A COMPARISON OF VISUAL ACUITY, PREDICTABILITY, AND VISUAL FUNCTION OUTCOMES AFTER INTRACORNEAL RING SEGMENTS AND LASER IN SITU KERATOMILEUSIS*

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ABSTRACT

Purpose: To compare correction of low myopia by intrastromal corneal ring segments (ICRS) and by laser in situ keratomileusis (LASIK) with respect to early visual recovery and refractive outcomes.

Methods: Eighty-two eyes implanted with ICRS in a phase III study for US Food and Drug Administration review were matched with 133 eyes treated with LASIK by criteria of age (>18 years, <65 years), preoperative myopia (-1.00 to -3.50 diopters [D]), astigmatism (≤1.00 D), single treatment, and attempted full correction. Examinations were performed preoperatively and postoperatively at days 1 and 7 and months 1 and 3. Visual acuity and manifest refraction data were collected retrospectively. Visual function scores were assigned, and summarized results were compared.

Results: Uncorrected visual acuity was 20/20 or better at day 1 in 24% of eyes (20/82) after ICRS and in 55% of eyes (73/133) after LASIK, and at month 3 in 75% of eyes (58/77) after ICRS and in 67% of eyes (84/126) after LASIK. Spherical equivalent refraction at month 3 was within ±1.00 D of intended correction in 99% of eyes (76/77) after ICRS and in 96% of eyes (121/126) after LASIK. Excellent visual function scores were noted at month 3 in 90% of eyes (69/77) after ICRS and in 78% of eyes (98/126) after LASIK.

Conclusion: Patients treated with LASIK showed better uncorrected visual acuity immediately following surgery; however, beyond 1 month, patients treated with ICRS achieved better uncorrected visual acuity that continued to improve with time. Visual function scores indicate that ICRS eyes see at higher levels of uncorrected visual acuity than LASIK eyes do with the same refractive error. The ICRS and LASIK were comparable in the correction of mild myopia.

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INTRODUCTION

In a refinement of Barraquer's myopic keratomileusis[1] and the noncryolathe technique of in situ keratomileusis, Pallikaris and colleagues[2] in 1991 reported their initial experience using the excimer laser for precise tissue removal with the hinged-flap technique of in situ keratomileusis. This procedure, subsequently termed laser in situ keratomileusis (LASIK), has rapidly become the refractive surgeon's first choice for correcting myopic refractive errors. Physicians and patients alike have embraced LASIK because of its ease of use, minimal postoperative discomfort, and rapid and excellent visual corrections.[3]

In the last decade, various designs of the intrastromal corneal ring have been clinically tested in the United States. The current design consists of 2 150°-arc intrastromal corneal ring segments (ICRS).[4] Phase III trials of ICRS in conjunction with application for US Food and Drug Administration (FDA) licensing began in May 1996 and culminated with FDA approval in April 1999. We conducted a retrospective study comparing visual and refractive outcomes with ICRS and LASIK. To our knowledge, this is the first reported comparative study of these techniques.

METHODS

STUDY DESIGN

In this retrospective analysis, we collected data of 82 eyes from a single site in the phase III investigational device study of ICRS. This phase III trial was governed by FDA study protocol, and informed consent was obtained from each patient before enrollment. Patients were eligible for

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the study if they had binocular vision with best spectacle-corrected visual acuity (BSCVA) of 20/20 or better in both eyes, cycloplegic refraction spherical equivalent between -1.00 and -3.50 diopters [D], and manifest cylinder refraction of 1.00 D or less.

We also collected data from 133 eyes treated with LASIK through a university-based clinical practice of the same surgeon (D.J.S.). These eyes were selected from a database of patients who had received LASIK through this practice, matching the ICRS eyes for age (>18 years, <65 years), preoperative myopia (-1.00 to -3.50 D), astigmatism (≤1.00 D), intended full correction, and single treatment. Only eyes with data from nearly all postoperative visits were selected.

EXAMINATION SCHEDULE AND ASSESSMENTS

In the phase III study from which the ICRS data were collected, independent observers obtained data at follow-up examinations to minimize surgeon bias. Data on uncorrected visual acuity (UCVA) were collected for both the ICRS and LASIK groups at the preoperative visit, on postoperative days 1 and 7, and at months 1 and 3. Data for BSCVA and manifest refraction spherical equivalent (MRSE) also were collected at all time points except for day 1, when eyes were not refracted during the ICRS study, so no intergroup comparison was possible. The last postoperative visit analyzed was set at 3 months, because at this time, LASIK-treated eyes were enhanced if necessary.

