

The Introduction of IOLs

How the struggle for lens implants' acceptance was won.

BY NORMAN S. JAFFE, MD

Introduction by Herve M. Byron, MD

Cataract surgery was performed with various instruments and procedures during the first 60 years of the 20th century. Whether it was an intra- or extracapsular extraction with forceps, or an erisophake or cryoextraction, surgeons were frustrated by problems with aphakia. Early attempts were made to insert IOLs at the time of cataract extractions with disastrous results. Sir Harold Ridley's serendipitous discovery of the solution for aphakia marked the real evolution of modern-day cataract surgery.

When the first group of four American ophthalmologists (Miles Galin, MD; Marvin Kwitko, MD; Irving Baras, MD; and myself) visited Cornelius D. Binkhorst, MD, in Holland in 1967, and returned with glowing reports about what we had observed, the New York Medical College Department of Ophthalmology allowed me to start performing cataract extraction with the insertion of an intraocular implant. My very good friend Norman Jaffe, MD, who had one of the busiest cataract practices in Miami, called me and asked whether I would be willing to visit him for a week and teach him the procedure on his patients. For me, this was the best of all worlds, because I knew that Norman would quickly master the technique and spearhead the movement to gain acceptance for this controversial operation. I eagerly accepted his offer and visited him a few months later.

We operated on his patients in the morning. By the time I left Miami, Norman had mastered the procedure, as I had anticipated, and began to expertly perform the operation. The rest of his amazing story is revealed in his narrative below.

American implant surgery was born in Miami because of two factors: (1) Norman was the ideal surgeon with the perfect personality to withstand the severe criticism by his colleagues; and (2) the Chief of the Department of Ophthalmology at Bascom Palmer Eye Institute was Ed Norton, MD, the perfect academician to maintain an open mind about the possible benefits to all patients suffering from the disease known as aphakia.

Therefore, in acknowledgment of his pioneering accomplishment, I have asked Norman to share his personal story as the first contributor to this new column.

My surgical experience with cataracts spans more than 50 years to include intracapsular and extracapsular cataract extraction (ICCE and ECCE, respectively) as well as phacoemulsification. As a practitioner during the era before lens implants, I can attest that many patients were disabled to a greater degree after a technically perfect cataract operation than they were previously.

I admire the imagination of the investigators who contemplated placing a relatively large foreign body within the delicate structure of the eye when the surgical instrumentation and techniques were extremely crude. My own interest in lens implantation began in 1966, when I first saw a patient who had received an

IOL. Warren Reese, MD, of Philadelphia, had inserted the Ridley lens 10 years earlier. I was thus convinced that an eye could tolerate an IOL.

On December 4 and 5, 1967, I implanted 11 IOLs, six after ICCE and five after ECCE. Herve Byron, MD, who had just returned with others from Holland where they had observed surgery performed by Cornelius Binkhorst, MD, stood over my shoulder and guided me through those 11 operations. These cases were presented 6 weeks later at grand rounds at the Bascom Palmer Eye Institute in Miami, where I received some heckling, although all of the eyes looked excellent (Figures 1 and 2).

I invited community ophthalmologists to observe the surgery with the intent that we could accumulate enough

cases to draw conclusions about the early safety and efficacy of the procedure. Edward Norton, MD, Chairman of the Department of Ophthalmology at the Bascom Palmer Eye Institute in Miami, was the only US university professor who encouraged us to proceed with IOL implantation, and he was not even a cataract surgeon.

My early approach to IOLs was conservative regarding the patient's age and the indications for the surgery. Patients' safety was my major concern. Thereafter, there were several significant events in my career with IOLs.

MIAMI MORATORIUM AND EARLY CRITICS

By 1969, surgeons in Miami had performed 243 cataract extractions with IOLs and were increasingly coming under fire from the more conservative local ophthalmologists. My colleagues and I voluntarily agreed to a self-imposed, 2-year moratorium on implants. Beginning on October 1, 1969, all patients who had received lens implants were examined by nonimplant surgeons. They found the results to be successful at the conclusion of this 2-year study, and implant surgery resumed on October 1, 1971. The moratorium proved our point and gave the surgeons who performed the procedure a great measure of respect and credibility throughout the country for the next several years.

Despite Dr. Norton's praise for my efforts on behalf of implant surgery, I led a nightmarish existence during the first few years when I was implanting IOLs, as evidenced by the reaction to a talk that I gave in 1970 at the New England Ophthalmological Society. Some of my close colleagues suggested to me that I had lost my mind to implant a plastic material inside the eye and expect it to last a lifetime.

I received the same kind of criticism when I spoke at one of the quadrennial meetings of José Barraquer, MD,



Figure 1. Dr. Jaffe performed his first IOL implantation on December 4, 1967. He placed a Binkhorst iris-clip lens after completing an ICCE. The same eye is shown here on December 15, 1997.

in Bogotá, Columbia. Joaquin Barraquer, MD, of Barcelona, Spain, said that my patients would suffer the same fate encountered by those in the early 1950s and 1960s. Jules François, MD, of Ghent, Belgium, jumped to his feet and agreed with everything Professor Barraquer had said, and the audience broke into wild applause. I was embarrassed and humiliated to say the least. I later invited Professor José Barraquer to visit me in Miami and observe my surgery, which he did. He was impressed and began to perform implant surgery a few years later.

