Intraocular Lens Implantation in the Absence of Capsular Support

A Report by the American Academy of Ophthalmology

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Objective: This review was conducted to determine the safety and efficacy of open-loop anterior chamber, scleral-sutured posterior chamber, and iris-sutured posterior chamber intraocular lenses (IOLs) in eyes with inadequate capsular support for posterior chamber implantation in the capsular bag or ciliary sulcus. It also attempted to determine whether there is a preferred IOL or fixation site of choice in eyes with inadequate capsular support.

Methods: A literature search conducted for the years 1980 to 2001 yielded 189 citations related to IOL implantation in the absence of capsular support. An update search, conducted in March 2002, yielded an additional 28 articles. The Anterior Segment Panel members reviewed these abstracts and selected 148 articles of possible clinical relevance for review. Of these, 89 were considered sufficiently clinically relevant for the panel methodologist to review and rate according to the strength of evidence. A level I rating was assigned to properly conducted, well-designed, randomized clinical trials; a level II rating was assigned to well-designed cohort and case-control studies; and a level III rating was assigned to case series. Articles comparing the safety and efficacy of the IOL type and fixation site were further evaluated for the quality of the statistical methods used in the study. Studies with a rating of A or B were considered acceptable, C was borderline, and D and F were considered unacceptable as medical evidence.

Results: Forty-three articles with data concerning outcome of IOL insertion in eyes with inadequate capsular support had an evidence rating of level III or higher and were used in the final review of the safety and efficacy of one or more lens types and/or fixation sites. Seven articles had data about more than one lens type. Six had a statistical method rating of C or higher and were used to evaluate differences in visual outcomes and complication rates between lens types and fixation sites.

Conclusions: The literature supports the safe and effective use of open-loop anterior chamber, scleral-sutured posterior chamber, and iris-sutured posterior chamber IOLs for the correction of aphakia in eyes without adequate capsular support for placement of a posterior chamber lens in the capsular bag or ciliary sulcus. At this time, there is insufficient evidence to demonstrate the superiority of one lens type or fixation site. Precise determination of small differences in visual outcome or complication rates will require a large prospective, randomized clinical trial. *Ophthalmology 2003;110:840–859 © 2003 by the American Academy of Ophthalmology.*

Introduction

The American Academy of Ophthalmology (AAO) prepares Ophthalmic Technology Assessments (OTAs) to evaluate new and existing procedures, drugs, and diagnostic and screening tests. The goal of an OTA is to evaluate the peer-reviewed published scientific literature, to define what is well established, and to help refine the important questions to be answered by future investigations. After appropriate review by all contributors, including legal counsel, assessments are submitted to the Academy's Board of Trustees for consideration as official Academy statements. The purpose of this assessment is to evaluate options for intraocular lens (IOL) implantation in the absence of capsular support and to determine whether any of these techniques are the method of choice.

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Background

The development of safe, effective IOLs to eliminate the optical problem of aphakia is one of the great successes of modern ophthalmology. Whereas early lens designs and

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fixation sites were associated with an unacceptably high rate of complications,[1,2]modern posterior chamber IOLs have a track record of remarkable safety and provide excellent visual outcome after insertion into the capsular bag or sulcus after uncomplicated cataract surgery. Excellent visual outcome with acceptably low complication rates can often be achieved after complicated cataract surgery in which the capsular bag is not preserved or after secondary IOL implantation or exchange with or without penetrating keratoplasty. There is no consensus, however, on the optimal choice of lens or method and site of fixation in such situations.

Open-loop anterior chamber intraocular lenses (AC IOLs) can be used in the absence of capsular support unless extensive congenital or traumatic abnormalities of the anterior chamber angle provide insufficient support for fixation.[3,4] Despite the relative technical ease of primary or secondary insertion of these lenses, there has been a reluctance on the part of many ophthalmologists to embrace their use, because of the well-deserved poor reputation of closed-loop AC IOLs.[5] These lenses were associated with an unacceptably high incidence of progressive corneal endothelial damage and decompensation and chronic ocular inflammation, with secondary glaucoma and/or cystoid macular edema (CME).[5–8] The cause of these complications was excessive vaulting of the lens with chronic endothelial injury and attrition. Furthermore, fibrosis of the haptics into the chamber angle led to eventual erosion into uveal tissue, resulting in breakdown of the blood–aqueous barrier and intraocular release of inflammatory mediators.[6–8] Fortunately, the only resemblance of the modern, flexible, open-loop AC IOL to the older, closed-loop AC IOL is the anatomic site of implantation.[3] These lenses are manufactured to have minimal vault under high compression, minimizing injury to the corneal endothelium.[3] The minimal area of contact provided by the open-loop haptic design greatly reduces the tendency for haptic fibrosis and erosion into angle structures.[3] When compared to closed-loop AC IOLs, open-loop AC IOLs have a statistically significant lower rate of corneal endothelial cell loss and corneal decompensation, intraocular inflammation, glaucoma, hyphema, and CME, as well as a lower rate of explantation, at all postoperative intervals.[4]

Scleral-sutured posterior chamber intraocular lenses (PC IOLs) can be used in eyes without capsular support even if there is significant anterior segment disruption from congenital anomalies or trauma.[9] Many ophthalmologists have adopted this technique on the assumption that anatomic placement of the IOL in the posterior segment will result in sufficiently less corneal decompensation, glaucoma, and CME than with the use of an open-loop AC IOL. Suturing a PC IOL into the ciliary sulcus is technically more difficult and requires more operative time than use of an open-loop AC IOL.

Iris-sutured posterior chamber intraocular lenses (PC IOLs) can be placed in eyes without capsular support, but are not useful for eyes with significant disruption of the anterior segment from congenital anomalies or trauma.[10] This technique, especially when a limbal approach is required, is also much more technically difficult than insertion of an open-loop AC IOL.

Questions for Assessment

The focus of this assessment is to address the following questions:

- Are open-loop anterior chamber, scleral-sutured posterior chamber, and iris-sutured posterior chamber IOLs safe and effective in eyes with inadequate capsular support for posterior chamber lens implantation in the capsular bag or ciliary sulcus?
- Is there a preferred intraocular lens and fixation site of choice in eyes with inadequate capsular support?

Description of the Evidence

The peer-reviewed literature was analyzed and all possible relevant articles were selected. The literature search was conducted in May 2001 in MEDLINE for 1980 to 2001 and was limited to articles published in English. The Cochrane Library of clinical trials was also investigated. The MeSH terms used were *lenses*, *intraocular*, or *lens implantation* and *anterior chamber*, and the text words were *open-loop*, *iris fix* (truncated), *iris claw*, *iris suture* (truncated), *transscleral*, *posterior*, and *chamber*. This search yielded 189 citations. An update search, conducted in March 2002, yielded an additional 28 articles. Abstracts of meeting presentations are not subject to peer review and were not included in the analysis.

The panel reviewed the abstracts and selected 148 articles of possible clinical relevance for review. Of these, 89 were considered sufficiently clinically relevant for evaluation by the panel methodologist, who used the following rating scale to assess the level of evidence provided by each article: a level I rating was assigned to properly conducted, well-designed, randomized clinical trials; a level II rating was assigned to well-designed cohort and case-control studies; and a level III rating was assigned to case series.

Articles comparing the safety and efficacy of flexible, open-loop AC IOLs to scleral- or iris-sutured PC IOLs were further evaluated for the quality of statistical methods used in the study. Studies with a rating of A and B were considered acceptable, C was borderline, and D and F were considered unacceptable as medical evidence.

Forty-three articles with data concerning outcome of IOL insertion in eyes with inadequate capsular support had a level III rating or higher and were included in the final review.[11–53] These included 24 articles with data about open-loop AC IOLs,[11–29,48–52] 19 articles with data about scleral-sutured PC IOLs,[18,24,28,30–42,49–51] and 8 articles about iris-sutured PC IOLs.[42–47,51,53] Seven articles had data about more than one lens type. Six of the 43 articles had a statistical method rating of C or higher concerning comparisons of lens types and fixation method and site.[48–53]

Table 1A. Open-loop AC IOLs. Uncomplicated ICCE: Primary Insertion of AC IOLs

Study	Type of Study	Number	Level of Evidence	Follow-up	Results	Data Comparison to No IOL in Same Study
Hennig et al[11]	Randomized clinical trial	2002 (ICCE + AC IOL = 1002) (ICCE + no IOL = 1000)	I	91% were measured at 1 yr	Visual outcome: 2.2% had BCVA of <20/200 attributable to surgical complications Corneal edema: none Glaucoma escalation: 1.3% Cystoid macular edema: 0.2% Lens tilt or dislocation: not specified Retinal detachment: none Endophthalmitis: 0.4%	Visual outcome: 1.7% had BCVA of <20/200 attributable to surgical complications (NS) Corneal edema: 0.1% Glaucoma escalation: 0.2% ($P = 0.05$) Cystoid macular edema: none Lens tilt or dislocation: NA Retinal detachment: 0.4% Endophthalmitis: 0.7%

AC IOLs = anterior chamber intraocular lenses; BCVA = best-corrected visual acuity; ICCE = intracapsular cataract extraction; NA = not applicable; NS = not significant.

