The FDA Report on Intraocular Lenses

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Abstract: Clinical studies of intraocular lenses (IOLs) as investigational devices have been regulated in the United States by the Food and Drug Administration (FDA) since February 9, 1978. As of August 1982, data have been collected on more than one million IOLs implanted. During the last 12 months of the study, 409,000 IOLs were implanted. Visual acuity of 20/40 or better at one year after surgery was present in 85% of over 45,000 cases reviewed. Increasing patient age, surgical problems, postoperative complications, and adverse reactions were factors that reduced the visual acuity. The current trend in the USA is for implantation of the posterior chamber and anterior chamber IOLs. [Key words: cataract, intraocular lenses, pseudophakos, U.S. Food and Drug Administration (FDA).] Ophthalmology 90:311–317, 1983

Cataract is the second leading cause of existing blindness in the United States and, therefore, a significant public health problem. The use of intraocular lens (IOL) implantation at the time of cataract extraction has been increasing steadily since the early 1970s. In February 1978, national studies of IOLs were begun under investigational device exemption (IDE), approved by the FDA, to determine the safety and effectiveness of IOLs as a medical device for the correction of aphakia.[1-3]

The purpose of this report is to present information on the numbers, the types, and the current usage trends of the IOLs being implanted in the United States and to provide data on those lenses that have been reviewed by the Ophthalmic Device Section of the FDA Ophthalmic; Ear, Nose, Throat, and Dental Devices Panel of the Office of Medical Devices, and have been recommended for premarket approval as being safe and effective.

MATERIALS AND METHODS

Beginning February 9, 1978, all IOL patients in the United States were implanted by surgeons who were clinical investigators under an approved IDE. Cases were categorized as either "CORE" or "Adjunct Safety" depending on the frequency of postoperative reporting (Table 1). Data on a minimum of 500 CORE study cases followed for 12 to 14 months were required by the FDA before an IOL could be considered for premarket approval. One hundred completed CORE cases were required for any potentially significant modification of an existing IOL. Adverse reactions, sight-threatening complications, and surgical complications were reported by the physician to the manufacturer. Visual acuity results were provided at the standard reporting intervals. Satisfactorily completed premarket approval applications (PMAs) were reviewed in sequence. Some were delayed because of incomplete data.

Data submitted to the FDA from the manufacturers were analyzed for clinical significance by the Ophthalmic Device Section, an FDA Advisory Committee. In some cases additional information on complications, tracking

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Table 1. Frequency of Follow-up Visits Reported to the FDA

	Core Study*	Adjunct Study
Lens Accounting	X	X
Preoperative and operative	X	X
Adverse reactions (complications developing within five days)	X	X
Postoperative		
1-6 days		
2-3 weeks	X	
4-8 weeks	X	
3-6 months	X	X
7-11 months	X	
12-14 months	X	X

* CORE study cases had more detailed postoperative reporting. Five hundred CORE cases required for review of a new IOL.

of cases lost to follow-up, age, type of extraction, and other influencing factors were requested. Attempts were made to account for cases lost to follow-up to insure a better data base. These data were reviewed and analyzed by both the Ophthalmic Device Section of the FDA and the FDA staff. During both open and closed section meetings the PMAs were reviewed in detail, and the manufacturers were given the opportunity to present clarifying information in the hearing or by written submission at a later date. The IOL results were compared to a "historical" grid that was developed by summarizing the visual results and complications previously reported in the literature of cataract surgery.[4-40]

If the data in the PMA provided reasonable assurance that the device is safe and effective for its intended use, the Ophthalmic Device Section recommended that the FDA approve the PMA. The four classes of IOLs are the anterior chamber (AC), iris fixation (IF), iridocapsular (IC), and posterior chamber (PC) intraocular lenses.

RESULTS

During the 4½ years between February 1978 and August 1982, 1,088,640 intraocular lenses were implanted. Figure 1 shows the number of lenses in each of the four classes implanted during each six-month interval of the study. Between August 1978 and August 1979, 154,000 intraocular lenses were implanted. The number of IOLs used has steadily increased, and during the last year (August 1981–August 1982), 409,000 intraocular lenses were implanted. If one assumes that about 525,000 cataract operations were performed during the same 12-month period, then over 70% of all cataract operations were associated with IOL implantation.

