PRECISION STANDARDIZATION OF RADIAL KERATOTOMY*

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INTRODUCTION

WE BELIEVE RADIAL KERATOTOMY IS AN UNSATISFACTORY OPERATION. IT CHALLENGES our traditional view of indications for ophthalmic surgical intervention, offering more cosmetic and psychological than functional benefit for the majority of potential patients for whom it seems intended. The extraordinarily rapid rise of interest in radial keratotomy in this country, in our opinion, has been based partly on economics and public demand stimulated by manipulation of the media. "Corneal dysplasia" has even been suggested as an alternative term for "myopia" for purposes of insurance collection.¹

Nevertheless, it must be acknowledged that Americans seem to detest their spectacles to a degree which has been astonishing to ophthalmologists, and we should face the disquieting fact that radial keratotomy operations are being performed on human eyes in this country at what may be a geometrically increasing rate. Because a number of important research and training institutions have recognized this development, they have undertaken their own clinical evaluations of this procedure, and the institution of my discussant today (UCLA) is one of these. The dimensions of the problem have also been recognized by the National Eye Institute, and an ambitious, expensive, multi-center collaborative study (PERK) has been funded.²

Our position is that with presently available radial keratotomy techniques, even the most carefully designed clinical study which uses accepted clinical trial methodology may not provide meaningful data, because the study will include within it unavoidable variations in the main surgical variable itself—namely, the surgical technique. What we propose

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to present is information about a system we have designed at the University of California, San Francisco which minimizes to an extent greater than any other presently proposed surgical technique, the variables in the radial keratotomy operation.

INSTRUMENTATION

The system described in this paper consists of two components: first, a cutting template for making radial corneal incisions which is affixed to the cornea by suction, and second, a specially adapted super blade and handle which integrates with the suction template so as to provide eight radial incisions of the same length and depth.

The suction template is a transparent, plastic, dome-shaped device, the inner curvature of which matches the average curvature of the human cornea. The outer curvature is slightly steeper than the inner curvature to allow for deepening of the radial incisions in the periphery where the cornea is thicker. A photograph of the suction template is shown in Figure 1 and a diagram is shown in Figure 2.

The suction template is substantially hollowed out from the base with a suction port attached so that a partial vacuum can be applied to attach the instrument to the cornea. A series of radially oriented slits perforate the instrument, and each slit is surrounded by a plastic strut which joins the outer and inner surfaces of the template. Thus, when suction is applied, the cornea is held firmly against the inner surface of the instrument, particularly against the struts at the lower opening of each slit, and the curvature of the cornea is closely matched by the lower curvature of each strut.

A surgical "super blade" is attached to a handle in such a way that the handle functions as a stop preventing penetration of the blade below the lower opening of each slit beyond a pre-determined depth. The handle is modified to integrate with grooves on the surface of the template to facilitate stability and precision of blade movement during cutting.

The center of the template has a circular opening through which the pupil and optic axis can be visualized, and it is possible for the patient to look through this opening to be certain that the instrument is appropriately centered. A solid ring is fixed at the lower extreme of this central opening, and this acts as a "fail safe" stop mechanism to prevent cutting toward the center of the cornea beyond the limit of a pre-determined optical zone.

After suction is applied the instrument remains in position during performance of the complete series of radial incisions while causing a rise

of intraocular pressure of only approximately 5 mm Hg. As each incision is made, the cornea does not relax and change its configuration because the suction action of the template maintains corneal position and shape. In use the blade integrates with the surface of the suction template, and after blade depth is set, the blade is placed through the template into the cornea and then moved along the template surface from one extreme of the slit to the other to complete an incision of fixed length and depth. Even when we intentionally set the blade to perforate the cornea the template maintains a deep anterior chamber and protects the iris and lens despite the corneal leak, in the manner of a Flieringa Ring.

METHODS

To test the reproducibility of radial corneal incisions with the instrumentation system just described, a series of 36 fresh pig eyes were used. The intraocular pressure was maintained at 20 mm of mercury by intravitreal injection.

In all 36 eyes the suction template was used to make eight radial corneal incisions 3 mm in length and 0.5 mm in depth. In all cases a central 3 mm optical zone was chosen and the limbus was not crossed.