Published Results

Open-loop AC IOLs, scleral-sutured PC IOLs, and iris-sutured PC IOLs were evaluated with respect to their use in eyes without adequate capsular support in specific clinical situations.[11–53] Visual outcome and safety data were analyzed separately for IOL implantation associated with cataract surgery or penetrating keratoplasty. Results with cataract surgery were analyzed separately for primary and secondary IOL insertion and in complicated and uncomplicated cases.

The principal outcome indicator was final best-corrected visual acuity (BCVA). This indicator was usually reported as the percentage of eyes achieving a visual acuity of 20/40 or better and the percentage of eyes that had a visual acuity of 20/200 or worse. Specific complications extracted from each clinical series were corneal edema or graft failure, glaucoma escalation, CME, lens tilt or dislocation, retinal detachment, and endophthalmitis. "Glaucoma escalation" was defined in this assessment as the development of new-onset glaucoma or the need for more aggressive control of preexisting glaucoma with one or more additional medications or surgical intervention. Many of the series reported glaucoma data using this definition. In series that did not use this definition, it was usually possible to extract and translate the data into this reporting mechanism. "Lens tilt or dislocation" was defined as decentration along the horizontal or vertical meridian (tilt) or actual displacement into the vitreous (dislocation). Of all of the complications reviewed, this was the one most likely not to be specified by the authors.

It is necessary to emphasize that there was considerable variability among the investigators in the definition, tabulation, and diligence in detecting and reporting surgical complications. For example, variation in the incidence of corneal edema or graft failure between series could be attributed, in part, to variable investigator threshold for reporting edema (e.g., merely clinically detectable vs. visually significant) or to the length of follow-up. Considerable variation in the rates of CME could have been related to the relative diligence in obtaining angiographic documentation of this complication.

Open-loop Anterior Chamber Intraocular Lenses

Clinical evidence is available for the evaluation of the safety and outcome of primary flexible, open-loop AC IOL insertion during uncomplicated[11] and complicated[12–18] cataract surgery and secondary open-loop AC IOL insertion after uncomplicated[15,16,19,20] or complicated[14,16,21,22] cataract surgery or at the time of penetrating keratoplasty.[23–29]

Cataract Surgery. One large prospective clinical trial provided data about the safety and outcome of *primary* open-loop AC IOL insertion vs. no IOL insertion at the time of *uncomplicated intracapsular cataract surgery* (Table 1A).[11] The frequency with which surgical complications resulted in a final visual outcome of less than 20/200 was not statistically different in the AC IOL group vs. the no IOL group (2.2% vs. 1.7%). There was a statistically significant escalation in glaucoma after AC IOL insertion vs. no IOL insertion (1.3% vs. 0.2%, $P = 0.05$), but no significant difference between the two groups in the incidence of corneal edema, CME, retinal detachment, or endophthalmitis.

Seven clinical case series provided data about the safety and outcome following *primary* open-loop AC IOL insertion at the conclusion of *complicated cataract surgery* (Table 1B).[12–18] In five of these series, an open-loop AC IOL was inserted after extracapsular cataract extraction (ECCE) in which posterior capsule complications precluded placement of a PC IOL in the capsular bag or ciliary sulcus.[12–16] When the results are combined, 123 (68.3%) of 180 eyes achieved a BCVA of 20/40 or better, whereas 6 (4.2%) of 143 eyes (one series did not specify the number of patients who had a visual acuity of 20/200 or worse) achieved a final visual acuity of 20/200 or worse, due to CME (5 cases) and

Table 1B. Open-loop AC IOLs. Complicated ECCE: Primary Insertion of AC IOLs

Study	Type of Study	Number	Level of Evidence	Follow-up	Results
Rattigan et al[12]	Case series	50	III	Mean = not specified Range = 3–81 mos	Visual outcome 20/40 or better: 41 (82%) 20/200 or worse: none Corneal edema: none Glaucoma escalation: 1 (2%) Cystoid macular edema: 3 (6%) Lens tilt or dislocation: none Retinal detachment: 2 (4%) Endophthalmitis: none
Bergman and Laatikainen[13]	Case series	40	III	Mean = 28 mos Range = 6–77 mos	Visual outcome 20/40 or better: 27 (67.5%) 20/400 or worse: 4 (10%) Corneal edema: none Glaucoma escalation: 6 (15%) Cystoid macular edema: 5 (12.5%) Lens tilt or dislocation: none Retinal detachment: none Endophthalmitis: none
Hykin et al[14]	Case series	37	III	Mean = not specified Range = 24–42 mos	Visual outcome 20/40 or better: 23 (64%) 20/200 or worse: not specified Cornea edema: 1 (3%) Glaucoma escalation: 4 (11%) Cystoid macular edema: 5 (14%) Lens tilt or dislocation: none Retinal detachment: 1 (3%) Endophthalmitis: none
Bayramlar et al[15]	Case series	35	III	Mean = not specified Range = 12–38 mos	Visual outcome 20/40 or better: 19 (65%) 20/200 or worse: 1 (3%) Corneal edema: 1 (3%) Glaucoma escalation: 1 (3%) Cystoid macular edema: 2 (6%) Lens tilt or dislocation: none Retinal detachment: none Endophthalmitis: none
Weene[16]	Case series	18	III	14 were followed for >12 mos 4 were followed for <12 mos	Visual outcome 20/40 or better: 13 (72%) 20/200 or worse: 1 (5%) Corneal edema: none Glaucoma escalation: 1 (5%) Cystoid macular edema: 4 (22%) Lens tilt or dislocation: 2 (11%) Retinal detachment: 1 (5%) Endophthalmitis: none
Kazemi et al[17]	Case series	36	III	Mean = 14 mos Range = 1–59 mos	Visual outcome 20/40 or better: 27 (75%) 20/200 or worse: 1 (3%) Corneal edema: none Glaucoma escalation: none Cystoid macular edema: 3 (8%) Lens tilt or dislocation: none Retinal detachment: 2 (5%) Endophthalmitis: none
Omulecki et al[18]	Case series	12	III	Mean = 5.8 mos Range = 2–10 mos	Visual outcome 20/40 or better: 9 (75%) 20/200 or worse: none Corneal edema: none Glaucoma escalation: none Cystoid macular edema: 1 (12.5%) Lens tilt or dislocation: none Retinal detachment: none Endophthalmitis: none

AC IOLs = anterior chamber intraocular lenses; ECCE = extracapsular cataract extraction.

Table 1C. Open-loop AC IOLs. Uncomplicated ICCE: Secondary Insertion of AC IOLs

Study	Type of Study	Number	Level of Evidence	Follow-up	Results
Bayramlar et al[15]	Case series	22	III	Mean = not specified Range = 12–31 mos	Visual outcome 20/40 or better: 16 (76.5%) 20/200 or worse: none Corneal edema: none Glaucoma escalation: none Cystoid macular edema: 1 (5%) Lens tilt or dislocation: none Retinal detachment: none Endophthalmitis: none
Weene[16]	Case series	28	III	25 were followed for >12 mos 3 were followed for <12 mos	Visual outcome: 23 (82%) were equal to, or better than, preoperative BCVA Corneal edema: 4 (14%) Glaucoma escalation: 1 (7%) Cystoid macular edema: 1 (7%) Lens tilt or dislocation: 1 (7%) Retinal detachment: none Endophthalmitis: none
Ellerton et al[19]	Case series	81	III	Not specified	Visual outcome 20/40 or better: 60 (75.0%) 20/200 or worse: 3 (3.7%) Corneal edema: 2 (2.5%) Glaucoma escalation: not specified Cystoid macular edema: 2 (2.5%) Lens tilt or dislocation: none Retinal detachment: 2 (2.5%) Endophthalmitis: none
Drolsum and Haaskjold[20]	Case series	22	III	Not specified	Visual outcome 20/40 or better: 17 (77%) 20/200 or worse: none Corneal edema: none Glaucoma escalation: none Cystoid macular edema: 1 (5%) Lens tilt or dislocation: none Retinal detachment: none Endophthalmitis: none

AC IOLs = anterior chamber intraocular lenses; BCVA = best-corrected visual acuity; ICCE = intracapsular cataract extraction.

pseudophakic corneal edema (1 case). In the other two series, a primary open-loop AC IOL was inserted after the removal of a dislocated crystalline lens by pars plana lensectomy, which precluded placement of a primary PC IOL in the capsular bag or ciliary sulcus.[17,18] The aggregate results were that 36 (75%) of 48 eyes achieved a BCVA of 20/40 or better. Only one (2.1%) eye had a final BCVA of 20/200 or worse, secondary to a retinal detachment.

Four clinical series provided data about the safety and outcome of *secondary* open-loop AC IOL insertion after *uncomplicated intracapsular cataract surgery* (Table 1C).[15,16,19,20] The collective results were that 136 (90.1%) of 151 eyes achieved a postoperative BCVA within one Snellen line or better than preoperatively. The loss of two or more lines of Snellen acuity in 15 (9.9%) of 151 eyes was due to pseudophakic corneal edema (6 eyes), CME (4 eyes), retinal detachment (2 eyes), and not specified (3 eyes).

