WORLD VIEW

A comparison of anterior and posterior chamber lenses after cataract extraction in rural Africa: a within patient randomised trial

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Background: Extracapsular cataract extraction (ECCE) with a posterior chamber intraocular lens (PC IOL) is the preferred method of cataract surgery in developed countries. However, intracapsular cataract extraction (ICCE) with an anterior chamber lens (AC IOL) may be appropriate in rural Africa. A randomised controlled trial was carried out to compare these surgical strategies.

Methods: Participants over 50 years requiring bilateral cataract surgery were recruited from outreach clinics in rural north and east Uganda. One eye was randomly allocated to AC IOL or PC IOL, the other eye being allocated to the second strategy. The main outcome measure was WHO distance visual acuity (VA) category after a minimum of 1 year. Secondary outcomes were numbers and causes of complications and refractive corrections.

Results: Of the 110 participants recruited, 98 (89%) were assessed at least 1 year after the operation (median follow up 17.5 months). Nine eyes randomised to PC IOL were converted to AC IOL; one eye randomised to AC IOL inadvertently received PC IOL. There was no difference in VA between 95 pairs of eyes for which data for both eyes were available (uncorrected VA, $p=0.26$; corrected VA, $p=0.59$). 80 (82%, 95% CI 73 to 89) and 82 (84%, 95% CI 75 to 90) eyes randomised to AC IOL and PC IOL respectively had corrected VA of 6/18 or better. 16 (16%, 95% CI 10 to 25) and eight (8%, 95% CI 4 to 15) eyes respectively had secondary procedures or other complications.

Conclusions: Where both strategies are available, ECCE with PC IOL should be first choice because of fewer complications. Where ECCE with PC IOL is not immediately feasible, ICCE with AC IOL is an acceptable interim technique.

About three million people are blind from cataract in Africa.¹ At the present rate of cataract extraction many of them are likely to die never having had surgery. Until recently, intracapsular cataract extraction (ICCE) has been the usual surgical strategy, with the consequent disadvantages of spectacle correction. Around 1995, good quality intraocular lenses (IOLs) became widely available at an affordable price, and a policy of universal lens implantation became the aim even for resource poor places.² This policy raised the question of the relative merits of anterior chamber (AC) and posterior chamber (PC) IOLs. In western countries PC IOLs are considered clearly superior to AC ones. However, the situation in Africa may be different. The design of modern AC IOLs has eliminated most of their faults³ and they could still be appropriate in Africa for the following reasons:

- In implementing the above policy quickly, it would be easier to train surgeons to add implantation of an AC IOL to their current ICCE technique. Training surgeons for the PC IOL technique could come later
- Some eyes require AC IOLs because the zonule and capsule are too degenerate to support a PC IOL
- Many aphakic people could benefit from secondary AC IOL implantation
- Posterior capsule opacification may occur with PC IOLs, which would usually go untreated in remote areas.

Since the new policy affects millions of blind people, we considered that the alternative surgical strategies should be compared in an African setting, including operations done by a visiting team away from a specialised eye hospital. Their

advantages and disadvantages seemed reasonably balanced, so a randomised trial was considered ethical. The main study objective was therefore to compare the long term outcome of surgery by ICCE plus AC IOL, with extracapsular cataract extraction (ECCE) plus PC IOL.

METHODS

Setting, participants, and randomisation

Participants were recruited from outreach clinics in rural general hospitals in rural north and east Uganda, which were visited periodically. Follow up visits were attempted when the surgeon was visiting each clinic. Repeated visits were attempted if necessary.

People estimated to be ≥ 50 years were eligible if cataract surgery was required in both eyes (vision 6/60 or worse). Exclusion criteria were vision worse than perception of light with projection, significant keratopathy, obvious glaucoma or any other pathology likely to reduce vision markedly, and home too inaccessible to visit. Eyes were examined using a torch and binocular loupes, and visual acuity (VA) measured. Tonometry was not done routinely owing to patients' apprehension. Slit lamp examination was also available at some locations but not all. The study was explained to participants and families in their vernacular. Consent for surgery and home visits to assess long term outcome was obtained verbally or by obtaining a thumbprint on a consent form. Since the study was not based on an institution, there was no appropriate ethics committee to give approval.

A comparison of IOL types *within patients* was possible because patients often presented with bilateral cataracts. This design has the advantage of controlling for individual differences between patients that may influence outcome—for

example, the inflammatory reaction to surgery. The eye with poorer vision, or the right eye if vision was equal, was chosen for the first operation. Cards allocating the first eye either to AC IOL or PC IOL were contained in sealed opaque envelopes; the second eye was allocated to the other strategy. When a patient was recruited, an envelope was opened. The allocations were generated randomly by computer and sealed in envelopes in London (by BR) before the study started.

Surgery and follow up

Local anaesthesia was done by an assistant. One surgeon (KW) performed all operations using a portable microscope (Scanoptics, Australia), irrespective of IOL type. The ICCE extraction was done by expression or tumbling through a corneoscleral incision, and the ECCE extraction by expression of the nucleus after "can opener" capsulotomy and irrigation/aspiration using normal saline. For AC IOLs, one iridectomy was done between 10 and 2 o'clock and subsequently tested for patency. AC IOLs (Aurolab, India) were 4 feet multiflex style of 18 or 19 dioptres, selected from lengths 12, 12.5, and 13 mm on the basis of "horizontal corneal diameter plus 1 mm." PC IOLs (Aurolab, India) were 21 or 22 dioptres and all were inserted under air with methyl cellulose on the lens surfaces. Closure was by four or five interrupted 9.0 nylon sutures with closure of the conjunctiva over the section. Subconjunctival gentamicin 20 mg and dexamethasone 2 mg were given at the end.

