Radial Keratotomy in the United States: The Turbulent Decade

Atorney William Duffey’s rational and balanced review of two anti-trust suits concerning radial keratotomy in this issue of the Journal (Radial Keratotomy on Trial: New Surgical Procedures and the Antitrust Laws,” pages 232-240) serves as a platform from which we can survey the introduction of radial keratotomy surgery in the United States. This perspective leaves us with two major conclusions: 1) Although creative ideas, trial and error refinement, and informal testing are necessary to develop new ophthalmic surgical procedures, well-designed formal clinical trials are the best way to determine the safety, effectiveness, predictability, and stability of the results of new procedures; and 2) Until such clear-cut information can be obtained, conflict over new procedures can best be resolved not by political manipulation and litigious attack, but by vigorous debate and detailed reporting of clinical information among well-intentioned ophthalmologists who place the needs and welfare of ophthalmic patients and public health above all other considerations.

Radial Keratotomy Arrives

In late 1979, only one article appeared in the English ophthalmic periodical literature presenting results of radial keratotomy: Fyodorov’s articles in the Annals of Ophthalmology.1 In the early 1980s, the ophthalmic practitioners and nearsighted patients faced an onslaught of information about radial keratotomy in the news media. The upbeat coverage focused on the import of high technology from the Soviet Union and often featured a local practitioner doing his first or second procedure. For example, in 1983 Family Circle carried an article in its True Life Drama section entitled, “Lee Teste’s Private Miracle,” in which a 30-year-old woman acquired “perfect vision” from radial keratotomy just in time to get married without her glasses.2 The Los Angeles Times’ headlines reflected the atmosphere: “Eye Surgery Pitch—Is it Hype or Hope?”3

This intense publicity generated a stampede of inquiries from eager myopes. Most beleaguered ophthalmic practitioners took a wait-and-see attitude, resisting the idea of doing surgery on a structurally normal eye. A few rushed to Moscow or took regional courses, responding to the increased competitive pressures with the anxious feeling, “I missed out on phaco, I missed out IOLs, I ain’t missin’ out on RK.” A handful made radial keratotomy a major part of their practice, renaming their office an “institute” and launching marketing campaigns.

In this climate, conflicts arose, pitting the enthusiastic innovators against the conservative skeptics. The enthusiasts claimed that their personal experience and extensive practices would unravel the mysteries of radial keratotomy and that opposition from their colleagues, institutional review boards, and state ophthalmological societies were politically and economically motivated.

The cautious majority feared that the procedure was being evaluated in the marketplace rather than in the laboratory and the clinic, so that it was in danger of becoming popular before it could be adequately tested according to peer-reviewed scientific standards. They reacted to protect the public interest and customary practice by urging restraint. In their zeal to prevent damage from the keratotomy wildfire, some authorities created unrealistic constraints, such as the Arizona hospital that stipulated that only a PERK investigator working on the PERK protocol could perform radial keratotomy. There was no PERK center in Arizona.4

Another concern among practitioners was that avaricious keratotomies would launch a marketing blitz,
not only bilking the unwary public with an unestablished operation, but also drawing patients away from established clinical practices with unfounded claims. Articulate expressions of this opinion appeared as editorials, "The Buccaneer Eye Surgeon"5 and "They Are Not My Colleagues."6

Economic and Legal Conflicts Intervene

The economic force was powerful, the arithmetic simple. Approximately ten million myopes in the United States were potential candidates for radial keratotomy. At 1500 dollars per eye, this represented a 30 billion dollar market, approximately 2 billion dollars for each of the 15,000 ophthalmologists in the United States. An ophthalmologist who might do five radial keratotomies two mornings per week would add three quarters of a million dollars to his annual billings (500 eyes × $1500). As expected, competition increased. The Los Angeles Times headlined, "Medical Price War Erupts Over Controversial Eye Surgery. The Competition for Radial Keratotomy Business in Phoenix Drops the Cost from $1500 to $495."7

A few ophthalmologists took to the courts to get their due. For example, in 1980 a patient of Dr. Robert Marmer's in Atlanta who had had radial keratotomy in one eye filed suit against himself and others, claiming that our invited opinions by a hospital review board had interfered with his ability to receive radial keratotomy on his second eye. The patient later dropped the lawsuit, but in 1982 Dr. Marmer, Dr. Leo Bores, and a handful of patients filed the antitrust suit reviewed by Duffy in this issue of the Journal. The no-fault, out-of-court settlement of that suit was followed immediately in 1984 by the filing of an almost identical antitrust suit by Drs. R. Schachar, D. Leslie, L. Schachar, N. Stahl, J. Zellman, T. Farkas, H. Bruckner, and G. Simon in the name of the Keratorefractive Society against members of the Board of the American Academy of Ophthalmology, as reviewed by Duffy. A jury trial recently resolved this suit in favor of the American Academy of Ophthalmology.