Four clinical case series provided data about the safety and outcome of *secondary* AC IOL insertion after *complicated cataract surgery* (Table 1D).[14,16,21,22] In two of these series, posterior capsule complications during ECCE precluded placement of a primary PC IOL in the capsular bag or ciliary sulcus.[14,16] The combined results of these two studies were that 20 (80%) of 25 eyes achieved a postoperative BCVA within one line of Snellen acuity or better than preoperatively. The loss of two or more lines of Snellen acuity was due to CME (3 eyes), pseudophakic corneal edema (1 eye), and retinal detachment (1 eye). In the other two series, secondary AC IOL insertion was performed at the time of removal of nuclear fragments that resulted during complicated cataract surgery or at the time of removal of a PC IOL that had dislocated into the posterior segment.[21,22] The aggregate results were that 11 (84.6%) of 13 eyes achieved a postoperative BCVA within one line of Snellen acuity or better. Both cases of loss of two or more lines of Snellen acuity were due to CME.

Penetrating Keratoplasty. Seven clinical case series provided data about the safety and outcome of *secondary* open-loop AC IOL insertion at the time of *penetrating keratoplasty* for pseudophakic or aphakic corneal edema (Table 1E).[23–29] Almost all 352 cases reported in these series were due to pseudophakic corneal edema in which IOL exchange for an open-loop AC IOL was performed. In most cases, a closed-loop AC IOL, inserted at the time of complicated cataract surgery in which capsular support was lost, was explanted. In a few cases, corneal edema or

Table 1D. Open-loop AC IOLs. Complicated Cataract Surgery: Secondary Insertion of AC IOLs

Study	Type of Study	Number	Level of Evidence	Follow-up	Results
Hykin et al[14]	Case series of ECCE	10	III	Mean = not specified Range = 24–42 mos	Visual outcome 20/40 or better: 6 (60%) 20/200 or worse: not specified Corneal edema: none Glaucoma escalation: none Cystoid macular edema: 3 (30%) Lens tilt or dislocation: none Retinal detachment: 1 (10%) Endophthalmitis: none
Weene[16]	Case series of ECCE	15	III	11 were followed for >12 mos 4 were followed for <12 mos	Visual outcome: 14 (93%) were equal to, or better than, preoperative BCVA Corneal edema: 1 (7%) Glaucoma escalation: none Cystoid macular edema: none Lens tilt or dislocation: none Retinal detachment: none Endophthalmitis: none
Malinowksi et al[21]	Case series with concurrent removal of nuclear fragments	6	III	Mean = 14 mos Range = 1–41 mos	Visual outcome 20/40 or better: 3 (50%) 20/200 or worse: 1 (17%) Corneal edema: none Glaucoma escalation: none Cystoid macular edema: 2 (33%) Lens tilt or dislocation: none Retinal detachment: none Endophthalmitis: none
Mittra et al[22]	Case series with concurrent removal of dislocated PC IOLs	7	III	Mean = 14.8 mos Range = 2.5–54 mos	Visual outcome 20/40 or better: 5 (71.4%) 20/200 or worse: 1 (14.3%) Corneal edema: none Glaucoma escalation: none Cystoid macular edema: 1 (14.3%) Lens tilt or dislocation: none Retinal detachment: none Endophthalmitis: none

AC IOLs = anterior chamber intraocular lenses; BCVA = best-corrected visual acuity; ECCE = extracapsular cataract extraction; PC IOLs = posterior chamber intraocular lenses.

scarring was present in an eye that was aphakic, but did not have adequate capsular support for placement of a PC IOL in the capsular bag or ciliary sulcus. When these data are pooled, 124 (35.2%) of 352 eyes achieved a BCVA of 20/40 or better and 124 (35.2%) of 352 eyes had a BCVA of 20/200 or worse. When specifically tabulated in the reported series, the overall incidence of graft failure was 12.5%, glaucoma escalation was 28.4%, and CME was 19.0%. Retinal detachment occurred in 6 (1.7%) of 352 eyes. Lens tilt or dislocation was not reported.

Scleral-sutured Posterior Chamber Intraocular Lenses

Clinical evidence is available for evaluation of the safety and outcome of primary scleral-sutured PC IOL insertion during complicated cataract surgery[18,30–33] and of secondary scleral-sutured PC IOL insertion either after uncomplicated cataract surgery[32–35] or at the time of penetrating keratoplasty.[24,28,36–42]

Cataract Surgery. Five clinical case series provided data about the safety and outcome after *primary* scleral-sutured PC IOL insertion at the conclusion of *complicated cataract surgery* (Table 2A).[18,30–33] In three of these series, a scleral-sutured PC IOL was inserted after ECCE in which posterior capsule complications precluded placement of a PC IOL in the capsular bag or ciliary sulcus.[30–32] The combined results were 33 (80.5%) of 41 eyes achieved a BCVA of 20/40 or better, whereas only 2 (4.9%) of 41 eyes achieved a final visual acuity of 20/200 or worse due to retinal detachment (1 eye) and CME (1 eye). In the other two series, a scleral-sutured PC IOL was inserted after the removal of a dislocated crystalline lens by either ICCE[33] or pars plana lensectomy,[18] which precluded placement of a primary PC IOL in the capsular bag or ciliary sulcus. After pars plana lensectomy, all 10 (100%) eyes achieved a BCVA of 20/40 or better, compared with only 7 (54%) of 13 eyes achieving a similar result after ICCE. Three (23%) of 13 eyes with ICCE had a BCVA of 20/200 or worse due to corneal edema (2 eyes) and retinal detachment (1 eye).

Four clinical series provided data about the safety and outcome of *secondary* scleral-sutured PC IOL insertion after *uncomplicated cataract surgery* (Table 2B)[32–35] Almost all of these cases were in eyes that were monocularly

Table 1E. Open-loop AC IOLs. Penetrating Keratoplasty: Secondary Insertion of AC IOLs

Study	Type of Study	Number	Level of Evidence	Follow-up	Results
Lois et al[23]	Case series	101	III	Mean = 49.8 mos Range = 1–144 mos	Visual outcome 20/40 or better: 33 (32.7%) 20/200 or worse: 32 (31.6%) Corneal edema/graft failure: 18 (18%) Kaplan-Meier analysis of probability of clear graft: 1 yr = 93% 2 yrs = 87% 4 yrs = 78% 6 yrs = 65% 8 yrs = 65% Glaucoma escalation: 46 (45.5%) Cystoid macular edema: 14 (14%) Lens tilt or dislocation: not specified Retinal detachment: 2 (2%) Endophthalmitis: none
Brunette et al[24]	Case series	90	III	Mean = 25.2 mos Range = 4.4–46.3 mos	Visual outcome 20/40 or better: 19 (21.1%) 20/200 or worse: 47 (52.2%) Corneal edema/graft failure: exact failure rate not specified Kaplan-Meier survival curve: 1 yr = 86.2% 2 yrs = 75.3% Glaucoma escalation: 21 (29.6%) Cystoid macular edema: not specified Lens tilt or dislocation: none Retinal detachment: none Endophthalmitis: none
Hassan et al[25]	Case series	40	III	Mean = 24.5 mos Range = 3–51 mos	Visual outcome 20/40 or better: 17 (42.5%) 20/200 or worse: 10 (25%) Corneal edema/graft failure: 5 (12.5%) Endothelial cell loss compared to preoperative values was 11.5% at 1 yr, 21.3% at 2 yrs, and 25.0% at 3 yrs Glaucoma escalation: 16 (40%) Cystoid macular edema: 13 (32.5%) Lens tilt or dislocation: not specified Retinal detachment: 1 (2.5%) Endophthalmitis: none
Kornmehl et al[26]	Case series	40	III	Mean = 24 mos Range = 7–59 mos	Visual outcome 20/40 or better: 23 (57.5%) 20/200 or worse: 11 (27.5%) Mean = 20/44 Corneal edema/graft failure: 2 (5%) Glaucoma escalation: 7 (12.5%) Cystoid macular edema: 4 (10%) Lens tilt or dislocation: not specified Retinal detachment: 1 (2.5%) Endophthalmitis: none
Zaidman and Goldman[27]	Case series	36	III	Mean = 15 mos Range = 3–32 mos	Visual outcome 20/40 or better: 11 (31%) 20/200 or worse: 13 (36%) Corneal edema/graft failure: 5 (14%) Glaucoma escalation: 5 (14%) Cystoid macular edema: 9 (25%) Lens tilt or dislocation: not specified Retinal detachment: 1 (3%) Endophthalmitis: none

(continues)

aphakic because of previous ICCE. Eighty-two (97.6%) of 84 eyes achieved a postoperative BCVA within one Snellen line or better than preoperatively. Two eyes lost more than two lines of Snellen acuity due to endophthalmitis (1 eye) and CME (1 eye).