UCVA was measured at each time point using standardized ETDRS visual acuity charts for the ICRS group and standard Snellen charts for the LASIK group. To assess predictability of refractive effect at 3 months, the intended correction was compared with the achieved correction, and the percentages of eyes within ±0.5 D and ±1.0 D of intended correction were calculated. Stability was assessed by comparing mean MRSE over time.

Because visual function scoring, as described by Waring,[5] involves defining the relationship between visual acuity and refractive error, we plotted UCVA against MRSE data for each patient in each group, and thus derived a visual function score for each eye (Table I). To assess safety, BSCVA values preoperatively and at month 3 were compared and lines gained or lost were determined.

STATISTICAL METHODS

Means and standard deviations (SD) derived from the individual data are presented. Comparisons between the treatment groups were made by inspection of proportional change of the 2 populations.

TABLE I: QUALITATIVE CATEGORIES FOR THE OUTCOME OF REFRACTIVE SURGERY

REFRACTIVE ERROR (D)	POINTS	UCVA	VFS
-1.00 to +0.50	0	≥ 20/25	0 points = excellent
-1.12 to -2.00 or +0.62 to +1.00	1	20/30 to 20/40	1-2 points = good
-2.12 to -3.00 or +1.12 to +2.00	2	20/50 to 20/80	3-4 points = fair
< -3.00 or > +2.00	3	20/100 or worse	5-6 points = poor

UCVA; uncorrected visual acuity; VFS, visual function score.
Adopted from Waring.[5]

RESULTS

Postoperative data were available for 100% of LASIK eyes at day 1, day 7, and month 1, and for 95% at month 3. Postoperative data were available for 100% of ICRS eyes at day 1, 79% at day 7, 95% at month 1, and for 94% at month 3.

At day 1, a greater proportion of eyes after LASIK than after ICRS had UCVA of at least 20/40 (95% versus 87%), 20/20 (55% versus 24%), and 20/16 (14% versus 6%; Table II). This trend was reversed as time progressed, so that by month 3 (when 94% of ICRS eyes and 95% of LASIK eyes had UCVA data), a greater proportion of ICRS than LASIK recipients had UCVA of at least 20/40 (99% versus 95%), 20/20 (75% versus 67%), and 20/16 (38% versus 29%).

At month 3, 70% of eyes (54/77) with ICRS versus 82% of eyes (103/126) after LASIK were within ±0.5 D of

TABLE II: PERCENT OF PATIENTS WITH UCVA AT LEAST 20/40, 20/20, AND 20/16

FOLLOW-UP EXAM	UCVA ≥ 20/40 %(N/N)	UCVA ≥ 20/20 %(N/N)	UCVA ≥ 20/16 %(N/N)
Day 1			
ICRS	87% (71/82)	24% (20/82)	6% (5/82)
LASIK	95% (126/133)	55% (73/133)	14% (8/133)
Day 7			
ICRS	97% (63/65)	62% (40/65)	29% (19/65)
LASIK	96% (128/133)	65% (87/133)	21% (28/133)
Month 1			
ICRS	96% (75/78)	67% (52/78)	37% (29/78)
LASIK	96% (128/133)	71% (94/133)	28% (37/133)
Month 3			
ICRS	99% (76/77)	75% (58/77)	38% (29/77)
LASIK	95% (120/126)	67% (84/126)	29% (37/126)

ICRS, intrastromal corneal ring segments; LASIK, laser in situ keratomileusis; UCVA: Uncorrected Visual Acuity

the intended correction, and 99% (76/77) with ICRS versus 96% (121/126) after LASIK were within ±1.0 D of the intended correction. Preoperatively, mean MRSE in the ICRS group was –2.28 D ±0.65 (SD) and in the LASIK group, –2.70 D ±0.71 (SD). At month 3, mean MRSE in the ICRS group was –0.17 D ±0.47 (SD) and in the LASIK group, –0.11 D ±0.44 (SD; Fig 1).

