Clinical Trial Stirs Legal Battles

Legal disputes in Atlanta and Chicago over surgery for myopia raise issue of how controversial surgical techniques should be assessed

Atlanta, Georgia. A lawsuit filed in federal court here 3 years ago has split the ophthalmology community and is inching toward a resolution that could have major implications for clinical trials of controversial surgical techniques. The suit, which seeks $78 million in damages, charges a group of academic physicians with attempting to monopolize a surgical procedure for correcting nearsightedness by urging restraint on use of the procedure, labeling it experimental, and conducting a $2.5-million clinical study funded by NIH to determine whether it is safe and effective.

The defendants, who are associated with some of the nation's most prestigious academic ophthalmological institutions, have said in court documents that they acted solely to ensure that the surgical procedure is safe and effective. They have argued that the lawsuit will have a chilling effect on future public discussions of controversial medical techniques.

Their concern stemmed from the fact that no clinical trials of the surgery, which is known as radial keratotomy, had been conducted before it began to be widely used. Millions of Americans are potential candidates for the procedure, which consists of making incisions in the corneas of myopic but healthy eyes.

The suit contends, however, that private physicians had enough information to judge the procedure safe and effective, and charges that the actions of the academic physicians were aimed at shutting private practitioners out of a potentially lucrative area of medicine. A great deal of money is at stake: at an average of $1000 per eye, use of the procedure could develop into a business totaling billions of dollars.

A broader issue is at stake as well: how should surgical procedures—which, unlike drugs and medical devices, are unregulated—be assessed before they are brought into widespread use? Underlying this dispute is a history of tension between private physicians and their university counterparts over that issue.

The suit, which was filed in February 1982, was initiated by two private physicians, Leo Bores and Robert Marmer, who contend that their practices have been damaged, and seven individuals who say that they have been hampered in their desire to undergo the surgery by the controversy swirling around it. It is a so-called class action, brought on behalf of all physicians and patients who believe they have suffered harm.

After 3 years of legal skirmishing, which has not dealt with the merits of the case, the parties have agreed to a settlement involving a payment by the defendants of $250,000 and a statement by the most prominent defendant that the procedure is "effective in reducing myopia" in qualified patients and should no longer be considered "experimental." The statement is based on early results of the clinical trial at the heart of this case, which still has 2 years to run.

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The settlement faces some procedural hurdles before it is accepted by the court, however, and the matter has been complicated by a second suit, raising similar allegations, that was brought last year in federal court in Chicago. Filed by nine physicians led by Ronald Schachar, an ophthalmologist who practices in Denison, Texas, the suit accuses the American Academy of Ophthalmology of attempting to control the procedure. Schachar's lawyers have objected to the proposed settlement in Atlanta and raised the possibility of eventually suing the Atlanta defendants in Chicago.

Radial keratotomy was developed a decade ago by a Soviet surgeon, Svyatoslav Fyodorov. Fyodorov noted that the myopia of one of his patients, a 16-year-old boy, was diminished after his cornea was lacerated when his glasses shattered during a fight. Fyodorov later achieved the same results surgically in other patients by making delicate incisions part of the way through the cornea in a pattern radiating like spokes of a wheel from an area at the center of the eye. The cuts weaken the cornea, causing the central area to flatten and thereby reducing its resolving power.

In 1978, Bores, who was then practicing in Detroit, visited Fyodorov, learned the technique, and later that year performed the first radial keratotomies in the United States. The procedure rapidly gained popular attention through articles in newspapers and magazines, and a growing number of physicians began to offer it. In 1979, Bores established the National Radial Keratotomy Study Group, a private foundation, to collect data on the safety and efficacy of the technique, and a similar body, the Keratorefractive Society, was established the same year by Schachar and a group of associates.