After conclusion of all eight incisions in each eye, the length of each incision was measured with a precision caliper accurate to 0.01 mm. The depth of each incision was measured at mid-point using a micrometer controlled micro-manipulator adapted to measure depth under high magnification with an operating microscope. The micro-manipulator advanced a movable probe with a blunted end into the incision while a fixed plate oriented perpendicular to the probe touched the surface of the cornea tangentially. The end point was readily observed under high magnification as a slight distortion in the corneal surface caused by the first touch of the base of the incision by the advancing probe. At this point a micrometer reading was made and taken as the depth measurement.

RESULTS

Length and depth measurements were made on eight separate incisions on each of 36 eyes, for a total of 288 incisions. Table I gives the mean

FIGURE 1

Photograph of suction template. A: Superior surface and B: inferior surface.

TABLE I: LENGTH AND DEPTH OF INCISION FOR 8 CUTS IN EACH OF 36 EYES

EYE NUMBER	MEAN LENGTH ± STD. DEVIATION	LENGTH RANGE (MIN. TO MAX.)	MEAN DEPTH ± STD. DEVIATION	DEPTH RANGE (MIN. TO MAX.)
1	2.96 ± 0.18	0.5 (2.6-3.1)	0.549 ± 0.033	0.11 (0.50-0.61)
2	3.11 ± 0.25	0.7 (2.7-3.4)	0.486 ± 0.055	0.16 (0.41-0.57)
3	3.28 ± 0.22	0.7 (3.0-3.7)	0.506 ± 0.033	0.10 (0.45-0.55)
4	3.30 ± 0.28	0.6 (2.8-3.6)	0.505 ± 0.035	0.10 (0.47-0.57)
5	3.13 ± 0.25	0.7 (2.8-3.5)	0.480 ± 0.056	0.16 (0.41-0.57)
6	3.14 ± 0.30	0.7 (2.7-3.4)	0.511 ± 0.038	0.11 (0.46-0.57)
7	3.22 ± 0.12	0.3 (3.1-3.4)	0.561 ± 0.026	0.08 (0.50-0.58)
8	2.98 ± 0.36	0.9 (2.5-3.4)	0.367 ± 0.038	0.10 (0.32-0.42)
9	2.86 ± 0.15	0.4 (2.7-3.1)	0.375 ± 0.046	0.11 (0.34-0.45)
10	2.88 ± 0.32	0.6 (2.7-3.3)	0.514 ± 0.056	0.16 (0.40-0.56)
11	2.68 ± 0.38	0.9 (2.2-3.1)	0.470 ± 0.033	0.11 (0.42-0.53)
12	2.62 ± 0.16	0.4 (2.4-2.8)	0.465 ± 0.058	0.15 (0.39-0.54)
13	3.16 ± 0.16	0.5 (2.9-3.4)	0.506 ± 0.018	0.05 (0.48-0.53)
14	2.99 ± 0.13	0.4 (2.8-3.2)	0.490 ± 0.185	0.05 (0.46-0.51)
15	3.16 ± 0.15	0.5 (2.9-3.4)	0.490 ± 0.044	0.13 (0.42-0.55)
16	3.06 ± 0.15	0.3 (2.9-3.2)	0.501 ± 0.025	0.06 (0.47-0.53)
17	2.94 ± 0.18	0.5 (2.7-3.2)	0.480 ± 0.029	0.09 (0.44-0.53)
18	2.91 ± 0.20	0.5 (2.7-3.2)	0.506 ± 0.032	0.10 (0.46-0.56)
19	3.11 ± 0.21	0.6 (2.9-3.5)	0.491 ± 0.023	0.07 (0.44-0.51)
20	3.13 ± 0.18	0.5 (2.9-3.4)	0.473 ± 0.027	0.07 (0.44-0.51)
21	3.04 ± 0.19	0.6 (2.7-3.3)	0.473 ± 0.028	0.08 (0.43-0.51)
22	2.99 ± 0.17	0.6 (2.7-3.3)	0.508 ± 0.021	0.06 (0.49-0.55)
23	3.06 ± 0.20	0.6 (2.8-3.4)	0.489 ± 0.024	0.06 (0.45-0.51)
24	3.05 ± 0.16	0.5 (2.8-3.3)	0.504 ± 0.032	0.10 (0.44-0.54)
25	2.88 ± 0.18	0.3 (2.8-3.1)	0.478 ± 0.028	0.07 (0.45-0.52)
26	3.11 ± 0.16	0.4 (2.8-3.2)	0.511 ± 0.023	0.06 (0.48-0.54)
27	2.91 ± 0.20	0.5 (2.6-3.1)	0.498 ± 0.018	0.06 (0.46-0.52)
28	2.83 ± 0.10	0.3 (2.7-3.0)	0.473 ± 0.022	0.07 (0.44-0.51)
29	3.10 ± 0.13	0.4 (2.9-3.3)	0.510 ± 0.019	0.05 (0.49-0.54)
30	2.94 ± 0.11	0.3 (2.8-3.1)	0.484 ± 0.023	0.06 (0.45-0.51)
31	3.00 ± 0.24	0.6 (2.7-3.3)	0.470 ± 0.025	0.07 (0.44-0.51)
32	2.84 ± 0.17	0.5 (2.5-3.0)	0.476 ± 0.032	0.09 (0.43-0.52)
33	2.99 ± 0.16	0.2 (2.9-3.1)	0.495 ± 0.019	0.05 (0.46-0.51)
34	2.95 ± 0.09	0.3 (2.8-3.1)	0.496 ± 0.019	0.06 (0.46-0.52)
35	3.05 ± 0.16	0.5 (2.8-3.3)	0.505 ± 0.009	0.03 (0.49-0.52)
36	2.94 ± 0.11	0.3 (2.8-3.1)	0.488 ± 0.017	0.03 (0.48-0.51)