In 1978, the iris fixation lenses were implanted most frequently; but beginning in 1980 there was a decline in the use of those lenses, associated with a marked increase in the use of posterior chamber IOLs and a moderate increase in the use of anterior chamber IOLs. This trend toward posterior chamber and anterior chamber IOLs is best demonstrated by plotting the percentage, by class, of all lenses implanted during each six-month time interval (Fig 2). During the first six months of the study, iris fixation lenses accounted for 52% of all IOLs implanted; anterior chamber, 25%; iridocapsular, 19%; and posterior chamber, 4%. With each six-month ac-

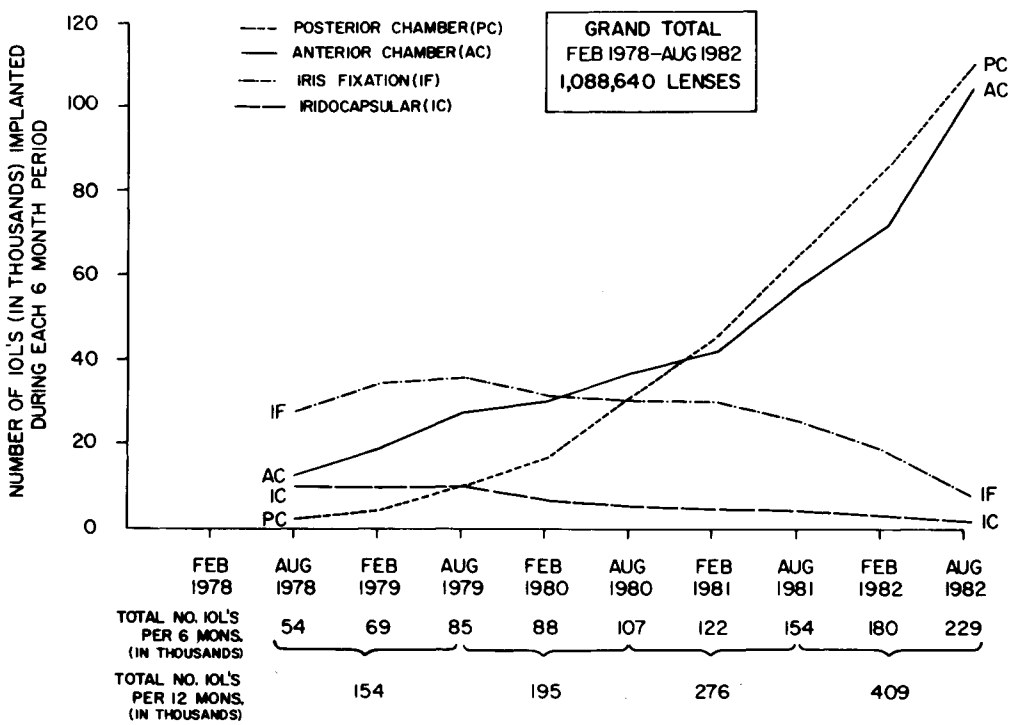

Fig 1. Number of intraocular lenses (in thousands) plotted for each six-month period since FDA study began in February 1978.