"I led a nightmarish existence during the first few years when I was implanting IOLs."

Another critic was Howard Agatston, MD, a well-known ophthalmologist from New York. He often told his patients who wintered in Miami to avoid coming to my office, because I was putting implants in eyes. Several years later, he retired to Boca Raton, Florida, and developed cataracts. I reminded him of his caustic comments when he asked me to perform the surgery using lens implants on both his and his wife's eyes. His request was a sign that the procedure was gaining acceptance.

AMERICAN INTRAOCULAR IMPLANT SOCIETY

The American Intraocular Implant Society (AIOIS) was incorporated in California on August 28, 1974. The four founding fathers identified 13 leaders in the field and invited them to become the first Scientific Advisory Board. I was invited to join by Kenneth Hoffer, MD, of Los Angeles. Shortly thereafter, I was elected President and presided over several tumultuous years.

The AIOIS' first meeting was held at the Statler Hilton Hotel in Dallas, 1 day before the 1975 meeting of the AAO, which totally ignored us. We had a huge turnout for our meeting, which featured the first Binkhorst Medal Lecture given by Dr. Binkhorst himself. The AIOIS voted to hold independent scientific meetings every spring starting in 1978 at the Century Plaza Hotel in Los Angeles. Under the direction of David Karcher, who would become the society's executive director, we met at the Century Plaza seven times before we finally outgrew the hotel.

One of our harshest critics was Paul Henkind, MD, PhD, the editor of *Ophthalmology*. He wrote many negative

articles about IOLs until he was finally neutralized by many AAO members who objected to his using his position as editor to write biased articles.

At the request of *The New England Journal of Medicine*, I submitted an article to the Medical Intelligence section titled, "A Modern Attitude Toward a Technologic Explosion" in 1978.¹ I received more requests for reprints of and more congratulatory letters on this article than any I wrote before or have since.

IOL SYMPOSIUM ACADEMY

After ignoring us for several years, the AAO held its first IOL symposium on September 21, 1975. It was moderated by Dr. Norton, who said, "The Academy is a forum for continuing education for all of us. This is a procedure that is gaining in popularity and will not be arrested by the Program Committee of the Academy ignoring it."

BATTLES WITH THE FDA, NADER, AND WOLFE

Because of a lack of jurisdiction over lens implants, they were suddenly classified as a drug. The state of California's FDA (the only state FDA in the country) was prepared to outlaw the use of IOLs. Surgeons from California and around the country funded a legal battle led by Henry Hirschman, MD, and Mary Michaelis, MD. When Los Angeles Superior Court Judge Harry Hupp dismissed the state's attempt to call a plastic implant a drug and issued a temporary restraining order barring the state from prohibiting the manufacture, sale, and implantation of IOLs, the battle was won.

While everyone was celebrating this victory, IOLs were being attacked by the US FDA, which asked for greater regulatory political action over devices such as pacemakers and IOLs. As President of the AIOIS, I met with Representative Paul Rodgers (D-FL) and convinced him of



Figure 2. Dr. Jaffe implanted his third IOL on December 4, 1967. The Binkhorst two-loop lens was fashioned by excising the two anterior loops of an iris-clip lens after an ECCE. The eye is shown here 18 years later.

the merits of IOLs, so he included a brief passage in the final bill that read, "The device shall be made reasonably available to physicians." The FDA, however, created an IDE for IOLs that went into effect in early 1978. This change meant that every implant surgeon had to be an approved investigator for at least one IOL manufacturer. During the next 2 years, 170,000 lenses were implanted under the IDE, but the biggest battle was yet to come.

The Health Research Group (HRG) of Ralph Nader's Consumer Organization, Public Citizen, waged a relentless campaign against IOLs. This activity forced the FDA into action. On January 7, 1980, the FDA's Ophthalmic Device Panel convened in Washington, DC, to review the IOL studies and decide whether they should be continued. The HRG's director, Sidney Wolfe, MD, a general practitioner, testified that thousands of people had been needlessly injured because of inadequate premarket testing or control over the manufacturers of IOLs, the inadequate training of the surgeons, and/or the inadequate selection of patients. During a phone conversation with me, Dr. Wolfe said that, every time I placed an IOL in an eye, I was committing an immoral act. The FDA was poised to ban implants, so I wrote two letters to AIOIS members and was able to raise about \$175,000 to fight this battle.

In 1980, a meeting was held in a large room at the FDA headquarters and was packed with surgeons, reporters, and legislators. Several of us presented data demonstrating the virtues of IOLs. It was the testimony of a single patient, however, that ensured victory for US implant surgeons. His name was Robert Young, the actor who played the role of Marcus Welby, MD, on a popular television show by the same name. He also starred in *Father Knows Best*. With great eloquence, he described how lens implants placed in his eyes by Richard Kratz, MD, in 1976 had saved his career. His stunning speech made a tremendous impact. The FDA decided that, if IOLs were good enough for Dr. Welby, they were good enough for the country.