length, with standard deviation and range, as well as the mean depth, with standard deviation and range, for the eight incisions in each of the 36 eyes.

The overall mean *length* of all 288 incisions, expressed as the mean of the means for each eye, was 3.01 mm with a standard deviation of 0.15 mm. The overall range of incision length was 1.5 mm with a minimum length of 2.2 mm and a maximum length of 3.7 mm. The mean incision

FIGURE 2

Diagram of suction template. A: Central opening for visual axis. B: Curved base. C: Solid struts. D: Radially oriented slits. E: Suction source.

length range per eye was 0.50 mm with a standard deviation of 0.17 mm. Eighty-eight percent of the incision lengths fell within two standard deviations of the mean as shown in Figure 3.

The overall mean *depth* for all 288 incisions, expressed as the mean of the means for each eye, was 0.49 mm with a standard deviation of 0.04 mm. The overall range of incision depth was 0.29 mm with a minimum depth of 0.32 mm and a maximum of 0.61 mm. The mean incision depth range per eye was 0.09 mm with a standard deviation of 0.04 mm. Ninety-three percent of the incision depths fell within two standard deviations of the mean as shown in Figure 4.

Two eyes, the eighth and ninth eyes in the series, had distinctly shallower cuts than all of the other eyes. The mean incision depth for each of these two eyes was 0.37 mm with a standard deviation of 0.04 mm. If these two eyes with their 16 cuts are excluded from the overall group, the mean depth of the remaining 272 cuts, expressed as the mean of the

FIGURE 3
Distribution of incision lengths in 288 radial corneal incisions (eight per eye in 36 eyes).

means for each eye, is 0.50 mm with a standard deviation of 0.02. This would suggest that the system is capable of cutting a 500 μ depth incision with a standard deviation of 20 μ .

This system has an impressive degree of reproducibility even if the two eyes in question are included, but it may be legitimate to eliminate them, since a T-test for differences between means indicates that these two eyes are in a different statistical population ($P < 0.05$). We do not know why the system behaved differently on these two particular eyes, but unusually shallow cuts were created in all 16 incisions of these two eyes. It is at least possible that the blade setting may have been inadvertently shallow in these two eyes. The mean values and standard deviations for length and depth of the overall series as well as the mean range is summarized in Table II.