At month 3, the visual function score was excellent in 90% of eyes (69/77) with ICRS versus 78% (98/126) after LASIK, good in 10% (8/77) with ICRS versus 18% (23/126) after LASIK, fair in no eyes with ICRS versus 4% (5/126) after LASIK, and poor in no eyes in either group (Figs 2 and 3).

Before treatment, nearly all eyes had BSCVA of 20/20 or better in both groups, but 85% of eyes in the ICRS group had 20/16 or better, compared with 37% of eyes in the LASIK group (Table III). With both procedures, BSCVA decreased in the early posttreatment period but then recovered over time to, or near, baseline levels by month 3; however, nearly 12% of ICRS-implanted eyes that had visual acuity of 20/16 or better before treatment had not regained that level at 3 months. The BSCVA decreased from pretreatment by 2 or more lines in 9% (7/76) with ICRS versus 1% (1/126) after LASIK, was unchanged in 45% (34/76) with ICRS versus 46% (59/126) after LASIK, and increased by 1 line in 26% (20/76) with ICRS versus 37% (46/126) after LASIK (Fig 4).

DISCUSSION

On the day following surgery, UCVA was 20/20 or better in more than twice the percentage of LASIK recipients (55%) as ICRS-treated eyes (24%). By day 7, however, the proportions of eyes seeing 20/20 or better were nearly equal in the 2 groups (62% with ICRS and 65% after LASIK), and by month 3, a higher percentage of ICRS

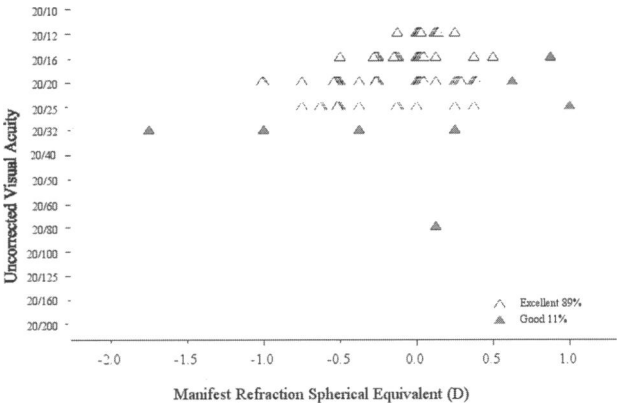

FIGURE 2

Visual function scores at 3 months for eyes treated with intrastromal corneal rings (n=77).

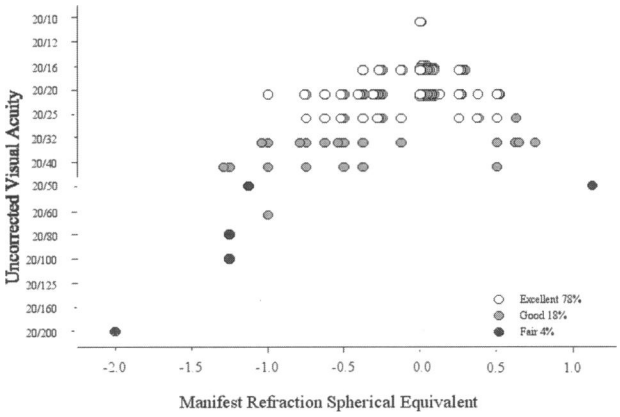

FIGURE 3

Visual function scores at 3 months for eyes treated with laser in situ keratomileusis (n=126).

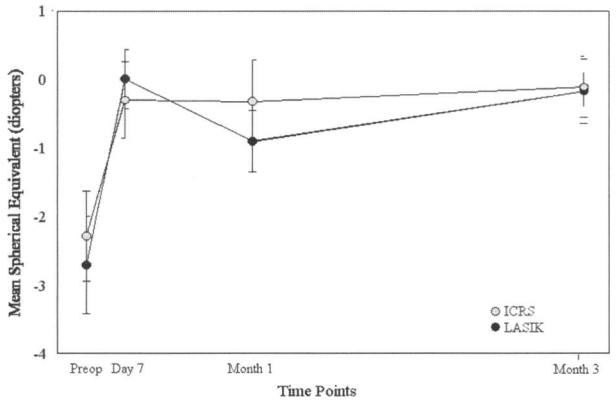

FIGURE 1

Mean manifest refraction spherical equivalent over time for eyes treated with with intrastromal corneal rings (ICRS) and laser in situ keratomileusis (LASIK).