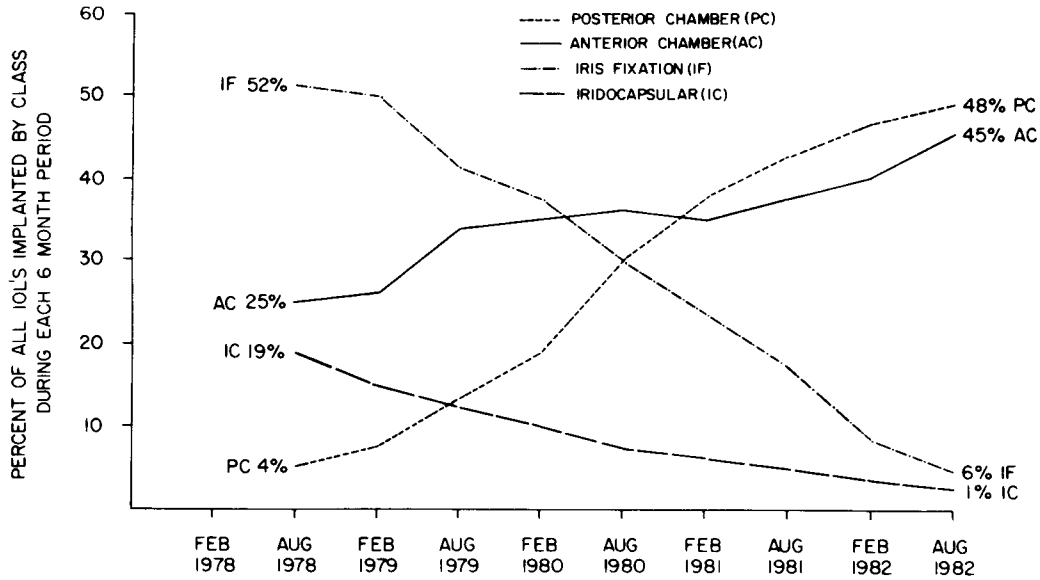

Fig 2. Percentage of all intraocular lenses implanted by class for each six-month period.

counting, there was a steady decline in the percentage of iris fixation and iridocapsular lenses, and a steady increase in the percentage of posterior chamber and anterior chamber lenses being implanted. During the most recent six months of the study, the posterior chamber lenses accounted for 48% of all IOLs implanted and the anterior chamber lenses, 45%. The iris fixation lenses dropped to 6% and the iridocapsular lenses to 1% of all IOLs used. Between August 1980 and February 1981, the posterior chamber IOL became the lens most frequently implanted in the United States.

The following data are from all those IOLs that have been reviewed by the Ophthalmic Device Section and recommended as being safe and effective by July 1982. We are not able to provide confidential information on IOLs that have not been reviewed by the FDA Section and recommended for approval. These data represent information on 17 different intraocular lenses from seven manufacturers, which include a total of 45,543 study cases. At the end of one year of follow-up, 84.8% of the 45,543 study eyes had 20/40 or better vision in the operated eye. Iris fixation lenses had the lowest overall percentage of eyes with 20/40 or better, namely 81.4%. Iridocapsular and posterior chamber had the highest percentage of patients with 20/40 or better (Table 2).

CORE patients had the most detailed postoperative reporting and, therefore, were analyzed in greater detail (Table 3). Visual acuity results for CORE cases also showed a smaller percentage of the iris fixation lens cases achieving 20/40 or better vision. It was also apparent that those patients 80 years of age or older, in all four IOL groups, generally had poorer visual acuity. To determine if the difference in visual results were due to the intraocular lens used or to patient selection, we performed a best-case analysis by excluding those patients with pre-existing pathology such as abnormal corneas, glaucoma, macular degeneration, and amblyopia. For the best cases, all visual results were better—with 90 to 94% of eyes achieving 20/40 acuity or better (Table 4). Statistically, patients receiving a posterior chamber lens achieved a slightly better visual acuity than those in the other three groups. Age appeared to be a factor in reducing visual outcome. In combining all of the best-case eyes, and excluding those with macular degeneration, the group of patients over the age of 80 still had a significantly smaller percentage with 20/40 or better vision (Table 5).

Table 2. Final Visual Acuity of 20/40 or Better after IOL Implantation

	Type of IOL							
	AC*		IF*		IC*		PC*	
Study	No.	%	No.	%	No.	%	No.	%
Core	4170	83.5	525	80.4	1207	86.5	2524	88.0
Adjunct	18019	83.2	259	83.4	12000	87.7	6839	83.9
Total	22189	83.2	784	81.4	13207	87.6	9361	85.0

Grand total—45,541 lenses; 84.8%—20/40 or better.

* AC = Anterior chamber IOL; IF = Iris fixation IOL; IC = Iridocapsular IOL; and PC = Posterior chamber IOL.