The litigious stakes were high, because antitrust lawsuits carry triple damages, so that the awards in the Bores' suit could have been 75 million dollars, and the awards in the Schachar suit 36 million.

Ophthalmic Organizations Respond

Some have characterized this uproar as a struggle between academic professors and private practitioners, a classical "town-grown" conflict. I think they were wrong. Most university eye departments were not interested in radial keratotomy, and the two major collaborative trials—the Prospective Evaluation of Radial Keratotomy (PERK) and the Analysis of Radial Keratotomy (ARK) studies—were combined efforts of individuals in both universities and private practice. No, the struggle followed another classical pattern: the conflict between enthusiastic innovators anxious to promulgate their new procedure and traditional conservatives. In fact, the major opposition to the rampant spread of radial keratotomy came from grass roots, private, practicing ophthalmologists. Consensus would not come easily. Perhaps the best understanding of the first decade of radial keratotomy in the United States emerges from a review of the ophthalmic organizations involved with the procedure.

A Proposed Clinical Trial

In 1979, Drs. John W. Cowden, Leo Bores, and William Myers wrote a protocol for a collaborative study of radial keratotomy among five university departments and one private medical center. The philosophy was strict: "independent data verification, both preoperatively and postoperatively, was mandatory by a surgeon other than the operating surgeon. As a matter of fact, performance of the surgery would disqualify the surgeon from data collection. At 6-month intervals, the patients were to be seen by a third physician who had never seen them before . . . In this way we hope to prevent bias from entering the basic studies that were undertaken."8 The proposed study was never implemented, but the early findings of the three authors were published.9

The National Radial Keratotomy Study Group

In late 1979, Dr. Bores moved to Santa Fe, New Mexico, where he established the National Radial Keratotomy Study Group, consisting of a "core" group of approximately 25 ophthalmologists and an ever-increasing number of "adjunct" investigators who took Bores' courses. A press release in early 1980 indicated that "the operation must be performed under carefully controlled circumstances. Our organization is prepared to train only qualified microsurgeons, who will be required to follow the investigatory protocol and report their data to the national group."10 The group gradually dissolved without publishing collaborative results.

The Keratorefractive Society

In 1979, a more populist approach to radial keratotomy caught the fancy of ophthalmologists in the form of the Keratorefractive Society, begun by Drs. Ronald and Les Schachar. The Society sought to draw on the insights, skills, and experience of all those interested in refractive surgery and espoused a liberation philosophy: "The society firmly believes that no single subgroup of surgeons should be the exclusive evaluator of any single procedure."11 This come-one-come-all approach was immensely popular, and the first meeting of the society during the American Academy of Ophthalmology in November 1979 packed the ballroom and extended late into the evening, electric, full of excitement and confusion. At
this and some subsequent meetings, the presentations were recorded and the slides were photographed, both being published verbatim in a series of proceedings without editing by the authors. These volumes make fascinating reading, capturing the flavor of both scientific inquiry and political fighting.

The Society worked diligently to capture the information and experience in radial keratotomy by establishing a Registry. No refractive or visual acuity results have been published in the peer-reviewed ophthalmic literature from the Registry, although a press release in November of 1984 described a study of “63,000 patients out of 103,000 compiled by 2,000 members of the Keratorefractive Society.”

In an attempt to get the American Academy of Ophthalmology to view radial keratotomy more favorably, the Keratorefractive Society encouraged the establishment of an ad hoc committee to review the records in the Registry. The committee was formed and apparently received some 5,000 case records, but the study was never completed.

The National Radial Keratotomy Study Group and the Keratorefractive Society pooled their respective protocols and submitted them as a grant to the National Institutes of Health for a study called CLERK (Collective Logical Evaluation of Radial Keratotomy). Apparently, the CLERK study was approved but not funded.

