

Accommodative Intraocular Lenses for Age-related Cataracts

Summary

- ✓ The standard intraocular lens (IOL) that is used to replace a cataractous lens cannot change focus from distant to near objects, so most patients need glasses for near vision after cataract surgery.
- ✓ Limited evidence suggests that accommodative IOLs provide better near vision than monofocal IOLs, but not better than multifocal IOLs.
- ✓ Long-term follow-up is needed to confirm patient outcomes, and determine whether the benefits justify the additional cost.

The Technology

Light entering the eye is focused by the lens onto the back of the eye to obtain an image. For near vision, the ciliary muscle contracts, and the lens increases its optical power by bulging toward the cornea.¹⁴ The eye's ability to focus on near objects by changing its refractive power is known as accommodation (see Figure 1).²³

By age 40, the accommodative ability of the lens declines, and focusing on near objects becomes more difficult (presbyopia). Proteins begin to accumulate in the lens, and in some people, these eventually lead to an irreversible cloudiness or cataract.²⁵ Patients with cataracts have blurred vision, increased sensitivity to glare, and impaired night vision.⁶ While the visual impairment produced by mild cataracts can be counteracted with glasses, those with more severe cataracts need surgery.^{6,7}

Cataract surgery involves removal of the cataractous lens, which is replaced with an artificial intraocular lens (IOL). In an effort to restore normal eye function, a number of lens designs have been developed that mimic the accommodative ability of the natural lens (Table 1).

Single Optic

These have a single optic and flexible supports (haptics) that are braced against the capsular bag. When the haptics of a single optic lens are compressed, the optic moves toward the cornea to enable the patient to focus on near objects.^{8,9} The accommodative ability of these lenses depends on how far forward they can move in the eye.¹⁰

Dual Optic

The dual optic lens consists of an anterior plus lens and a posterior minus lens. Spring-like haptics move the anterior lens forward to facilitate accommodation.^{3,11} This allows more accommodation per millimetre of lens movement than with single optic systems, but predicting the distance correction can be challenging.¹²

Lens Refilling or Capsular Filling

With lens refilling or capsular filling, the capsular bag is filled with an elastic substance that mimics the flexibility of the original lens. Problems associated with other lens designs, such as cell growth and fibrosis, decentration, and edge glare, may be eliminated.¹¹ However, there may be more secondary cataract formation and unpredictable postoperative refraction resulting from the mechanical instability of the material.³

Figure 1 : the eye

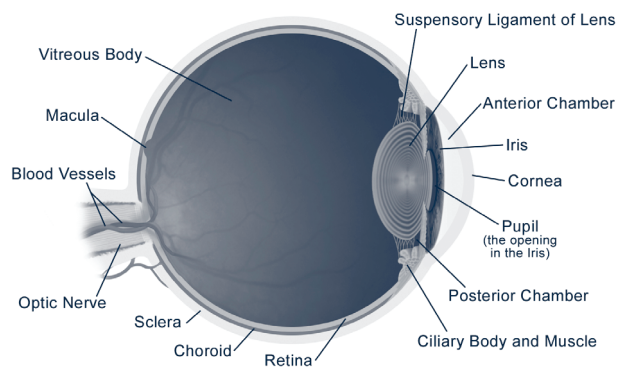


Image courtesy of Greystone.net.

Table 1: Details of Accommodative IOLs

Lens Type	Manufacturer	Regulatory/Development Status
Single optic		
Akkommodative® 1CU	HumanOptics AG	Not approved in Canada or the US.
Crystalens® (AT-45, AT-45 SE)	Eyeonics, Inc.	Health Canada Class 3 Licence (July 13, 2005) US FDA Premarket approval (November 14, 2003)
FlexOptic	Advanced Medical Optics, Inc./Quest Vision Technology, Inc.	Only implanted in cadaver eyes to date.
Tek-Clear™ Accommodative IOL	Tekia, Inc.	Not approved in Canada or the US.
Tetraflex™ Presbyopic IOL	Lenstec, Inc.	US FDA clinical trial underway. Approved in Europe, Australia, and the Middle East since early 2003.
Dual optic		
Sarfarazi Twin-optic Elliptical Accommodating IOL	Bausch & Lomb Surgical	Not yet approved or commercially available in any country. In clinical trials conducted by Bausch & Lomb.
Synchrony IOL	Visiogen, Inc.	Not yet approved or commercially available in any country. US FDA Phase II trial started in November 2005. Clinical trials underway in Europe and South America.
Capsular filling		
SmartIOL (formerly the SmartLens)	Medennium, Inc.	Only implanted in cadaver eyes to date.

FDA – Food and Drug Administration; IOL – intraocular lens

Regulatory Status

Several manufacturers produce accommodative IOLs, but only the Crystalens® has been approved for sale in North America (Table 1). The Crystalens has been issued a Class 3 medical device licence by Health Canada and will be available in Canada in mid-to-late 2006 (Paul Kramsky, Eyeonics, Aliso Viejo, CA: personal communication, 2006 Mar 24).

