

chapter 2

Development and Growth of the ISRK

By Drs. Larry F. Rich, Casmir A. Swinger and Richard A. Villaseñor



Drs. Villaseñor and Troutman

Incorporated in 1979, two years after lamellar surgery's introduction in the United States, Dr. Troutman described the early ISRK as a "small group of Barraquer disciples," who sought to study refractive keratoplasty procedures and advance education through an exchange of ideas and information.

One of the Society's key objectives was to increase the accessibility and acceptance of refractive keratoplasty, often in the face of controversy and criticism from mainstream ophthalmologists, many of whom did not approve of operating on, and potentially weakening, a structurally normal eye in order to correct refractive error.



Drs. Friedlander, Kaufman, McDonald and Rowsey

Expansion of the ISRK

The Society began to design educational programs for interested and qualified surgeons worldwide and, in 1980, conducted its first symposium on refractive surgery during the American Academy of Ophthalmology's Annual Meeting in Chicago, a tradition that would continue until the Society joined forces with the Academy in 2003.

Throughout the 1980s, the ISRK offered educational opportunities in the United States and at international venues including Argentina, Belgium, Brazil, Canada, Colombia, Denmark, Italy, Mexico, New Zealand and Switzerland.

Society leaders, such as Swinger dedicated a great deal of time and effort to teaching and promoting the ISRK's mission in Asian countries that included Hong Kong, India, Indonesia, Malaysia, Thailand and Vietnam, in addition to Greece, Israel, Mexico, Saudi Arabia and Turkey.

In 1981, the ISRK held its first international meeting and, during an invited lecture at a meeting of the Bombay Ophthalmic Society, Swinger coined the



Drs. Villaseñor, Friedlander and Werblin, Ms. Friedlander and Drs. Krumeich and Elander



Drs. Friedlander, Barraquer and McDonald and Ms. Friedlander



Drs. Dominguez, Friedlander and Villaseñor in Bogotá



Ms. Forstot, Drs. Forstot and Chandler, Ms. Chandler and Dr. and Ms. Holladay



Drs. Barraquer, Aron-Rosa, Robin and Swinger, Ms. Swinger and Dr. Salz

term “refractive surgery.” He was one of the first ophthalmologists to dedicate his practice solely to refractive surgery, which he defined as “surgery at any point in the entire visual system that would alter the eye’s refractive errors, improve vision and lead to a greater quality of life for patients.”

The Society held its first European seminar on refractive surgery in Paris in 1983, followed by its second European meeting in Helsinki in 1984 where Troutman delivered the first Barraquer Lecture with a paper entitled, “The Quest for Sphericity,” a compendium of two decades of investigation of corneal astigmatism, its etiology and refractive surgical management. Also during that year, Barraquer also hosted the Tertium Forum Ophthalmologicum in Bogotá, a meeting that featured invited papers from around the world with extensive participation from ISRK members.

As the ISRK sought to expand global refractive surgery education, a number of members joined the quest to simplify lamellar surgery procedures with the goal of increasing accessibility and availability to interested ophthalmologists worldwide. The Society also steadfastly encouraged the scientific study of procedures such as radial keratotomy (RK).

Yet, even as lamellar surgery gained greater acceptance among an increasing number of committed “believers,” the cost and complexity of the equipment and steep learning curve remained obstacles to increasing its popularity among ophthalmologists.

Radial Keratotomy: A Need for More Data

Despite an initial shortage of scientific data, RK became popular among some ophthalmologists because it was easier to learn and perform, with the potential for promising results. RK also transformed the practice of ophthalmology into more of a “business.” The Federal Trade Commission granted permission to physicians to advertise as early as the 1960s yet some surgeons chose to dedicate their practices to RK, and actively promoted the procedure to potential patients with increasingly aggressive marketing tactics. This form of advertising was a relatively new concept for many ophthalmologists and even considered offensive by some.

RK’s lack of scientific validation stirred controversy in the 1980s, and concerns about safety and efficacy inspired some ISRK members to speak out about the need for a more scientific approach to RK.

In a June 1980 ISRK Newsletter Swinger wrote, “As you know there has been a tremendous interest in the radial keratotomy procedure...at the present time, there is only one scientific paper in the English literature (*Annals of Ophthalmology*: December, 1979).” The paper, according to Swinger, discussed about 600 cases with results that indicated, “Low degrees of myopia...stable over several years.” He also noted that eliminating spectacles was only a likely possibility “for the low myope of less than 3D.”

