degrees and a range of change from 0 to 15 degrees. One patient has been reported to have had a loss of more than one line of best-corrected visual acuity [Snellen chart] due to an addition of 1.75 diopters of residual astigmatism.

COMPPLICATIONS

Since its introduction to the United States in 1978, radial keratotomy has been a subject of increasing interest and controversy in the ophthalmologic community. Post-surgical complications found in the literature range from mild and temporary to severe and vision threatening. More recently, a death associated with radial keratotomy has been reported. At this time sight threatening complications include endophthalmitis, corneal edema, and cataracts. Endothelial cell loss is potentially the most serious long term complication of radial keratotomy, and this issue is at the center of the present controversy surrounding the procedure. To date, there is disagreement over both the number of endothelial cells lost initially during surgery, and whether there is progressive cell loss after surgery. The range of initial cell loss reported varies from 0 to 11% in humans and from 10% to 20% in animal studies.

Yamaguchi, et al report scanning and transmission electron microscopic evidence of endothelial cell edema and damage in rhesus monkeys after radial keratotomy, and further state that the endothelial loss is progressive. Similarly, in a separate study, Yamaguchi, et. al report histologic evidence of progressive endothelial cell loss and morphologic cellular changes in rabbit eyes three months after radial keratotomy. This is a surprising finding since the rabbit, unlike the human, has a regeneratable endothelium. Progressive endothelial cell loss following radial keratotomy in humans has
been reported. Most studies find no evidence of progressive cell loss in humans at one and two year intervals following radial keratotomy; however, almost all authors agree that longer term followup is required to determine the full effect of surgery on the endothelium.

The mechanism of the initial damage to the endothelium is not known. Both mechanical and inflammatory etiologies have been suggested. Some studies speculate that during the procedure, bending of the cornea and or microperforation occurs, causing trauma to the endothelial-Descemet's membrane complex, leading to endothelial cell death. Binder, et al. and Yamaguchi, et al. have noted linear folds and protrusions beneath and parallel to the surgical incisions and have associated these findings with endothelial cell damage. An alternate possibility is that acute endothelial damage results from a low grade post-surgical inflammation. At least one author has reported finding inflammatory cells at the level of the endothelium. Jester, et al. proposes an inflammatory etiology for endothelial cell loss based on histological studies of nonhuman primates. More recently, however, Yamaguchi, et al. administered corticosteroid injections to Green monkey eyes after radial keratotomy had been performed to study the effect of reducing post-surgical inflammation on endothelial cell loss. Although the corticosteroid therapy reduced cell loss during the first month, there was no significant difference in cell densities after nine months, suggesting a non-inflammatory mechanism of cell loss.

Several histologic studies of human corneas that had previously undergone anterior radial keratotomy have been published recently. In all cases, histopathology of the cornea after the procedure showed diffuse epithelial edema, epithelial ingrowth into the incisions, variable incision depth, irregularly thickened basement membranes, stromal hypercellularity, posterior folds in Descemet's membrane, and endothelial cell abnormalities. One study also noted marked inflammatory cell infiltrates in all corneal layers, vascularization, Descemet's membrane break, and loss and attenuation of endothelial cells. Two cases of complications leading to corneal transplant after radial keratotomy have been reported, but many others are known to exist. Both cases had the similar feature of perpendicular transecting incisions apparently used to correct for astigmatism. Other studies also indicate that circumferential or transverse incisions which transect radial incisions result in wound gape, epithelial defects, delayed healing, and corneal edema.

Corneal perforation at the time of surgery is a potentially serious, frequently reported complication of radial keratotomy. The reported incidence ranges from 0 to 35% with an average of about 11%. Uniform incision depth is difficult to achieve even with improved techniques utilizing micrometer diamond blades, ultrasonic pachymetry, and blade gauges. Corneal dehydration during the procedure due to high intensity lighting can cause as much as a 10% thinning of the cornea. Changes in intraocular pressure due to the force required to make each incision also
decreases uniformity of incision depth. Other histological studies, also done on cadaver eyes, show large variations in incision depth with as much as a 30% difference between adjacent incisions, and microperforations not apparent at the time of surgery. Surprisingly, Salz, et al. found no difference in the consistency of incision depth between micrometer diamond blades and manually set metal blade fragments in a study of incision depth after radial keratotomy in cadaver eyes. Both instruments achieved an average depth of approximately 87% with a range of 61-98%.