Patient Group

Cataracts are the leading cause of blindness in the world.¹³ Nearly 20.5 million (17.2%) Americans 40 years of age or older have cataracts, with up to 400,000 new visually disabling cataracts occurring annually.⁶ By the age of 80, one in two people have cataracts.¹⁴ Similar prevalence rates have been reported in Canada.¹⁵

Cataracts cannot be prevented, but certain lifestyle factors, including over exposure to sunlight, cigarette smoking, diet, and alcohol consumption have been implicated in their development.^{6,16}

Current Practice

Traditionally, a monofocal IOL with fixed refractive power is used to replace a cataractous lens. Most patients remain presbyopic after cataract surgery, and usually require glasses for near vision.^{3,17}

Newer IOLs can attempt to create the functional equivalent of accommodation by dividing the light into bifocal or multifocal points.^{3,7} These lenses are prone to deficiencies, such as reduced contrast sensitivity and night halos, and the image quality is inferior to that of a monofocal lens. Also, the patient must cope with several in-focus images appearing on the retina simultaneously.^{7,9,12,18}

The Evidence

Studies of patients 40 years of age or older who received an accommodative IOL replacement after cataract surgery were identified (Table 2). For studies that reported on overlapping patient groups, only the paper reporting on the most comprehensive data set was used.

Table 2: Summary of Included Studies and Main Results

Authors	Study Design; Follow-up	Lens Comparison; Patient Number	Main Results
Akkommodative 1CU			
Kamppeter et al. ¹⁹	Randomised controlled trial 4 weeks	Monofocal IOL (13 eyes, 11 patients) 1CU (10 eyes, 9 patients)	No difference in mean contrast or glare sensitivity between the two groups.
Mastropasqua et al. ²⁰	Randomised double-blind controlled trial 180 days	Monofocal IOL (28 eyes, 28 patients) 1CU (14 eyes, 14 patients)	No difference in mean spherical equivalent, uncorrected distance VA, or corrected distance VA between the two groups. Mean distance corrected near VA significantly better in 1CU group (P < 0.001).
Sauder et al. ²¹	Randomised controlled trial Mean 8 months	Monofocal IOL (80 eyes, 40 patients) 1CU (80 eyes, 40 patients)	No difference in mean corrected distance VA, corrected near VA, or uncorrected near VA between the two groups. Mean distance corrected near VA significantly better in 1CU group (P < 0.03).
Dogru et al. ¹⁷	Prospective non-randomised comparative study with case-matched controls 12 months	Monofocal IOL (20 eyes, 10 patients) 1CU (22 eyes, 16 patients)	No difference in mean spherical equivalent, uncorrected distance VA, corrected distance VA, corrected near VA, or contrast VA between the two groups. Mean uncorrected and distance corrected near VA significantly better in 1CU group (P < 0.5).
Küchle et al. ²²	Prospective non-randomised comparative study with age-matched controls 6 months	Monofocal IOL (20 eyes, 20 patients) 1CU (20 eyes, 20 patients)	Median distance corrected near VA significantly better in 1CU group (P < 0.001).
Claoué ²³	Prospective non-randomised comparative study with concurrent controls 6 to 18 months	Multifocal IOL (34 eyes, 17 patients) 1CU (9 eyes, 5 patients)	No difference in uncorrected distance VA between the two groups. Uncorrected near VA significantly better in the multifocal group (P = 0.0068) Spectacle independence; 50% for 1CU group versus 94% for multifocal group.
Crystalens			
Koepl et al. ²⁴	Prospective non-randomised comparative study with age-matched controls 3 months	Monofocal IOL (58 patients, eye number not stated) Crystalens (54 eyes, 28 patients)	No difference in corrected distance VA, distance corrected near VA, or corrected near VA between the two groups.
FDA Data ²⁵	Prospective case series study 12 months	Crystalens (497 eyes, 324 patients)	93.5% achieved uncorrected VA of 20/32* or better. 93.8% performed most visual functions without glasses.
	Non-randomised sub-study comparison 3 to 12 months	Monofocal IOL (64 eyes, 64 patients) 1CU (126 eyes, 126 patients)	VA of at least 20/40: 88.4% for Crystalens group versus 35.9% for monofocal group. VA of at least 20/25: 24% for Crystalens group versus 0% for monofocal group. No difference in mean contrast sensitivity with glare between the two groups.

IOL – intraocular lens; VA – visual acuity

*Normal VA is 20/20.