As radial keratotomy became more widespread, it attracted mounting controversy. George O. Waring III, an associate professor of ophthalmology at Emory University School of Medicine in Atlanta, who is one of the chief defendants in the Atlanta suit, summed up his concerns in an affidavit filed in court in 1982. "To my knowledge no indepth scientific peer-reviewed study of the procedure had been conducted, and hence the safety and efficacy of radial keratotomy was unknown. Since eyeglasses and contact lenses were available as a safe and effective means of correcting myopia, there was need to verify the claims and document the risks of this largely untested operation which was being performed on structurally normal eyes."

Waring, who on the advice of his lawyer declines to be interviewed until the case is settled, arranged a meeting in Atlanta on 15 March 1980 to discuss radial keratotomy and the need for a clinical trial of the technique. The meeting, which was attended by 14 ophthalmologists, most of them associated with university hospitals or clinics, approved a statement labeling the procedure experimental and urging that a clinical trial be undertaken.

Following discussions with officials of the National Eye Institute, which is part of the National Institutes of Health, 11 institutions around the country submitted grant applications for a 5-year, multicenter study of radial keratotomy to be headed by Waring at Emory. Patients would be treated free of charge.

A grant to Emory was approved in September 1980, seven others were giv-

en the go-ahead in February 1981, and a ninth center was added later that year. Called the Prospective Evaluation of Radial Keratotomy, the study is widely known by its acronym PERK.*

In the meantime, several state ophthalmology societies passed resolutions urging that radial keratotomies only be performed as part of a clinical trial. The National Eye Institute's advisory council adopted a resolution declaring radial keratotomy an "experimental" procedure and expressing "grave concern" about its widespread use. The board of the American Academy of Ophthalmology also labeled radial keratotomy experimental in a statement issued in July 1980.

As a result of all this, some insurance companies and other third-party payers have refused to provide coverage for radial keratotomies because experimental procedures are frequently exempt from insurance coverage. A few patients also contend they have been denied jobs after having the surgery. Some airlines, for example, require applicants for jobs as pilots to sign a statement saying they have not had corrective eye surgery.

In addition, some physicians have been denied hospital privileges to perform the operation. For example, both Bores, who was then practicing in Santa Fe, and Marmer, who practices in Atlanta, had their hospital privileges revoked in 1980, according to court documents. Consequently, many physicians took to doing the operation in their offices. (Although it usually costs at least $1000, the operation takes only a matter of minutes and is performed under local anesthesia.)

Bores and Marmer filed suit on 19 February 1982, claiming that antitrust laws had been violated. Named as individual defendants were most of the physicians who participated in the original meeting called by Waring in Atlanta, many of those taking part in the PERK study—including officials of the National Eye Institute—some members of the institute's advisory council, and members of the board of the American Academy of Ophthalmology. All were charged with being part of a conspiracy designed to monopolize the practice of radial keratotomy.

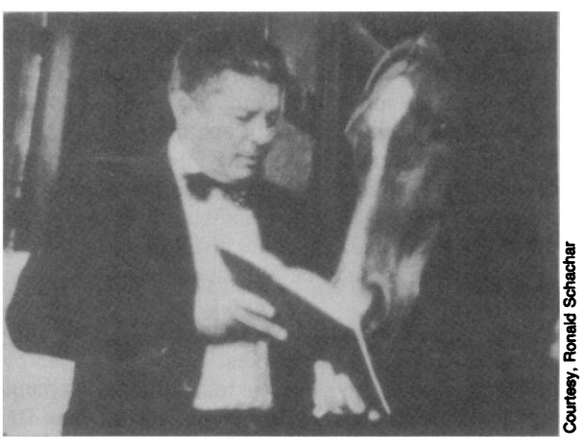
Documents filed in court to support this charge note that most of the physicians who took part in the Atlanta meeting subsequently became investigators in the PERK study. They also allege that some of the defendants were instrumental in persuading state societies, the American Academy of Ophthalmology, and the National Eye Institute's advisory council to adopt resolutions designed to discourage use of the technique. "The moratorium resolutions along with other devices which have effectively 'shut down' radial keratotomy in the private ophthalmic community have herded potential radial keratotomy patients to the defendant physicians involved in the PERK study, and to the institutions they serve," one brief charges.

