cials have been burying Minuteman with unseemly haste." Both he and Kosta Tsipis, a weapons adviser and physics professor at MIT, claim that missile failures, communications breakdowns, and guidance errors would all limit the success of a Soviet first strike, as would the possibility that U.S. missiles would be launched before attacking missiles ever exploded. That and the possibility of retaliation from submarines and bombers is sufficient deterrence, they say. Therefore, the MX is not needed for deterrence. George Rathjens, another weapons expert at MIT, also says that the United States need not be concerned about Minuteman vulnerability. He says that advocates of one deployment scheme or another have been "giving away the ball game."

—R. JEFFREY SMITH

Institute, Keratotomists Don't See Eye to Eye

Physicians challenge National Eye Institute for funding clinical trial to test new type of eye surgery

A new and relatively simple surgical procedure that reportedly eliminates the need for eyeglasses or contact lenses to correct nearsightedness has touched off an acrimonious debate between practitioners of the surgery and the National Eye Institute. Surgeons who perform the procedure, known as radial keratotomy, argue that the institute is suffering from its own case of myopia by funding an expensive 5-year evaluation of the surgery's safety and effectiveness.

The keratotomists say the surgery has been performed on 1500 patients and that the data are available for the asking. Furthermore, they contend that the evaluation—a $2.4-million grant—was awarded despite conflict of interest among the advisory committee members. There is an even broader issue, they say. At stake "is the role of the private practitioner in research," says Ronald Schachar, an ophthalmologist in Denison, Texas, who says he has performed radial keratotomy on hundreds of patients.

On the other hand, eye institute officials point out that very little about radial keratotomy has been published in refereed journals. Although the keratotomists contend that data have been collected, the institute has yet to see this information. Given the paucity of data, officials say, the institute has funded a controlled clinical trial to test the surgery's safety and effectiveness. The officials note that, in the past, apparently successful surgical techniques became widely used before a thorough evaluation was made.

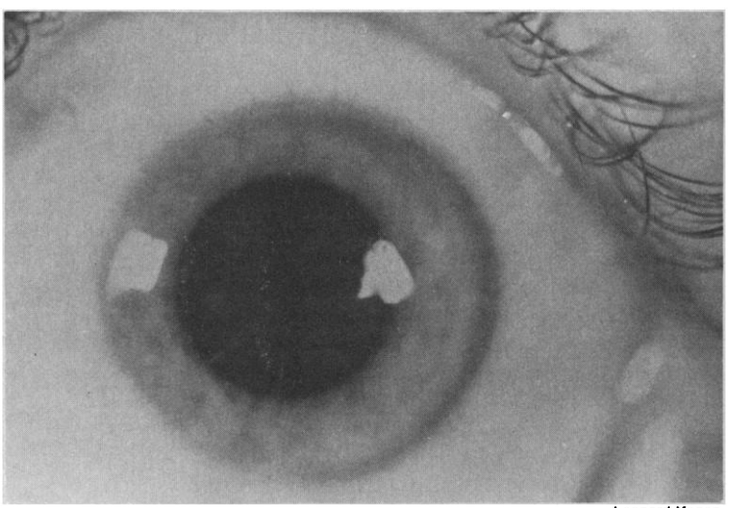
The surgery is a 30-minute procedure performed on an out-patient basis. The eye receives a topical anesthetic and small delicate incisions are made on the cornea so that it bulges slightly, thereby correcting the myopia.

The surgery was first reported by a Russian ophthalmologist 7 years ago and has gained rapid popularity in the United States in the past year. Schachar estimates that 500 eye specialists now perform the operation. In May 1980, the eye institute's advisory council said that radial keratotomy should be considered an experimental procedure and urged restraint in its use. The American Academy of Ophthalmology, which represents most of the country's 10,000 eye specialists, has issued a similar warning.

But already hundreds of nearsighted eye patients have undergone the surgery. With a price tag of $1000, the surgery is an expensive alternative to corrective lenses. Given that 10 million Americans are nearsighted, the eye institute is concerned about the surgery's short- and long-term effects. At the suggestion of the eye council, the institute called for grant proposals to evaluate the procedure and last fall awarded its grant to a collaborative group of eight institutions. The study, known as PERK (Prospective Evaluation of Radial Keratotomy), is headed by George Waring of Emory University. Investigators are now screening patients to find 480 who are suitable for their controlled study.

After the PERK study was funded, keratotomists complained to the institute that they already had enough data to judge the safety and effectiveness of the surgery. They also took their complaint to Representative Eugene Johnston (R–N.C.), who underwent a radial keratotomy last year and is a satisfied patient. Johnston, who is a member of the Budget Committee, wrote the institute that the PERK study "would reinvent the wheel." The institute took heed and held a meeting last month to let the keratotomists present their data that purportedly would answer the questions posed in the PERK study.

The meeting was held to discuss data from two groups, the National Radial Keratotomy Study Group and the Keratorefractive Society. Both groups are composed of practitioners who voluntarily submit patient data to a central registry. But the eye institute never re-



Leonard Kogen

Focus of debate: patient's eye after surgery with eight incisions.