The basic philosophy of the Keratorefractive Society turned out to be its major weakness. Every person could have his say. Quality control was minimal. As a result many members resigned, particularly when the Society became politically active in its opposition to formal clinical studies of radial keratotomy. The Society continues to meet annually during the American Academy of Ophthalmology meeting.

The National Eye Institute and the PERK Study

In the late 1970s, before radial keratotomy hit the American scene, there was an emerging interest in the lamellar refractive keratoplasty techniques of Dr. Jose Barraquer, resulting in some grant applications to the National Eye Institute. In early 1979, the National Advisory Eye Council recommended guidelines for the study of refractive keratoplasty. Among them: “Refractive keratoplasty as a clinical procedure is experimental.” By 1980, the intense interest in radial keratotomy pressed the Council to update its opinion: “The Council considers radial keratotomy to be an experimental procedure because it has not been subjected to adequate scientific evaluation in animals and humans... The Council calls for carefully controlled research...”

The American Academy of Ophthalmology adopted the position of the Eye Council, an action considered illegally conspiratorial by Schachar and colleagues. The International Society of Refractive Keratoplasty also adopted the Council's position.

In response to his hubbub, a group of approximately 15 academic ophthalmologists, including some who had performed radial keratotomy and some who had studied with Fyodorov in Moscow, met in March of 1980 for a one-day workshop to explore possibilities of collaborative research. This meeting was characterized by some as a conspiratorial plot—held secretly in an airport hotel—to control the dissemination of keratotomy in the United States. The participants published their conclusions.

A follow-up workshop in May, 1980 created the protocol for the Prospective Evaluation of Radial Keratotomy (PERK) Study, which was funded by the National Eye Institute in early 1981 with the caveat, “The human being is really used as a basic research tool in looking at radial keratotomy. This is conceivably only because of the fact that if a small clinical study is not completed now, even greater pressure will exist for the use of the procedure untied and without any knowledge of how safe and efficacious it might be. There is probably no study contemplated now that might have a greater impact on a larger number of patients than this one.”

An interesting scenario was played out in the Spring of 1981. Dr. Ronald Schachar, on behalf of the Keratorefractive Society, mounted a campaign to prevent the implementation of the PERK study, through telegrams and letters to Federal congressional officials. Taking up the charge was United States Representative Eugene Johnston, Republican from North Carolina, who had had an apparently successful radial keratotomy and who accused the National Eye Institute of “re-inventing the wheel” by funding a study of an operation that had already been “proven safe and effective.” In response, the National Eye Institute convened a panel of ophthalmologists and biostatisticians to review the information collected by the Keratorefractive Society, the National Radial Keratotomy Study Group, and others.

A reporter captured the scene:

A modern day medicine show surged into the usually composed National Institutes of Health campus Thursday, sending forth an array of claims, confessions, and cajolery in behalf of radial keratotomy... A Washington public relations firm fired off a news release heralding a government versus private doctor battle over the new surgery and announcing the “confrontation” would come Thursday afternoon. The NEI quickly countered, holding a news conference Thursday morning during which Carl Kupfer, MD, NEI Director, outlined the skepticism toward the experimental procedure and the protocol behind the 5-year, 2.4 million dollar PERK study. The medicine wagon ascended that afternoon, driven by keratomists Ronald Schachar, William Myers, and Leo Bores. They had varied and telling support from a
seeing-is-believing North Carolina congressman, a Canadian statistician who compared eye surgery to hip replacement, a boisterous lawyer accusing the medical-research establishment of cover-up, and a dozen very satisfied patients reading 20/15 to 20/40 from an illuminated eye chart. The review panel concluded:

Although their data exceeded requirements for medical and surgical practice purposes, they nonetheless were grossly inadequate for a critical and comprehensive evaluation of the safety and efficacy of radial keratotomy. Their data do not answer questions to be addressed by the PERK study. Consequently, it is appropriate that the NEI proceed with plans to support a clinical trial of radial keratotomy.

In response to critics, the PERK Study Group added ophthalmologists with extensive experience, balancing the investigators to include 12 full-time university professors (29%), 18 geographic full-time practitioners (44%), and 11 full-time private practitioners (27%).

By 1988, members of the PERK Study Group had published over 55 articles and abstracts on the results of the study. 