Villaseñor encouraged the Society to evaluate RK because, “a great deal of controversy has developed concerning these procedures, much of it in reaction to the numerous advertisements in such papers as the *National Enquirer* and the *Star* (tabloids renowned for celebrity news and gossip) promoting radial keratotomy surgeries.”

Villaseñor continued, “I think it is our responsibility to insist that ophthalmologists perform such surgeries using uniform protocols developed under careful university investigations. Our work indicates that refractive surgery does have valid applications, and many of the cases that we observed produced quite acceptable results. Nevertheless, there are significant problems with these surgeries...I would encourage any of you who are interested in performing RK...to follow established guidelines used in other institutions.”

Magazine and newspaper articles amplified the public’s awareness and interest in RK procedures, leading to increased scientific scrutiny and prompting a position paper from the National Advisory Eye Council that stated the potential dangers of refractive keratotomy and classified it as “experimental” due to a lack of scientific evaluation.

The paper also noted that reports from the United States and abroad did not provide adequate assurance of safety. The American Academy of Ophthalmology and the ISRK also adopted the Council’s position.

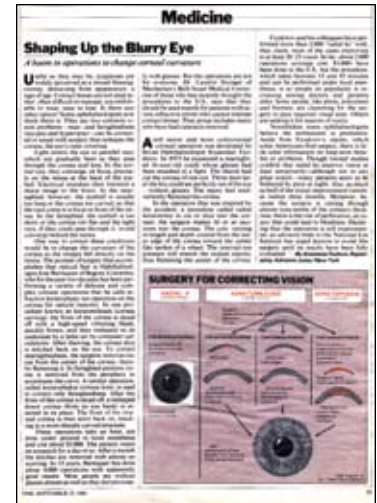
The PERK Study: Clinical Research Methods Enter Refractive Surgery

In response to long-term safety and efficacy concerns, a group of ophthalmic surgeons approached the NEI with a proposal for a multicenter clinical trial to evaluate the potential benefits and risks of radial keratotomy.

In April 1981, the surge of public interest led the NEI to fund the Prospective Evaluation of Radial Keratotomy (PERK) Study, the first methodical and organized study of a refractive surgical procedure. The nine-center clinical trial led by Dr. Waring was a significant milestone for the ISRK as it transformed refractive surgery from an “art of enthusiasts” to a clinically validated science with a systematic analysis of outcomes and approach to complications.

The goal was to evaluate the short- and long-term safety and efficacy of one RK technique by documenting the safety and stability of refraction, as well as changes in corneal curvature and patients’ subjective response. It involved 435 patients and 99 pilot patients who had 2 to 8D of myopia, correctable to 20/20 with glasses or contact lenses. For 10 years, PERK Study clinicians produced nearly 30 peer-reviewed publications that described clinical outcomes and fulfilled the Study’s goal of establishing RK as a safe and effective procedure.

While the PERK Study was a step in the right direction for RK, it was not universally embraced and accepted, especially when investigators suggested that ophthalmologists not associated with the Study refrain from performing RK procedures until objective results became available—a process that could take years.



Time Magazine (September 1980)



Dr. Waring

Compared to other procedures, RK required less time from surgeons, and many practices could thrive with a smaller number of patients each week. Thus, for ophthalmic practices dominated by RK procedures the PERK Study represented potentially dire financial consequences.

The Academy: Early Advocate of Public Safety and Education

The American Academy of Ophthalmology supported the PERK Study's scientific approach stating, "The Academy believes that this clinical trial is necessary to validate the predictability of this surgical procedure [radial keratotomy], its safety and short-term and long-term effects. Using individual surgical experiences to answer questions of safety and efficacy of a new surgical procedure does not serve to protect the health and well-being of our nation's citizens."

Because of their support, the Academy became a codefendant in two antitrust lawsuits in 1982 and 1984, filed by ophthalmologists who wished to continue the advance of RK unimpeded. Eventually, both lawsuits settled in favor of the Academy.

Dr. H. Dunbar Hoskins Jr., executive vice president of the American Academy of Ophthalmology, remembers, "Eyes were being badly damaged and many of us wanted to bring some sanity and science to refractive surgery." The Academy, he said, tried to act as a moderator, concerned about "who was guiding the educational process [because] anyone could conduct a refractive surgery course back then."