Although most perforations that occur at the time of surgery are self-sealing and do not cause any problems, serious associated complications have been observed. A case of endophthalmitis that developed nine days after radial keratotomy due to a microperforation has been reported. Despite topical and systemic antibiotics, core vitrectomy, and topical steroids, best corrected acuity was reduced from 20/20 to 20/30-2. Stark, et al. described a case of cataract in a 31 year old man sixteen weeks after radial keratotomy. The presence of spoke-like lines conforming to the radial incisions implicate unrecognized corneal perforations at the time of surgery as the cause of the cataract formation.

Inability to consistently achieve a uniform incision depth is most likely a major factor in accounting for the poor predictability of the results obtained with radial keratotomy. In the Prospective Evaluation of Radial Keratotomy Study (PERK), which followed a carefully standardized procedure and utilized the most modern surgical techniques, it was not possible to accurately predict the refraction at one year after surgery for individual patients. There was an approximate 5.0 diopter range in myopia reduction in individuals with a baseline preoperative refraction of -4.50 diopters or less. The range increases to approximately 7.50 diopters in individuals with baseline refractions of greater than -4.50 diopters. Although many reports on radial keratotomy do not provide the standard deviations necessary to access predictability, similar inconsistent results are found in the literature. Earlier studies have not been able to relate such factors as preoperative keratometry, intraocular pressure, number or depth of incisions, or corneal thickness to changes in refractive error after surgery.

Since the changes in refraction generally parallel the changes in keratometry, the literature suggests that corneal wound healing is not complete between one and four years after surgery. Previous experimental studies of corneal wound healing have been on animal models and have been short term. Although initial reports suggested that human corneas were healed a short time after radial keratotomy, more recent studies indicate that there is a long delay in corneal wound healing after surgery. One recent study, of 84 eyes from patients enrolled in the PERK study, documents the presence of fine, gray spicules along the edges of the incisions in some eyes as long as three years after surgery. The spicules correspond to areas of reorganization of the stroma, and their presence suggests that wound healing is not yet complete. Steinberg, et al., reported that the scars from
keratotomy continued to change for at least three years after surgery; the fine spicules that protruded from both sides of the wound gradually disappeared from the anterior toward the posterior cornea during this time.

A failure in corneal wound healing associated with the formation of epithelial inclusion cysts in a 26 year old woman who underwent radial keratotomy six months previously has been reported. In the first study to describe the histopathology of the human cornea after radial keratotomy to correct myopia, Ingraham, et al reports an average of 25.3% epithelial ingrowth in the radial incisions of a 36 year old man who died from unrelated causes 17 months after the procedure. Good visual results were obtained in both eyes after the surgery. The presence of epithelium in the wounds is thought to play a role in the delayed wound healing, and the gradual replacement of the epithelium by fibrous scarring is a probable mechanism in the regression of corneal flatting. Nelson, et al describes corneal epithelial basement membrane changes, similar to those seen in map-fingerprint-dot dystrophy, in 33 of 71 eyes following radial keratotomy. Although the changes tended to be transient and not affect acuity, three eyes had changes that lasted for 12 months.

In a similar study, Jester, et al document "reduplication" of basement membrane that has usually been associated with recurrent corneal erosion, diabetes, Fabry's disease, Meesman's corneal dystrophy, keratoconus, herpes simplex, and herpes zoster. Other studies have noted similar abnormal histological features that indicate a delay in both epithelial and stromal wound healing following radial keratotomy. The time after surgery when wound healing is complete and corneal shape will stabilize is not known.

A frequently overlooked, but potentially serious complication of radial keratotomy is the decreased wound strength that occurs following surgery. A case of corneal rupture through the keratotomy scars two years after surgery, following blunt head trauma in a 24 year old woman who was involved in a automobile accident, has been reported. Studies of corneal tensile strength in animal eyes show significant differences between eyes that have had radial keratotomy and controls with regard to the amount of energy required for rupture. Larsen, et al report that rabbit eyes that have had surgery require 50% less energy to rupture than control eyes over the 90 day study period and eyes that had microperforations during surgery ruptured with 50% of the energy required to rupture the operated eyes that had no perforations. In addition, 98% of the eyes that had surgery ruptured along one or more of the corneal incisions. Similar findings in other animal studies have been reported.