FIGURE 4

Distribution of incision depths in 288 radial corneal incisions (eight per eye in 36 eyes).

TABLE II: SUMMARY OF INCISION LENGTH AND DEPTH (288 INCISIONS—36 EYES,
8 INCISIONS EACH EYE)

Length		
Mean of the means of each eye	—	3.01 mm
Standard deviation	—	± 0.15 mm
Range (288 incisions)	—	1.5 mm
Minimum length — 2.2 mm		
Maximum length — 3.7 mm		
Mean range per eye	—	0.50 mm
Standard deviation	—	± 0.17 mm
Number of incisions more than 2 standard deviations from mean — 34/288, 11%		
Depth		
Mean of the means for each eye	—	0.49 mm
Standard deviation	—	± 0.04 mm
Range (288 incisions)	—	0.29 mm
Minimum depth — 0.32 mm		
Maximum depth — 0.61 mm		
Mean range per eye	—	0.09 mm
Standard deviation	—	± 0.04 mm
Number of incisions more than 2 standard deviations from mean — 15/288, 5%		
Number of incisions more than 2 standard deviations deeper than mean — 3/288, 1%		

DISCUSSION

Surgically produced, radially oriented slits in the cornea to flatten its surface and reduce myopia were first described in Japan by Sato.³ At least some of the slits in the Sato procedure were made from the anterior chamber through the endothelial surface and corneal function was compromised with secondary corneal edema developing as an overriding problem. Fyodorov⁴ described a similar procedure with radially oriented slits made from the corneal surface and extending deep in the cornea but preferably not into the anterior chamber. With 16 such radial cuts extending from approximately 1.5 mm off the optical center out to or across the limbus, it was said that a correction of between two and eight diopters of myopia could be achieved.

In this country the procedure has recently been publicized by Bores⁵ and others,⁶⁻⁸ and intense interest in the procedure has been generated. The public, stimulated by presentations in the media, has been intrigued by an operation which offers the promise of eliminating the need for spectacles or contact lenses for myopes. Ophthalmic interest has also been stimulated by the prospect of a new, easy to perform operation with enormous remunerative potential. It has been estimated that if all the eligible patients in the country were to have the operation, each and every ophthalmologist could anticipate a substantial increase in surgical revenue.⁹

Unfortunately, it is not at all clear that radial keratotomy is a safe, predictable, or effective operation. No controlled clinical trial of the procedure has been published. Results appear to be highly variable with a marked tendency for regression toward the original refractive error. Anterior chamber perforation occurs in a significant proportion of cases. The length, spacing, and depth of the incisions has been very difficult to control. One study of incision depth in primate eyes showed that with use of the classic, free-hand technique, depth of incision in eight cuts on a single eye varied between 20% of corneal thickness to perforation into the anterior chamber.¹⁰

We believe our system produced far greater consistency of incision depth. Figure 4 illustrates our mean depth for 288 incisions (0.49 mm), and the number of incisions falling above and below the mean. For reasons already discussed, all 16 incisions in two eyes were especially shallow, and this led to a total of 18/288 incisions more than two standard deviations shallower than the mean. On the other hand, and more importantly, only three out of 288 incisions (less than 1%) were more than two standard deviations deeper than the mean.

We have elected not to report a comparison between free-hand radial keratotomy and the suction template technique, because we are admittedly not experienced radial keratotomy surgeons. Thus, if our free-hand group of eyes showed a much greater variability than those eyes done with the suction template, it could simply be stated by critics that we did not have adequate free-hand training. We have elected, therefore, to report our own newly described technique and its degree of reproducibility. We believe our data support the contention that the suction template system facilitates a high degree of reproducibility of depth, length, and spacing of radial incisions in the cornea.

An important reason for variability of results may be variability of technique. Even in the best of circumstances it seems difficult if not impossible to create a precisely oriented incision of known length and depth repeatedly, especially since the cornea itself weakens, relaxes, and changes its curvature drastically as each incision is made. The suction template and integrated blade system described in this paper is directed at reducing this currently unavoidable technical variability.