The legal file on the case occupies thousands of pages, most of which are concerned with procedural maneuverings on behalf of the defendants aimed at getting the charges dismissed. These have been only partly successful. Some 15 months after the suit was filed, Judge Robert H. Hall, who is presiding over the case, dismissed the National Eye Institute officials from the suit on the grounds that they were simply doing their job and he ruled that the court had no jurisdiction over about two-thirds of the remaining defendants. That left 10 defendants—three physicians from Emory and seven others who took part in the Atlanta meeting. Faced with mounting legal costs and the threat of a possible $78-million judgment, they began to explore the chances of reaching a settlement.

An agreement was reached last fall under which the defendants admitted no wrongdoing but agreed to pay a total of $250,000 in part to cover legal costs. In addition, Waring agreed to sign a statement about radial keratotomy. According to a notice of the proposed settlement signed by Judge Hall, "Plaintiffs anticipate that the statement will have the effect of encouraging insurance companies and other third-party payors to reimburse for the radial keratotomy procedure," and that it will "encourage public employers to accept applicants who have had the procedure performed on them."

The agreement has, however, run into some procedural obstacles. On 22 February, for example, Judge Hall refused to accept the settlement on the grounds that the classes that are supposed to be covered by it had not been properly informed. He gave the parties another 30 days to come up with an acceptable notification.

Meanwhile, Schachar and his associates filed suit in Chicago on 6 June last year against the American Academy of Ophthalmology. Schachar's attorney, James Elliott, has also entered an objection to the proposed Atlanta settlement, arguing that it provides too little compensation for those allegedly harmed. Elliott has requested that Schachar and his co-plaintiffs be exempt from any settlement in Atlanta because they may want to make the Atlanta defendants parties to the Chicago suit.



Courtesy, Ronald Schachar

Svyatoslav Fyodorov

Developed radial keratotomy technique.

While these lawsuits grind on—the Chicago suit is not even scheduled for trial until January 1987—use of the procedure has been mushrooming. According to estimates by both Bores and Schachar, as many as 120,000 radial keratotomies have now been performed in the United States, a figure that seems to contradict the contention that the controversy has "shut down" radial keratotomy in the private sector.

The PERK study has also been taking place as planned in spite of the legal controversy. The first-year results, which were presented at a meeting of the American Academy of Ophthalmology last November, indicate that the procedure is effective in reducing myopia, particularly in patients with mild to moderate degrees of nearsightedness. However, "even using a carefully standardized surgical technique, it was not possible to accurately predict the refraction one year after surgery for individual pa-

*The institutions participating in PERK are Emory University; the Bascom Palmer Eye Institute, Miami; Louisiana State University Eye Center; University of Minnesota; Mount Sinai School of Medicine; University of Southern California; University of Oklahoma McGee Eye Institute; the Wills Eye Hospital and Research Institute, Philadelphia; and the William Beaumont Eye Clinic, Detroit.

tients." No serious safety problems were encountered.

These results are in line with what private physicians were reporting 5 years ago, when the technique was spreading in the United States. "PERK corroborates our data," Bores said in an interview. All along, the private physicians have maintained that they had sufficient data from clinical experience to go ahead with the technique. By the time Bores introduced radial keratotomy into the United States, Fyodorov had nearly 5 years' experience with it, and both Bores and Schachar argue that the reports submitted to the National Radial Keratotomy Study Group and the Keratorefractive Society showed the procedure to be safe and effective. Waring and other investigators in PERK have argued, however, that these data do not constitute a proper clinical trial.

"The basic issue here is how should surgical procedures be brought into the health care delivery system," notes one defendant who asked not to be identified. Both Bores and Schachar regard the PERK study and the efforts to discourage widespread use of radial keratotomy as an attempt by academic physicians to regulate the practice of ophthalmology. They argued in separate interviews that decisions on surgical procedures should be left to individual surgeons and that medical ethics instilled during training should be sufficient to guard against abuses. "You don't regulate at the procedural level, you do it at the training level," argues Bores.

