INTRAOCULAR LENSES: COMPLICATIONS AND VISUAL RESULTS*

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INTRODUCTION

CATARACT IS THE SECOND LEADING CAUSE OF BLINDNESS IN THE UNITED STATES, and it is therefore a significant public-health problem.[1] The rate of cataract surgery has increased considerably in the past several years, primarily because of better means of aphakic correction. Also, recent reports indicate that over 70% of the 600,000 cataract operations performed in the USA in 1982 were associated with an intraocular lens (IOL) implant.[2-4]

Complications from cataract surgery with IOL implantation have decreased in recent years, partly because of the better design and improved quality of IOLs. Specific complications such as clinically-significant cystoid macular edema (CME) and corneal edema, however, are still problems. Clinically-significant CME (with reduced acuity) has been reported to develop in up to 8% of patients after cataract surgery, and to be detectable by fluorescein angiography in more than 50% of patients shortly after surgery.[5-10] Corneal edema appears to be a late-onset problem associated especially with certain types of IOLs.

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With special attention to the incidence of clinically significant CME and corneal edema, the purpose of this paper is to report on the complications after combined cataract extraction and IOL implantation at the Wilmer Institute and in studies of results reported to the Food and Drug Administration (FDA). We will also give preliminary data on the value of prostaglandin inhibitors used to prevent the development of CME in a prospective study being performed at the Wilmer Institute, and will discuss the importance of clinically-proven CME as compared to fluorescein-proven CME.

MATERIALS AND METHODS

CATARACT-IOL OPERATIONS PERFORMED AT THE WILMER INSTITUTE

The surgery in this study at the Wilmer Institute was performed by two of us (WJS and AEM). Binkhorst four-loop iris-clip lenses were inserted, in association with intracapsular cataract extraction (ICCE), using methods previously described.[11,12] Posterior chamber lenses were inserted after planned extracapsular cataract extraction (ECCE) with nuclear expression and then cortical removal using the 0.3 mm irrigating-aspiration tip of the Kelman Cavitron unit. An attempt was made to place the loops of the posterior chamber IOLs in the ciliary sulcus. All IOLs were soaked in balanced salt solution or aqueous dexamethasone phosphate (Decadron) solution for about 15 minutes and were inspected using the operating microscope prior to implantation. All the IOLs were inserted with air or sodium hyaluronate (after January 1982) present in the anterior chamber to avoid endothelial touch.

Patients were followed in a prospective concurrent manner with documentation of postoperative visual results and complications. Postoperatively, the eyes were examined 18 to 24 hours and again 36 to 48 hours after surgery, using a Haag-Streit slit lamp to detect the presence or absence of a hypopyon. "Persistent iritis" was defined as present in any eyes requiring continuing corticosteroid therapy to suppress intraocular inflammation if the intraocular inflammation recurred when topical corticosteroids were discontinued. "Clinical cystoid macular edema" was defined as a reduction in prior distance and/or near visual acuity of one line or more on the Snellen chart, associated with ophthalmoscopically visible cystoid changes in the macula or fluorescein angiographic evidence of CME. Eyes with 20/20 distance vision and Jaeger 1 near vision with a normal-appearing macula were not routinely tested by fluorescein angiography. Mean visual acuity results (as reported herein) were determined

by calculation using a log scale of Snellen visual acuity and then reconversion to the Snellen notation.

Twenty patients with less than 12 months of follow-up for the Binkhorst lenses were either deceased (11 patients) or unavailable (9 patients) and were listed as lost to follow-up. These patients are not included in the results section of this report. None of these 20 patients had had a significant complication or adverse reaction during the time of follow-up, and all had 20/40 or better vision at the time of the last examination (except for 3 patients with preexisting macular degeneration). In the entire study, 35 patients who received a Binkhorst IOL are now known to be deceased. A total of 70 patients receiving the posterior chamber IOL had less than 3 months of follow-up; 3 of these died within that time period. A total of eight persons who have received the posterior chamber IOL have died during follow-up. Several of those with less than 3 months' follow-up are from foreign countries and returned home before 3 months, and a few patients are mentally retarded and cannot be checked for visual acuity. None of those who were followed up for less than 3 months were known to have had a complication of the cataract-IOL surgery.

INTRAOCULAR LENS STUDIES REPORTED TO THE FDA

Cases reported herein from studies reported to the FDA have been updated since the results of a recent report.[4]

PROSTAGLANDIN INHIBITOR STUDY

Fluorescein angiographic (not clinical) evidence CME was determined as part of a prospective clinical trial using topical 0.5% suprofen, a prostaglandin inhibitor, every 4 hours beginning 24 hours before cataract surgery and continuing four times daily for 10 weeks after surgery. Patients were randomized, and all received topical neomycin and dexamethasone four times daily in addition to either the suprofen or placebo. Six weeks after surgery, the steroid-antibiotic combination was changed to fluoromethalone, once daily to be used for 1 year. All surgery in this study was performed by one of us (WJS). Fluorescein angiography of the fundus was obtained at 4 and 14 weeks after surgery. All fluorescein angiograms were read by one of us (AEM). CME was diagnosed and graded on the basis of standards used in two previous reports.[5,6]

RESULTS

COMBINED CATARACT-IOL SURGERY PERFORMED AT THE WILMER INSTITUTE

To compare results, we have divided our cases into three groups (Table I). Group 1 contains those eyes receiving Morcher-manufactured (European)

TABLE I: INTRAOCULAR LENSES: EXPERIENCE AT THE WILMER INSTITUTE

	GROUP 1: FOUR-LOOP ICCE (WET PACK*)	GROUP 2: FOUR-LOOP ICCE (DRY PACK†)	GROUP 3: POSTERIOR CHAMBER ECCE (DRY PACK)
Dates of use	Jan 1975-Dec 1977	Jan 1978-July 1979	Aug 1979-Feb 1983
Patient age (yr)	71 (55-94)	72 (60-90)	71 (46-93)
Follow-up (mo)	54 (12-76)	25 (12-70)	19 (3-44)
Total	200 eyes	103 eyes	1041 eyes

*"Wet pack" IOLs, sterilized with NaOH solution.
†"Dry pack" IOLs, sterilized with ethylene-oxide.
(ICCE = intracapsular cataract extraction; ECCE = extracapsular cataract extraction.)

four-loop Binkhorst IOLs sterilized by the sodium hydroxide ("wet pack") method. Between January 1975 and December 1977, we implanted 200 of these lenses. Group 2 contains those eyes implanted with four-loop Binkhorst IOLs sterilized by the ethylene-oxide ("dry pack") method and obtained from various American manufacturers. Between January 1977 and July 1979, we implanted 103 of these lenses. Group 3 contains those eyes with posterior chamber lenses implanted at the time of ECCE. Between August 1979 and February 1983, we implanted 1041 Shearing-type angulated posterior chamber IOLs. These lenses were obtained from the IOLAB and Intermedics companies and were sterilized by ethylene-oxide (dry pack).

The mean age of the patients in the three groups was essentially the same, averaging 72 years (Table I). The follow-up is longer for the four-loop Binkhorst lenses, extending up to 95 months for group 1. The mean follow-up for the posterior chamber lens group was 12 months, with a range of 3 to 44 months.

Operative complications were similar in the three groups and were generally slight (Table II). Eyes with occurrence of vitreous loss did not

TABLE II: MAJOR OPERATIVE COMPLICATIONS

TOTAL	GROUP 1: FOUR-LOOP ICCE (WET PACK) 200 EYES (%)	GROUP 2: FOUR-LOOP ICCE (DRY PACK) 103 EYES (%)	GROUP 3: POSTERIOR CHAMBER ECCE (DRY PACK) 1041 EYES (%)
Vitreous loss	0 (0.0)	2 (2.0)	1 (0.1)
Unplanned ECCE	5 (2.5)	2 (2.0)	. . .
Unintentional tear in posterior capsule	. . .	. . .	15 (1.4)*
Related to IOL insertion; rupture of vitreous face	2 (1.0)	2 (2.0)	2 (0.2)

*Implanted with four-loop Binkhorst IOL or anterior chamber IOL.

receive an IOL. In the event of extensive posterior-capsule rupture during ECCE, a four-loop Binkhorst IOL (eight cases) or anterior chamber IOL (seven cases) was implanted; these eyes have not been included in this series, and all had 20/40 or better vision after surgery. If a small tear in the posterior capsule developed without vitreous loss, a posterior chamber lens was inserted.