Penetrating Keratoplasty. Nine clinical case series provided data about the safety and outcome of *secondary* scleral-sutured PC IOL insertion at the time of *penetrating keratoplasty* for pseudophakic or aphakic corneal edema (Table 2C).[24,28,36–42,10] Almost all of the 471 cases reported

Table 1E (*continues*). Open-loop AC IOLs. Penetrating Keratoplasty: Secondary Insertion of AC IOLs

Study	Type of Study	Number	Level of Evidence	Follow-up	Results
Lass et al[28]	Case series	25	III	Data analyzed at 3, 6, and 12 mos	Visual outcome 20/40 or better: 6 (24%) 20/400 or worse: 6 (24%) Corneal edema/graft failure: 3 (12%) Endothelial cell loss compared to preoperative values was 32% at 12 mos Glaucoma escalation: none Cystoid macular edema: not specified Lens tilt or dislocation: not specified Retinal detachment: none Endophthalmitis: none
Koenig et al[29]	Case series	20	III	Mean = 15 mos Range = 4–45 mos	Visual outcome 20/40 or better: 15 (75%) 20/200 or worse: 5 (25%) Corneal edema/graft failure: none Glaucoma escalation: 5 (25%) Cystoid macular edema: 5 (25%) Lens tilt or dislocation: none Retinal detachment: 1 (5%) Endophthalmitis: none

AC IOLs = anterior chamber intraocular lenses.

in these clinical series were due to pseudophakic corneal edema in which IOL exchange for a scleral-sutured PC IOL was performed. In most cases, a closed-loop AC IOL, which was inserted at the time of complicated cataract surgery in which capsular support was lost, was the explanted lens. In a few cases, an IOL had not been inserted at the time of the original cataract surgery.

In the combined results of these series, nearly 40% of eyes achieved a BCVA of 20/40 or better and approximately 35% had a BCVA of 20/200 or worse. In the two largest series,[36,37] 100 (46.1%) of 217 eyes achieved a BCVA of 20/40 or better, whereas 68 (31.3%) of 217 eyes achieved a BCVA of 20/200 or worse. Graft failure occurred in 17 (7.8%) eyes; glaucoma escalation, in 80 (36.9%) eyes; CME, in 30 (13.8%) eyes; erosion of the suture through the conjunctiva, in 38 (17.5%) eyes; and retinal detachment, in 7 (3.2%) eyes. In the other seven series,[24,28,38–42] the visual outcomes and complications were similar. In all nine series, lens tilt or dislocation was reported in 7 (1.5%) eyes.

Iris-sutured Posterior Chamber Intraocular Lenses

Clinical evidence is available for evaluating the safety and outcome of secondary iris-sutured PC IOLs after uncomplicated[42,43] and complicated[42,43] cataract surgery or at the time of penetrating keratoplasty.[44–47,53]

Cataract Surgery. Two clinical series provided data about the safety and outcome of *secondary* iris-sutured PC IOLs after both *uncomplicated* (Table 3A) and *complicated cataract surgery* (Table 3B).[42,43] In the reported cases after uncomplicated ICCE, 25 (96.1%) of 26 eyes achieved a postoperative BCVA within one Snellen line or better than preoperatively. The decreased postoperative vision in the one eye was because of CME. In the reported cases in which either complicated ECCE with capsular complications or ICCE for a dislocated crystalline lens precluded insertion of a primary PC IOL, all 23 (100%) eyes achieved a postoperative BCVA equal to, or better than, preoperatively (Table 3B).[42,43]

Penetrating Keratoplasty. Five clinical case series provided data about the safety and outcome of *secondary* iris-sutured PC IOLs at the time of *penetrating keratoplasty* (Table 3C).[44–47,53] Most of the cases had pseudophakic corneal edema, in which IOL exchange of a closed-loop AC IOL for an iris-sutured PC IOL was performed. In a few cases, corneal edema or scarring was present in an eye that was aphakic, but did not have adequate capsular support for placement of a PC IOL in the capsular bag or ciliary sulcus.

In the two largest series,[44,53] 154 (47.2%) of 326 eyes achieved a BCVA of 20/40 or better, whereas 100 (30.7%) had a visual acuity of 20/100 or worse. The most common reasons for poor visual outcome were graft failure, macular edema and degeneration, and glaucoma. Glaucoma escalation was a major problem in the four series that reported this complication, with an overall incidence of 31.2%.[44–47] Lens tilt or dislocation was reported in two cases in one series,[53] but not specified in the other four series.[44–47]

Open-loop Anterior Chamber IOLs vs. Scleral- or Iris-sutured Posterior Chamber Intraocular Lenses

Clinical evidence is available for evaluating the safety and outcome of open-loop AC IOLs vs. scleral- or iris-sutured PC IOLs after cataract surgery[48,49] and at the time of penetrating keratoplasty.[50–52]

Cataract Surgery. Two clinical series provided data about the safety and outcome of *secondary* open-loop AC IOLs vs. scleral-sutured PC IOLs after *cataract surgery* (Table 4A).[48,49] Neither of these series was prospective or

Table 2A. Scleral-sutured PC IOLs. Complicated Cataract Surgery: Primary Suturing of PC IOLs in Ciliary Sulcus

Study	Type of Study	Number	Level of Evidence	Follow-up	Results
Omulecki et al[18]	Case series of pars plana lensectomy	10	III	Mean = 5.8 mos Range = 2–10 mos	Visual outcome 20/40 or better: 10 (100%) 20/200 or worse: none Corneal edema: none Glaucoma escalation: none Cystoid macular edema: none Lens tilt or dislocation: none Suture erosion: none Retinal detachment: none Endophthalmitis: none
Mittlelviefhaus and Witschel[30]	Case series of ECCE	21	III	Mean = 29.5 mos Range = 6–63 mos	Visual outcome 20/40 or better: 17 (80.9%) 20/200 or worse: 1 (4.7%) Corneal edema: none Glaucoma escalation: 1 (4.7%) Cystoid macular edema: 3 (14.3%) Lens tilt or dislocation: 1 (4.7%) Suture erosion: not specified Retinal detachment: 2 (9.5%) Endophthalmitis: none
Lanzetta et al[31]	Case series of ECCE	14	III	Mean = 9.8 mos Range = 3–26 mos	Visual outcome 20/40 or better: 10 (71.4%) 20/200 or worse: 1 (7.1%) Mean = 20/30 Corneal edema: none Glaucoma escalation: none Cystoid macular edema: 6 (42.9%) (fluorescein angiography done on all eyes) Lens tilt or dislocation: 1 (7.1%) Suture erosion: not specified Retinal detachment: none Endophthalmitis: none
Chang and Lee[32]	Case series of ECCE	6	III	Mean = 15.3 mos Range = 12–19 mos	Visual outcome 20/40 or better: 6 (100%) 20/200 or worse: none Corneal edema: none Glaucoma escalation: none Cystoid macular edema: none Lens tilt or dislocation: not specified Suture erosion: not specified Retinal detachment: none Endophthalmitis: none
Menezo et al[33]	Case series of ICCE	13	III	Not specified	Visual outcome 20/40 or better: 7 (53.8%) 20/200 or worse: 3 (23.0%) Corneal edema: 2 (15.3%) Glaucoma escalation: 2 (15.3%) Cystoid macular edema: 1 (7.6%) Lens tilt or dislocation: 3 (23.0%) Suture erosion: none Retinal detachment: 1 (7.6%) Endophthalmitis: none

ECCE = extracapsular cataract extraction; ICCE = intracapsular cataract extraction; PC IOLs = posterior chamber intraocular lenses.

randomized, and both had an evidence rating of IIIC. In the series by Lyle and Jin,[48] there was little difference between visual outcomes and complication rates when open-loop AC IOLs and scleral-sutured PC IOLs were compared. In eyes without preexisting pathology, a BCVA of 20/40 or better was obtained in 92.6% of eyes with an open-loop AC IOL and 91.4% of eyes with a scleral-sutured PC IOL. In eyes with preexisting pathology that was expected to potentially compromise the visual outcome, 67.4% of eyes with an open-loop AC IOL and 66.0% of eyes with a scleral-sutured PC IOL achieved a BCVA of 20/40 or better. The incidence of corneal edema and glaucoma escalation was slightly higher with open-loop AC IOLs than with scleral-sutured PC IOLs (3.4% vs. 0.9% and 1.7% vs. 0.9%, respectively). The incidence of CME, retinal detachment, and endophthalmitis was slightly higher with scleral-sutured PC IOLs than with open-loop AC IOLs (6.1% vs. 5.9%, 3.5% vs. 0.9%, and 0.9% vs. 0%, respectively). In the smaller series

Table 2B. Scleral-sutured PC IOLs. Uncomplicated Cataract Surgery: Secondary Suturing of PC IOLs in Ciliary Sulcus