"There's an art and a science to medicine," says Schachar. Regulation, he argues, "is like controlling Leonardo's hand. If you make him use a stencil, you won't have a Leonardo."

Clinical trials are, however, widely regarded as important for evaluating new techniques and practices. "If [the PERK] study and similar studies were to be discontinued—by discouraging voluntary participation by private physicians by lawsuits or for any other reason—the public would suffer, with potentially dangerous consequences," said Carl Kupfer, the director of the National Eye Institute, in a deposition in the Atlanta case.

James Rowsey, an Oklahoma ophthalmologist who is a defendant in the suit, added in a brief filed last year, "Insofar as this action may have a chilling effect on any physician speaking out in good conscience concerning the possible ramifications of a new procedure, the interests of the public and society in general have been severely damaged."

—COLIN NORMAN

NSF Selects Supercomputer Centers

The National Science Foundation (NSF) has announced the winners in the competition to host the agency's four new supercomputer centers. They are:

- Cornell University. The new Center for Theory and Simulation in Science and Engineering will be managed by Nobel Laurate Kenneth G. Wilson, one of the most vocal proponents of a federal supercomputer program.
- The University of Illinois in Urbana-Champaign. This facility will be directed by Larry L. Smarr, also a major advocate of the supercomputer initiative. It will work closely with the university's new Center for Supercomputer Research and Development, which is jointly funded by NSF and the Department of Energy.
- The San Diego supercomputer center. Supported by a consortium of 18 universities around the country, the center will be located on the campus of the University of California, San Diego, and managed by GA Technologies. The project director is Sidney Karin.
- The John Von Neumann Center at Princeton. The center will be managed by the Consortium for Scientific Computing, a collection of 12 universities. The director is Steven A. Orszag.

The new facilities will receive a total of $200 million from the NSF over the next 5 years. Further contributions from the host states, the host institutions, and industry will approximately double that figure.

NSF officials and the winners alike were understandably ebullient at the announcement. "We now have four Fermilabs for computing!" said John W. D. Connolly, director of the foundation's new Office of Advanced Scientific Computing. Indeed, the supercomputer initiative is a response to a widely perceived problem: a decline in academic computing analogous to the much discussed decline in academic instrumentation. Massive numerical simulation has become critical in fields ranging from astrophysics to climatology, yet university researchers have mostly had to beg, borrow, or steal time on supercomputers at the national laboratories.

The idea of the new centers is to provide the research community at large with access to supercomputers, in much the same way that the NSF's national observatories provide the astronomical community with access to telescopes. (As a temporary expedient, the NSF has already begun buying time for researchers on existing supercomputers; on most such machines that cost is around $2000 per hour.) A key component of the system will be a nationwide, high-speed data network that will allow researchers to communicate with the supercomputers from their desktop terminals without ever having to visit the centers personally.

One obvious concern in all this is that the program not be terminated after the first round of machines are in place. There is historical precedent: one reason for the poor state of academic computing in the 1970's was that the Nixon Administration terminated the NSF's support for campus computer centers in 1972. However, NSF director Erich Bloch is adamant that such will not be the case this time: "Technology is undergoing such rapid changes that present-day supercomputers will be obsolete in a couple of years," he says. "We have a commitment to maintaining the state of the art at these centers. This is not going to be a one shot deal."

—M. MITCHELL WALDROP

AID Tightens Antiabortion Measures

Proposed regulations to implement the Administration's antiabortion policy abroad could result in a loss of $50 to $80 million for family-planning programs, according to the Population Crisis Committee (PCC).

The regulations, which would apply to all grants to nongovernmental organizations (NGO's), represent the government's interpretation of the executive proscription against population aid to organizations that "actively promote" abortion.

They would require that all recipients of population money agree not to furnish funds to programs that include abortion services. Both recipients and "sub-recipients" would have to keep records to demonstrate adherence to