Analysis of postoperative noninflammatory complications has shown a clinically significant problem with the four-loop Binkhorst lenses (Table III). With continued long-term follow-up of our cases, the two four-loop Binkhorst IOL groups are developing a high rate of late-onset corneal edema (5.5% in group 1 and 2% in group 2). The incidence of corneal edema is less (0.1%) in eyes with the American-manufactured posterior chamber lens. The corneal edema in the Morcher-manufactured four-loop Binkhorst lens cases was delayed in onset in all cases and it developed at an average of 36 months after surgery, with a range of from 10 to 60 months. For the American-manufactured IOL, the onset of corneal edema was 10 and 36 months after surgery. In both groups, all patients had uncomplicated IOL implantation and had 20/30 or better vision (except for two eyes with macular degeneration) before the corneal edema developed. In only 3 of these 13 patients had subluxation of the IOL occurred, and in these cases the IOL was repositioned medically. Also, 2% of eyes with the Binkhorst IOL have shown mild peripheral corneal edema. Vision is good, and these eyes are not included as "corneal edema" cases at this time. We have had only one case of corneal edema with posterior chamber IOLs. This occurred immediately after surgery and was probably caused by inadvertent introduction of some toxic material into the anterior chamber during surgery. This patient is doing well, with 20/30 vision after keratoplasty.

TABLE III: NONINFLAMMATORY POSTOPERATIVE COMPLICATIONS

	GROUP 1: FOUR-LOOP ICCE (WET PACK)	GROUP 2: FOUR-LOOP ICCE (DRY PACK)	GROUP 3: POSTERIOR CHAMBER ECCE (DRY PACK)
TOTAL	200 EYES (%)	103 EYES (%)	1041 EYES (%)
Corneal edema	11 (5.5)	2 (2.0)	1 (0.1)
Retinal detachment	7 (3.5)	2 (2.0)	8 (0.8)
Subluxation of IOL	12 (6.0)	4 (4.0)	3 (0.3)
Pupillary capture	. . .	. . .	5 (0.5)
Opacification of posterior capsule	. . .	. . .	(15-20)*
2° glaucoma	0	3 (3.0)	2 (0.2)
Sphincter erosion	2 (1.0)	2 (2.0)	0

*Eighty-one percent, primary capsulotomy.

The prevalence of persistent postoperative macular edema at each 6-month period after surgery is shown in Fig 1. The cumulative risk of developing persistent corneal edema increased with time in both four-loop Binkhorst lens groups (Fig 2). For group 1 patients followed longer than 70 months, there is greater than a 15% risk of having persistent corneal edema.

Other noninflammatory postoperative complications are listed in Table III. Retinal detachment developed in from 0.8% to 3.5% of cases. We cannot state with certainty that there are statistically significant differences between the three groups, because of differences in follow-up times. Complications specific to the posterior chamber IOLs are also listed in Table III. Subluxation of one loop of the IOL developed in 0.3% of cases, requiring surgical repositioning. Posterior capsulotomy was performed at the time of surgery in 81% of cases; and of those left with an intact capsule, about 15% of the capsules opacified and required a secondary discission.

We have previously reported[12] a 7% incidence of hypopyon and a 20% incidence of excessive and prolonged postoperative intraocular inflammation in the group receiving American-made four-loop Binkhorst IOLs

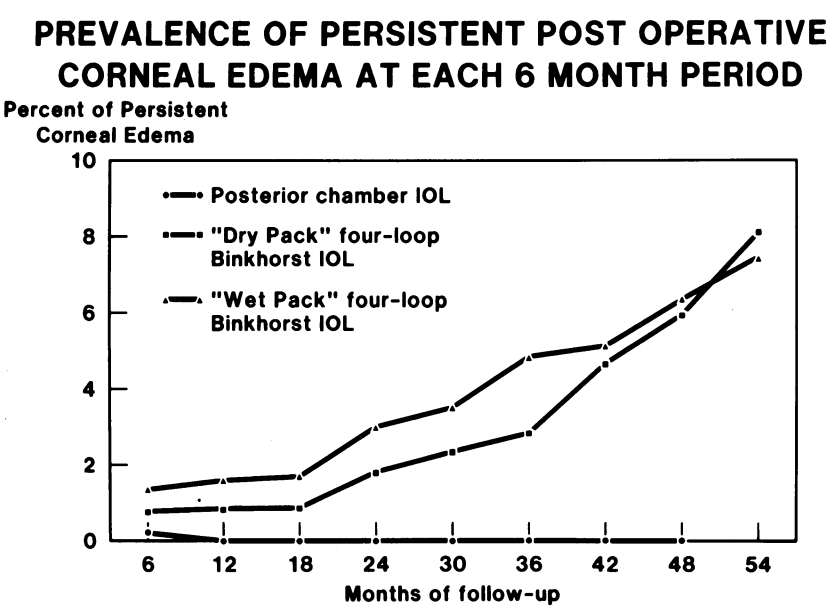

FIGURE 1
Prevalence of persistent postoperative corneal edema at each 6-month period after surgery.

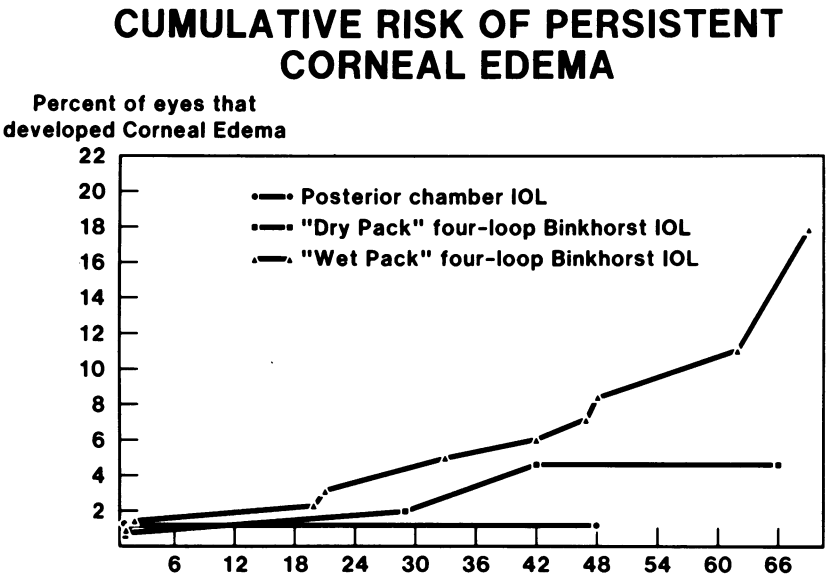

FIGURE 2
Cumulative risk of developing persistent corneal edema after surgery.

sterilized by the dry pack method (Table IV). There have been six hypopyons (0.6%) early in our series when using American-manufactured posterior chamber lenses, but overall there was less inflammation when using these ethylene-oxide sterilized lenses (Table IV).

Largely because of this inflammation, clinically significant CME developed much more frequently in the eyes receiving the American-manufactured four-loop Binkhorst IOLs (group 2; Table V). Overall, clinical CME with reduced visual acuity developed more frequently in both of the

TABLE IV: INFLAMMATORY POSTOPERATIVE COMPLICATIONS

	GROUP 1: FOUR-LOOP ICCE (WET PACK)	GROUP 2: FOUR-LOOP ICCE (DRY PACK)	GROUP 3: POSTERIOR CHAMBER ECCE (DRY PACK)
TOTAL	200 EYES (%)	103 EYES (%)	1041 EYES (%)
Endophthalmitis	1 (0.5)	0 (0.0)	2 (0.2)
Hypopyon	3 (1.5)	7 (7.0)	6 (0.6)
Vitritis and papillitis	0 (0.0)	3 (3.0)	6 (0.6)
Persistent iritis	14 (7.0)	21 (20)	6 (0.6)
Cystoid macular edema (CME)*	20 (10)	22 (23)	20 (2.0)

*Clinical CME with reduced acuity.