Study	Type of Study	Number	Level of Evidence	Follow-up	Results
Chang and Lee[32]	Case series	18	III	Mean = 14.0 mos Range = 12–21 mos	Visual outcome 20/40 or better: 14 (77.8%) 20/200 or worse: 3 (16.7%) Corneal edema: 2 (11.1%) Glaucoma escalation: 1 (5.6%) Cystoid macular edema: none Lens tilt or dislocation: not specified Suture erosion: not specified Retinal detachment: none Endophthalmitis: none
Menezo et al[33]	Case series	13	III	Not specified	Visual outcome 20/40 or better: 10 (76.9%) 20/200 or worse: 2 (15.3%) Corneal edema: 1 (7.6%) Glaucoma escalation: 4 (30.7%) Cystoid macular edema: 1 (7.6%) Lens tilt or dislocation: 2 (15.3%) Suture erosion: none Retinal detachment: none Endophthalmitis: 1 (7.6%)
Helal et al[34]	Case series	41	III	Mean = 12 mos Range = not specified	Visual outcome 20/40 or better: 25 (61.0%) 20/200 or worse: none Corneal edema: none Glaucoma escalation: 1 (2.4%) Cystoid macular edema: none Lens tilt or dislocation: 1 (2.4%) Suture erosion: not specified Retinal detachment: 1 (2.4%) Endophthalmitis: none
McCluskey and Harrisberg[35]	Case series	12	III	Mean = 14.6 mos Range = 6–31 mos	Visual outcome 20/40 or better: 7 (58.3%) 20/200 or worse: 2 (16.7%) Corneal edema: none Glaucoma escalation: none Cystoid macular edema: none Lens tilt or dislocation: none Suture erosion: 1 (8.3%) Retinal detachment: none Endophthalmitis: none

PC IOLs = posterior chamber intraocular lenses.

by Belluci et al,[49] identical mean BCVA (20/26) was obtained with either open-loop AC IOLs or scleral-sutured PC IOLs, and a similarly low incidence of complications was reported in both groups.

Penetrating Keratoplasty. Three clinical series provided data about the safety and outcome of *secondary* open-loop AC IOLs vs. scleral- or iris-sutured PC IOLs[50,52] and open-loop AC IOLs vs. iris-sutured PC IOLs (Table 4B).[51] One series, which compared all three IOL types was a prospective, randomized trial with an evidence rating of IB[50]; whereas the second series, providing the same comparison, was a nonrandomized clinical series with an evidence rating of IIIC.[52] The third series, which compared AC IOLs vs. iris-sutured PC IOLs, was a longitudinal cohort study with an evidence rating of IIB.[51]

In the prospective, randomized trial by Schein et al,[50] all three IOL types were associated with a low incidence of BCVA of 20/40 or better (15%–20%). There was a slightly lower, but statistically insignificant difference in the incidence of BCVA of 20/200 or worse with iris-sutured PC IOLs (35.3%) vs. scleral-sutured PC IOLs (45.4%) or open-loop AC IOLs (46.9%). This finding may be attributable to a statistically significant lower incidence of CME with iris-sutured PC IOLs vs. both scleral-sutured PC IOLs ($P = 0.02$) and open-loop AC IOLs ($P = 0.02$). There were no statistically significant differences comparing the incidence of corneal edema with that of CME. In the smaller clinical series by Davis et al,[52] there was a much higher incidence of glaucoma escalation with both scleral- and iris-sutured PC IOLs vs. open-loop AC IOLs, but these differences were not amenable to statistical analysis because the study was not randomized.

The longitudinal cohort study by Sugar[51] focused primarily on differences in corneal endothelial attrition from open-loop AC IOLs vs. iris-sutured PC IOLs during the first 2 years after penetrating keratoplasty. There was no statistically significant difference between the two groups, although slightly higher endothelial cell loss occurred with

Table 2C. Scleral-sutured PC IOLs. Penetrating Keratoplasty: Secondary Suturing of PC IOLs in Ciliary Sulcus

Study	Type of Study	Number	Level of Evidence	Follow-up	Results
Brunette et al[24]	Case series	32	III	Mean = 19.2 mos Range = 5.2–28.5 mos	Visual outcome 20/40 or better: 11 (34.3%) 20/200 or worse: 10 (31.2%) Corneal edema/failure: exact failure rate not specified Kaplan-Meier survival curve: 1 yr = 90.2% 2 yrs = 79.1% Glaucoma escalation: 1 (3.1%) Cystoid macular edema: not specified Lens tilt or dislocation: none Suture erosion: not specified Retinal detachment: none Endophthalmitis: none
Lass et al[28]	Case series	24	III	Data analyzed at 3, 6, and 12 mos	Visual outcome 20/40 or better: 7 (29%) 20/400 or worse: 6 (25%) Corneal edema/failure: 1 (4%) Endothelial cell loss compared to preoperative values was 27% at 12 mos Glaucoma escalation: 1 (4%) Cystoid macular edema: not specified Lens tilt or dislocation: not specified Suture erosion: not specified Retinal detachment: none Endophthalmitis: none
Heidemann and Dunn[36]	Case series	112	III	Mean = 17.2 mos Range = 4–47 mos	Visual outcome 20/40 or better: 17 (15.2%) 20/100 or worse: 29 (25.9%) Corneal edema/failure: 14 (12.5%) Glaucoma escalation: 48 (42.9%) Cystoid macular edema: 20 (17.9%) Lens tilt or dislocation: 3 (2.7%) Suture erosion: 17 (15.2%) Retinal detachment: 3 (2.7%) Endophthalmitis: none
Holland et al[37]	Case series	105	III	Mean = 26.8 mos Range = 6–43 mos	Visual outcome 20/40 or better: 29 (27.6%) 20/200 or worse: 39 (37.1%) Corneal edema/failure: 3 (2.9%) Glaucoma escalation: 32 (30.4%) Cystoid macular edema: 10 (9.5%) Lens tilt or dislocation: not specified Suture erosion: 21 (20%); 16 with conjunctival cover, 5 with scleral flap Retinal detachment: 4 (3.8%) Endophthalmitis: none
Walter et al[38]	Case series	89	III	Mean = 24.4 mos Range = 4–68 mos	Visual outcome 20/40 or better: not specified 20/200 or worse: not specified Mean: 20/70 Corneal edema/failure: 3 (3.3%) Glaucoma escalation: not specified Cystoid macular edema: not specified Lens tilt or dislocation: 2 (3.3%) Suture erosion: 6 (6.7%) Retinal detachment: 1 (1.1%) Endophthalmitis: not specified
Hill[39]	Case series	36	III	Mean = 16.8 mos Range = 9–36 mos	Visual outcome 20/40 or better: 16 (44.4%) 20/200 or worse: 11 (30.6%) Corneal edema/failure: 2 (5.5%) Glaucoma escalation: not specified Cystoid macular edema: 10 (27.8%) Lens tilt or dislocation: none Suture erosion: none Retinal detachment: none Endophthalmitis: not specified

(continues)

Table 2C (*continues*). Scleral-sutured PC IOLs. Penetrating Keratoplasty: Secondary Suturing of PC IOLs in Ciliary Sulcus

Study	Type of Study	Number	Level of Evidence	Follow-up	Results
Kocak-Altinas et al[40]	Case series	29	III	Mean = 22.8 mos Range = 14–31 mos	Visual outcome 20/40 or better: not specified 20/200 or worse: 23 (79.3%) Corneal edema/failure: 2 (6.9%) Glaucoma escalation: 7 (24.1%); 5 new onset Cystoid macular edema: 8 (27.6%) Lens tilt or dislocation: 2 (6.9%) Suture erosion: not specified Retinal detachment: none Endophthalmitis: 1 (3.4%)
Jensen et al[41]	Case series	21	III	Mean = 13 mos Range = 2–39 mos	Visual outcome 20/40 or better: 2 (9.5%) 20/200 or worse: 5 (23.8%) Corneal edema/failure: 1 (4.8%) Glaucoma escalation: 4 (19.0%) Cystoid macular edema: 1 (4.8%) Lens tilt or dislocation: none Suture erosion: 3 (14.3%) Retinal detachment: none Endophthalmitis: none
Hoh et al[42]	Case series	13	III	Mean = 14.5 mos Range = 2–21 mos	Visual outcome 20/40 or better: 1 (7.7%) 20/200 or worse: 11 (84.6%) Graft edema/failure: none Glaucoma escalation: 5 (3.8%) Cystoid macular edema: 3 (2.3%) Lens tilt or dislocation: none Suture erosion: none Retinal detachment: none Endophthalmitis: none

PC IOLs = posterior chamber intraocular lenses.

iris-sutured PC IOLs at 1 (19.0% vs. 16.5%) and 2 years (38.2% vs. 28.4%).

Table 3A. Iris-sutured PC IOLs. Uncomplicated Cataract Surgery: Secondary Suturing of PC IOLs to Iris

Study	Type of Study	Number	Level of Evidence	Follow-up	Results
Hoh et al[42]	Case series	6	III	Mean = 12.0 mos Range = 9–14 mos	Visual outcome 20/40 or better: 4 (67%) 20/200 or worse: 1 (17%) Corneal edema: none Glaucoma escalation: not specified Cystoid macular edema: 1 (16.7%) Lens tilt or dislocation: none Suture erosion: not specified Retinal detachment: none Endophthalmitis: none
Navia-Aray[43]	Case series	20	III	Mean = 40 mos Range = 24–64 mos	Visual outcome 20/40 or better: 13 (65%) 20/200 or worse: none Corneal edema: none Glaucoma escalation: 1 (5%) Cystoid macular edema: 1 (5%) Lens tilt or dislocation: none Suture erosion: not specified Retinal detachment: none Endophthalmitis: none

PC IOLs = posterior chamber intraocular lenses.