Table 3. Final Visual Acuity of 20/40 or Better: "Core" Patients

	Type of IOL							
	AC		IF		IC		PC	
Age (years)	No.	%	No.	%	No.	%	No.	%
<60	418	91.4	35	88.6	222	93.2	332	93.7
60-69	1239	91.0	137	88.3	391	91.8	879	90.8
70-79	1690	81.8	229	83.4	470	84.7	919	88.6
>80	823	71.7	124	63.7	124	64.5	391	75.2
Total	4170	83.5	525	80.4	1207	86.5	2521	88.0

Table 4. Final Visual Acuity of 20/40 or Better for Best-Case Analysis of Primary Implant Eyes

Age (years)	Type of IOL							
	AC		IF		IC		PC	
	No.	%	No.	%	No.	%	No.	%
<60	286	95.1	21	90.5	210	94.8	286	96.9
60-69	985	93.5	109	93.6	352	94.3	776	93.8
70-79	1070	88.6	185	90.8	397	90.4	672	94.9
>80	386	83.9	78	85.9	79	74.7	206	87.9
Total	2727	90.4	393	90.6	1038	91.4	1940	94.0*

* $P < .02$.

Final visual acuity of 20/40 or better was present less frequently in patients with preoperative corneal disease, glaucoma, iritis, iris neovascularization, diabetic retinopathy, previous retinal detachment or, as would be expected, macular degeneration and amblyopia. All values were statistically significant when compared to cases without preoperative pathology (Table 6).

Adverse reactions that were required to be reported to the manufacturer were: hypopyon, acute corneal decompensation, intraocular infection, and secondary surgical intervention. The incidence of each varied slightly among the various classes of IOLs (Table 7). Iris fixation lenses had a significantly greater incidence of hypopyon and dislocation of the IOL. The higher incidence of hypopyon for the iris fixation lens was related to two "hot" production lots, but this complication did not appear to reduce significantly visual outcome. A problem peculiar to iris fixation lenses is dislocation of the IOL that may increase the chances of corneal decompensation in the future.

If an adverse reaction developed it was often associated with a clinically significant reduction in visual acuity (Tables 8, 9). Such events as corneal decompensation, endophthalmitis, and lens removal for corneal touch or inflammation seriously affected visual acuity results.

Sight-threatening complications were tabulated in two ways: (1) "cumulative," if the complication occurred at any time during the first year; or (2) "persistent," if the complication was present at the 12- to 14-month follow-up visit. Clinically significant "cumulative" sight-threatening complications—such as hyphema, secondary glaucoma, macular edema, and pupillary block—developed in a higher percentage of anterior chamber and iris fixation IOL cases. The iris fixation lenses also had a higher incidence of lens dislocation (Table 10).

Clinically significant "persistent" sight-threatening complications—such as corneal edema, secondary glaucoma, and macular edema—developed more frequently in the anterior chamber and the iris fixation lens cases (Table 10).

Final visual acuity was affected adversely if the patient had a sight-threatening complication. If none of the sight-threatening complications developed, 88% of all the core study eyes achieved 20/40 or better vision. However, the number with 20/40 or better acuity dropped to 72% if a sight-threatening complication developed during the year. Only 42.5% of those eyes that had persistent corneal edema, iritis, or macular edema achieved 20/40 or better vision (Table 11).

Surgical problems were reported more frequently for anterior chamber lenses (14% vs 9% for the other IOLs). This may reflect the tendency to implant the anterior

Table 5. Final Visual Acuity of 20/40 or Better for Best-Case Analysis of Primary Implant Patients

Age	No. of Eyes	% Patients
<60	803	95.5
60-69	2,224	93.7
70-79	2,325	90.9
>80	749	84.2*
Total	6,101	91.8

* $P < 0.01$.

Table 6. Final Visual Acuity of 20/40 or Better: Percentage for Core Patients with Preoperative Pathology*

Pathology	No.	%
Corneal disease	505	75.2
Glaucoma	501	72.1
History of iritis	22	63.6
Iris neovascularization	3	33.3
Diabetic retinopathy	32	75.0
Previous retinal detachment	17	70.6
Macular degeneration	665	64.4
Amblyopia	30	56.7

* All percentages were significant ($P < 0.02$) compared to best-case analysis (91.8%).