TABLE V: CYSTOID MACULAR EDEMA

TOTAL	GROUP 1: FOUR-LOOP ICCE (WET PACK) 200 EYES (%)	GROUP 2: FOUR-LOOP ICCE (DRY PACK) 103 EYES (%)	GROUP 3: POSTERIOR CHAMBER ECCE (DRY PACK) 1041 EYES (%)
Total no CME*	20 (10)	23 (23)	23 (2.3)
Persistent CME	2 (1.0)	10 (10)	3 (0.3)
Onset (median)	6 mo	9.5 mo	2 mo
(range)	(2-26 mo)	(2.5-55 mo)	0.5-15 mo)
Duration (median)			
Persistent CME	35 mo	29 mo	6.5 mo
Transient CME	12 mo	9 mo	2.5 mo
(range)	(0.5-48 mo)	(2-26 mo)	(1-5 mo)
Worst vision (mean)	20/60	20/100	20/70
Final vision (mean)			
Persistent CME	20/77	20/92	20/180†
Transient CME	20/23	20/55	20/25

*Clinical CME with reduced acuity.
†Associated macular degeneration in all three cases.

groups with four-loop Binkhorst IOLs (10% in group 1 and 23% in group 2) as compared to the group with ECCE and posterior chamber IOL (2.3%) (Table V). The macular edema was more frequently persistent in the dry pack four-loop lens group (10%) than in the wet pack four-loop lens group (1%) or in the posterior chamber IOL group (0.3%). Although there was a statistically significant greater incidence of overall or total CME in the European (wet pack) four-loop IOL group than in the American (dry pack) posterior chamber IOL group (10% vs 2.3%; $P < 0.001$), there was no statistically significant difference in the rate of persistent clinical CME with reduced visual acuity between these two groups (1% vs 0.3%; $P > 0.05$). The incidence of total and persistent CME for the dry pack four-loop IOL cases (group 2) was significantly greater than for the other two groups (groups 1 and 3).

For the posterior chamber IOL group the CME seemed to be earlier in onset, to have a shorter duration, and to be less severe than that seen with the four-loop Binkhorst groups (Table V). The median time of onset of the macular edema was 6 months (range, 2 to 26), 9.5 months (range, 2.5 to 55), and 2 months (range, 0.5 to 16) for groups 1 through 3, respectively. CME with the posterior chamber IOL group was earlier in onset and similar to that with non-pseudophakic CME. In 95% of the posterior chamber IOL cases, the onset of the CME was less than 7 months. Although the follow-up of the Binkhorst cases is longer, we have discovered the onset of CME in patients more than 55 months after surgery in group 2 cases. We attribute this to the chronic low grade inflammation

associated with this lens,[12,13] and we suspect that even more late cases of CME will be seen with this group. The cumulative risk of patients developing CME with longer follow-up is up to 40% (Fig 3). The prevalence of CME during each 6 months of postoperative follow-up is shown in Fig 4. With longer follow-up it is apparent that the prevalence of CME remains higher for the four-loop Binkhorst cases than the posterior chamber IOL cases, and this is especially true for the group 2 "hot lenses."

The duration of the CME was calculated for those cases with transient CME that cleared, and those cases that were persistent. The median duration of the transient and the persistent CME cases was greater with the four-loop lenses than with the posterior chamber lenses (Table V).

The mean "worst visual acuity" and "final visual acuity" for cases of CME was calculated by using a log of the Snellen visual acuity and then reconverting to the Snellen notation. Overall mean worst vision was poorer for eyes with the American-manufactured dry pack four-loop Binkhorst IOLs than for the other two groups, but the differences were not statistically significant (Table V). At the time of worst visual acuity, approximately 30% of CME cases in all three groups had 20/40 or better vision. Final vision of the eyes with persistent CME was worse in the

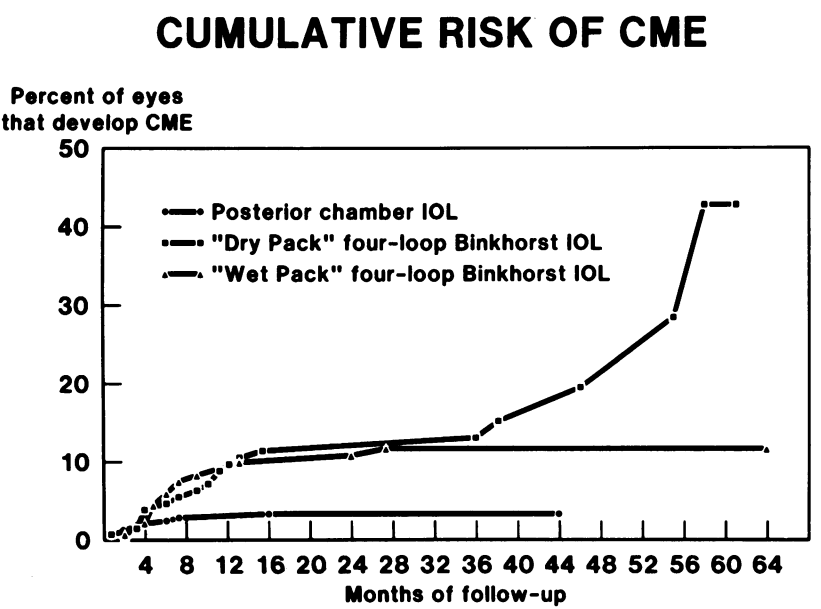

FIGURE 3
Cumulative rate of developing CME during each 6-month postoperative interval.

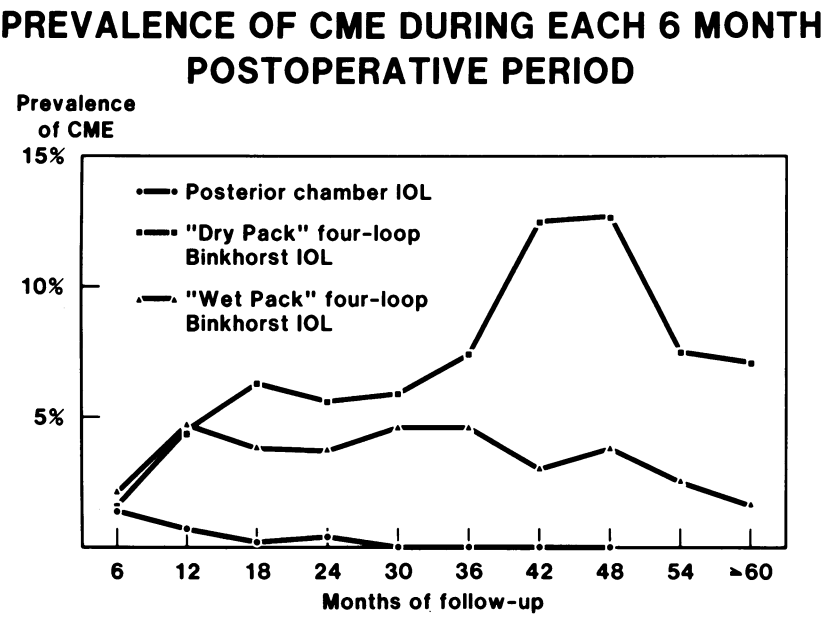

FIGURE 4
Prevalence of CME during each 6-month postoperative interval.

group with the posterior chamber IOL, probably because two of the three persistent cases had macular degeneration and the third one had previously had a retinal detachment with some contraction of the internal limiting membrane. Final visual acuity of eyes with transient CME was significantly better in the group with the European four-loop IOLs and the posterior chamber IOL than with the American four-loop lens. This, again, was probably due to inflammation in the group with the original American-manufactured four-loop Binkhorst IOLs. The problem seems to have been solved by better quality control by IOL manufacturers. Of the cases of transient CME with the posterior chamber IOL, all eyes except one recovered 20/30 vision, and 6 of the 20 such eyes had 20/25 or better vision.