Table 3B. Iris-sutured PC IOLs. Complicated Cataract Surgery: Secondary Suturing of PC IOLs to Iris

Study	Type of Study	Number	Level of Evidence	Follow-up	Results
Hoh et al[42]	Case series	13	III	Mean = 11.9 mos Range = 7–18 mos	Visual outcome 20/40 or better: 8 (61.5%) 20/200 or worse: 1 (7.7%) Corneal edema: none Glaucoma escalation: not specified Cystoid macular edema: none Lens tilt or dislocation: none Suture erosion: not specified Retinal detachment: none Endophthalmitis: none
Navia-Aray[43]	Case series	10	III	Mean = 40 mos Range = 27–63 mos	Visual outcome 20/40 or better: 6 (60%) 20/200 or worse: none Corneal edema: none Glaucoma escalation: 3 (30%) Cystoid macular edema: 1 (10%) Lens tilt or dislocation: none Suture erosion: not specified Retinal detachment: none Endophthalmitis: none

PC IOLs = posterior chamber intraocular lenses.

Discussion of Results

Open-loop Anterior Chamber Intraocular Lenses

Modern open-loop AC IOLs are not susceptible to the unacceptably high rates of corneal endothelial decompensation, secondary glaucoma, and CME associated with closed-loop AC IOLs.[1–8] In the series analyzing open-loop AC IOLs individually[11–29] or comparing them to scleral-[48–50,52] or iris-sutured PC IOLs,[50–52] there was no evidence to suggest that visual outcomes were less satisfactory with open-loop AC IOLs.

Currently, a prospective study of *primary* open-loop AC IOL insertion after *uncomplicated cataract surgery* is not indicated, because extracapsular techniques that retain the posterior capsule and permit placement of a PC IOL are now the cataract procedures of choice. Fortunately, Hennig et al[11] has provided extensive prospective data regarding the outcome of open-loop AC IOL insertion after uncomplicated ICCE and compared the outcome to a control population not receiving an IOL, thereby permitting analysis of the actual risks introduced by the IOL itself. This study was large enough to detect clinically meaningful differences in complication rates. Hennig et al confirmed that the placement of an open-loop AC IOL did not result in a statistically significant increase in corneal decompensation or CME vs. no IOL. There was a statistically significant escalation in glaucoma with IOL insertion vs. no IOL insertion, but the actual percentage of patients developing this complication was relatively low (1.3%), suggesting that this statistically significant difference is not clinically meaningful. This study supports the recommendation that primary insertion of an open-loop AC IOL in settings in which high-volume intracapsular cataract surgery is being performed is acceptable practice. The optical problems of monocular or bilateral aphakia in these patients outweigh the very low risk of developing secondary glaucoma attributable to the AC IOL in these settings.

Clinical studies support the use of *primary* open-loop AC IOLs inserted at the time of *complicated cataract surgery* (most frequently, ECCE with posterior capsule tear with or without vitreous loss). In seven clinical series, good visual acuity was obtained in most cases and the complication rate was low.[12–18] The most common cause of visual loss was CME, but it is impossible to attribute the cause of the CME to the AC IOL or to the surgical complications (e.g., capsule rupture, vitrectomy) in the absence of a control group. The safety and efficacy of an AC IOL is indirectly demonstrated by comparing best-corrected preoperative vs. postoperative visual acuity in eyes undergoing *secondary* open-loop AC IOL insertion after *complicated* and *uncomplicated cataract surgery*. After uncomplicated cataract surgery, more than 90% of eyes achieved a BCVA within one line or better of the preoperative acuity.[15,16,19,20] After complicated cataract surgery, more than 80% of eyes had a similar result.[14,16,21,22] Overall, the incidence of corneal decompensation, glaucoma escalation, and CME was low.[14–16,19–22] In the largest series of secondary open-loop AC IOL insertion after cataract surgery, the incidence of CME and glaucoma escalation was almost identical to that of a nonrandomized control group receiving scleral-sutured PC IOLs, but the incidence of corneal edema was higher with open-loop AC IOLs.[48]

Clinical studies also support the use of an open-loop AC IOL during corneal transplantation. Pseudophakic corneal edema became the leading indication for penetrating keratoplasty in the United States by the late 1970s and remains so today.[1,2,5,54,55] Although cumulative data from 10 se-

Table 3C. Iris-sutured PC IOLs. Penetrating Keratoplasty: Secondary Suturing of PC IOLs to Iris

Study	Type of Study	Number	Level of Evidence	Follow-up	Results
Zeh and Price[44]	Case series	93	III	Mean = 22.3 mos Range = 1 day–52 mos	Visual outcome 20/40 or better: 23 (25.6%) 20/100 or worse: 43 (47.8%) Corneal edema/failure: 10 (11.8%) Glaucoma escalation: 23 (24.7%) Cystoid macular edema: not specified Lens tilt or dislocation: not specified Suture erosion: not specified Retinal detachment: 1 (1.1%) Endophthalmitis: none
Gaster and Ong[45]	Case series	21	III	Mean = 10 mos Range = 2–19 mos	Visual outcome 20/50 or better: 7 (33%) 20/200 or worse: 5 (24%) Mean: 20/62 Corneal edema/failure: none Glaucoma escalation: 13 (61.9%) Cystoid macular edema: 3 (14.3%) Lens tilt or dislocation: not specified Suture erosion: not specified Retinal detachment: none Endophthalmitis: none
Busin et al[46]	Case series	14	III	Mean = 7.6 mos Range = 3–18 mos	Visual outcome 20/60 or better: 4 (28.6%) 20/200 or worse: 1 (7.1%) Corneal edema/failure: 1 (7.1%) Glaucoma escalation: 4 (28.6%) Cystoid macular edema: 4 (28.6%) Lens tilt or dislocation: not specified Suture erosion: not specified Retinal detachment: none Endophthalmitis: none
Chu et al[47]	Case series	13	III	Mean = 30 mos Range = 4–52 mos	Visual outcome 20/40 or better: 6 (46%) 20/200 or worse: 3 (23%) Corneal edema: none Glaucoma escalation: 4 (34%) Cystoid macular edema: 5 (38%) Lens tilt or dislocation: not specified Suture erosion: not specified Retinal detachment: none Endophthalmitis: none
Price and Whitson[53]	Case series	233	III	Mean = 26 mos Range = 12–68 mos	Visual outcome 20/40 or better: 131 (59.5%) 20/100 or worse: 57 (26.1%) Corneal edema/failure: 10 (4.5%) Glaucoma escalation: not specified Cystoid macular edema: 8 (3.4%) Lens tilt or dislocation: 2 (0.9%) Suture erosion: not specified Retinal detachment: 2 (0.9%) Endophthalmitis: 1 (0.5%)

PC IOLs = posterior chamber intraocular lenses.

ries[23–29,50–52] found that only about 35% of eyes receiving a *secondary* open-loop AC IOL at the time of *penetrating keratoplasty* achieved a BCVA of 20/40 or better, and a similar percentage achieved a BCVA of 20/200 or worse, historical data have shown that this result is principally because of the presence of preexisting CME.[1,2,5,54] The incidence of graft failure from endothelial decompensation because of nonimmunologic causes was not higher in these 10 series than would be expected in the setting of penetrating keratoplasty for pseudophakic or aphakic bullous keratopathy.[1,23–29,50–52] In one series, which specifically analyzed endothelial attrition associated with open-loop AC IOLs and compared it to iris-sutured PC IOLs, the incidence of endothelial cell loss was slightly less with open-loop AC IOLs at both 1 and 2 years.[51] Another series failed to demonstrate a statistically significant difference in corneal endothelial failure in open-loop AC IOLs vs. either scleral- or iris-sutured PC IOLs.[50] Glaucoma escalation was a problem in a fairly high percentage of patients in all studies, with an incidence as high as 45%.[23] In two comparative studies,

Table 4A. Comparative Clinical Trials. Cataract Surgery: Secondary Insertion of Open-loop AC IOLs vs. Scleral-sutured PC IOLs