Table 7 Incidence of Adverse Reactions: Core Study (8597 Eyes)

Adverse Reaction	% Patients
Hypopyon	0.4 (IF, 2.2)*
Acute corneal decompensation	0.2
Intraocular infection	0.1
Secondary surgical intervention:	
Iridectomy for pupillary block	0.3
Vitreous aspiration for pupillary block	<0.1
Repositioning of lens	0.8 (IF, 2.8)*
Lens suturing	0.2
Loop amputation for corneal touch	<0.1
IOL removal for corneal touch	0.1
IOL removal for inflammation	0.1
IOL replacement	0.2
Corneal transplant	0.1

* Iris fixation lenses had a significantly greater incidence than other lenses only for hypopyon and repositioning of lens. No other statistically significant difference among different IOL classes was present.

Table 8. Final Visual Acuity of 20/40 or Better for Patients with "Adverse Reaction"

	Type of IOL*					
	AC		TP		PC	
Adverse Reaction	No.	%	No.	%	No.	%
Hypopyon	9	67	16	88	2	50
Corneal decompensation	13	31	5	20	2	0
Infection	7	29	—	—	1	100
Secondary surgery	68	56	48	81	25	76
Total	96	47	69	78	30	70

Grand total—195 adverse reactions; 62%—20/40 or better.
* IOL = intraocular lens; AC = anterior chamber; TP combines iris fixation and iridocapsular lenses; PC = posterior chamber.

chamber lens when surgical problems prevented use of one of the other types of IOL. Surgical problems also tended to reduce final vision. Specifically, posterior capsular rupture for the anterior chamber lens, and vitreous loss for the anterior and posterior chamber lenses were associated with a statistically significant reduction in visual acuity (Table 12).

The results of intracapsular vs extracapsular cataract extraction (ICCE vs ECCE) for the anterior chamber IOLs were evaluated. The analysis was complicated in that the ECCE group may have contained cases in which the anterior chamber lens was used as a "back-up" lens after vitreous loss or inadvertent rupture of the posterior capsule. A slightly lower percentage of cases in the ECCE group achieved 20/40 or better vision (Table 13), but the difference was not statistically significant. Postoperative macular edema occurred more frequently with ECCE than with ICCE (10% with ECCE vs 7% with ICCE, $P < 0.05$). Other postoperative complications were not significantly different among the four IOL types (Table 14).

For *secondary* IOL implantation, a best-case analysis (excluding preoperative pathology) showed similar postoperative acuity compared to primary lens implant cases (Table 15). However, if an eye had 20/40 or better before secondary anterior chamber lens implantation, there was a 10.4% chance of having less than 20/40 best-corrected vision after secondary lens implantation (Table 16).

Table 9. Overall Final Visual Acuity of 20/40 or Better for IOL Patients with Adverse Reactions

Adverse Reaction	No.	%
Hypopyon	27	77.8
Acute corneal decompensation	20	25.0
Intraocular infection	8	37.5
Secondary surgical intervention:		
Iridectomy for pupillary block	22	81.8
Vitreous aspiration for pupillary block	4	75.0
Repositioning of lens	55	74.5
Lens suturing	18	88.9
Loop amputation for corneal touch	2	None
IOL removal for corneal touch	6	33.3
IOL removal for inflammation	9	44.4
IOL replacement	4	71.4
Corneal transplant	11	36.4

Table 10. Core Study Sight-Threatening Complications (%)

	IOL* Type			
	AC	IF	IC	PC
"Cumulative" (0 to 12 months)				
Number of eyes	3587	538	1213	2703
Macular edema	8.0%	6.3%	2.8%	3.5%
Secondary glaucoma	5.5	4.3	0.7	1.6
Hyphema	4.9	3.2	2.6	1.0
Lens dislocation	0.2	5.6	1.1	0.4
Pupillary block	0.8	0.6	0.2	0.3
Retinal detachment	0.9	0.4	0.2	0.5
Endophthalmitis	0.1	0.2	0.0	0.0
"Persistent" (at one year)				
Number of eyes	4132	538	1213	2465
Macular edema	2.2%	2.4%	0.3%	0.8%
Secondary glaucoma	1.2	0.9	0.1	0.5
Hyphema	0.1	0.0	0.1	0.3
Iritis	1.2	0.9	0.4	1.0
Corneal edema	1.2	1.5	0.6	0.6
Cyclitic membrane	0.1	0.2	0.0	0.0
Vitritis	0.1	0.2	0.1	0.1

* IOL = intraocular lens; AC = anterior chamber; IF = iris fixation; IC = irido capsular; PC = posterior chamber.