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ceived a report from either group. During the session, several keratotomists submitted information that was sketchy at best. What was presented was not given in the standard scientific format, including methodology, a statistical summary, analysis of results, and a conclusion.

Schachar, who is one of the most vocal critics of PERK, submitted four slides and no written report at the meeting. He says that the protocol did not need to be written down in a report because it is already detailed in a manual published by the Keratorefractive Society. "We have the data," Schachar said. "It may not have been in the way the institute's statisticians wanted it, but all you have to do is fine-tune the data."

"The institute didn't say what format it wanted the data in," Schachar says. But a letter written by Robert Sperduto of the institute's office of biometry and epidemiology asks that the presentations "follow the usual format of scientific presentations."

Schachar says that the society will have the information the institute wants in 6 months, after it runs the data through computer analysis.

The institute's observation that results of radial keratotomy have not been published in peer-reviewed ophthalmology journals does not sit well with the keratotomists. Leonard Bores, a private practitioner in Phoenix, who has probably performed more keratotomies than any surgeon in the nation, says that the journals are run by the members of the medical establishment who are skeptical of this maverick procedure on nearsighted eyes that are otherwise healthy.

A study by Bores of 400 patients after 1 year of follow-up is to be published in the August issue of *Annals of Ophthalmology*, a journal that conducts internal review. Bores found that patients most often complain of glare and visual fluctuation within the first month after surgery. The complications generally subside after 3 months. About 14 percent of the 303 eyes that underwent surgery regressed partially, which means that these patients still need corrective lenses although their vision is not as blurry as before. Some eyes also lose about 6 percent of their endothelial cells, which, Bores says, appears to be no cause for worry. Officials at the eye institute say that they do not have enough data to judge the significance of the cell loss.

Bores and Schachar take a dim view of the PERK study and charge that it has several flaws. They point out, for example, that the study lacks enough surgeons with experience in radial keratotomy. As the study stands now, about half of the participating surgeons have performed anywhere from 6 to 132 keratotomies. Although the surgery is a fairly straightforward procedure, Bores and Schachar contend that experience is a big help. On the other hand, the two physicians claim to their colleagues that the technique can be learned in a weekend workshop that they teach (at $1000 per participant).

The institute's associated director of extramural and collaborative programs, Ronald Geller, says the study is valid even though it does include some ophthalmologists without keratotomy experience. To run the study with only experienced keratotomists "is not the real world," Geller said. "There's some merit in monitoring any effect of surgical experience on the outcome. There are ophthalmologists taking weekend courses. We'd like to know the successes [under a controlled setting]." Because of the criticisms heard at the June meeting, the institute is now planning to increase the number of patients who will be operated on by the experienced keratotomists in the study. It is also considering asking another keratotomist to join the study.

Bores and Schachar believe that the PERK study represents a continuing problem of "town and gown rivalry," as Bores puts it. The institute is ignoring the data of the private practitioners, they argue. "There's been a fight for the past 30 to 40 years about who's going to control ophthalmology—private practitioners or academia. The universities have always won," Bores says. Schachar contends that the PERK study allows the universities to gain control of the market for the keratotomies.

But most, if not all, of the PERK surgeons are donating their services. Under the terms of the grant, they cannot perform radial keratotomies outside of the PERK study or give workshops for the duration of the study. Geller says that Schachar has little reason to complain, noting that Schachar has a $54,000 grant for optical research at the University of Texas at Arlington, where he is an adjunct professor.

The keratotomists add to their complaint the accusation that there was a conflict of interest in the award of the PERK grant because three members of the Eye Institute's advisory council work at institutions that will receive PERK money. Geller defends the institute, saying that a special ad hoc study section was formed to review the grant proposal and that when the advisory council met to vote on the matter, a conflict of interest was avoided because those three members left the room. Neither Edward Norton of the University of Miami, Thomas Duane of the Wills Eye Hospital in Philadelphia, nor Herbert Kaufman of Louisiana State University participated in the PERK vote, Geller says.

PERK's director, George Waring, says the keratotomists' complaints about conflict of interest and the rivalry between town and gown are "red herring issues." He says, "To broach these subjects causes explosions and our job in PERK is to take a step away from the explosions. The data on radial keratotomy is wanting and not substantial. That's not to say it's worthless, but PERK takes the lead to study keratotomies."

The keratotomists' strongest objection to PERK is that it is redundant of their own efforts. They were given an opportunity to inform the institute in June of their findings. But they have yet to present data in a form that the eye institute may use to judge the worthiness of the procedure. That data may be forthcoming in 6 months. Meanwhile, the number of patients undergoing the surgery is increasing. Some ophthalmologists on the West Coast are advertising their services in radial keratotomy. Until the surgeons come forward with their data, it is difficult to fault the institute for funding a study to assess the operation and its effects. Although some of keratotomists' criticisms have only cluttered the argument, others have yielded revisions that should strengthen the study. Even Representative Johnston has changed his original stance and says that a government study with revisions would be worthwhile. PERK surgeons will begin operating this month.—MARJORIE SUN

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