Study	Type of Study	Level of Evidence	Follow-up	Results: Open-loop AC IOLs	Results: Scleral-sutured PC IOLs
Lyle and Jin[48]	Case series (nonrandomized)	IIIC	*AC IOLs* Mean = 18.8 mos Range = 2–57 mos *PC IOLs* Mean = 20.9 mos Range = 2–77 mos	n = 234 Visual outcome No preexisting pathology (n = 148) 20/40 or better: 137 (92.6%) 20/200 or worse: 1 (0.7%) Visual outcome Preexisting pathology (n = 86) 20/40 or better: 58 (67.4%) 20/200 or worse: 15 (17.4%) Corneal edema: 8 (3.4%) Glaucoma escalation: 4 (1.7%) Cystoid macular edema: 14 (5.9%) Lens tilt or dislocation: 4 (1.7%) Suture erosion: NA Retinal detachment: 2 (0.9%) Endophthalmitis: none	n = 114 Visual outcome No preexisting pathology (n = 148) 20/40 or better: 64 (91.4%) 20/200 or worse: 3 (4.3%) Visual outcome Preexisting pathology (n = 86) 20/40 or better: 29 (66.0%) 20/200 or worse: 4 (9.0%) Corneal edema: 1 (0.9%) Glaucoma escalation: 1 (0.9%) Cystoid macular edema: 7 (6.1%) Lens tilt or dislocation: 3 (2.6%) Suture erosion: not specified Retinal detachment: 4 (3.5%) Endophthalmitis: 1 (0.9%)
Bellucci et al[49]	Case series	IIIC	Not specified	n = 35 Visual outcome Mean = 20/26 Corneal edema: 1 (3%) Glaucoma escalation: 1 (3%) Cystoid macular edema: 1 (3%) Lens tilt or dislocation: 1 (3%) Suture erosion: NA Retinal detachment: 1 (3%) Endophthalmitis: none	n = 33 Visual outcome Mean = 20/26 Corneal edema: none Glaucoma escalation: none Cystoid macular edema: 3 (3%) Lens tilt or dislocation: 4 (12%) Suture erosion: 9 (27%) Retinal detachment: 2 (6%) Endophthalmitis: none

AC IOLs = anterior chamber intraocular lenses; NA = not applicable; PC IOLs = posterior chamber intraocular lenses.

no significant difference was detected between open-loop AC IOLs and scleral- or iris-sutured PC IOLs.[50,52]

Scleral-sutured Posterior Chamber Intraocular Lenses

Scleral-sutured PC IOLs offer potential advantages by moving the site of IOL fixation from the anterior to the posterior chamber. When posterior chamber fixation was introduced as an alternative to open-loop AC IOLs in eyes without capsular support,[9] many ophthalmologists believed that PC IOLs would reduce the risks of corneal decompensation, glaucoma escalation, and CME associated with AC IOLs.[1,5] The anticipated reduction in these complications was believed to justify the additional surgical time and technical complexity required to perform this procedure (35 to 60 minutes vs. 8 to 16 minutes for open-loop AC IOLs),[49] as well as additional risks unique to this procedure.[56–61] Inaccurate placement of the scleral fixation sutures[56–58] can be associated with an increased risk of lens tilt,[59] suprachoroidal or vitreous hemorrhage,[62] or retinal detachment.[57] Erosion of the fixation suture through the conjunctiva may be associated with endophthalmitis,[61] and breakage of the suture may be associated with dislocation of the IOL.[60]

Scleral-sutured PC IOLs had good visual outcomes and acceptable safety profiles when implanted as a *primary* procedure at the time of *complicated cataract surgery*.[18,30–33] In these eyes, complications related to capsule rupture, such as CME and retinal detachment, would be expected to reduce the visual prognosis to less than that associated with uncomplicated procedures. Achievement of a BCVA of 20/40 or better in slightly more than 80% of eyes is acceptable in this setting.[18,30–33] Complications of corneal edema, glaucoma escalation, and CME were relatively minor, but similar to those seen with comparable cases treated with open-loop AC IOLs. Although the series were too small to draw conclusions, there was a 4.6% incidence of retinal detachment and a 7.8% incidence of lens tilt and dislocation, suggesting that these unique complications of scleral-sutured PC IOLs must be addressed when comparing the relative safety of IOL techniques. There were no control eyes in which a scleral-sutured PC IOL was not inserted and the eyes were rehabilitated with a contact lens. Although such a randomized study will probably never be performed, it would offer the opportunity to assess the impact of the small incidence of complications introduced by the IOL and its insertion to the final outcomes.

Excellent outcomes were achieved with *secondary* scleral-sutured PC IOLs after *uncomplicated cataract surgery*.[32–35] In such cases, the preoperative BCVA offered an excellent control measure for assessing the direct impact of the insertion of the IOL on the final visual outcome. More than 95% of eyes achieved a postoperative BCVA within one line of preoperative best-corrected Snellen acuity. Loss of more than one line of BCVA was attributed to corneal edema (2 eyes), retinal detachment (1 eye), and endophthalmitis (1 eye).

Table 4B. Comparative Clinical Trials. Penetrating Keratoplasty: Secondary Insertion of Open-loop AC IOLs vs. Scleral- or Iris-sutured PC IOLs

Study	Type of Study	Level of Evidence	Follow-up	Results: Open-loop AC IOLs	Results: Scleral-sutured PC IOLs	Results: Iris-sutured PC IOLs
Schein et al[50]	Randomized clinical trial 176 consecutive randomized cases of secondary AC IOL, scleral- or iris-sutured PC IOL insertion at time of PK for PBK Data for visual acuity, corneal failure, glaucoma escalation, and cystoid macular edema extracted from cumulative risk tables at 12 mos	IB	6 mos = 98% 12 mos = 90% 18 mos = 61%	n = 60 Visual outcome 20/40 or better: 16.3% 20/200 or worse: 46.9% Corneal edema/failure: 4% Glaucoma escalation: 26% Cystoid macular edema: 38% Lens tilt or dislocation: 1 (1.6%) Suture erosion: NA Retinal detachment: 2 (3.3%) Endophthalmitis: none	n = 60 Visual outcome 20/40 or better: 20.0% 20/200 or worse: 45.4% Corneal edema/failure: 3% Glaucoma escalation: 33% Cystoid macular edema: 41% Lens tilt or dislocation: 4 (6.7%) Suture erosion: not specified Retinal detachment: 1 (1.6%) Endophthalmitis: none	n = 56 Visual outcome 20/40 or better: 15.7% 20/200 or worse: 35.3% Corneal edema/failure: 3% Glaucoma escalation: 31% Cystoid macular edema: 20% $P = 0.02$ vs. AC IOLs and scleral-sutured PC IOLs Lens tilt or dislocation: none Suture erosion: not specified Retinal detachment: none Endophthalmitis: none
Sugar[51]	Longitudinal cohort study Not randomized: "The IOL selected was the one that was believed to be the best available at the time of surgery." Data from closed-loop AC IOL or unsutured PC IOL not presented Main focus of study was endothelial cell attrition and graft survival	IIB	Mean = 19.5 mos Range = 1–101 mos	n = 19 Graft edema/failure: 5.3% Endothelial cell attrition: 1 yr = 16.5% 2 yrs = 28.4%		n = 60 Graft edema/failure: 8.3% Endothelial cell attrition: 1 yr = 19.0% 2 yrs = 38.2%
Davis et al[52]	Case series (nonrandomized)	IIIC	*AC IOLs* Mean = 14.2 mos Range = 9–21 mos *Scleral-sutured PC IOLs* Mean = 12.7 mos Range = 5–22 mos *Iris-sutured PC IOLs* Mean = 16.4 mos Range = 6–24 mos	n = 10 Visual outcome 20/40 or better: 2 (20%) 20/200 or worse: 3 (30%) Corneal edema/graft failure: none Glaucoma escalation: none Cystoid macular edema: not specified Lens tilt or dislocation: not specified Suture erosion: NA Retinal detachment: none Endophthalmitis: none	n = 23 Visual outcome 20/40 or better: 6 (26%) 20/200 or worse: 6 (26%) Corneal edema/graft failure: none Glaucoma escalation: 6 (26%) Cystoid macular edema: not specified Lens tilt or dislocation: 1 (3.8%) Suture erosion: 1 (3.8%) Retinal detachment: none Endophthalmitis: none	n = 8 Visual outcome 20/40 or better: 3 (37.5%) 20/200 or worse: 4 (50.0%) Corneal edema/graft failure: none Glaucoma escalation: 1 (12.5%) Cystoid macular edema: not specified Lens tilt or dislocation: none Suture erosion: none Retinal detachment: none Endophthalmitis: none

AC IOLs = anterior chamber intraocular lenses; NA = not applicable; PBK = pseudophakic bullous keratopathy; PC IOLs = posterior chamber intraocular lenses; PK = penetrating keratoplasty.

The large series of *secondary* scleral-sutured PC IOLs by Lyle and Jin[48] after either *complicated* or *uncomplicated cataract surgery* provided insight into outcomes that can be achieved in eyes with and without predisposing factors that can potentially compromise the final visual outcome. When no predisposing risk factors were present, more than 90% of eyes achieved a BCVA of 20/40 or better. If risk factors such as glaucomatous optic nerve damage or maculopathy were present, the percentage of eyes achieving a BCVA of 20/40 or better was reduced to 66%. The incidence of retinal detachment was 3.5%; lens tilt or dislocation, 2.6%; and endophthalmitis, 0.9%. In a smaller series, Belluci et al[49] achieved similar visual outcomes, with a retinal detachment rate of 6%, lens tilt or dislocation of 12%, and no cases of endophthalmitis.