Dr. Hoskins

ISRK Education

In 1984, five years after the ISRK incorporation, president-elect Swinger decided to transform the Society's newsletter into a formal, peer-reviewed publication. He met with Slack, Inc., and they agreed to begin publication of the *Journal of Refractive Surgery*.

Established in 1985, with Salz as editor-in-chief, the Journal has consistently maintained high standards within clinical scientific publications. This peer-reviewed publication devotes itself exclusively to refractive surgery and related topics and is a consistent source of new and reliable information.

Indexed in many scientific databases, the Journal creates an archive of refractive surgery information that will be accessible for decades to come.

With a limited number of articles in scientific literature during the 1980s, establishing a scientific journal was a significant milestone for the Society. In addition to announcing scientific meetings, covering the development of new procedures or the simplification of existing ones, the Journal provides accurate information from interested ophthalmologists around the world and serves as an important educational tool for refractive surgeons.

The international aspect of the Society shines through the Journal, with the majority of published articles submitted from authors residing outside the United States, continuing decades of international emphasis and contribution to refractive surgery.



Dr. Waring leading an early RK course



Students in RK course

International contributors often work in less restrictive environments, making advances that are not always possible in countries with a more formal regulatory climate such as the United States. Some U.S. surgeons have noted that at times, articles from international contributors can be almost “prophetic,” alerting colleagues to what the future holds in the subspecialty.

Today, the Journal continues to thrive and flourish under the leadership of its second editor-in-chief, Dr. Waring and recognizes superior work through two awards. The first is the Richard C. Troutman MD DSc (HON) Prize, for “the best article in a given year by an author under 45 years of age published in the *Journal of Refractive Surgery*.”

The Foundation of the American Academy of Ophthalmology has administered the Troutman Prize since 2005, when Dr. Troutman funded it in perpetuity with a \$100,000 grant “to encourage the younger refractive surgeons who continue to revitalize the ISRS/AAO, and to recognize the scientific excellence of the ISRS/AAO and the Journal.”

The second award is the Waring Medal, established in 2006 by Slack, Inc., in recognition of the impressive contributions of Dr. Waring. The medal is awarded to an author in any age group for an outstanding paper published in the Journal in a one-year period.

Award recipients nominated by the Editorial Board each receive a \$5,000 cash prize and a handsome obelisk (Troutman) or medal (Waring).

The ISRK at a Crossroads

In the 1980s, keratomileusis and keratophakia procedures were still complicated in comparison with radial keratotomy, and surgeons such as Kaufman, Krumeich, McDonald, Ruíz, Swinger and Werblin actively sought to develop simpler procedures.

Yet, through the mid-1990s RK continued to dominate refractive surgery, despite assertions by early practitioners like Troutman who believed that lamellar surgery had a “more supportable scientific basis and greater long-term promise.”

Radial keratotomy’s allure also led a significant number of interested ophthalmologists to pay exorbitant attendance fees for a competing society’s workshops and meetings described by some as “informal, ad-hoc and without scientific basis.”

As RK’s growth and popularity thrived, ISRK meeting attendance experienced a decline, temporarily slowing the Society’s growth. Dissatisfaction and discontent rattled within the ranks of ISRK leadership, and some board members suggested that the ISRK reorganize as a “club” to reflect its smaller size.

The board decided that its options included becoming a small club or taking the necessary steps to grow the organization. Binder notes, “We [the ISRK board of directors] decided to stay the course, but it was obvious that we needed to increase membership and our exposure to mainstream ophthalmology in order to grow and thrive.”



Dr. Salz teaching an RK course



Dr. Swinger teaching lamellar surgery



Student in early RK course



Drs. Waring, Pouliquin and Binder in Hamburg, Germany (1984)



Drs. Fyodorov, Werblin and Binder with other attendees in Rio de Janeiro (1987)



Drs. Colin, Uusoloto, Binder, Malet and Baikoff in Zurich (1989)

Merger Discussions

To promote the Society's growth, some board members supported an alliance with other ophthalmic societies. In 1986, as both ISRK president-elect and president of the Contact Lens Association of Ophthalmologists (CLAO), Binder pursued a potential merger between the two organizations.

In January 1987, CLAO and ISRK held a joint meeting in Las Vegas. While the ISRK enjoyed its largest attendance, other obstacles ultimately prevented a union between the two groups.