The Analysis of Radial Keratotomy (ARK) Study

By 1981, even though thousands of cases of radial keratotomy had been done in the United States, Donald Sanders, MD found it difficult to extract data from that experience that would satisfy critical observers. Therefore, he established the Analysis of Radial Keratotomy (ARK) Study, a “high-quality, scientifically rigorous” study involving three private surgeons and two university-based biostatisticians, begun with a National Eye Institute grant. Although the ARK group disbanded in 1983 over disputes concerning commercial aspects of predictability software packages, the members have continued to publish meaningful results from their individual practices, emphasizing the value of collaboration between clinicians and statisticians.

The International Society of Refractive Keratoplasty

This is the oldest U.S. society devoted to refractive surgery. Established in the mid-1970s as a study group for the Barraquer lamellar refractive surgical procedures, it was formally incorporated in 1979 "to promote, aid, encourage, and foster scientific research, study, and investigation of refractive surgery. Not drawn directly into the radial keratotomy fray, the Society opted for a broader perspective, meeting annually, holding courses and programs balanced among a variety of refractive surgery procedures, sponsoring the Journal of Refractive Surgery, and publishing a consensus statement on radial keratotomy in 1988 that rescinded the "experimental-investigational" label.

Local Ophthalmological Societies

Some local eye societies fostered programs to enhance understanding of radial keratotomy. For example, in 1980 the Georgia Society of Ophthalmology created a community-based study of radial keratotomy. Directed by a committee of private practitioners, the study consisted of a practical prospective protocol, a laboratory training course, a provision of both equipment and a technician-coordinator by a private hospital. The protocol stipulated a standardized surgical technique done without charge to the patient, and routine, fee-for-service follow-up care in the surgeon's office. After a year of planning and implementation, a total of four cases had been completed; the study was abandoned.

The American Academy of Ophthalmology

The American Academy of Ophthalmology provided leadership by clarifying questions about radial keratotomy for both practitioners and the public. In 1981, the Academy did the simple and logical thing, endorsing the statement issued by the National Advisory Eye Council. In 1983, the Academy issued its own terse statement, labeling the procedure "investigational" and calling for cautious evaluation. In 1985, the Academy's Ad Hoc Committee on Ophthalmic Procedures Assessment assembled a panel of eight experts to prepare a consensus document on radial keratotomy, but as the panel gradually expanded to 17 members, it became hopelessly bogged down in rancorous debate, nit-picking obstructionism, and reactionary bickering. In 1988, under the leadership of David Guyton, MD, the panel self-selected a smaller group of ten participants, who successfully produced a consensus document that was approved by the Academy Board of Directors.

Radial Keratotomy Finds its Place

In the late 1980s, two forces calmed the debate over keratotomy: 1) The publication of studies from the PERK group, the ARK group, and other investigators who took a lot of the mystery out of the operation and statistically defined its safety, efficacy, predictability, and stability, findings which are summarized in the consensus statements of the International Society of Refractive Keratoplasty and the American Academy of Ophthalmology; and 2) Reduced insurance coverage dampened the popularity of the procedure, some companies refusing to pay for the procedure (many hiding behind the skirts of the Academy's 1983 "investigational" statement) and others raising malpractice premiums for keratotomy surgeons.

Approximately 10% of ophthalmologists in the U.S. routinely do radial keratotomy, making the procedure available to those patients who elect it. The operation is finding its appropriate place in the management of myopia.

I hope that the May 3, 1988 decision in the Chicago
Federal District Court, which cleared members of the Board of Directors of the American Academy of Ophthalmology of the allegation that they illegally conspired to restrain the practice of an "interstate commerce" in radial keratotomy, has drawn the final curtain on the dark drama of radial keratotomy in the U.S. (The plaintiffs' motion for a new trial was denied. Appeals are pending.) The jury's opinion serves notice that responsible individuals and organizations can legally speak their minds concerning new ophthalmic procedures, as Duffy emphasizes.

In late 1988, radial keratotomy has emerged from the fiery storm of publicity, politics, and litigation, settling into the more rational world of alternative medical procedures, with both strengths and weaknesses, waiting for further improvements.

References
2. Libman J: Lee Testa's private miracle. Family Circle, September 13, 1983
6. Demorest B: They are not my colleagues. Argus 1987: 10:4

GEORGE O. WARING III, MD
Associate Editor
Atlanta, Georgia