For the posterior chamber IOL group, 20 of the 23 (87%) eyes with CME had had a posterior capsulotomy at the time of surgery, and a capsulotomy was performed in two of the three cases (67%) that have persistent CME. Since 81% of the posterior chamber cases had a capsulotomy at the time of surgery, the presence of a capsulotomy in our cases of ECCE and posterior chamber IOL implantation did not seem to increase the chances of either transient or persistent CME.

Analysis of the three cases of persistent CME with use of a posterior chamber IOL shows that two of three cases had macular drusen with several "window defects" in the pigment epithelium of the macular region. Although they had fluorescein leakage that was typical of CME, this leakage may have been present before cataract surgery, or it may have been associated with the macular degeneration. The third eye that had CME present with a posterior chamber IOL had previously had a retinal detachment with contraction of the internal limiting membrane of the macular region. Fluorescein leakage in a CME pattern was present postoperatively, but this may also have been present before cataract removal.

Although it is our impression that diabetes mellitus without retinopathy is associated with a higher incidence of CME after cataract surgery, we found no significant difference in the prevalence of diabetes in the CME vs the non-CME group. This finding may be due to our patient selection, and the small percentage of diabetic patients who received an IOL at the Wilmer Institute. Likewise, we found no significant difference in the presence or absence of systemic hypertension between the non-CME vs the CME patients.

Our results for final visual acuity among the three groups overall cannot be directly compared because the length of follow-up in the groups is different (Table VI). However, it is apparent that there has been a noteworthy reduction in average vision in the eyes receiving the four-loop Binkhorst IOLs. In part, this decrease in vision can be explained by the onset of senile macular degeneration (with longer follow-up) as this population ages. However, 5.5% of those patients receiving the European-manufactured Binkhorst lens have developed corneal edema, and 10% of the patients receiving the American-manufactured Binkhorst lens have

TABLE VI: VISUAL ACUITY RESULTS: MOST RECENT FOLLOW-UP

TOTAL	GROUP 1: FOUR-LOOP ICCE (WET PACK) 200 EYES (%)	GROUP 2: FOUR-LOOP ICCE (DRY PACK) 103 EYES (%)	GROUP 3: POSTERIOR CHAMBER ECCE (DRY PACK) 1041 EYES (%)
20/20 or better	99 (49.5)	49 (48)	625 (60)
20/25	27 (13.5)	15 (15)	187 (18)
20/30	22 (11)	14 (14)	115 (11)
20/40	11 (5.5)	8 (8)	73 (7)
20/50-20/100	27 (13.5)	7 (7)	21 (2)
20/200	3 (1.5)	4 (4)	10 (1)
< 20/200	11 (5.5)	6 (6)	10 (1)
20/15-20/40*	137/159 (86)	80/93 (86)	918/937 (98)

*Excluding cases with known macular degeneration or amblyopia.

persistent (and probably permanent) CME. Ninety-eight percent of the patients receiving a posterior chamber IOL have 20/40 or better vision at last examination, excluding those patients with known macular degeneration or amblyopia.

INTRAOCULAR LENS STUDIES REPORTED TO THE FDA

During the 4½ years between February 1978 and August 1982, a reported 1,088,640 IOLs were implanted in the USA. Fig 5 shows the number of lenses in each of the four classes implanted during each 6-month interval of the study. The number of IOLs used each year has steadily increased, and during the last year (August 1981 through August 1982), 409,000 IOLs were implanted. If one assumes that about 600,000 cataract operations were performed during the same 12-month period,[2,3] then over 68% 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 (Fig 6). During

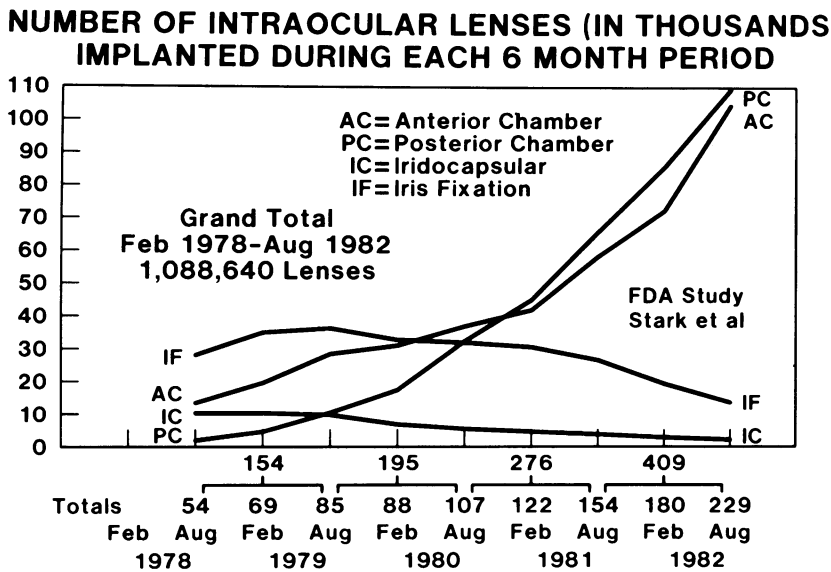

FIGURE 5
Number of intraocular lenses (in thousands) plotted for each 6-month period since FDA study began in February 1978. (Reprinted with permission from reference 7.)

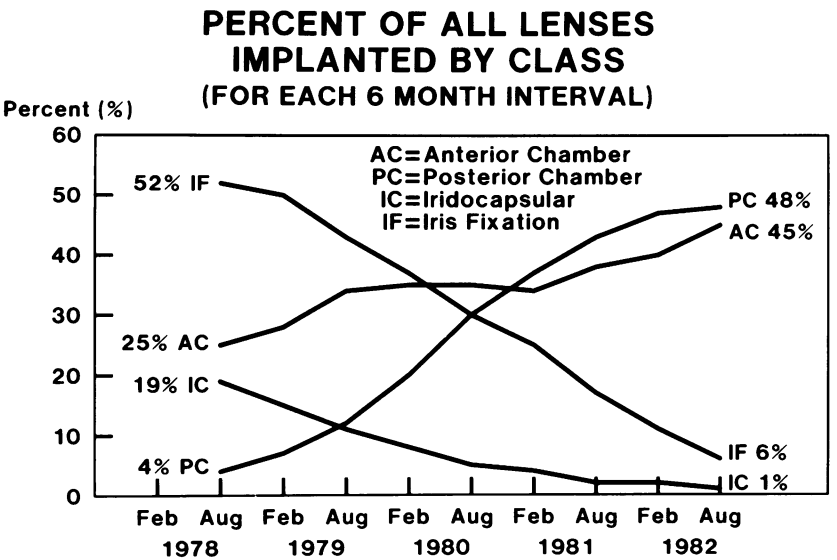

FIGURE 6
Percentage of all intraocular lenses implanted, by class, for each 6-month period. (Reprinted with permission from reference 7.)

the first 6 months of the study, iris fixation lenses accounted for 52% of all IOLs implanted; anterior chamber, 25%; iridocapsular, 19%; and posterior chamber, 4%. During the most recent 6 months of the study, the posterior chamber lenses accounted for 48% of all IOLs implanted and the anterior chamber lenses, 45%. The percentage of iris fixation lenses had 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 December 1982. We are not able to provide confidential information. Manufacturers have agreed to the release of data from premarket approval applications which have not yet been approved. The data that are reported represent information on 37 different IOLs from seven manufacturers, which include a total of 50,537 study cases. At the end of 1 year of follow-up, 84.6% of the 50,537 study eyes had 20/40 or better vision in the operated eye (Table VII). 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 acuity (Table VII).