Even if the incisions can be made absolutely precise, and we believe that the suction template and integrated blade are an approach to a higher degree of precision, it remains to be shown whether the biological corneal response is predictable, whether the operation is effective in the long run, and whether it can be done safely without an unacceptable incidence of significant complications. It must be considered that almost any incidence of complications is unacceptable in an invasive operation in eyes with normal corrected visual acuity.

Nevertheless, since this operation is being done in increasing numbers on human eyes, and since studies are being designed to evaluate it, we believe it is reasonable to propose the use of a technique which is likely to afford a high degree of reproducibility. It is our hope that the system we have described in this paper will be a contribution toward the achievement of this goal.

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DISCUSSION

DR BRADLEY R. STRAATSMAN. Radial keratotomy is an experimental surgical procedure for correcting myopia by using radial, partial-thickness incisions from the external surface of the peripheral cornea to produce flattening of the central cornea. Based on the work of Sato in Japan and Pureskin and Fyodorov in Russia, the first cases of radial keratotomy were performed in the United States by Bores in 1978. Sensational news media reports, public information statements, and the large number of potential patients focused attention on this operation.

It is essential to recognize that this operation is in flux. Information is coming at a rapid pace from basic studies and from clinical investigations.

Basic contributions pertinent to radial keratotomy are animal studies of radial keratotomy, human autopsy eye studies of simulated surgery, fabrication of the ultrasonic pachymeter, development of the corneoscope to quantitatively assess corneal contour, origination of the optical "glare" analyzer, and manufacture of corneal marking devices, incision depth gauges and special knives.

Against this background of evolving basic science and instrumentation, Doctor Kramer and co-authors have developed an innovative and potentially valuable device. Essentially, it is an incision template affixed to the cornea by suction and a specially adapted superblade that facilitates incisions of standardized length and depth. The authors warrant special commendation for providing experimental data, based on pig eye incisions, that strongly suggest the value of their device in achieving standardized corneal incisions.

Reflecting on this device and my experience with experimental surgery on pig eyes and skin incision templates, it is appropriate to ask if this device remains

firmly affixed and reliably positioned even when multiple, nearly full-thickness incisions markedly distort the anterior corneal surface? Is intraocular pressure maintained at a uniform level throughout the operation? Is evaluation of the diamond knife planned?

Clinical studies are equally important to the assessment and development of radial keratotomy. At UCLA, radial keratotomy clinical investigation commenced in 1979 under direction of Kenneth J. Hoffer, MD, Thomas H. Pettit, MD, Richard Elander, MD, John J. Darin, MD, John D. Hofbauer, MD, and Jeremy Levenson, MD. This study is a formal scientific investigation with a detailed protocol, approval by the UCLA Human Subject Protection Committee, provision for informed consent, and elimination of bias by separating the operating surgeons from preoperative and postoperative patient evaluations. Preliminary results of this study, reported at the American Academy of Ophthalmology meeting in 1980 and scheduled for publication in *Ophthalmology*, describe the preoperative, operative and 3-month postoperative results of this study. Six month postoperative results are now available. In essence, 85 eyes with preoperative uncorrected visual acuity of 20/200 or less and preoperative refractive error of -2.00 to more than -8.00 (spherical equivalent) had standardized 16-incision radial keratotomy. In 19 of these eyes, preoperative and postoperative endothelial cell counts showed an average decrease of about 10%. Three months postoperatively, uncorrected visual acuity in 85 eyes was 20/20 to 20/40 in 50%, 20/50 to 20/100 in 20%, and 20/200 or less in 30%. Six months postoperatively, uncorrected visual acuity in 63 eyes was 20/20 to 20/40 in 38%, 20/50 to 20/100 in 27%, and 20/200 or less in 35%. Uncorrected visual acuity regression in 63 eyes during the three to six month postoperative period is most appropriately illustrated in a scatter diagram. Variable vision markedly decreased and the symptom of "glare" also substantially diminished during the three to six month postoperative period, but these symptoms are still significant in some patients.

Additional follow-up studies are planned during at least a one year postoperative period. However, while these studies are continuing, a moratorium has been declared and no additional radial keratotomy procedures are being performed.