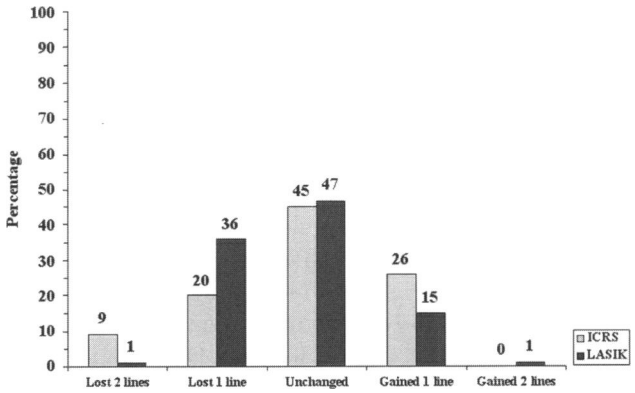

FIGURE 4

Gain or loss in best spectacle-corrected visual acuity for eyes treated with intrastromal corneal rings (ICRS) (n=76) and laser in situ keratomileusis (LASIK) (n=126).

TABLE III: BEST SPECTACLE-CORRECTED VISUAL ACUITY AFTER LASIK AND ICRS

ACUITY	PREOP.	DAY 1	DAY 7	MONTH 1	MONTH 3
≥ 20/16					
ICRS	85.3%	NA	65.1%	77.8%	73.7%
LASIK	37.1%	29.3%	45.1%	51.1%	58.4%
≥ 20/20					
ICRS	100%	NA	96.8%	98.6%	97.4%
LASIK	98.5%	85.7%	90.2%	97.0%	99.2%
≥ 20/25					
ICRS	100%	NA	100%	100%	98.7%
LASIK	100%	96.2%	97.7%	98.5%	100%
≥ 20/40					
ICRS	100%	100%	100%	100%	100%
LASIK	100%	NA	100%	100%	100%

ICRS, intrastromal corneal ring segments; LASIK, laser in situ keratomileusis; NA, not applicable (refraction not done at this time point in the phase III ICRS study).

recipients (75%) than LASIK-treated eyes (67%) saw 20/20 or better. Results were similar between the groups for percentage of eyes seeing 20/40 or better at the month 3 examination (99% with ICRS, 95% after LASIK). The decrease between month 1 and month 3 in percentage of LASIK recipients who saw 20/20 or better or 20/40 or better may have been caused by myopic regression before LASIK correction.

The percentage of eyes that saw 20/16 or better at day 7, month 1, and month 3 was higher in ICRS than in LASIK recipients (38% versus 29% at month 3). Maintenance of prolate asphericity by the ICRS and its avoidance of central corneal manipulation may underlie this difference. Farah and associates,[6] in reviewing the published abstracts on LASIK, found that a mean of 57% of eyes saw at least 20/20 postoperatively. Our results with LASIK (67%) are roughly comparable to this finding.

The percentages of eyes within ±1.0 D of intended correction were similar between the ICRS group (99%) and the LASIK recipients (95%) at month 3, demonstrating good predictability with both methods. The mean percentage of eyes within ±1.0 D of intended correction in published abstracts of LASIK trials was 83%.[6] The percentage of eyes within ± 0.5 D of intended correction at month 3, however, was lower with ICRS (70%) than with LASIK (82%). Each increase in ICRS thickness achieves about 0.7 D of additional refractive change, whereas the excimer laser can be programmed for increases of 0.01 D. This difference in the devices may account for the greater proportion of LASIK eyes within ±0.5 D of intended correction. At 3 months, mean MRSE was nearly equal between the 2 groups, indicating good predictability.

At month 3, 90% of ICRS recipients had a visual function score of excellent, compared with 78% of LASIK-treated eyes. The main difference between the groups occurred in those eyes with MRSE above +0.5 D and below -1.0 D (Figs 2 and 3). Eyes with ICRS in these ranges had better resultant visual acuity than those treated with LASIK, so the ICRS recipients had better visual function scores. Decreased spherical aberration consequent to the prolate central corneal shape maintained after ICRS implantation may have accounted for this difference.