TABLE VII: FINAL VISUAL ACUITY OF 20/40 OR BETTER AFTER IOL IMPLANTATION: FDA STUDY

TYPE OF IOL: STUDY	AC*		IF*		IC*		PC*	
	NO	%	NO	%	NO	%	NO	%
CORE†	5628	(83.4)	525	(80.4)	1207	(86.5)	3995	(87.3)
Adjunct	19,015	(82.5)	259	(83.4)	12,000	(87.7)	7908	(84.2)
Total	24,643	(82.7)	784	(81.4)	13,207	(87.6)	11,903	(85.2)

Grand total, 50,537 lenses; 84.6% of eyes had 20/40 or better acuity.
*AC = Anterior chamber IOL; IF = iris fixation IOL; IC = iridocapsular IOL; PC = posterior chamber IOL.
†CORE cases = more detailed postoperative reporting; Adjunct = other reported cases.

"CORE" patients in studies reported to the FDA had the most detailed postoperative reporting, and were therefore analyzed in greater detail (Table VIII). Visual acuity results for CORE cases also showed that a smaller percentage of eyes with an iris fixation lens achieved 20/40 or better vision. It was also apparent that those patients who were 80 years of age or older, in all four IOL groups, generally had poorer visual acuity. To determine whether the differences 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 preexisting pathologic conditions such as abnormal corneas, glaucoma, preoperative and postoperative macular degeneration, and amblyopia. For the best cases, all visual results were better—with 90.1% to 93.2% of eyes achieving 20/40 acuity or better (Table IX). Statistically, patients receiving a posterior chamber lens achieved a slightly better visual acuity than those receiving an anterior chamber lens, for the 70 to 79 age group and for the overall anterior chamber IOL group. Also, the eyes with a posterior chamber lens achieved better vision than those receiving an iridocapsular lens, in the age group of 70 years and older. There were no other statistically significant differences (Table X).

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 class of IOLs (Table XI). 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 group was related to two "hot" production lots that produced more inflammation, but this complication did not appear to significantly reduce visual outcome. A problem peculiar to iris fixation lenses is an increased tendency to dislocation of the IOL, which may increase the chances of corneal decompensation in the future.

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 XII).

Clinically significant "persistent" sight-threatening complications—such as corneal edema, secondary glaucoma, and macular edema—devel-

TABLE VIII: FINAL VISUAL ACUITY OF 20/40 OR BETTER: "CORE" PATIENTS (FDA STUDY)

	AC		IF		IC		PC	
TYPE OF IOL	NO	%	NO	%	NO	%	NO	%
Age (yr)								
< 60	596	(91.4)	35	(88.6)	222	(93.2)	488	(93.3)
60-69	1707	(90.0)	137	(88.3)	391	(91.8)	1290	(90.5)
70-79	2224	(82.2)	229	(83.4)	470	(84.7)	1550	(87.9)
> 80	1091	(71.1)	124	(63.7)	124	(64.5)	664	(75.0)
Total	5618	(83.4)	525	(80.4)	1207	(86.5)	3992	(87.3)

TABLE IX: FINAL VISUAL ACUITY OF 20/40 OR BETTER FOR BEST-CASE ANALYSIS OF PRIMARY IMPLANT EYES (FDA STUDY)

	AC		IF		IC		PC	
TYPE OF IOL	NO	%	NO	%	NO	%	NO	%
Age (yr)								
< 60	410	(94.4)	21	(90.5)	210	(94.8)	429	(96.0)
60-69	1278	(93.1)	109	(93.6)	352	(94.3)	1099	(93.2)
70-79	1433	(89.0)	185	(90.8)	397	(90.4)	1114	(94.3)
> 80	534	(82.6)	78	(85.9)	79	(74.7)	363	(86.5)
Total	3655	(90.1)	393	(90.6)	1038	(91.4)	3005	(93.2)

TABLE X: STATISTICALLY SIGNIFICANT DIFFERENCES FOR FINAL VISUAL ACUITY OF 20/40 OR BETTER FOR BEST-CASE ANALYSIS OF PRIMARY IMPLANT PATIENTS

AGE (YR)	TYPE OF IOL	*P*
70-79	AC vs PC	< 0.001
70-79	IC vs PC	$= 0.012$
> 80	IC vs PC	$= 0.025$
Total	AC vs PC	< 0.001

oped more frequently in eyes with the anterior chamber and the iris fixation lens (Table XII).

The results of ICCE vs ECCE for the anterior chamber and iris fixation IOLs were evaluated. The analysis was complicated because the ECCE groups contains cases in which both types of lenses were used as a "back-up" lens for use after vitreous loss or inadvertent rupture of the posterior capsule. A similar percentage of cases in the ECCE and ICCE groups achieved 20/40 or better vision with the anterior chamber IOL (Table XIII). Postoperative macular edema and lens dislocation occurred more frequently with ECCE than with ICCE for the iris fixation lenses. This can probably be accounted for by the fact that the surgeons had had experience with ECCE and by the use of those lenses after vitreous loss.

TABLE XI: INCIDENCE OF ADVERSE REACTIONS: FDA "CORE" STUDY (11,428 EYES)

REACTION	% PATIENTS
Hypopyon	0.3 (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	0.5 (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	0.1
Corneal transplant	0.1

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

TABLE XII: FDA "CORE" STUDY: SIGHT-THREATENING COMPLICATIONS (%)

IOL TYPE	AC	IF	IC	PC
"Cumulative" (0 to 12 mo)				
No of eyes	5667	538	1213	3991
Macular edema	7.7	6.3	2.8	4.6
Secondary glaucoma	5.8	4.3	0.7	1.5
Hyphema	4.8	3.2	2.6	1.3
Lens dislocation	0.4	5.6	1.1	0.5
Pupillary block	1.0	0.6	0.2	0.3
Retinal detachment	0.8	0.4	0.2	0.6
Endophthalmitis	0.1	0.2	0.0	0.1
"Persistent" (1 yr)				
No of eyes	5665	538	1213	3991
Macular edema	2.4	2.4	0.9	0.8
Secondary glaucoma	1.3	0.9	0.2	0.2
Hyphema	0.1	0.0	0.1	< 0.1
Iritis	1.3	0.9	0.4	0.7
Corneal edema	1.2	1.5	0.6	0.6
Cyclitic membrane	0.1	0.2	0.0	0.1
Vitritis	0.1	0.2	0.1	0.1

Other postoperative complications were not significantly different among the four IOL types (Table XIV).

For *secondary* IOL implantation, no new IOLs have been approved by the FDA since our last report.[4] A best-case analysis (excluding preoperative ocular pathology) showed postoperative acuity results similar to those with primary lens implantation (Table XV). However, if an eye had 20/40 or better acuity 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.

PROSTAGLANDIN INHIBITORS

The prostaglandin inhibitors study at the Wilmer Institute is in progress, and the numbers of cases are small. Therefore, no statistically significant difference in incidence of CME as detected by fluorescein angiography at

TABLE XIII: FINAL VISUAL ACUITY OF 20/40 OR BETTER: BY METHOD OF CATARACT EXTRACTION AND IOL TYPE

	TYPE OF IOL					
	AC		IF		IC	
METHOD	NO	%	NO	%	NO	%
ICCE	3819	(84.8)	476	(80.9)	. . .	. . .
ECCE	902	(84.7)	62	(77.4)	1207	(86.5)

TABLE XIV: SIGHT-THREATENING COMPLICATIONS VS METHODS OF CATARACT EXTRACTION AND IOL TYPE

	TYPE OF IOL				
	ECCE			ICCE	
	AC	IF	IC	AC	IF
	%	%	%	%	%
"Cumulative" (0 to 12 mo)					
Macular edema	6.9	8.1	2.8	7.9	6.1
Retinal detachment	1.1	1.6	0.2	0.8	0.2
Lens dislocation	0.3	12.9*	1.1	0.5	4.6*
"Persistent" (1 yr)					
Macular edema	2.1	6.5	0.9	2.1	1.9
Iritis	1.0	0.0	0.4	1.5	1.1
Total no of eyes	902	62	1213	3830	476

*$P = 0.03$.

4 weeks and at 12 weeks after surgery is yet present among the treated and the nontreated groups (Table XVI). There is, however, a trend toward a lower rate of fluorescein-positive CME in the group receiving topical suprofen.