Table 11. Final Visual Acuity of 20/40 or Better in Group with "Sight-threatening" Complications

	No.	%
None	2253	88.1
At any time (0 to 12 months)		
Hyphema	258	82.9
Macular edema	498	65.7
Secondary glaucoma	308	81.8
Pupillary block	39	79.5
Retinal detachment	56	33.9
Vitritis		63.3
Cyclitic membrane	22	50.0
Endophthalmitis		25.0
IOL* dislocation	64	82.8
		72.2
At one year (persisting)		
Corneal edema	69	43.5
Iritis	78	59.0
Macular edema	135	32.6
		42.5

* IOL = intraocular lens.

Table 12. Final Visual Acuity of 20/40 or Better for Patients with and without Surgical Problems

	IOL* Type					
	AC		PC		IF & IC	
	No.	%	No.	%	No.	%
Without surgical problems	3693	84.0	1510	88.2	1597	85.0
With surgical problems	515 (14%)	80.2†	135 (9%)	79.3	139 (9%)	82.7

* IOL = intraocular lens; AC = anterior chamber; PC = posterior chamber; IF = iris fixation; IC = iridocapsular.

† $P < 0.04$ for effect of capsule rupture (AC) and "other" problems (AC & PC) including vitreous loss.

Table 13. Final Visual Acuity of 20/40 or Better: By Method of Cataract Extraction

	AC IOL	
Method	No.	%
ICCE*	3056	86.2
ECCE	511	83.0

* ICCE = intracapsular extraction; ECCE = extracapsular extraction.

Table 14. Sight-Threatening Complications with Anterior Chamber IOL*: Versus Methods of Cataract Extraction

Complication	ECCE (No. = 489)	ICCE (No. = 3066)
"Cumulative" (0 to 12 months)		
Macular edema	10.0†	7.4†
Retinal detachment	1.8	0.9
Lens dislocation	0.4	0.4
"Persistent" (at one year)		
Macular edema	2.7	1.9
Iritis	1.0	1.4

* IOL = intraocular lens; ECCE = extracapsular extraction; ICCE = intracapsular extraction.

† $P < 0.05$.

Table 15. Final Visual Acuity of 20/40 or Better (Best-Case Analysis)

	IOL* Type							
	AC		IF		IC		PC	
	No.	%	No.	%	No.	%	No.	%
Primary	2727	90.4	393	90.6	1038	91.5	1944	94
Secondary	350	88.6	none		none		33	94

* IOL = intraocular lens; AC = anterior chamber; IF = iris fixation; IC = iridocapsular; PC = posterior chamber.

Table 16. Anterior Chamber Lens Secondary Implantation Best Case Analysis

20/40 or better preoperative acuity = 328 cases;
20/40 or better postoperative acuity = 294 cases (89.6%);
Thus, a 10.4% chance of losing a previous level of 20/40 or better with secondary IOL.*

* IOL = intraocular lens.

DISCUSSION

Data from the FDA studies on IOLs are being evaluated to determine the safety and efficacy of intraocular lenses as a medical device for the correction of aphakia. The lenses that have been recommended for approval by the Ophthalmic Device Section of the FDA appear safe and effective as compared to the results of cataract surgery without intraocular lens implantation.[4–40]

Sight-threatening complications, such as hyphema, secondary glaucoma, macular edema, and pupillary block, developed in a higher percentage of anterior chamber and iris fixation IOL cases. These problems may have been partially related to manufacturing techniques or sterilization methods and appear to have been corrected. Also, both types of IOLs are used as "back-up lenses" when complications at the time of surgery prevent the use of the posterior chamber or iridocapsular IOLs. The iris fixation lenses also had a higher incidence of lens dislocation. This complication may increase the chances of later corneal decompensation.

