EDITORIAL

The Current Status of Intraocular lenses and the Indications and Contraindications for their use

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I am indeed honored to have been asked to write this comment for you by your distinguished Editor and my dear friend, Rubens Belfort Mattos. The invitation was extended during the great Pan American Congress in Miami last March — my tardiness in response has been done purposely, knowing that the status of intraocular lenses in this country was about to make dramatic progress.

Intraocular lenses in the United States, as elsewhere in the world, have been a very controversial subject. They are controversial first in concept, violating fundamental principles of ocular health by the intrusion of a massive foreign body within the delicate and responsive ocular tissues. This violation was confirmed by the disastrous results of the early types of intraocular lenses. Can modern intraocular lenses truly be safely used? Or are their reputed successes an exaggeration of early results and a prelude to long-term catastrophy?

The acceptance of intraocular lens surgery in the United States had a very slow beginning. Only a handful of surgeons used them 12 years ago; the number was not much larger 5 years later. 7 years ago interest began to grow and in the past 5 years there has been an explosive growth in their use, leveling off during the past 18 months because of the investigation of safety imposed by the United States Food and Drug Administration's Bureau of Medical Devices. (FDA).

But the current rate of use speaks volumes by itself; today 10,000 intraocular lenses are implanted in the United States each **month**. One out of every four cataract operations in 1978 was done with lens implantation: this number will be somewhat larger in 1979; and will see a significant increase, in my opinion, in 1980. In the first 18 months of the FDA Study, 177,503 lenses were implanted by about 6,000 surgeons in over 3,000 hospitals in the United States. **Why?!** Because the undeniable visual benefit to our patients has been accompanied by good ocular health, now documented in large and increasing numbers of patients **long-term**.

Are there no problems? Of course there are. The production of large numbers of lenses of the superb quality essential for success, by 14 manufacturers, has presented several major problems. The task of training 6,000 surgeons in the exacting microsurgical techniques necessary to minimize ocular injury during implantation, has been monumental. And the problems of patient selection and the variations in patient response remain major challenges.

In September, the National Eye Institute of the United States National Institutes of Health held a Consensus Development Converence on Intraocular Lenses. The results are now published and emphasize areas of concern, with future research and development needs, as well as current status. But it was concluded that the clinical status of intraocular lenses — beyond the investigations being conducted — has been settled. They now have an essential place in the care of patients with cataract — held by merit, and only partially challenged by such developments as extended-wear contact lenses.

The FDA investigation of intraocular lenses was begun on February 9, 1978. It already constitutes by far the largest study ever undertaken by man. At a cost of $9 million so far, 80 million "bits" of data have been amassed on 177.500 patients with intraocular lenses and 3,000 control patients. The controls were selected as patients who were equally good candidates for an intraocular lens, who elected to have cataract surgery without one.

Just the data on the control patients constitutes the largest and most thorough prospective study ever done on cataract surgery. If patients with intraocular lenses de-

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velop problems, it is essential to know how much of an increase this represents over conventional cataract surgery. (I hasten to note that "conventional surgery" has made significant advances as a result of the technical analysis and stringent requirements imposed by the advancements of lens implant surgery!).

At the American Academy of Ophthalmology meeting in San Francisco in November, the early results of the FDA study were presented by Dr. David Worthen, Professor and Head of the Department of Ophthalmology at the University of California in San Diego, and Chairman of the FDA Ophthalmic Advisory Panel. These **early** results constitute a major vindication of the use of lens implants.

TABLE 1. COMPLICATIONS
FDA CORE STUDY

Complication	Cataract Surgery	With Intraocular Lens
Lens dislocation	—	0.9%
Retinal detachment	0.9%	0.3%
Endophthalmitis	0.2%	0.1%
Vitritis	1.7%	1.7%
Cyclitic membrane	0.1%	0.3%
Pupillary block control	0.4%	0.3%
Secondary glaucoma	3.6%	4.0%
Hyphema	2.4%	3.3%
Macular edema	3.2%	3.2%
Upper corneal edema	1.4%	2.0%
Lower corneal edema	0.8%	1.0%
Iritis	2.1%	4.3%
Acuity 20/40 or better	78%	80%

Note: Dr. Worthen's paper giving these figures in much greater detail will be published in a forthcoming issue of Ophthalmology. (The Journal of the American Academy of Ophthalmology).

I would urgently caution that the good results currently being achieved are the results of hard lessons learned from many disasters, the development and practice of remarkably refined microsurgical techniques, and careful and conservative patient selection. Any relaxation of standards will result in disasters again. In the words of Dr. C. Binkhorst, "Errors of technique or judgment shall be punished!".

Indications and Contraindications

Criteria which are essential to help insure the success of lens implantation are now well established. Even those criteria that are not absolute, are violated with perfil. Like most good laws, they are not arbitrary, but represent lessons learned by bitter experience — better obeyed than those experiences relived. "Those who will not learn the lessons of history are doomed to repeat them", Santayana admonished.

What are the INDICATIONS for lens implantation?

Absolute: None !

No one should feel obligated to do lens implant surgery. This is always an elective procedure. The patient with a successful lens implant in his first eye may present a special challenge however.

Relative:

The elderly patient who has good ocular health except for the cataract, who would be a monocular aphake, and who is not a good candidate for contact lens use, where surgery is **indicated** (such as in a mature or hypermature cataract), and who does not present technical problems at surgery — is the ideal candidate.

To list:

1. The elderly.
2. Those who would be monocular aphakes.
3. Those unable to use a contact lens.
4. Ocular health good.
5. Easy surgery.

In addition, consideration may be given to:

6. The frail.
7. Those with trouble walking.
8. Those with special occupational needs.
9. Younger patients with limited life expectancy.
10. Patients with known macular degeneration (with **advanced** cataract).
11. Other special cases where the patient's needs are best served.

When in doubt, get a consultation.

The CONTRAINDICATIONS include:

Absolute:

1. The patient doesn't want an intraocular lens.
2. Inadequate skill or training in lens implantation on the part of the surgeon.
3. Only one eye with pontentially good vision.
4. Failure of an intraocular lens in the other eye.
5. Uncontrolled glaucoma.
6. Proliferative diabetic retinopathy.
7. Recurrent uveitis.
8. Corneal dystrophy (exc
tion with, or in preparation for, a corneal graft.)

Relative:

1. Pre-cataract myopia greater than 7 diopters, or axial length greater than 24 mm.
2. History or family history of retinal detachment.
3. Diabetes mellitus.
4. Glaucoma.

5. Decreased endothelial cell density or increased guttata.
6. Small anterior segment.
7. Iris atrophy.
8. Patients who rub their eyes.
9. Patients who sleep face down.
10. Problems at surgery. Patients must be informed before surgery that lens implantation will not be done if it is found to be unsafe.

Arthur Steele of England summarized the contraindications succinctly and very well when he said:

"Sick eyes do not make good homes for intraocular lenses."

RESUME

The immense popularity of intraocular lenses in the United States is based on their remarkable contribution to visual rehabilitation, and our current good results. Good results require conservative patient selection, lenses of excellent quality, and exacting microsurgical techniques.