Of importance is an analysis of visual results in those patients classified as having fluorescein-positive CME. To date, nine patients have had

TABLE XV: ANTERIOR CHAMBER LENS SECONDARY IMPLANTATION BEST-CASE ANALYSIS

20/40 or better preoperative acuity = 328 cases (100%)
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.

leakage of fluorescein into the macula, and these have been classified as having fluorescein-positive CME. None of the patients had clinically significant CME with reduced acuity, and all except two—who had 20/25 vision—had 20/20, Jaeger 1 or better vision at the time of the CME positive fluorescein angiography.

TABLE XVI: FLUORESCEIN POSITIVE CME TREATMENT WITH TOPICAL 0.5% SUPROFEN (PRELIMINARY RESULTS)

TESTING TIME AFTER SURGERY	CONTROL GROUP % POSITIVE	TREATED GROUP % POSITIVE
4 wks	22 (2/9)	9 (1/11)
	$P = 0.57$	
10 wks	50 (3/6)	20 (2/10)
	$P = 0.30$	

DISCUSSION

Other than macular degeneration, CME with reduced visual acuity may be one of the main causes of reduced visual acuity after cataract extraction. The true incidence of clinically significant CME, however, appears to be very low in uncomplicated cases. We cannot state from our data whether CME occurs more frequently after uncomplicated ICCE and IOL implantation than after uncomplicated ECCE and IOL implantation. In our nonrandomized prospective concurrent studies comparing the two different surgical methods, transient CME developed more frequently with ICCE and IOL implantation (10%) than with ECCE and IOL implantation (2.3%), but the incidence of persistent CME between the two groups was not significantly different (1% vs 0.3%; ICCE vs ECCE). For ECCE with an IOL, the presence or absence of a posterior capsulotomy did not appear to influence the development or persistence of CME. It is possible that the presence of a posterior chamber IOL helps to restrain forward movement of the vitreous, and thus reduces the incidence of CME, but our study was not designed to answer that question.

Designers of future research studies to evaluate various means of reducing the rate of CME after cataract extraction and IOL implantation will need to take into consideration the low incidence of clinically significant persistent CME in uncomplicated cases, and the questionable significance of statistics on fluorescein positive CME. If clinically significant persistent CME developed in only 0.3% of uncomplicated cases, then any modification of technique that had a favorable treatment effect in 50% of cases (ie, reduces the rate of CME to 0.15%) would require a study of about 25,000 cases to demonstrate statistical significance. If one used the rate of fluorescein-positive CME as an indicator of treatment effectiveness, then fewer study patients would be needed. However, we question the value of fluorescein-positive CME studies alone—since in our clinical trial, 78% of patients with fluorescein-positive CME had 20/20, Jaeger 1 vision and the remainder had 20/25, Jaeger 1 vision. Therefore, future projects to evaluate various CME preventive measures should consider the rate of clinically significant (rather than only fluorescein-positive) CME as the important measure of CME occurrence.

Pupillary-supported IOLs have recently become less popular, because of the reported higher rate of CME.[10] We have attributed this problem in part to the inflammation associated with the ethylene-oxide sterilized ("dry pack") IOLs used in 1978 and 1979. Pupillary-supported IOLs were being used in the USA in over 50% of cases at that time, and thus were also blamed as the cause of the associated CME. We believe the pupil-

lary-supported IOLs do cause more iritis and probably more clinically significant CME, but the main problem with pupillary-supported IOLs is the higher incidence of late-onset corneal edema. Therefore, we advise caution in the use of these lenses in younger patients. The uveitis, glaucoma, and hyphema (UGH syndrome) reported with the use of some anterior chamber IOLs has been corrected by better manufacturing techniques. We, at the Wilmer Institute, have had minimal experience with the use of anterior chamber IOLs, and we do not personally know whether late-onset corneal edema will be a problem. Regarding the use of posterior chamber IOLs, we have up to 4 years of follow-up results. Because of the position of that IOL behind the iris, we do not expect to see late-onset corneal edema or macular edema. To date, we are not aware of any long-term complications with use of the posterior chamber IOLs, and we are beginning to relax somewhat our patient selection criteria for posterior chamber IOL implantation.

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DISCUSSION

DR ROBERT C. DREWS. I want to thank both of these colleagues for sending me their papers well in advance of this meeting. This courtesy is very much appreciated.

Doctor Hamilton speaks of the dislocation of posterior chamber lenses. The rate of dislocation of intraocular lenses varies, depending on the lens type. It is rare but not zero with anterior chamber lenses. Three percent to 4% of iris fixated lenses dislocate; hence the routine use of sutures or clips to limit the dislocation to a subluxation rather than a luxation. Because of failure of capsular fixation, up to 9% of capsular fixated lenses may dislocate if the lenses are completely dependent on free capsular fixation; hence the loss of popularity of lenses such as the Binkhorst two-loop style. The rate of dislocation with posterior chamber lenses is less than 1% in most series.

The "Sunset syndrome" specifically refers to the progressive displacement of a posterior chamber lens. This can occur because of: (1) Failure of capsular fixation in lenses which depend on this mechanism (such as the Pearce). (2) Zonular dialysis or capsule rupture in lenses dependent on ciliary sulcus fixation. (3) Use of a normal (13.5 mm) lens in an eye with a large anterior segment so that the lens does not reach the ciliary sulcus, "Windshield wiper syndrome." (4) Epithelial proliferation or fibrotic closure of the periphery of the bag causing progressive displacement of a loop centrally, with secondary displacement of the lens body. (5) "Late sunset in the bag" with rupture of the zonules with age.

Let me offer two suggestions: First, using a YAG laser to perform an anterior capsulotomy can obviate the significant problems that Doctor Hamilton refers to in the actual performance of a mechanical capsulotomy. And afterwards, tags of capsule are much less frequently encountered and, when inadvertently left, are much more easily removed than if the capsulotomy has been made mechanically. If the laser capsulotomy is performed conservatively (capsulotomy not capsulectomy) with a maximum of 30 to 40 openings in the lens capsule, the problems of secondary acute glaucoma can be avoided even if surgery is delayed 24 to 48 hours. Delay allows ripening of at least the anterior cortex making the subsequent surgery easier. The sum of these effects is to make extracapsular surgery signifi-

cantly safer, and I recommend the YAG laser especially for those who are relatively inexperienced in extracapsular technique. Last, Simcoe's technique for the repositioning and suturing of a subluxated posterior chamber lens is both ingenious and worth knowing (Fig 1). The lens is first doubly entrapped in the pupil by lifting forward on the loops with a hook or spatula. This maneuver insures that the lens is centered and that the loops are held firmly forward against the back of the iris, making their position much easier to judge. McCannel sutures are now placed around one or both loops as needed. The suture should be placed in the periphery of the iris and not tied too tightly; otherwise, the pupil cannot be made round afterward. Finally, the lens is delivered back through the pupil into the posterior chamber.

I have reservations about leaving a lens doubly entrapped in the pupil. Early there is chronic, mild inflammation, with lens precipitates near the area of sphincter touch and synechia to the loops. Our experience with pupil fixated lenses makes be believe that a lens which distorts the pupil will probably produce late progressive erosion of the sphincter margin.