With National Eye Institute sponsorship, the multi-center Prospective Evaluation of Radial Keratotomy (PERK) study is being planned. This clinical trial is certain to provide information concerning the procedure.

At this time, radial keratotomy is experimental. Basic studies such as the work of Doctor Kramer and his associates are highly commendable and offer substantial promise for the future. Clinical studies are necessary but should be carried out as carefully designed investigations and conducted with due regard for all the principles and safeguards of clinical investigations.

DR THOMAS D. DUANE. I am not sure I got the message or understood the philosophy behind the paper presented by Doctor Kramer. He has a very precise way of doing something that he isn't going to do and it strikes me as being somewhat akin to a father coming home and telling first the good news to his family, namely, that he has detailed plans for a house that can be built in Peru, Majorca, or Bermuda.

He explains that this is the way the building will appear. The bad news is: that he has no intention of building it. I guess one of the spinoffs from such efforts is that we can appreciate that young individuals in our departments do become stimulated to improve existing techniques. We have such a gentleman in our department—a former resident who completed his training last year. The techniques that this young fellow perfected had been performed on humans in other hospitals. He has perfected a blade holder. (SLIDE) This is the old methodology and here is the new precision blade that he has worked on and can control to a fraction of a millimeter in its depth. (SLIDE) He has also perfected this instrument to determine corneal thickness to an astonishing accurate degree. The amazing thing is that he has found that the apex of the cornea and the periphery do not have the same depth and contrary to previous reports the periphery is thicker than the apex so that he can use this instrument preoperatively, during the operation, and postoperatively. Now we're part of a PERK study so we do not permit any other radial keratotomies to be performed at our hospital but even if we were not part of that study I do not think Doctor Laibson nor I would permit this operation to be performed. The National Eye Council, including such AOS members as Doctors Laties, Blodi, Norton and myself as ophthalmologists, has declared that this procedure is experimental and we have received a lot of flak for our stand. One response is from the surgeons who perform the procedure and they tell us that we are just hindering mankind's advancement. The other type of objection is why waste millions of dollars on a study such as this when we could be putting it into better use sponsoring basic research. I think the message that we should bear in mind is that these are experimental procedures which are truly hazardous to the American public and should be surveyed by groups such as can be convened by the NEI. In other words, there should be a segment of the AOS which combines with the Academy which combines with the Advisory Council and so forth so that we can determine and stand before the public and our fellow ophthalmologists and say whether certain procedures should be performed or not. In my opinion during the rest of this century ophthalmic procedures are going to be of such a nature that we cannot hide in a spa such as this and enjoy ourselves while we discuss esoteric ophthalmology without entering into the political area at various levels.

DR WALTER J. STARK. I would like to congratulate Doctor Kramer on his presentation. This is probably one of the most conservative papers regarding radial keratotomy I have heard.

From reading Doctor Maumenee's testimony to congress for the National Institute budget, it appears that the fear of blindness is second only to cancer as a public concern. This has generated much publicity in the lay press regarding miraculous new cures for blindness. Radial keratotomy has fallen into the sensationalism.

I have been interested in collecting articles on radial keratotomy. (SLIDE) This shows a picture of Doctor Fyodorov during his recent trip to Baltimore. He

indicated that one should sell his stock in eye glass companies because eye glasses were going to become obsolete once American surgeons learned about this new procedure to cure near sightedness.

Doctor Straatsma has presented a very nice review of the UCLA data on radial keratotomy. Doctors Hoffer and Cowden both presented papers to the American Academy of Ophthalmology and have given me permission to relate their prepublished data. It appears that a high percentage of patients in both series see 20/40 or 20/60 or better but we are not told how many patients had this vision preoperatively. It is of interest that 15% to 25% of patients had a reduction by one line in best corrected vision following radial keratotomy. Perforations and wound epithelial defects occurred in a small percentage of cases. Regression of the effect of the surgery is still an unknown factor. Fifteen percent of Doctor Cowden's patients continued to have regression of myopic correction at six months. Glare is a problem that occurs in up to 50% of cases and is reported to be significant in 10% to 20% of cases. Fluctuating vision is also a problem in 15% of cases. Doctor Hoffer's study showed an endothelial cell loss of 10% after radial keratotomy. This is of some concern since a high percentage of cases undergoing the original Sato operation developed corneal edema one to five years after the operation.