Discussions about merging with another ophthalmic society also proved to be unsuccessful. "In retrospect I'm happy that we didn't unite with any other group," Binder recalls, "because the ISRK would have lost its unique international identity."

Securing the Future

Fortunately, a number of key events during this time took the Society in a new direction and set it back on course. In 1990, the board appointed Waring as the editor-in-chief of the Journal and the ISRK hired a director to actively began to recruit international members. These actions bolstered the Society's membership, and by 1988, attendance at the Barraquer Lecture, given by Binder, was standing room only.

After delivering his lecture, Binder felt that something was missing, that "there should have been a celebration of some type," and decided that future award recipients would enjoy an organized celebration that recognized their achievements.

The next year, Binder instituted the ISRK Award Dinner to commemorate and celebrate award recipients. This dinner, now called the ISRS/AAO Gala Dinner and Dance, Binder notes, "Is a large gathering that ISRS/AAO members still look forward to during the Academy's Annual Meeting."

The ISRK also added new awards in recognition of the many important contributions to the subspecialty, which further stimulated interest in the Society.

"A Broader Perspective in Refractive Surgery"

The ISRK survived the changes in this new era of refractive surgery by acting as a champion of a steady, methodical and scientific approach to new surgical procedures. Organizations that maintained a singular focus on one popular procedure were not destined to survive the emergence of exciting new technologies like the excimer laser.

By sustaining an apolitical, nonpolemic position on refractive procedures, the ISRK circumvented controversy. In the book entitled, *Refractive Keratotomy for Myopia and Astigmatism*, Waring wrote, "the ISRK was not drawn directly into the refractive keratotomy fray, but instead opted for a broader perspective in refractive surgery, offering course and programs balanced among keratomileusis, epikeratoplasty and refractive keratotomy, with the later introduction of courses and programs on intracorneal lenses and refractive surgery."

The American Academy of Ophthalmology

For the most part, the Academy remained on the refractive surgery sidelines during the 1980s. In 1990, a refractive laser committee chaired by Waring, Marshall, Seiler and Trokel presented a refractive surgery symposium at the Academy's Annual Meeting.

At this first meeting, member interest was evident. The Academy assigned a meeting room with capacity for 200 to 300 people, but attendance far exceeded that number, requiring a fire marshal to clear safe passage through overflowing hallways. The message was clear—refractive surgery was here to stay.

Evolution of Refractive Surgery Technology

In the 1980s, Werblin introduced a new procedure called epikeratophakia, which promised to eliminate the need for the large, expensive and complicated cryolathe, a critical component of lamellar surgery.

The “Epi” procedure involved freezing donor corneal tissue that was processed and shaped on a cryolathe. The tissue was then freeze-dried, which produced a lenticle or “living contact lens.” After rehydrating the lenticle, the surgeon then sutured it onto the patient's cornea.

Kaufman and McDonald worked closely with Werblin to address some issues that had emerged in early cases. Epikeratophakia could be useful and appropriate for corrections ranging from +6 to +8D, but visual recovery was very slow. After operating on one eye, surgeons were required to allow six weeks of healing time before operating on the second eye.

Nonfreeze Method

Swinger, Troutman and others believed that cryolathe keratomileusis, epikeratophakia and RK all had severe limitations owing to the histology and biomechanics of the cornea.

While studying with Barraquer in 1977, Swinger envisioned a procedure that would radically simplify and improve keratomileusis by eliminating both the computer and complexity of the cryolathe, while still providing rapid visual recovery without weakening the cornea. Swinger was one of the first innovators to conceive of a procedure appropriate for myopia, hyperopia, astigmatism, spherical aberration and higher-order aberrations.

Swinger developed a nonfreeze method, called planar lamellar refractive keratoplasty (PLRK), first in collaboration with engineers, Mr. Daniel Cassiday and Mr. Jos  ph Hoppl, and subsequently with a German ophthalmologist, Krumeich. They first presented their research at the Seventh Congress of European Ophthalmology in 1984, followed by the 1986 publication of the procedure in the *Journal of Refractive Surgery*.



Dr. Swinger (1980)



Dr. Krumeich



Barraquer-Krumeich-Swinger (BKS) Set



Dr. Trokel and Waring at an excimer laser clinical trials site



Dr. Trokel's first experimental excimer laser (Lambda Physik) (1984)

Swinger and Krumeich also developed a device marketed under the name “Barraquer-Krumeich-Swinger (BKS) refractive set.” Barraquer was not directly involved in the device’s development, but Swinger and Krumeich added his name to their invention to honor his contributions to the subspecialty.