In an auxiliary experiment on nine freshly enucleated human eyes, Rylander, et al documents the same weakening and rupture patterns after radial keratotomy as those seen in animal studies. This suggests that the acute injury studies done on animal models to study the effects of radial keratotomy on corneal strength does apply to human situation.
Radial keratotomy is also associated with numerous short term post-surgical complications. Glare, fluctuating visual acuity throughout the day, and photophobia are frequently reported complications after surgery.14,19,26,32-36, 38,42,65

Although postoperative complaints of glare are found in most of the literature, various authors disagree as to its severity and frequency after radial keratotomy. Arrowsmith and Marks26 report that at six months after surgery 13% of 125 eyes reported mild glare, 6% moderate glare, and 0.6% severe glare occasionally. One year after surgery, 11% had mild glare, 2% moderate glare, and 1% severe glare at night only. Sawelson and Marks33 report the presence of glare at one and two years as 18% and 4%, respectively. Hoffer, et al.,14 in their two year evaluation report that 26% had mild glare, 16% had moderate glare, and 2.5% had severe glare. Nirankari, et al.36 report glare in only 1 patient at one year. According to Dietz, et al.,27 37% of the patients at 3 months and 27% at one year had complaints of glare. Rowsey51 reported glare in 50% of his patients at 3 months, while Bores2 recorded only 4% of his patients' having problems with glare at the same period. Cowden54 recorded complaints of glare at night in over 33 of his patients at 6 months.

This discrepancy is largely due to the lack of a standardized objective means of assessing glare. All but one study utilized subjective questionnaires before and after surgery to obtain their information. Only in the PERK study19 was a clinical glare tester used to gather objective information on glare sensitivity. This study reports that at one year after surgery, 62% of the patients saw either the same number or one to four more contrast sensitivity slides than at baseline; 33% saw one or two fewer slides; 5% saw three to five fewer slides. Until such an instrument and standardized procedure is used by all investigators, an accurate assessment of the frequency and severity of glare after radial keratotomy cannot be made.

The increased glare sensitivity in patients after radial keratotomy is thought to result from diffraction by the incisions and subsequent scarring. These areas of diffraction cause stray light to be scattered over the retinal image and thus reduce its contrast. This effect is even more pronounced at night when the dilated pupil exposes peripheral areas of scarring, and when the radial incisions are made obliquely resulting in wider incision scarring. It has been reported that there is no difference in the glare sensitivity between the 8 and 16 incision techniques, however, the 32 incision configuration is reported to increase the glare sensitivity by a factor of 1.5.55 It is generally accepted that the larger the optic zone and the narrower the incisional scar the less glare is produced. The decrease in glare sensitivity with time is most likely the result of scar contracture and perceptual adaptation.

Diurnal fluctuations is a frequently cited persistent side effect that involves from 1.9% to 100% of cases.3,14,19,21,27,29,31,61-64 As with glare, there is disagreement as to the frequency and severity of this complaint. The majority of the studies have reported that the fluctuating acuity is experienced only during a short period after surgery. However, most of these studies have been based
upon results obtained less than one year after surgery. In a recently released update of the PERK study, Schanzlin, et al., reveals diurnal changes in refraction, visual acuity, corneal curvature, and intraocular pressure after radial keratotomy. Examinations done between 7:00 and 8:00 a.m. and again between 7:00 and 8:00 p.m. the same day revealed diurnal fluctuations in refraction; at three months 36% of the eyes changed by 0.50 or more diopters and 44% changed at one year with the average change at three months being 0.39 diopters [SD=0.40] and 0.42 diopters [SD=0.38] at one year. [see figure 7.] In addition, uncorrected visual acuity changed from morning to evening, [see figure 8.] and best-corrected visual acuity showed, at three months, a 14% loss and a 16% gain of one Snellen line [3-6 letters], and at one year 11% of the operated eyes lost one line and 11% gained one line. Questionnaires filled out before and after surgery revealed that 40.3% of the study participants and 59.3% of the nonparticipants reported that they had "moderate to great trouble" with fluctuating vision before surgery, as compared with 83.9% of the participants and 72.8% of the nonparticipants reporting after surgery. It has been shown that following radial keratotomy, there is approximately a five Snellen line variation in the visual acuity for a given refraction. The PERK study has also revealed that for a given change in the refractive error, keratometric power, or the visual acuity, there was a considerable variation in the change in intraocular pressure. Schanzlin, et al. contributes that these fluctuations are related to radial keratotomy since these changes were not observed in the unoperated eye of each patient.