I am not making these comments to condemn radial keratotomy. I think we will learn a considerable amount regarding wound healing, corneal physiology and astigmatism correction. I do, however, want to echo the words of Doctor Duane and those stated by the Council of the National Eye Institute when they urged caution by both patients and physicians before having this investigational procedure performed. I can definitely state that until the long-term results of the National Eye Institute study or other good studies are available, radial keratotomy will not be performed at the Wilmer Institute.

DR DANIEL M. TAYLOR. I would like to make a brief comment concerning radial keratotomy. In contemplating the relative merit or value of this new surgical discipline it must be remembered that we are not considering the basic concepts of good and evil. In the long run the procedure will either prove beneficial to mankind or will be totally abandoned, and perhaps replaced by a different type of surgery. Doctor Duane in his discussion of Doctor Kramer's paper mentioned the word involvement and I would like to key into this word. I feel rather strongly that the corneal surgeons in this society should become involved in the evaluation of the radial keratotomy procedure. I am not opposed to the PERK study but do feel that other competent investigators from a rather broad base should lend their expertise to this evaluation. It is quite possible that the data provided by the limited PERK study will be insufficient and will perhaps lead to erroneous conclusions. Doctor George Weinstein in a recent editorial alluded to the problems generated by a group of so called "buccaneer" surgeons who appear to be increasing in numbers. If the expert corneal surgeons in this country fail to become involved in the radial keratotomy evaluation then we may have to accept the dictates of the "buccaneers." Let us not lose this one by default.

DR ROBERT C. DREWS. I think the time has come when we should stop pussyfooting on the subject of radial keratotomy. The very fine studies that have been done, for instance by Doctor Straatsma's group and some of the other properly conducted studies that have been reported to us, have already yielded significant insight into the results of this procedure.

It should be emphasized again that this is a procedure for a condition that is not a disease, and that the procedure is cosmetic. Cosmetic or prophylactic procedures are only acceptable if their complications are minor. The complications with radial keratotomy are not necessarily minor. The results are in: with radial keratotomy there has been loss of visual acuity, and there is frequently perforation during the surgery. The complications are known and the permanency and long term efficacy of this operation are not. Its short term efficacy varies widely from case to case, and is unpredictable. This operation should be condemned.

DR STEVEN G. KRAMER. I would like to thank Doctor Straatsma for his opening remarks and particularly for allowing me to see his discussion in advance. In answer to his specific questions: first, the multiple, nearly full thickness cuts are, in fact, stabilized by the device that I presented; second, the cornea does not relax and change its shape as it does when conventional technique is used; and third, an evaluation of a diamond blade in conjunction with the instrument is planned. Certainly the sharper the blade the more likely we are to narrow the distribution curves that I showed you.

I would also like to thank the other discussors. I don't know if I should include Doctor Duane without qualification, however. The fact is that I agree precisely with everything he had to say. I'm sorry that he missed my message, though, so I would like to restate it: I think that one of the problems in evaluating radial keratotomy in all the studies proposed—the one being done in Los Angeles and the PERK study included—is that one of the major variables, namely the surgical technique itself, is very imprecise. As long as the incisions are imprecise, especially when done by many surgeons, and especially when each cut causes a new curvature and a new state of corneal relaxation, the data will be difficult to evaluate if not meaningless.

We are pleading for controlled clinical evaluation in a setting in which the technique itself is as precise as today's technology can make it, and we think the instrumentation system we have designed is a step in that direction. We also believe that it is not "pussyfooting" to begin with a technique defined in the laboratory in terms of the accuracy and precision of its parameters. Once that is done if the technique is to be evaluated (and clearly it must be evaluated), then it appears to me it may be possible to come up with statements that are reasonable about radial keratotomy. I agree with Doctor Drews that at the present time any incidence of complications for a procedure which is done on a 20/20 eye is unacceptable. Whether the incidence of complications can be reduced by advanced technology is the question that I think we need to answer.