New technology and the procedures that accompany it have been introduced in the US in both traditional and nontraditional ways. Many years ago, it was almost exclusively through the university. However, it was not the universities that ushered in, for example, intraocular lenses, extracapsular cataract surgery, phacoemulsification, radial keratotomy, astigmatic keratotomy, and keratomileusis. Apparently, our centers of higher learning did not have the leadership or foresight to successfully study and introduce such revolutionary procedures. In fact, beginning with the intraocular lens, in the US, new procedures and technology increasingly have come from the private, non-university sector.

In more recent years, device-related technology largely has been the province of the Food and Drug Administration. Although its basic franchise is valid, through years of study of countless pharmaceutical agents and devices, including the excimer laser, it has been burdened with a bureaucracy and a political framework that actually impede the study and timely introduction of technology into the ophthalmologic marketplace. The recent introduction of photorefractive keratectomy (PRK) with the excimer laser is a very good example of this ineptitude. The rigidity of their protocols and of their methods of introducing information have served more to hinder timely technological innovation than foster it. Therefore, by default, the private sector is finding itself, again, to a large extent, in charge.

By "private sector" I mean practicing ophthalmologists, who may or may not have university affiliation, but who are not university-based, and, their essential partner, the ophthalmic industry, a large number of companies of various reputation whose primary aim is to manufacture goods and put them on the marketplace. Although they are required to operate so as to likely produce a profit and a return to the stockholders, they are not necessarily avaricious and devious; there are notable examples of caring and feeling people in management positions. Neither is the private physician necessarily motivated by greed; the desire to make available to his patients procedures likely to benefit them, in most cases remains the most important factor.

Given the failure of the universities and the ineptitude of the FDA, the private practitioner and industry have joined forces to create an effective operational unit for the introduction of technology.

Concerns that safety and effectiveness could be in jeopardy under this leadership have proved largely groundless. The introduction of automated lamellar keratoplasty (ALK) in the US is a notable example. For many years, keratomileusis had faltered. American practitioners and, for that matter, most of the ophthalmologists of the world, rejected it because they found it cumbersome and technically difficult and the results achieved with it disturbingly unpredictable. This occurred despite the interest of ophthalmologists and a very enthusiastic industrial base pushing it for it. The inadequacy of the procedure itself doomed it.

However, when Luis Ruiz introduced the automated corneal shaper, the instrument used in ALK, keratomileusis was given a new lease on life. All of a sudden a machine was available for performing keratomileusis with a reasonable degree of accuracy and safety. However, the machine, in fact, was already grandfathered under the provisions established in connection with the original Barraquer instrument, so there was no role for the FDA one way or the other.

When I first saw ALK performed by Dr Ruiz in Bogota in August, 1992, it was apparent to me that he had solved the basic mysteries and problems of keratomileusis. It was also obvious that ALK was coming to the US, with or without statistical back-up, and in fact, some 10 or 15 practitioners already had acquired the units and were beginning to do the procedure.

I was concerned because of the potential problems inherent in any new machinery, the difficulty of keratomileusis, and the necessity of a complete understanding of the procedure and its complications. Not only might many eyes be lost, but also the procedure itself, likely ultimately a viable one, might be prematurely rejected.

Because of this, I engaged in a venture with Chiron Corp, in which I had no financial interest in the equipment, to try to ensure that the introduction of ALK, which was coming regardless of what we did, was reasonably monitored and controlled.
Chiron and I agreed that we would introduce the equipment, to which they had acquired the rights at my request, through formal training courses. Ophthalmologists interested in purchasing and using the units would be required to undergo basic course training followed by a mini-fellowship given at one of three offices of people with reasonable experience. In other words, no one could do the procedure without having demonstrated adequate intellectual and clinical experience with it. As it has turned out, the mini-fellowship probably has been the most important reason that ALK, after a very difficult start, has become relatively widespread in the US. Now laser in situ keratomileusis, a variation of ALK, some day may well become one of the great procedures for treating refractive error.

Although the procedure was introduced without any American data, it must be recognized that Dr Ruiz had spent many years developing it and there was no apparent reason to doubt his veracity or the quality of his work. Because the procedure was ongoing anyway, it was decided to promptly start retrospective and prospective studies. These have now been under way for several years and the results are beginning to come in. Thus, we had the unusual situation in which the statistical basis for the procedure was being developed at the same time that the procedure was actually being introduced into the US. In fact, there was no alternative viable method.