Visual acuity results at one year are good, with 85% of IOL cases overall achieving 20/40 or better acuity. Best-case analysis (excluding those with preoperative pathology and postoperative macular degeneration) shows that over 90% of all cases achieved 20/40 or better visual acuity. Statistically, the posterior chamber IOLs give significantly better visual acuity results than the other three types of IOLs ($P < 0.02$). This may partly be the result of better case selection and the tendency of the surgeon to switch to the use of an anterior chamber or iris fixation lens if significant complications develop at the time of ECCE.

Manufacturers of approved lenses have established telephone numbers to facilitate continued reporting of adverse reactions that may be lens related. In addition, late onset complications of IOLs are being evaluated in the results from the academic and private-practice communities. These findings will guide the decisions and control the trends in IOL implantation.

CONCLUSION

More than one million intraocular lenses have been implanted during the first 4½ years of the FDA study, and 409,000 IOLs were implanted during the last 12 months. Forty-five thousand cases with one-year follow-up examinations showed a postoperative visual acuity

of 20/40 or better in 85% of cases. Increasing age, preexisting ocular pathology, surgical problems, and adverse reactions and complications, such as corneal edema and macular edema, had an unfavorable effect on visual outcome. The current trend in the United States is for implantation of anterior chamber or posterior chamber intraocular lens. To date, 17 lenses from seven manufacturers have been reviewed by the Ophthalmic Device Section of the Food and Drug Administration and have been recommended as being safe and effective.