Other complications that are associated with radial keratotomy include: corneal erosions, superficial keratitis, iritis, iridocyclitis, pain, stromal and filamentary keratitis, epithelial iron lines, Hudson-Stahli line formation, presumed herpes simplex infection, corneal ulcers, blood in the incisions, corneal scarring and vascularization, subconjunctival hemorrhage, and contact lens refitting difficulties.

At present, complications in contact lens wear following radial keratotomy are not well documented. It is not known if the little information available on contact lens wear after radial keratotomy in animal models is applicable to the human situation. In the studies that do present postsurgical contact lens information, gas permeable lenses are usually cited as the best choice of correcting residual refractive error because they are able to mask changes in corneal contour caused by surgery and also are thought to allow more oxygen to the cornea than do soft lenses. However, gas permeable lenses have been reported as having a tendency to re-steepen the cornea after surgery, and in so doing reduce the effect of surgery. In patients who are fitted with soft lenses after surgery, especially extended wear lenses, neovascularization in the incisions is a common occurrence. This is thought to be due to decreased amount of oxygen available to the cornea while wearing a soft lens and the route provided by the incisions which most likely allow such vasculization to occur more easily. Soft lenses are also associated with inducing visual fluctuations due to the abnormal movement and
collection of tears between the lens and surgically altered cornea. In addition, breaks in the epithelium surrounding the incisions and recurrent erosions have been reported following both hard and soft contact lens wear after radial keratotomy.56

DISCUSSION

The results reported on the effect of radial keratotomy have tended to compare the spherical equivalent before surgery, to postoperative visual acuity. The validity of this type of analysis is questionable. Patients have shown to have increased visual acuity one year postoperatively with the same amount of refractive error as baseline exhibited. For example in the PERK study,19 56 eyes with a refraction of -2.00 to -2.50 diopters at baseline had a mean uncorrected visual acuity of 20/125 [range of 20/40 to 20/200], whereas 29 eyes with the refraction of -2.00 to -2.50 diopters one year postoperatively had a mean uncorrected visual acuity of 20/60 [range of 20/30 to 20/125].

Based upon a review of the current literature on radial keratotomy, some conclusions can be made about this procedure: [1] Studies presently available are not sufficient to fully assess the risks of this procedure. Most have a followup period of one year or less, and use an unsatisfactory method of evaluation [surgeon evaluating his own results]. Studies with a followup of as long as 20 years may be necessary to fully document the long term effects of radial keratotomy; [2] Several complications, including blindness [20 reported cases] and death, can and have occurred; [3] Undercorrection, overcorrection, irregular astigmatism, glare, diurnal fluctuations of vision, longterm regression are frequent complications of surgery; [4] Although there have been improvements in instruments and techniques, poor predictability with variable results is still a major problem with radial keratotomy.

The PERK study found that by reducing myopia, radial keratotomy will induce the earlier onset of symptomatic presbyopia, especially in individuals who were left with hyperopic refractive errors [19% of the PERK study's patients]. Most patients who are overcorrected will replace their dependance on an optical correction for nearsightedness with an earlier dependence on reading glasses.19 The occurrence of hyperopia is just now appearing as longer term studies are released. Deitz and Sanders46 have found the occurrence of significant hyperopia [ > 1.0 diopter ] between one and four years which was not significantly affected by the patients' age or sex, IOP, average keratometry, optical zone diameter, mean incision depth or the number of incisions. Analysis of the individual's results, rather than groups of patients, show a high percentage of significant over and undercorrections. The best results were obtained in patients with preoperative myopia of less than 3 diopters. As longer term data now becomes available, patients need to be informed of the risks and advantages that result from radial keratotomy.
APPENDIX

Table 1.