There are sufficiently large series of *secondary* scleral-sutured PC IOLs at the time of *penetrating keratoplasty* both in individual IOL series[24,28,36–42] and in comparative trials[50,52] to conclude that this technique is effective and safe. Visual outcomes are consistent with the guarded prognosis that is present in these cases.[1] Analysis of data from comparative trials does not lend support to the initial theory

that PC IOLs would be associated with a reduced rate of corneal endothelial decompensation, glaucoma escalation, or CME compared to open-loop AC IOLs.[50–52] The lower incidence of retinal detachment, lens tilt or dislocation, and endophthalmitis associated with scleral-sutured PC IOLs in the penetrating keratoplasty series[18,24,36–42] than in the cataract series[18,30–35] may be attributable to better access to the ciliary sulcus through the open-sky approach, resulting in more accurate suture placement.

Iris-sutured Posterior Chamber Intraocular Lenses

Iris-sutured PC IOLs offer the same potential advantage of IOL placement in the posterior chamber and the same disadvantage of increased surgical time as scleral-sutured PC IOLs. Iris fixation is technically more difficult to perform through the limbus than is scleral fixation. This fact may account for the reduced number of primary and secondary iris-fixated PC IOLs reported in the literature in association with cataract surgery.[42,43] At the time of penetrating keratoplasty, iris fixation is considered technically easier than scleral fixation by many ophthalmologists, resulting in more data for evaluation in penetrating keratoplasty series.[44–47,50–53] As with scleral-sutured PC IOLs, there were expectations that the posterior segment localization of the lens would reduce the major complications attributable to open-loop AC IOLs while simultaneously reducing the risks associated with scleral fixation. There were concerns about potential problems related to chronic iris chafing, which could result in chronic inflammation and CME.

Excellent outcomes were achieved with *secondary* iris-sutured PC IOLs after *complicated* and *uncomplicated cataract surgery*. As with other IOL techniques for correction of monocular aphakia without adequate capsular support, the preoperative BCVA offered an excellent control measure for assessing the direct impact of the insertion of the IOL on the final visual outcome. More than 95% of eyes achieved a postoperative BCVA within one line of preoperative best-corrected Snellen acuity. Two eyes lost more than one line of BCVA because of CME.

Corneal edema did not occur in any of the 49 patients receiving secondary iris-sutured PC IOLs after cataract surgery.[42,43] The incidence of graft failure due to endothelial attrition was not a major cause of vision loss in studies of penetrating keratoplasty.[44–47,53] Sugar[51] did not demonstrate any statistically significant difference in endothelial attrition with iris-sutured PC IOLs compared to AC IOLs.

Glaucoma escalation was not statistically significantly higher with iris-sutured PC IOLs vs. open-loop AC IOLs or scleral-sutured PC IOLs in the comparative penetrating keratoplasty studies[50,52] or when used as a secondary IOL after cataract surgery.[42,43] In the individual series of iris-sutured PC IOLs at the time of penetrating keratoplasty, there was considerable variation in the incidence of glaucoma escalation, with one study reporting an incidence as high as 91.9%,[45] whereas another study did not mention it.[53]

Schein et al[50] did demonstrate a statistically significant reduction in CME with iris-sutured PC IOLs compared to both open-loop AC IOLs and scleral-sutured PC IOLs at the time of penetrating keratoplasty. This finding did not correlate with a higher percentage of eyes achieving a BCVA of 20/40 or better, but did correlate with fewer eyes achieving a final acuity of 20/200 or worse.[50] Price and Whitson[53] also reported a low rate of CME, with nearly 60% of eyes achieving a final BCVA of 20/40 or better and approximately 25% achieving 20/200 or worse. On the other hand, CME was the leading cause for poor visual outcome after iris-sutured PC IOL insertion at the time of penetrating keratoplasty in three small series.[45-47]

Open-loop Anterior Chamber Intraocular Lenses vs. Scleral- or Iris-sutured Posterior Chamber Intraocular Lenses

There is no evidence in the few clinical trials comparing AC IOLs vs. scleral- or iris-sutured PC IOLs[48-52] or in studies of these lens types individually[11–47] that documents the clear superiority of any of them. The open-loop AC IOL is technically much easier and quicker to insert than either a scleral- or an iris-sutured PC IOL, especially when a limbal approach must be used.[49]

Visual outcomes are similar for all three lenses when used for the same clinical indication.[11–52] Overall, the incidence of corneal endothelial cell loss, glaucoma escalation, and CME is relatively low with open-loop AC IOLs[11–29,48–52] and is probably not further reduced by the use of scleral-[18,24,28,30–42,48–50,52] or iris-sutured PC IOLs.[42–52]

There was no statistically significant difference in visual outcome in secondary open-loop AC IOLs vs. scleral-sutured PC IOLs after cataract surgery in two nonrandomized clinical series,[48,49] whether or not there was preexisting pathology.[48] No striking differences were present in visual outcomes among several clinical series that evaluated these lenses individually. After secondary IOL implantation in eyes without complicated cataract surgery, more than 90% of eyes achieved a BCVA within one line of the preoperative BCVA, irrespective of the lens selected.[15,16,19,20,32–35,42,43]

There was no statistically significant difference in visual acuity outcome after penetrating keratoplasty in eyes receiving open-loop AC IOLs vs. either scleral- or iris-sutured PC IOLs.[50,52] In individual IOL case series, there was remarkable consistency of approximately 33% to 40% of eyes achieving a BCVA of 20/40 or better, although one large series of iris-sutured PC IOLs reported nearly 60% of eyes with a final visual acuity of 20/40 or better.[53]

The longitudinal cohort study that evaluated endothelial cell loss after secondary open-loop AC IOL vs. iris-sutured PC IOL insertion at the time of penetrating keratoplasty documented no difference during the first 2 postoperative years.[51] In individual series, the incidence of pseudophakic corneal edema after cataract surgery or corneal graft failure attributable to endothelial attrition was not a significant problem, irrespective of lens choice, with approximately equal incidence.[11–47] One study did show a statistically insignificant increase in corneal edema after secondary open-loop AC IOL insertion in association with cataract surgery when compared to scleral-sutured PC IOL insertion.[48]

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Category	Abbrev	Specific Financial Interests
Product	P	Financial interest in equipment, process, or product presented.
	Pc	Such interest in potentially competing equipment, process, or product.
Investor	I	Financial interest in a company or companies supplying the equipment, process, or product presented.
	Ic	Such interest in a potentially competing company.
Consultant	C_	Compensation received within the past 3 years for consulting services regarding the equipment, process, or product presented.
	Cc_	Such compensation received for consulting services regarding potentially competing equipment, process, or product.
		Examples of compensation received include:
	C1 or Cc1	1. Retainer
	C2 or Cc2	2. Contract payments for research performed
	C3 or Cc3	3. Ad hoc consulting fees
	C4 or Cc4	4. Substantial nonmonetary perquisites
	C5 or Cc5	5. Contribution to research or research funds
	C6 or Cc6	6. Contribution to travel funds
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There was no statistically significant increase in glaucoma escalation for open-loop AC IOLs vs. scleral-sutured PC IOLs in two comparative studies of secondary IOL insertion after cataract surgery[48,49] or between open-loop AC IOLs, scleral-sutured PC IOLs, and iris-sutured PC IOLs inserted at the time of penetrating keratoplasty.[50,52] The individual case series did not show any significant glaucoma escalation with open-loop AC IOLs, scleral-sutured PC IOLs, or iris-sutured PC IOLs in association with cataract surgery.[11–22] The incidence of glaucoma escalation was much higher after penetrating keratoplasty for all three lens types,[23–29,36–42,44–47] with rates ranging up to 45% for open-loop AC IOLs,[23] up to 43% for scleral-sutured PC IOLs,[36] and up to 62% for iris-sutured PC IOLs.[45]

It is difficult to interpret data regarding the relatively high incidence of CME in most series with all three lens types, especially since the preoperative incidence of CME cannot be established with certainty, but may have been high.[1,5] There did not appear to be a higher incidence of CME after secondary open-loop AC IOL insertion compared to scleral-sutured PC IOLs in two series making these comparisons during penetrating keratoplasty.[50–52] One series did report a statistically significantly lower incidence of CME with iris-sutured PC IOLs vs. both scleral-sutured PC IOLs and open-loop AC IOLs during penetrating keratoplasty.[50] The relatively small number of cases, as well as a short period of postoperative follow-up, mandates additional prospective studies before a definitive conclusion can be drawn.

Conclusions

Open-loop AC IOLs, scleral-sutured PC IOLs, and iris-sutured PC IOLs have all been demonstrated to be comparably safe and effective devices and methods of correcting aphakia in eyes without adequate capsular support for placement of a PC IOL in the capsular bag or ciliary sulcus. At this time, the literature supports the use of any of these three IOL types and fixation sites in eyes that have no anatomic contraindications. Precise determination of the differences in visual outcome or complication rates among these IOL placement techniques will require a large prospective, randomized clinical trial.

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