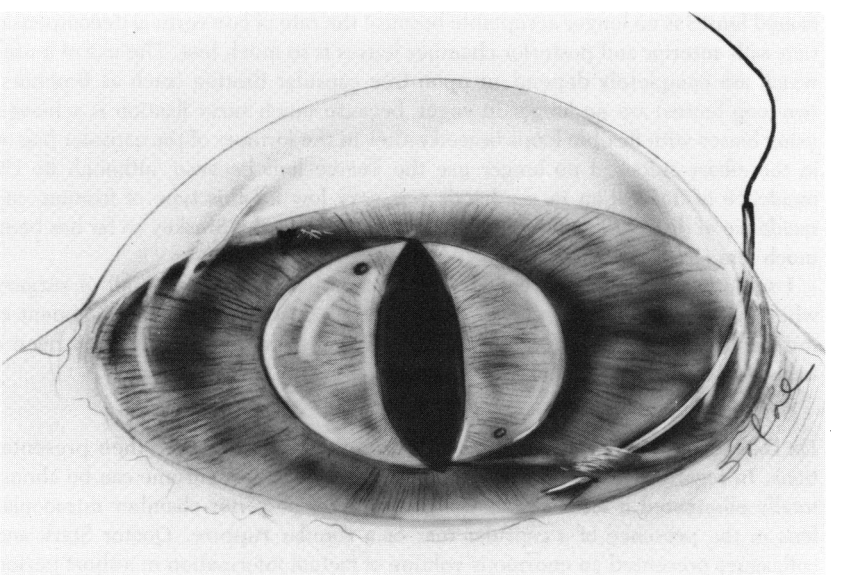

FIGURE 1

Simcoe technique: McCannel sutures are most easily placed around dislocated posterior chamber lens by first doubly entrapping lens in pupil. This will center the lens and hold the loops firmly against the iris posteriorly while suturing is done. The sutures should be placed in the periphery of the iris. The lens is then replaced behind the pupil.

Turning to the paper by Doctor Stark and colleagues at the Wilmer Institute, rates of cystoid macular edema are very difficult to compile and evaluate. The best one can conclude from the literature is that the rate of cystoid macular edema as demonstrated by routine fluorescein angiography after cataract surgery is very high, and that the rate of clinically significant cystoid macular edema varies between 1% and 30% depending on the circumstances and is fortunately usually temporary. This paper compares data, but has two surgeons, two manufacturers, two lens styles, two time periods, and too many variables. Most importantly, the cases are not random but sequential. The authors seem to emphasize the switch of manufacturer from one continent to another, but the method of sterilization was also changed. I can say that I persisted in using lenses made by a good European manufacturer after the FDA-mandated switch to ethylene-oxide and had a 4% incidence of sterile hypopyon in the first 6 months.

There is much ado today about the rates of late corneal decompensation with iris fixated lenses. The authors are alarmed to find rates in their own cases of 2% to 5.5%. These rates, however, are well within the range of rates presented in the literature for a number of years.

One of the most interesting developments in the last 10 years in lens implantation is the remarkable tightening of rates of complications which are now considered to be "acceptable." For example, a 4% late corneal edema rate with iris fixated lenses is no longer acceptable because the rate of late corneal decompensation with anterior and posterior chamber lenses is so much less. The use of lenses which are completely dependent upon free capsular fixation (such as Binkhorst two-loop lenses) are no longer in vogue because much surer fixation is achieved using lenses with flexible loops braced either in the fornices of the capsular bag or in the ciliary sulcus. I no longer use the Pearce lens because, although its 1% incidence of dislocation in my hands was very low for this type of fixation, my incidence of dislocation with open loop lenses such as the Sinskey so far has been much less (4 of 300 versus 0 of 300).

I submit that there are very few other complex techniques in all of surgery where a 95% to 99% success rate is considered unacceptable! The refinement of intraocular lens techniques and designs in the last decade has certainly been a major technological triumph.

Dr Daniel M. Taylor. I would like to congratulate the authors on their presentations. In regard to Doctor Hamilton's paper, the Sunset syndrome can be almost totally eliminated if one refrains from inserting a posterior chamber intraocular lens in the presence of a capsular tear or a zonular rupture. Doctor Stark and colleagues presented an enormous volume of factual information in a short period of time and I assume that not all of it was absorbed by everyone present. My own experience with intraocular lenses totalling some 1400 cases closely approximates Doctor Stark's. We both started to implant intraocular lenses in 1975 utilizing the intracapsular iris supported lens technique and independently experienced similar complications and disenchantment after several years. We both converted to

the extracapsular posterior chamber technique in 1979 and have observed a marked reduction in serious complications. In my experience, the intracapsular iris supported lens era between 1975 and 1979 resulted in a high incidence of long-term complications. In a series of 850 intracapsular extractions with iris supported lenses of various designs, we experienced 84 cases of clinically significant cystoid macular edema (CME) for an incidence of 9.9%. Of the 84 cases of CME, 21 when on to develop pseudophakic bullous keratopathy for an incidence of 25%. When we proceeded to graft these decompensated patients and left the intraocular lens in place, the ultimate visual result was often unsatisfactory because of the high incidence of underlined CME. In addition, 36% of the successfully grafted patients decompensated in 1 to 3 years, indicating that there was a continuing underlying disease process. The underlying disease was that of chronic low grade inflammation that was due to chronic iris irritation produced by the constant iris pseudophakic contact. Pseudophakic CME tended to be persistent, recurrent, and at times severe with ultimate irreversible anatomical changes in the macula. This led to a permanent reduction of visual acuity to between 20/50 and fingercounting in 38% of the patients with CME. This high incidence of retinal and corneal complications caused us to reevaluate and ultimately change our approach to the extracapsular-posterior chamber technique. After converting to the extracapsular technique, both Doctor Stark and I noted a dramatic reduction in the incidence of serious complications. I have now performed approximately 475 extracapsular cataract extractions with insertion of a posterior chamber intraocular lens and have had only five cases of clinically significant CME and one case of pseudophakic bullous keratopathy. The latter was attributable to surgical trauma to the endothelium during the cataract extraction. None of the five cases of CME have progressed to pseudophakic bullous keratopathy as occurred in the intracapsular series. To gain further insight into the problem of clinically significant CME following cataract extraction, I retrospectively reviewed a series of simple intracapsular cataract extractions performed between 1970 and 1974. I had only 13 cases of CME in a series of 630 simple, intracapsular cataract extractions. Only 2 cases of the 630 eyes developed pseudophakic bullous keratopathy and both of these had preexisting endothelial dystrophy. There were no cases of CME combined with pseudophakic bullous keratopathy. Of the 13 patients with CME, all 13 improved (11 spontaneously, 2 with aid of systemic steroids) and the final visual acuity ranged from 20/20 to 20/30. Simple aphakic CME in contrast to pseudophakic CME following intracapsular cataract extraction had a low incidence (2%) and was a relatively benign disease that tended to undergo spontaneous resolution. In my judgment, the etiology of pseudophakic CME and bullous keratopathy is inflammatory in nature and is due to chronic iris irritation. The incidence is unacceptably high with intracapsular iris supported lens and is relatively low with the extracapsular posterior chamber fixation technique. The latter results in secure, stabilized fixation of the implant at the furthest possible sight from the cornea. We also observed that young patients between the ages of 50 and 60 have a particularly high incidence of CME with intracapsular iris supported

lenses that approaches the 25% level. This undoubtedly is due in part to the more active lifestyle of these patients and the presence of more resilient vitreous gel that, in turn, results in greater degrees of iridodonesis and chronic iris irritation. In addition, the immunological systems of younger patients are usually more responsive to chronic irritation.

I again congratulate Doctor Stark on his large volume of information and reiterate that our independent experiences and conclusions have been quite similar.

DR SAMUEL MCPHERSON. For those who prefer the simple things in life, I would like to suggest a feasible alternative, namely flexible anterior chamber lenses. Despite Doctor Drews' beautiful movie, when one tries to remove a posterior chamber lens, the scene is even worse. [SLIDE] We have worked with three anterior chamber lenses: the Leiske by Surgidev, the Optiflex by Cilco, and the 91Z from Iolab. We feel it is important not to dilate the pupil before operation, because from the retrobulbar injection alone a sufficient dilatation is obtained. At operation, we do a routine intracapsular extraction, preplacing our two corneoscleral sutures 7 mm apart. After the lens is extracted, we instill miochol, air and finally Healon to reform the anterior chamber. The desired anterior chamber lens is slid into place. Anyone who can remove a cataract can certainly slip one of these lenses in. I think too much has been made of the courses that one should take to perform these simple operations. After the lens is secured, five additional postplaced sutures of 8-0 collagen are put in, and two x-sutures of 16 to 18 μ nylon are placed to reduce postoperative astigmatism. During this wound closure, a colored contact lens is applied to obviate the exposure problems from too much light. This is the final wound closure with two figure-eight sutures between the chromic collagen sutures, [SLIDE] and this is the lens in place with slit-lamp biomicroscopy. [SLIDE] These are really simple operations. Our staff does extracapsular extractions with posterior chamber lenses as well as intracapsular extractions with anterior chamber lenses. It is our impression that the latter is a much less traumatizing procedure. This does not necessitate later capsulotomies and gives equivalent results.