Maintenance of BSCVA after ICRS and LASIK was similar between the groups. Seven ICRS recipients lost 2 or more lines of BSCVA from preoperative baseline, as compared with only 1 LASIK-treated patient (Table IV). However, nearly 3 times as many ICRS recipients had BSCVA of 20/16 or better preoperatively, which may have accounted for the greater number of ICRS recipients who lost 2 lines. This difference in preoperative BSCVA could have been a product of study design, because different scales of visual acuity were used between the 2 populations and ICRS patients were possibly tested more stringently prior to surgery. All 7 ICRS patients were seeing at baseline or within 1 line of BSCVA at the 6-month postoperative visit, indicating a slower visual recovery with ICRS. Furthermore, only 2 ICRS patients and 1 LASIK patient had BSCVA worse than 20/20 at 3 months, when 99% of LASIK-treated eyes and 97% of ICRS-implanted eyes saw 20/20 or better. Farah and associates[6] reported that a mean of 8% of LASIK recipients in published studies lost 2 or more lines of BSCVA. In our study, 9% of eyes in the ICRS group lost 2 or more lines, as compared with only 1% of LASIK-treated eyes

CONCLUSION

Our study suggests that implantation with ICRS provides a safe and effective alternative to LASIK in those patients with low to moderate myopia. ICRS has the additional benefit of being reversible and potentially adjustable.

TABLE IV. PATIENTS WHO LOST 2 OR MORE LINES OF BSCVA

PATIENT NO.	PREOP BSCVA	MONTH 3 BSCVA	MOST RECENT BSCVA
ICRS 1	20/12.5	20/20	20/12.5
ICRS 2	20/12.5	20/20	20/16
ICRS 3	20/12.5	20/20	20/12.5
ICRS 4	20/12.5	20/20	20/16
ICRS 5	20/12.5	20/20	20/12.5
ICRS 6	20/12.5	20/25°	20/12.5
ICRS 7	20/16	20/32	20/16
LASIK 1	20/20	20/30	20/25

BSCVA, best spectacle-corrected visual acuity; ICRS, intrastromal corneal ring segments; LASIK, laser in situ keratomileusis.
° Paracentral metallic foreign body removed at month 3 examination.

Longer follow-up data and analysis of both procedures will help to validate our results.

REFERENCES

1. Barraquer J. The history and evolution of keratomileusis. *Int Ophthalmol Clin* 1996;36(4):1-7.
2. Pallikaris I, Papatzanaki M, Siganos D, et al. A corneal flap technique for laser in-situ keratomileusis: Human studies. *Arch Ophthalmol* 1991;145:1699-1702.
3. Dulaney D, Barnet R, Perkins S, et al. Laser in situ keratomileusis for myopia and astigmatism: 6 month results. *J Cataract Refract Surg* 1998;24:758-764.
4. Schanzlin D. Studies of intrastromal corneal ring segments for the correction of low to moderate myopic refractive errors. *Trans Am Ophthalmol Soc* 1999;46:815-890.
5. Waring GO III. Standardized data collection and reporting for refractive surgery. *Refract Corneal Surg* 1992;8(suppl):1-42.
6. Farah S, Azar D, Gurdal C, et al. Laser in situ keratomileusis: Literature review of a developing technique. *J Refract Surg* 1998;24(7):989-1006.

DISCUSSION

DR LARRY F. RICH. First let me begin by thanking the American Ophthalmological Society for inviting me to discuss this excellent paper. I also thank the authors for providing me with the manuscript in a timely manner.

Although the surgical correction of refractive errors has been attempted for over 100 years, ophthalmologists and the lay public have become increasingly interested in this discipline in more recent times. Advancing technology has greatly influenced our ability to correct or minimize optical abnormalities of the human eye surgically, and this study compares two methods for correcting low, spherical myopia: laser in-situ keratomileusis (LASIK) and intracorneal ring segments (ICRS). This is the first published comparative study of these 2 techniques.

It is important at the outset to recognize that the refractive error range evaluated in this study is limited to low myopia (1-3.5 Diopters) with less than 1 diopter of astigmatism. The authors have appropriately eliminated subjects treated for refractive errors outside this specific range. Too often in refractive surgery outcomes reporting, data are not comparable because comparisons are made of groups with different refractive error ranges. The authors are to be commended for matching the age, preoperative refractive errors, the intended correction, and the fact that each group compared had a single treatment.