According to Swinger, keratomileusis was almost disappearing from the scene, because of “the marketing of epikeratophakia and radial keratotomy.” He adds, “Although laser technology was being developed, it would take years to be approved, and it had not yet been proven that excellent vision could be maintained after a keratectomy across the visual axis followed by tissue modification and suturing. Nonfreeze BKS for keratomileusis was the first to demonstrate that 20/20 to 20/25 uncorrected vision was possible on the first day postoperatively.”

Further Developments

In the late 1980s, while using the BKS microkeratome, Dr. Ruíz noticed that his initial keratectomy was too thin for full correction. Instead of abandoning the procedure, Ruíz opted to make a second microkeratome pass on the stromal bed and discovered that this technique could also correct myopia. He called the procedure variant in-situ keratomileusis. Later, Ruíz developed a microkeratome with gears that advanced it across a track in conjunction with an adjustable height ring. This automated microkeratome created an even lamellar resection and a smooth corneal surface, with more consistent postoperative outcomes. The in-situ keratomileusis procedure was then renamed automated lamellar keratoplasty or ALK.

Improved, automated equipment increased the surgical community’s acceptance of the ALK procedure, and this early foray into flap creation paved the way for future refractive surgery developments.

Werblin commented, “We have seen the evolution of the epikeratoplasty procedure for almost a decade and continue to see procedural changes which may increase the accuracy and stability of the procedure...but its inaccuracy in the treatment of myopia remains a significant problem. Will the epithelial healing problems and postoperative care be too cumbersome for the general ophthalmologist? Will the excimer laser fill the needs of myopic refractive surgery?”

The Excimer Laser

The history of laser vision correction is a long and complex one, influenced by the contributions of many individuals.

However, Drs. McDonald, Charles Munnerlyn and Stephen Trokel are widely recognized as the first to demonstrate that the excimer laser could directly ablate and gently change the corneal shape over a wide area, rather than being used as a scalpel to perform RK.

Several other clinicians, including Drs. Carmen Puliafito, Roger Steinert, Francis L’Esperance, Marshall, Seiler, and Olivia Serdarevic worked on excimer laser vision correction, but by the mid-1980s, their efforts focused on RK or phototherapeutic keratectomy (PTK)—like applications with other types of laser equipment.

Excimer Laser Concept

Expanding upon Dr. Rangaswamy Srinivasan's discovery of ablative photodecomposition, and Dr. John Taboada's work on damage thresholds, Trokel discovered that the excimer laser could precisely remove exact volumes of corneal tissue, creating smooth, uniform surfaces with no thermal effect on surrounding tissue. He first reported the essentials of excimer laser–cornea interaction in a landmark 1983 paper and later demonstrated that rabbit and monkey corneas treated with the excimer healed clearly.

Development

In July 1983, Trokel confided his ideas to Munnerlyn, who was interested in using laser technology to reshape the cornea in a procedure he called photorefractive keratectomy (PRK). In 1984, the two worked together on the first series of rabbits to test corneal clarity versus depth. During that summer, Dr. Ronald Krueger, still a medical student, assisted with Trokel's experiments on cow, rabbit and pig eyes in the Columbia University laboratory in New York.

Munnerlyn provided the formulations for tissue removal that led to the development of the first PRK laser system and still serve as the scientific basis for excimer laser surgery today. He contracted with Louisiana State University Eye Center and Dr. McDonald to perform animal studies in 1985. The description of the system, and McDonald's PRK rabbit study, presented at the 1986 Berlin meeting established a viable alternative to the laser RK work of others and planted "the seed" for future developments in laser vision correction.

Clinical Studies

McDonald conducted the controlled trials for this new laser method. Beginning in 1985, she performed the first shaped ablations for refractive change in rabbits and primates and, on April 4, 1988, performed the first viable PRK procedures in a sighted human eye slated for exenteration. During the early human trials, McDonald influenced the ultimate design of the laser to meet clinician needs. Her work demonstrated that corneas healed normally and that refractive change was predictable, and she established perioperative clinical protocols for anesthesia, suction, the ablation procedure and postoperative care.