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REFERENCES

1. Federal Register. November 11, 1977; 42(#218):58874-76.
2. Worthen DM, Boucher JA, Buxton JN, et al. Interim FDA report on intraocular lenses. Ophthalmology 1980; 87:267-71.
3. Worthen DM, Boucher JA, Buxton J, et al. Update report on intraocular lenses. Ophthalmology 1981; 88:381-5.
4. Wheeler JM. A study of hemorrhage into the anterior chamber subsequent to operations for hard cataract. Trans Am Ophthalmol Soc 1916; 14:742-52.
5. Hughes WF, Jr, Owens WC. Extraction of senile cataract. A statistical comparison of various techniques and the importance of preoperative survey. Am J Ophthalmol 1945; 28:40-9.
6. Theobald GD, Haas JS. Epithelial invasion of the anterior chamber following cataract extraction. Trans Am Acad Ophthalmol Otolaryngol 1948; 52:470-85.
7. Kirsch RE. Glaucoma following cataract extraction associated with use of alpha-chymotrypsin. Arch Ophthalmol 1964; 72:612-20.
8. Kaufman IH, Stahl N. Intraocular pressure after lens extraction. Am J Ophthalmol 1965; 59:722-3.
9. Gehring JR. Macular edema following cataract extraction. Arch Ophthalmol 1968; 80:626-31.
10. Miller D, Dohlman CH. Effect of cataract surgery on the cornea. Trans Am Acad Ophthalmol Otolaryngol 1970; 74:369-74.
11. Irvine AR, Bresky R, Crowder BM, et al. Macular edema after cataract extraction. Ann Ophthalmol 1971; 3:1234-40.
12. Lantz JM, Quigley JH. Intraocular pressure after cataract extraction: effects of alpha chymotrypsin. Can J Ophthalmol 1973; 8:339-43.
13. Scheie HG, Morse PH, Aminlari A. Incidence of retinal detachment following cataract extraction. Arch Ophthalmol 1973; 89:293-5.
14. Allen HF, Mangiaracine AB. Bacterial endophthalmitis after cataract extraction. II. Incidence in 36,000 consecutive operations with special reference to preoperative topical antibiotics. Arch Ophthalmol 1974; 91:3-7.
15. Hurite FG. The contraindications to phacoemulsification and summary of personal experience. Trans Am Acad Ophthalmol Otolaryngol 1974; 78:OP14-17.
16. Shafer DM. Retinal detachment after phacoemulsification. Trans Am Acad Ophthalmol Otolaryngol 1974; 78:OP28-30.
17. Fahmy JA. Endophthalmitis following cataract extraction; a study of 24 cases in 4,498 operations. Acta Ophthalmol 1975; 53:522-36.
18. Hitchings RA, Chisholm IH, Bird AC. Aphakic macular edema: incidence and pathogenesis. Invest Ophthalmol 1975; 14:68-72.
19. Schlaegel TF, Jr. Uveitis following cataract surgery. In: Bellows JG, ed. Cataract and Abnormalities of the Lens. New York: Grune & Stratton, 1975; 429-34.
20. Abel R, Jr, Binder PS, Bellows R. Postoperative bacterial endophthalmitis. Section I. Ann Ophthalmol 1976; 8:731-44.
21. Azar RF. Intraocular lens implantation vs. conventional cataract surgery. Contact Intraocul Lens Med J 1976; 2(3):72-80.
22. Jaffe NS. Cataract Surgery and Its Complications, 2nd ed. St. Louis: CV Mosby, 1976; 282:466-7.
23. Meredith TA, Kenyon KR, Singerman LJ, Fine SL. Perifoveal vascular leakage and macular oedema after intracapsular cataract extraction. Br J Ophthalmol 1976; 60:765-9.
24. Galin MA, Obstbaum SA, Boniuk V, et al. Iris-supported lens implantation *v.* simple cataract extraction. An analysis of data. Trans Ophthalmol Soc UK 1977; 97:74-7.
25. Stark WJ, Hirst LW, Snip RC, Maumenee AE. A two-year trial of intraocular lenses at the Wilmer Institute. Am J Ophthalmol 1977; 84:769-74.
26. Emery JM, Wilhelmus KA, Rosenberg S. Complications of phacoemulsification. Ophthalmology 1978; 85:141-50.
27. Fung WE. Phacoemulsification. Ophthalmology 1978; 85:46-51.
28. Hunter JW. Early postoperative sterile hypopyons. Br J Ophthalmol 1978; 62:470-3.
29. Jaffe NS, Eichenbaum DM, Clayman HM, Light DS. A comparison of 500 Binkhorst implants with 500 routine intracapsular cataract extractions. Am J Ophthalmol 1978; 85:24-7.
30. Snyder HP. Intravenous chloramphenicol to prevent postoperative endophthalmitis in cataract surgery—520 consecutive cases. Ann Ophthalmol 1978; 10:1041-2.
31. Wilkinson CP, Anderson LS, Little JH. Retinal detachment following phacoemulsification. Ophthalmology 1978; 85:151-6.
32. Williamson DE. Outpatient cataract-implant surgery compared with outpatient cataract-standard surgery. Ann Ophthalmol 1978; 10:957-65.
33. Emery JM, Little JH. Phacoemulsification and Aspiration of Cataracts: Surgical Techniques, Complications and Results. St Louis: CV Mosby, 1979; 317.
34. Kraff MC, Sanders DR, Lieberman HL. Total cataract extraction through a 3-mm incision: a report of 650 cases. Ophthalmic Surg 1979; 10(2):46-54.
35. Meredith TA, Maumenee AE. A review of one thousand cases of intracapsular cataract extraction: I. Complications. Ophthalmic Surg 1979; 10(12):32-41.
36. Meredith TA, Maumenee AE. A review of one thousand cases of intracapsular cataract extraction: II. Visual results and astigmatic analysis. Ophthalmic Surg 1979; 10(12):42-5.
37. Moses L. Cystoid macular edema and retinal detachment following cataract surgery. Am Intraocul Implant Soc J 1979; 5:326-9.
38. François J, Verbraeken H. Complications in 1,000 consecutive intracapsular cataract extractions. Ophthalmologica 1980; 180:121-8.
39. Krieglstein GK, Duzanec Z, Leydhecker W. Cataract surgery: types and frequencies of complications. Albrecht Von Graefes Arch Klin Exp Ophthalmol 1980; 214:9-13.
40. Roper-Hall MJ, ed. Stallard's Eye Surgery, 6th ed. Bristol: John Wright & Sons, 1980; 902.