The 2 surgical procedures in question have different typical postoperative treatment courses. In the case of LASIK, enhancements (reoperation intending to improve outcome) are usually performed 3 months after the initial operation. The time for enhancement varies in the case of ICRS patients but is usually greater than the 3rd postoperative month. For this reason, the authors correctly limit their data collection for this study to the 3rd postoperative month and exclude LASIK patients who may later have had an enhancement. To include patients with longer follow-up would artificially favor LASIK cases and would have improved the LASIK outcomes. Thus, the relatively short 3 month follow-up observation time in this study is understandable.

These data show that intracorneal ring segment implantation is a viable and effective method for treating patients with low to moderate myopia. This study suffers from the drawbacks typically found in retrospective studies, namely, that the study was not specifically designed to test particular questions but was performed to answer questions raised after the data were collected. For example, uncorrected visual acuity in the ICRS eyes was measured using ETDRS visual acuity charts, whereas the LASIK eyes were tested with standard Snellen charts and converted to LogMAR equivalents. Although this conversion achieves numerical equivalency, the testing methods are distinctly different.

The authors found that patients receiving the intracorneal rings segments recovered visual acuity a bit slower than those treated with LASIK. At 1 day postoperatively, for example, 30% of the ICRS patients saw 20/20 or better whereas 69% of the LASIK patients achieved 20/20 one day after surgery. This difference explains the "wow factor" in which the LASIK patient is dazzled by a dramatic improvement of vision the first postoperative day. This phenomenon has been described both verbally and in the literature and is largely responsible for the widespread acceptance of LASIK as the current standard for refractive error correction. The fact that the 3 month data show slightly better percentages of 20/20 or better vision in the ICRS group than the LASIK group is minimal consolation when considering the expectation of the prospective refractive surgery patient for rapid recovery.

Because the achievement of maximum visual acuity was not attained in the ICRS patients until nearly the 12th postoperative week, predictability data in this manuscript are reported at 3 months. Curiously, the percentage attaining ±0.50 D of intended correction is slightly higher in the LASIK group, whereas those attaining ±1.00 D is 3% higher in the ICRS group. The mean refractive spherical equivalent (MRSE) is slightly lower in the LASIK group with similar standard deviations. Thus, it appears that the predictability is roughly equal between the 2 groups.

Visual function scores, as defined by George Waring in 1992, is used as a third measurement parameter in this study. This score is an expression of uncorrected visual acuity versus manifest refraction and is aimed at comparing the relationship between the two. The visual function

scores at 3 months postoperatively are distinctly better in the ICRS group with 100% of patients receiving either a good or excellent score, whereas the LASIK patients received good or excellent 96% of the time with 4% receiving a fair score.

This presentation by Drs Suiter, Twa, and Schanzlin is a retrospective, observational study. The authors have done an excellent job of helping us reconcile the objective clinical outcomes and subjective reports of our patients who have had refractive surgery by 1 of these techniques. Ideally, the information in this comparative study will stimulate the scientific community to design a prospective, clinical trial comparing two or more refractive surgical procedures for the outcomes generated by each. In this manner, the discipline of refractive surgery will gain stature and acceptance to a greater degree than it currently enjoys.

Again, I would like to thank the American Ophthalmological Society for inviting me to discuss this paper.

DR STEVEN F. KRAMER. My comment and question comes under the category that nothing is new under the sun. About 26 years ago, when I was in the military service, I had an idea about changing the corneal curvature by inserting a ring in the cornea and thereby altering the refractive error. I made a slide of the procedure and presented it at various meetings. My question to the author is what does he think Kera Vision will pay me for my 26-year-old slide?

DR ARTHUR JAMPOLSKY. It appears that there are transient changes in intraocular pressure with some of the refractive surgical techniques and perhaps damage to ganglion cells. I wonder if the presenter will share with us any data he may have on the intraocular pressure before and after surgery, and any changes in the retina, measured by either psychophysics or electrophysiology.