I will be the first to admit that the introduction was difficult. However, there is no question in my mind that it was the unique combination of the caring private practitioner, with reasonable investigative skills and education, and controlled sale of the instrumentation through education, that led to a successful outcome.

My conclusion is that traditional methods of solving problems do not always work. Also, it should be recognized that certain realities in the marketplace will operate whether the universities or governmental institutions like them or not. I would submit that the fruitful wedding of industry and the private practitioner demonstrated by this example is well worth pondering. The successful transformation of new knowledge into improved patient care it illustrates represents, I believe, simply a better way of doing things.

Ultimately, it is a question of power and the fact that, as everyone knows, no one will relinquish power voluntarily. The monitoring process assumed by universities has made them, at least historically, perhaps the most powerful arbiters in the introduction of new technology. It is not a role they will give up easily. But the data-gathering process should be in the interest of those it is designed ultimately to serve—patients through their doctors. To whom it brings power or prestige is a secondary issue at best.

J. Charles Casebeer, MD

The editor responds.

Dr Casebeer rightly argues that education forms an important basis for the introduction of new ophthalmic procedures and technology and that such education can be promulgated effectively by joint ventures between industry and ophthalmology. I support this concept, and have written an editorial stating that the collaboration between industry and medicine "...is a fruitful one that we heartily endorse and for which there is a growing need."1

The focus of my argument in the editorial2 that spurred Dr Casebeer's response was how new procedures are introduced, not who introduces them. Whether a new procedure is introduced by a commercial firm, by a private practitioner, by a university-based research group, or by persons outside the US is ultimately irrelevant. We have a responsibility to our patients and our peers to evaluate new procedures gradually, with documentation of the results—both positive and negative—prior to widespread educational dissemination. This is the thrust of my 10 idealistic proposals for a more rational evaluation of new procedures, proposals that both encourage innovation and early adapters and at the same time prevent complications in large numbers of patients.

I heartily endorse the educationally based approach that Dr Casebeer describes as his motivation for helping spread automated lamellar keratoplasty (ALK). But, Dr Casebeer points out a crucial weakness in his approach: "Because the procedure was ongoing anyway, it was decided to promptly start retrospective and prospective studies. These have now been under way for several years and the results are beginning to come in. Thus, we had the unusual situation in which the statistical basis for the procedure was being developed at the same time that the procedure was actually being introduced into the US." This statement highlights a central problem—we proceed with active teaching of hundreds or thousands of ophthalmologists to use a technique that we are simultaneously figuring out how to do—including the identification of complications and statistical outcomes. Is it not safer for patients and more rational for the profession to proceed in a graduated manner, refining the techniques and improving the results on smaller numbers of
patients (or in the laboratory), and saving our mass education for the time when we have worked the bugs out of the technique and have acquired reasonably quantitative descriptions of safety and efficacy?

We can keep track of this progress in ophthalmic newspapers and in peer-reviewed journals, which will publish rapidly letters to the editor, brief reports, case studies, and preliminary results—as well as full original articles more slowly. Examples are the reports from the PERK study in the early to mid-1980s at 1, 2, 3, 4, and 5 years after radial keratotomy and the series of reports about excimer laser photorefractive keratectomy that emerged from US clinical trials. This cautious approach seems particularly appropriate when the disorder under consideration—refractive errors—can be managed by spectacles or contact lenses or by other elective surgical procedures.

Raising the medieval argument of town-gown conflicts is irrelevant. Both groups have contributed significantly to contemporary surgical techniques: academic and university-related groups have contributed vitrectomy, excimer laser corneal surgery, the PERK study, epikeratoplasty, the intracorneal ring, and currently the largest LASIK trial in the United States. Dr Casebeer rightly lists the many contributions from private practitioners. Of course, all of us North Americans should be aware that the vast majority of refractive surgical procedures have originated outside the US, but this certainly does not indicate that the US has somehow lost its ability to contribute early and meaningfully to refractive surgery. We live in an age of merger and synthesis; ophthalmic private practitioners, university-based ophthalmology groups, the ophthalmic industry, and the international ophthalmic community are working together in active collaboration. The town-gown debate died years ago.

Dr Casebeer concludes by pointing out that the introduction of new technology leads to power. He is correct. The lust for that power is one of the forces that drives free-market madness. I hope my 10 proposals for rational evaluation of new refractive surgical procedures will stimulate more correspondence and discussion, such as Dr Casebeer has provided, and will reduce somewhat the appetite for personal, institutional, and corporate power in the treatment of our patients.

REFERENCES


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