DR STEVEN KRAMER. I was intrigued by the juxtaposition of these two papers; one was a technical paper without presentation of the results and the other was an overwhelming statistical analysis of an enormous number of results. In the "result paper" there was no discussion of technique, but one of the important complications mentioned was corneal edema—the reason it was particularly interesting to me. In Doctor Hamilton's paper in his discussion of extracapsular nuclear expression he spoke of occasionally having to bring the 6 o'clock instrument up onto the cornea. That is a maneuver that we recommend strongly against, because we did a study of this which I will describe very briefly.

We looked at the corneal thickness regionally in the superior cornea and inferior cornea in a series of 30 extracapsular procedures with posterior chamber

lens implants. Especially with surgeons beginning extracapsular techniques, the surgical maneuvers themselves, not involving the implant may be traumatic; one of these is the expression of the nucleus by sliding the inferior instrument up onto the cornea. In our series when that was done, the ratio of corneal thickness superiorly to corneal thickness inferiorly decreased. The thickness was normally greater above than below, but when the inferior instrument was brought up onto the cornea, this relationship was reversed, indicating greater trauma to the inferior cornea. Therefore, I would recommend against this maneuver.

DR ALTON V. HALLUM. I am one of very few ophthalmologists who has accepted an intraocular lens (IOL) into his own eye. A year and a half ago, my former eye resident and now my office partner, Doctor Barrie Thrasher, Jr, performed an extracapsular cataract extraction and posterior chamber lens implant into my right eye. I was back in the office 2 days later, it could have been 1 day later, doing routine office examinations in perfect comfort. He used ultrasound preoperatively to determine the strength of the IOL that would leave the eye slightly myopic. My distance correction for my right eye is −1.50 D sphere and I see 20/20 at distance and read J1 print with a +2.50 D add. Without glasses, my right eye sees well enough to pass the drivers test and I can read newspaper print with ease. This is such a superior procedure compared to the "old fashioned" cataract removal, that it should be performed on nearly 100% of cataracts removed from healthy eyes. My plea to each of you is to train your residents to be super experts in doing this procedure. When your resident gets out into private practice, if he only does the "old fashioned" cataract removal, he will find that his patients will go to other ophthalmologists for IOL implants.

DR WILLIAM H. JARRETT II. I want to follow-up on the discussion of bullous keratopathy and corneal edema in pseudophakic eyes. Doctor Waring recently reported his experience at Emory with corneal grafts in pseudophakic bullous keratopathy. He found that the final visual results in the pseudophakic cases, even when the graft remained crystal clear, were worse than in a comparable series of aphakic bullous keratopathy (without an intraocular lens).

Last year at this meeting, Doctor Hagler reported on a series of pseudophakic retinal detachment cases which he and I had operated upon, and our experience was quite similar to that reported by Doctor Waring. That is, even when the retina was anatomically reattached, the visual results were not as good as in a comparable series of aphakic retinal detachments in which an intraocular lens had not been utilized.

My question to you is, "Has it been your experience that the final visual acuity, when the graft is clear, is worse in pseudophakic bullous keratopathy than in aphakic bullous keratopathy?"

DR RALPH S. HAMILTON. I would like to thank Doctor Drews and the other discussors for their kind comments. I agree with what Doctor Drews said about

incarcerating this lens in the pupil, and I suppose it is rather presumptuous for me to talk about a complication that I've had so little experience with, having only had the opportunity to repair three of these Sunset syndromes. The only thing I can say about the McCannel suture is that it is the most difficult procedure that I have ever tried to do without traumatizing the cornea first. So that is the reason that I left it in the pupil. The few cases that I have repaired have maintained good vision and quiet eyes. Doctor Kramer's comment is a good one and I don't mean to leave the impression that I advocate moving the instrument up on the cornea in any case that it is not necessary to deliver the equator into the wound. I think that when you do, you are going to see some changes in the inferior cornea. Certainly 99% of these nuclei can be delivered easily into the incision by maintaining the hook at the limbus at 6 o'clock and not moving up. If you have a lens that tumbles, it may be necessary to move the lens hook up on the cornea a little. I have noted some corneal edema below when this is necessary. I did not mean to leave the impression that you can with impunity move that hook up on the cornea. I would just like to show you the repositioning. This is not an easy technique. [MOVIE] This is the lady whose lens would slip when she turned her head. You can see the pressure at the limbus pushing the implant back in place. At this time we are going into the anterior chamber and trying to manipulate this implant with the positioner and rotate it. This was not successful. If you can rotate it away from the zonular rupture, then you can leave it alone in the new position away from the zonular rupture. Here is the optic anterior to the iris at this particular moment. We're getting the lens up out of the dislocated position here. Now we have the haptic and the optic in the anterior chamber and this time we are taking the positioner and putting the haptic back behind the iris. At this point, Doctor Drews made the point that it is a difficult thing. It looks very easy to do but it is very difficult. You have two small stab wounds here and here. Finally, this lens is back in place. Doctor Drews advocates placing McCannel sutures at this point and repositioning the optic behind the iris. It would be very easy to reposition the optic behind the iris, but McCannel sutures are difficult.

I would like to take this opportunity to thank Doctor Richards and the Society for giving me the opportunity to present this information.

Dr Walter Stark. I want to thank the discussers for their kind comments. At least, I think they were kind for the most part. Before beginning my comments, I would like to say a couple of words about the other discussions. Doctor Drews did point out the safety of the YAG laser. That has not been established by the FDA Committee as yet and the procedure is still considered investigational. This is especially true for cutting the anterior capsule prior to cataract surgery. We have five concerns about the YAG laser. I won't go through all the material on the YAG but many of the manufacturers were not even aware that there may be a great pressure spike between 2 to 4 hours after the YAG laser application. We have seen the pressure rise up to 50 to 60 mm Hg 2 to 3 hours after treatment in about

40% of our cases. This may be potentially dangerous to patients that are predisposed to glaucoma or already have significant optic nerve cupping.

For the closing comments of my paper. We presented the results of a prospective concurrent study. It is easy to criticize 99.9% of articles in ophthalmology saying that they are not randomized controlled studies. It is almost impossible to do a randomized controlled study with currently available intraocular lenses looking specifically at one lens as opposed to an entirely different one. For the four-loop Binkhorst IOL the corneal edema rate was 5% overall, but with adjustments for loss of follow-up and death, edema developed in up to 15% of our closely followed cases. We are specifically looking for complications and we continue to report complications and will do the same for posterior chamber lenses if complications do develop after longer follow-up. Let me emphasize we have 4½ years maximum follow-up on the posterior chamber lenses. With this lens we are not as concerned about long-term complications. We do not expect any with the posterior chamber IOL because of its position behind the iris, but we are not ready to say that this lens is without late-onset complications.

Doctor Jarrett made some very nice comments about his results and the results at Emory of keratoplasty and retinal detachment surgery. The results are not as good with an intraocular lens in place, and we agree with this. I usually recommend removing the lens at the time of keratoplasty unless it is an uncomplicated posterior chamber IOL. I am not sure what one should do at the time of retinal detachment but lenses can complicate an already complicated situation. Finally, Doctor Hallum's remarks about the value of the vision with an intraocular lens. It has been said that the intraocular lens may be one of the greatest things that has happened to the elderly cataract patient because of the excellent visual rehabilitation. I think this may be true. I mentioned at the end of my talk we are now beginning to gradually relax our selection criteria. We are not ready to put the lens in 21- or 35-year-old patients but we are lowering the age down from the 60 years that we maintained for so long in our prospective concurrent study.