

Multiflex open-loop anterior chamber intraocular lens was equivalent to aphakic spectacles

Hennig A, Evans JR, Pradhan D, et al. **Randomised controlled trial of anterior-chamber intraocular lenses.** *Lancet.* 1997 Apr 19;349:1129-33.

Objective

To compare intracapsular cataract extraction (ICCE) surgery and a multiflex open-loop anterior chamber intraocular lens (ACIOL) with ICCE and aphakic spectacles in patients with bilateral cataract.

Design

1-year randomised controlled trial.

Setting

Eye hospital in southern Nepal.

Patients

2000 patients who were 40 to 64 years of age (mean age 55 y, 51% women) and had bilateral cataracts with vision 6/36 or less in both eyes. Exclusion criteria were pre-existing ocular disease, hypertension, diabetes, or remote residence. 1827 patients (91%) were available for follow-up at 1 year.

Intervention

Patients were allocated to ICCE and ACIOL ($n = 1002$) or ICCE and aphakic spectacles ($n = 998$). The first

operated eye of each patient was entered into the trial. ICCE was done with a cryoextractor. Patients in the ACIOL group received a 19.0- or 19.5-dioptre single-piece 4-point fixation CILCO Kelman Multiflex III lens (ALCON, Hemel Hempstead, UK). Patients in the spectacle group received +11-dioptre spectacles.

Main outcome measure

Visual acuity < 6/60 (severe visual impairment or blindness) in the operated eye at 1 year.

Main results

The study had a power of 90% to detect a doubling of poor visual outcome. At 1 year, 5% of patients who received ACIOL had visual acuity < 6/60 compared with 5.4% of patients who received spectacles ($P = 0.71$) (Table).

Fewer patients who received ACIOL achieved visual rehabilitation (visual acuity 6/18 or better) than did patients who received spectacles (without refractive correction 45.3% vs 59.4%, $P < 0.001$; with refractive correction 89.9% vs 93.2%, $P = 0.01$).

Conclusions

A multiflex open-loop anterior chamber intraocular lens was as effective as aphakic spectacles in improving vision after cataract surgery. Spectacles were associated with greater visual rehabilitation.

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Multiflex open-loop anterior chamber intraocular lens (ACIOL) vs aphakic spectacles*

Outcome at 1 y	ACIOL EER	Spectacles CER	RRR (95% CI)	ARR EER - CER (CI)	NNT
Visual acuity < 6/60	5.0%	5.4%	7.0% (-37 to 37)	0.4% (-1.7 to 2.5)	NS

*NS = not significant. Other abbreviations defined in Glossary; RRR, ARR, NNT, and CI calculated from data in article.

Commentary

Hennig and colleagues are to be commended on the excellent follow-up they achieved at 1 year in this well-designed study done under difficult circumstances. The results indicate that the intermediary step from ICCE and aphakic spectacles to ICCE and ACIOL is advantageous. However, until adequate operating microscopes become available, the question of which IOL to insert is somewhat moot for the average ophthalmic surgeon: Most surgeons have difficulty safely inserting any IOL without appropriate magnification. The study shows that competent surgeons can obtain excellent results with minimal additional equipment when they implant ACIOL after ICCE. For them, ICCE with ACIOL provides a good bridging step before microsurgery becomes available.

Two decades ago, extracapsular cataract extraction (ECCE) with posterior chamber IOLs replaced ICCE as the standard procedure in developed countries, and its use is increasing in urban and some rural areas of developing countries. Although ICCE can be (and in developing countries is) done without an operating microscope, ECCE is best done as microsurgery. If ophthalmologists have the operating microscope needed to safely implant IOLs, they might as well do the safer and better ECCE surgery and implant a posterior chamber IOL.

Here is how we think the results of this study should be applied: If no operating microscope is available, surgeons are adequately skilled, and they evaluate the outcomes in their patients, then ACIOL is

preferable to intracapsular surgery with aphakic spectacles because of the problems inherent with spectacles (loss and breakage). If an operating microscope is available, ECCE with IOL is the preferred option.

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Author's response

Ongoing studies are evaluating the long-term results of both ECCE and ICCE in developing countries. When these results are available, it will be possible to give recommendations about the benefits and disadvantages of alternative surgical techniques in high-volume cataract surgery with limited resources to address cataract blindness in the developing world.