Figures 1-8.
<table>
<thead>
<tr>
<th>Amount of Preoperative Myopia</th>
<th>Group I 0-3 Diopters</th>
<th>Group II 3-6 Diopters</th>
<th>Group III 6-10 Diopters</th>
</tr>
</thead>
<tbody>
<tr>
<td>1979, Fyodorov and Durnev {18}</td>
<td>94.5</td>
<td>67.7</td>
<td>19.5</td>
</tr>
<tr>
<td>1981, Bores et al {21}</td>
<td>29</td>
<td>29</td>
<td>0</td>
</tr>
<tr>
<td>1982, Fyodorov and Agranovsky {16}</td>
<td>100</td>
<td>100</td>
<td>91.1</td>
</tr>
<tr>
<td>1983, Kremer and Marks {31} *20/50</td>
<td>93</td>
<td>82</td>
<td>45</td>
</tr>
<tr>
<td>1984, Deitz et al {27}</td>
<td>97</td>
<td>87</td>
<td>70</td>
</tr>
<tr>
<td>1984, Arrowsmith and Marks {58}</td>
<td>95</td>
<td>83</td>
<td>56</td>
</tr>
<tr>
<td>1985, Waring et al, PERK study{19}</td>
<td>92</td>
<td>81</td>
<td>63</td>
</tr>
</tbody>
</table>

Studies Not Categorized in Groups

<table>
<thead>
<tr>
<th>Whole Study</th>
<th>0-5 Diopters</th>
<th>&gt; 5 Diopters</th>
</tr>
</thead>
<tbody>
<tr>
<td>1983, Hoffer et al {14}</td>
<td>65</td>
<td>-</td>
</tr>
<tr>
<td>1980, Bores et al {21}</td>
<td>65</td>
<td>-</td>
</tr>
<tr>
<td>1983, Hoffer et al {14}</td>
<td>50</td>
<td>-</td>
</tr>
<tr>
<td>1983, Rowsey et al {29}</td>
<td>82</td>
<td>-</td>
</tr>
<tr>
<td>1984, Singh et al {30} * 20/30</td>
<td>55.5</td>
<td>-</td>
</tr>
<tr>
<td>1983, Nirankari et al {8}</td>
<td>-</td>
<td>65</td>
</tr>
</tbody>
</table>

2 Year Evaluation

<table>
<thead>
<tr>
<th>Group I 0-3 Diopters</th>
<th>Group II 3-6 Diopters</th>
<th>Group III 6-10 Diopters</th>
</tr>
</thead>
<tbody>
<tr>
<td>1984, Arrowsmith et al {60}</td>
<td>92</td>
<td>80</td>
</tr>
<tr>
<td>1985, Sawelson and Marks {33}</td>
<td>83</td>
<td>76</td>
</tr>
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</table>

4 Year Evaluation

<table>
<thead>
<tr>
<th>Group</th>
<th>Group II</th>
<th>Group III</th>
</tr>
</thead>
<tbody>
<tr>
<td>1985, Deitz and Sanders {46}</td>
<td>NR</td>
<td>NR</td>
</tr>
</tbody>
</table>

*20/40 or Better
FIG. 1  Comparison of 1 Year Results with Visual Acuity of 20/40
FIG. 2  Comparison of 1 Year Results {see KEY} with 20/40 Visual Acuity

Year of Study and Researchers
FIG. 3 Sawelson and Marks, 1985

Percentage of Eyes with 20/40 Visual Acuity
{ 2 Years Postoperatively }

Groups in Amount of Preoperative Myopia
1980-81 are Years of Surgery

2 Year Evaluation
More Myopic Remained the Same
More Hyperopic

Shift Between 1 and 4 Years Postoperatively

4 Year Evaluation
FIG. 5 Reprint from PERK Study, Waring, et al. 1985

Change in Minus Power of the Cycloplegic Refraction (D) between Six Months and One Year after Radial Keratotomy

Baseline Refraction:
- -2.00 to -3.12
- -3.25 to -4.37
- -4.50 to -8.00

Hyperopic Shift
FIG. 6 Arrowsmith and Marks, 1984

Induced Astigmatism
Increased
1.12 to 2.00
9%

Increased
0.50 to 1.00
29%

Changed less
than 0.50
64%

Decreased
0.50 to 0.75
89%

Change in Minus Power of Manifest Refraction (D) from Morning to Evening

Diurnal Change Following Radial Keratotomy
FIG. 8  PERK Study, Schanzlin, et al. 1986

Diurnal Change Following Radial Keratotomy
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