Every major TV station covered Mr. Young's speech on the evening news, and the front page of the *Washington Post* the next morning reported our victory. The resulting public support drowned out the HRG critics for good. Banning IOLs was never again an option for the FDA. Two years later, the agency cleared the first IOL for market in the US.

ENDOTHELIAL STUDY: VISCOELASTICS

Herbert Kaufman, MD, was convinced that a major cause of postoperative edema was contact between the IOL's optic and the corneal endothelium during the lens' implantation. He and his colleagues conducted a pro-

Zyoptix® XP Microkeratome delivers precision & predictability

Scott M. MacRae, MD

spective study with me as the surgeon. They used a recently introduced specular microscope to measure the pre- and postoperative endothelial cell counts in patients undergoing cataract surgery, with and without a lens implant. From this study arose the introduction of the viscoelastic material called Healon (Advanced Medical Optics, Inc., Santa Ana, CA), which improved the results of all cataract surgeons by protecting the corneal endothelium during the procedure.

TECHNICAL CHANGES

Dr. Binkhorst initiated the transition from ICCE to ECCE in the late 1960s. Charles Kelman, MD, then accelerated the shift by introducing phacoemulsification, which faced the same antagonism that IOLs did in the first years of their use. That ingenious procedure changed cataract surgery forever and led to its eventual evolution to ambulatory surgery.

The popularity of implanting IOLs in the posterior chamber has grown dramatically in popularity during the past 30 years. With the advent of modern methods of creating the capsulorhexis, the fixation of PCIOLs in the capsular bag has replaced ciliary-sulcus fixation as the procedure of choice, because the latter is associated with a higher incidence of complications.

CONCLUSION

For patients with cataracts, the introduction of IOL implants was a blessing. The work done by many of my colleagues and me during the introductory phases and the battles fought for these lenses' acceptance has been amply rewarded by the huge success of this modality. I look back on my lifetime with IOLs with great satisfaction because of their tremendous impact on the quality of millions of peoples' lives. ■

Section Editor Herve M. Byron, MD, is Clinical Professor for the Department of Ophthalmology at the New York University School of Medicine in New York. He states that he holds no financial interest in the product or company mentioned herein. Dr. Byron may be reached at (212) 249-8494; byronmd@mac.com.



Norman S. Jaffe, MD, is Voluntary Professor of Ophthalmology at the Bascom Palmer Eye Institute of the University of Miami School of Medicine, and he is in private practice. He states that he holds no financial interest in the product or company mentioned herein. Dr. Jaffe may be reached via fax at (305) 933-0940.



Creation of the corneal flap is a critical step in the success of any LASIK procedure. While the intended flap thickness depends on such factors as the degree of refractive error correction required, the preoperative corneal thickness, and each surgeon's preference, unintended variation in flap thickness occurs all too frequently. I expect a variation in flap thickness of up to $\pm 20 \mu\text{m}$ around the nominal depth with a mechanical keratome, and know from published reports that there can be up to $\pm 19 \mu\text{m}$ with the IntraLase system.

I was interested to learn about a recent study conducted by Dr. Lee Hung Ming of Tan Tock Seng Hospital in Singapore, in which each patient had one eye treated with the Zyoptix® XP Microkeratome and the other with the IntraLase FS laser device. In interim results from the first 34 patients, the mean flap thickness obtained with Zyoptix XP Microkeratome was $117.6 \pm 14.6 \mu\text{m}$, compared to $156.3 \pm 14.8 \mu\text{m}$ with the IntraLase system. The nominal flap thickness was $120 \mu\text{m}$ for all eyes. In this study, the mean flap thickness was significantly different between the two systems ($p < 0.001$), but the variations from the mean were similar. Visual acuity assessment results were similar between the two groups, as were higher order root mean square (HORMS) wavefront aberrations.

These results are important for several reasons. First, they demonstrate that the Zyoptix XP microkeratome delivers a flap thickness that is very close to nominal—in other words, the surgeon obtained the flap thickness that was specified by the manufacturer. We have had a similar experience in a study on the Zyoptix XP where the 120 micron nominal (manufacture labeled) head cut at $115 \mu\text{m} \pm 13 \mu\text{m}$. This was not the case with the IntraLase system. At the recent ASCRS I saw a similar trend where some of the IntraLase results were good in some studies and not so good in others suggesting that the laser based system may vary depending on site, laser settings and laser maintenance. Second, these results show that the variability of the flap thickness with the Zyoptix XP is similar to that of the IntraLase system, providing the surgeon with repeatable performance. Spending extra money for a laser keratome may not buy precision, predictability, or better vision.

1. Jaffe NS. Current concepts in ophthalmology. Cataract surgery—a modern attitude toward a technologic explosion. *N Engl J Med.* 1978;299:235-237.