LASIK

In addition to the groundbreaking PRK studies, another significant turning point in excimer laser history took place at the University of Crete in Greece, where Dr. Ioannis Pallikaris and his group developed laser in situ keratomileusis (LASIK) by combining lamellar refractive corneal surgery with excimer laser photo ablation of the cornea under a hinged corneal flap.

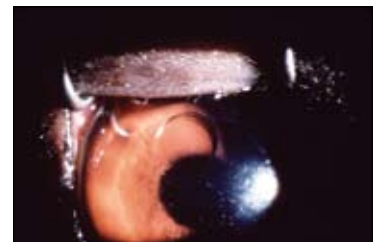
The first animal studies in 1987 were designed to determine the postoperative wound-healing response and involved an excimer laser and a microkeratome that created a 150-mm corneal flap.



Drs. Krueger and Trokel



Dr. McDonald



An early primate eye treated with a disc shaped ablation showing some refractive effect in displacing the iris/pupil margin



Dr. Pallikaris



Dr. Slade



Drs. Seiler and Krueger

In June 1989, the Pallikaris group performed the first LASIK blind human eye as part of an unofficial blind eye protocol, followed by human studies in 1990.

Dr. Lucio Buratto introduced an excimer laser for intrastromal keratomileusis of the corneal button in 1992 and suggested the term laser intrastromal keratomileusis.

The next year, Dr. Stephen G. Slade used the automated microkeratome to create a flap and called the procedure Excimer ALK.

Another Leap: Wavefront-Guided Technology

The next leap included technologies that incorporated wavefront-guided principles, enabling physicians to generate a unique “map” of the cornea used to create a customized laser vision correction treatment that promised outcomes superior to conventional treatments.

“Wavefront technology was another leap forward,” Krueger notes. “LASIK was already taking off, but we realized that some patients were not receiving good quality outcomes. Outcomes might be 20/20, but the quality of that 20/20 was not what we were aiming for. Researchers had been studying wavefront for years and helped refractive surgeons understand that wavefront would help us understand and even treat aberrations in connection with LASIK surgery.” In 2002, the FDA approved custom LASIK with wavefront technology, opening the door for significant advances in the future.

Femtosecond Laser

Swinger and colleagues made great strides in femtosecond laser applications in the 1980s. In the mid-1990s, Drs. David J. Schanzlin and Krueger participated in the first picosecond laser intrastromal ablation blind eye cohort for myopia in Phase I of an FDA trial in St. Louis, Missouri. Krueger explains that they attempted to “create a refractive change by putting the laser inside the cornea.”

However, the picosecond laser proved to be too energetic. Schanzlin recalls, “The problem with the picosecond laser was spot size—it was too large. It couldn’t create a flap because each laser pulse created too much energy.” Krueger adds, “The ablations were not smooth or precise enough.”

In 1997 Dr. Tibor Juhasz, a biomedical engineer familiar with earlier femtosecond research, expressed interest in exploring the femtosecond laser’s corneal ablation potential.

In 1999, Krueger and Schanzlin worked with Dr. Juhasz in the first femtosecond clinical studies in Budapest. Drs. Schanzlin and Lee T. Nordan were the first surgeons to perform femtosecond procedures in the United States.

Goals Fulfilled

Excimer laser developments by innovators, past and present, have etched an indelible mark in refractive surgery's history. The excimer laser, as Durrie says, "Brought refractive surgery to the masses," fulfilling one of the Society's original goals of increasing acceptance by mainstream ophthalmology.

Lindstrom adds, "The excimer laser offered better outcomes with a lower complication rate than radial keratotomy and made corneal refractive surgery mainstream."

In 20 years, laser vision technology has come a long way, with an increasing number of innovations. The introduction and acceptance of wavefront guided technology.

Growth of the ISRK



Dr. Barraquer, Dr. and Ms. Villaseñor and Dr. Castroviejo



Dr. Elander, Mr. Weinberg, Drs. Troutman, José Barraquer, Joaquín Barraquer, Friedlander, Villaseñor, Swinger and J. Barraquer in Bogotá



Drs. J. Barraquer, C. Barraquer Coll and Swinger



Drs. Osio, Joaquin Barraquer and Jose Barraquer with others in San Francisco



Drs. Gaster and Schanzlin



Dr. and Ms. Swinger and Drs. Binder and Hoffman in Rio de Janeiro



Dr. and Ms. Swinger with Dr. Villaseñor in San Francisco



Dr. and Ms. Villaseñor in San Francisco



Drs. Waring and Salz