Two moderately well-designed randomised controlled trials and two non-randomised comparative studies found that patients with a 1CU implant had superior distance-corrected near visual acuity (VA), compared to monofocal IOL recipients.^{17,20-22} The accommodative ability of the 1CU lens peaked between one and six months after surgery and declined thereafter, most likely because of capsule opacification and fibrosis.^{17,20} None of these studies reported rates of spectacle independence. In addition, most of the patients who were assessed had one IOL implant, whereas accommodative ability is potentially better when both eyes are treated.^{3,12}

The largest data set available on the Crystalens is an unpublished case series study that was submitted to the US Food and Drug Administration (FDA) by the manufacturer.²⁵ One year after surgery, 120 (94%) of the 128 patients who received implants in both eyes could perform most visual functions without glasses, and 33 (26%) no longer needed glasses. The lack of preoperative data makes it difficult to assess whether VA was improved by the IOL.

One poorly reported, prospective non-randomized comparative study found no difference between the Crystalens and a standard monofocal lens with respect to corrected-distance VA, distance-corrected near VA, and corrected near VA.²⁴

The only published study that directly compared the Akkommodative 1CU to the Crystalens was unavailable when this report was written.²⁶ The abstract indicated that the 1CU IOL provided slightly better uncorrected distance and distance-corrected near VA than the Crystalens.

For other lenses, published data are unavailable.

Adverse Effects

For the 1CU, postoperative complications were rare, with one study reporting a single incidence of anterior chamber hemorrhage.²¹ Postoperative inflammation and foreign body reaction were minimal and short lasting.²⁷

In one study, 12 months after surgery, 86% of patients with a 1CU implant had anterior or posterior capsule opacification, compared with 25% of monofocal IOL recipients.¹⁷ In a second study, no difference was found

in the capsule opacification rate between the two groups after six months.²⁰ The reason for this discrepancy is unclear.

The most common adverse effects reported after Crystalens implantation were cystoid macular edema (3.7%), persistent iritis (0.7%), and the need for a second surgical intervention (0.6%).²⁵

Administration and Cost

The price of a single Crystalens is US\$895 (Paul Kramsky: personal communication, 2006 Mar 24). This is several times the cost of monofocal or multifocal IOLs.²⁸ Accommodative IOLs are implanted using standard cataract surgery techniques, so the only extra cost to the health system is for the lens.^{11,28}

Concurrent Development

Improvements continue to be made in bifocal and multifocal IOL designs, and work on accommodative lenses continues. Several prototype accommodative lenses are in development.^{29,30} These include IOLs that change shape on accommodative effort; and a lens system that moves the capsular bag, including the IOL, with implanted magnets.³

Rate of Technology Diffusion

Cataract surgery is the most common surgical procedure performed in North America and approximately 267,000 cataract operations were performed in Canada between 2003 and 2004.^{31,32} With estimates that seniors will constitute 21% of the population by 2026,¹³ the diffusion of accommodative IOLs is likely to be rapid.

The rate of diffusion may be influenced by developments in the technology, regulatory considerations, limited data on clinically relevant outcomes such as spectacle dependence, cost, and the uptake of multifocal IOLs. In the US, Medicare covers the cost of cataract surgery and a standard monofocal IOL implant. In May 2005, approval was granted for patients to privately buy the more expensive Crystalens.³³ Once accommodative lenses become available in Canada, provincial health plans and regional health authorities may have to address similar coverage issues.

The Crystalens and Akkommodative 1CU are only indicated for lens replacement after cataract surgery in patients who are 50 years or older, but this profile may expand to include patients undergoing refractive lens exchange to treat presbyopia.¹²

Implementation Issues

The limited data suggest that accommodative IOLs have contrast and glare sensitivity profiles that are similar to those of monofocal and multifocal IOLs. Although accommodative IOLs provide better distance-corrected near vision than monofocal IOLs, it is unclear if this averts the need for reading glasses. A possible link with increased rates of capsule opacification requires more study.

Accommodative IOLs are unlikely to replace current IOL designs until their effect on patients' quality of life (visual outcomes and spectacle dependence) is clearly shown. The extra cost of accommodative IOLs might be offset by reduced social services and health care costs for seniors who would otherwise be visually impaired. Long-term results are lacking, and it is unclear whether the short- to medium-term benefits in near vision are durable. It is likely that the public demand for accommodative IOLs will be high despite the lack of evidence supporting their effectiveness.

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Cite as: Scott A. *Accommodative intraocular lenses for age-related cataracts* [Issues in emerging health technologies issue 85]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2006.

CADTH appreciates comments from its reviewers.

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This report and the French version entitled *Les lentilles intraoculaires accommodatives dans la cataracte liée à l'âge* are available on CADTH's web site.

Production of this report is made possible by financial contributions from Health Canada and the governments of Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland and Labrador, Northwest Territories, Nova Scotia, Nunavut, Ontario, Prince Edward Island, Saskatchewan, and Yukon. The Canadian Agency for Drugs and Technologies in Health takes sole responsibility for the final form and content of this report. The views expressed herein do not necessarily represent the views of Health Canada or any provincial or territorial government.

ISSN 1488-6324 (online)
ISSN 1488-6316 (print)
PUBLICATIONS MAIL AGREEMENT NO. 40026386
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