DR JOHN T. FLYNN. I would like to commend Dr Schanzlin for a paper on this topic that I could understand reasonably well. We have had 2 consecutive papers on the use of prosthetic devices in ocular surgery. We would never have thought of doing this a few years ago. The author mentioned clinical trials and randomized trials. My question is were these patients randomized; if not, how do you control for selection bias and author bias? If I read the graphs correctly, approximately 1 out of 10 patients ended up with a refractive error between minus 1 and minus 3 diopters. What did you do for these patients who had the surgery to eliminate the need for glasses?

DR RALPH C. EAGLE, JR. My lab has received 2 cases of intra-corneal rings in the past year. What is the incidence of removal of these rings, and does the refractive error return to its preoperative value after the rings have been removed?

DR DAVID J. SCHANZLIN. Thank you Dr Rich as well as all of the discussants who came forward with questions.

With regard to Dr Kramer's question, I have no idea what the value of a 28 year old idea is, but in fairness, Dr Kramer was one of the people originally who thought about putting objects into the cornea, as did Dr Kraznov in Russia in the 1970's, and we have people around the world who have also tried other designs of materials to put into the cornea, be it synthetic cornea material, allo plastic materials, as well as the PMMA elements that we talk about here. Most of the earlier ideas were to expand or contract the cornea rather than to just add substance and perhaps that is what is somewhat unique about this approach. If you are interested in a comprehensive review of prior work on intracorneal rings I would refer you to my recently published thesis in the TRANSACTIONS.

Dr Jampolski asked the question about intraocular pressure change. In the FDA series, we have extensive data on that, and we have subsequently published a paper on intraocular pressure measurement after corneal rings. We see no increase or decrease in intraocular pressure over time with the intracorneal ring implants. It is possible however to incorrectly measure intraocular pressure when you have an element of plastic in the cornea using Goldman aplination tonometry. If you try and check the pressure immediately over the ring, you'll be quite surprised, recording a very high pressure of 60 mm or larger, but of course that's not a true pressure. It's just caused by trying to measure a hard surface.

There have been no studies looking at ganglion cell loss with intracorneal ring segments. The suction time with the intracorneal ring is longer then with LASIK as you're applying the suction ring to the globe and making the dissection of the channels. On the other hand, the intraocular pressure appears to be lower in that most patients with rings tend to have more of a brownout than a total blackout of vision with the procedure. But certainly this is a concern, both with LASIK as well as with intracorneal ring implants. Any procedure where the intraocular pressure is raised during the implantation technique raises some concern. We do have visual field data over time from the patients in the clinical trial, and do not see any visual field loss, although the follow-up in the series is now only up to 3 years.

Dr Flynn did comment about randomization in these studies. Even in the FDA trials of the intracorneal ring, they were not technically randomized since patients were recruited to the study because they were attracted to the

perceived advantages of the ring, i.e. central cornea was not touched and the potential reversibility of the procedure. Most patients in the LASIK retrospective study were motivated to surgery because they wanted to eliminate their need for contact lens and glasses and did not want to be part of a clinical trial. Patient selection, therefore was totally different for the 2 groups of patients in this retrospective study. For clarification, I did not state that this was a randomized clinical trial. Rather that this was a retrospective analysis of 2 groups of patients: 1. From the FDA Phase 111 study of the intrastromal corneal ring; 2. A matched series of myopic patients who underwent LASIK during the same period of time.

With regards to your other question about what about these patients that had a falloff in vision at the 3-month time point. Well, you start with the patients who were -350 before and you saw 1 patient in the slide who was -2 postop. Well, certainly this patient went on to have an enhancement procedure, which you can do with the LASIK because we weren't in trials. With the studies in the FDA trial, the patients in the trial, we were unable to do any exchange procedures, which of course we're now doing after the commercialization of this, so that now we can do early exchanges of patients who are not corrected.

With regard to Dr Engle's question, overall in my practice, the incidence of removal of intrastromal corneal rings is approxamately 4%. In all cases, so far, the patients have resumed to within 0.75 diopters of original spherical equivalent refraction. Furthermore the patients who have not resumed to 0.75 diopters of their original equivalent refraction have all been less myopic than they were preoperatively. It appears that the stability of the refraction following intrastromal corneal ring segments is established by 2 months following examination.

So again I thank you for your attention, I thank you for these reviews, and I am honored to be a member of this society.