Eyes were examined daily as long as the team remained on site. Topical antibiotic and steroid was instilled four times daily, and patients were sent home with a supply of drops. If uveitis was marked, daily oral prednisone 20 mg was provided for up to 5 days. VAs were tested before discharge, including with a pinhole. Follow up examination at 1 year or longer consisted of external examination, direct ophthalmoscopy, objective and subjective refraction, Perkin's tonometry, and VA testing with and without correction.

Outcomes and statistical methods

The main outcome measure was distance VA (uncorrected and corrected) after a minimum of 1 year. In order to include as many participants as possible in the analysis, VA outcome for each eye is reported here as normal (if at least three letters on the 6/18 line were correctly read), visually impaired, severely impaired or blind, according to the World Health Organization classification (see table 1).⁴ Secondary outcomes were complications, second surgical procedures, and refractive corrections. Anisometropia was measured as the difference between eyes in spherical equivalent (PC IOL eye minus AC IOL eye). Participants were not told the type of IOL that was implanted in each eye. Assessment of complications could not be masked because the type of IOL was obvious from examination of the eye. Assessment of VA could not be masked because KW was the only qualified person available to carry out follow up.

The planned sample size for the study was 200, with two surgeons performing cataract surgery, one at an eye hospital and the other at various rural hospitals without any specialised facilities visited by a mobile team. This sample size assumed that Snellen acuities would be measured (transformed to logMAR units). It allowed the study to detect a standardised difference of 0.3 between eyes with PC and AC IOLs at a 5% significance level (two tailed) with 80% power. Primary analyses were by intention to treat, comparing outcomes between eyes within patients using Wilcoxon matched pairs signed ranks tests. Distributions of variables are described using medians, interquartile ranges, and ranges.

RESULTS

Participants, surgery, and follow up

Figure 1 shows the flow of participants through the study. The eye hospital declined to participate. Participants were recruited from rural hospitals between May 1998 and May 2000. Their median estimated age was 64 years, ranging from 50 to 80. Of the 110 recruited, 94 (86%) were illiterate, and the remaining 16 were fully or semiliterate. Before surgery, 103 of 110 eyes (94%) were "blind" (worse than 3/60), both for eyes allocated to PC IOL and eyes allocated to AC IOL. Nine eyes randomised to PC IOL were converted to AC IOL because of zonule dehiscence or wide posterior capsule rupture; one eye randomised to AC IOL inadvertently received PC IOL. Ninety eight participants were assessed at least 1 year after the operation; the median duration of follow up was 17.5 months (range 12–48).

Visual acuity

Numbers of eyes in each WHO VA category at final follow up are shown in table 1, for uncorrected and corrected VA. There were no differences in the VA distributions between 95 pairs of eyes which provided data for both eyes ($p = 0.26$ for uncorrected outcomes and $p = 0.59$ for corrected outcomes). Secondary analyses including only pairs of eyes with one AC IOL and one PC IOL ($n = 85$) also found no difference ($p = 0.18$ for uncorrected outcomes and $p = 0.68$ for corrected outcomes). In the 98 patients who were successfully followed up, 80 (82%, 95% CI 73 to 89) and 82 (84%, 95% CI 75 to 90) eyes randomised to AC IOL and PC IOL respectively had corrected VA of 6/18 or better. (Distance VAs were also transformed into logMAR units and compared for PC IOL and AC IOL eyes using paired t tests, as a more sensitive test of the difference between surgical strategies. No significant differences were observed for either uncorrected or corrected logMAR VAs.)

For the 12 participants lost to follow up, early post-operative uncorrected acuities were recorded for 10 and these were broadly similar to the rest of the sample. For eyes with AC IOLs, six were classified as "normal" and four as "visual impairment." For those with PC IOLs, five were "normal" and five "visual impairment." Five of the six people who died were reported by their families to have maintained good vision up to the time of death. The sixth was not traced.

VAs for eyes with PC and AC IOLs were also compared after excluding 11 patients in whom reduced vision in one or both eyes was judged to be the result of non-surgical complications (see below). The conditions excluded were macular degeneration, trauma, amblyopia, corneal opacity, and uveitis or vitreous haemorrhage occurring ≥ 6 months after surgery. Again, no significant differences were found ($p = 0.17$ for uncorrected outcomes and $p = 0.55$ for corrected outcomes). In these 87 patients, 75 eyes (86%) with AC IOLs and 79 eyes (91%) with PC IOLs had "normal" corrected VA classified.

Complications and secondary procedures

Data about complications and secondary procedures were available for both eyes of the 98 patients who were followed up. Of these, 78 (80%) had no complications or secondary procedures in either eye, four in both eyes (1%); 10 (10%) in the eye randomised to PC IOL, and six (6%) in the eye randomised to AC IOL. Based on these intention to treat data, there was no evidence of a difference in the overall incidence of complications and secondary procedures between strategies (McNemar test, exact $p = 0.45$).

A total of 118 eyes received AC IOLs and 102 PC IOLs. These denominators were 106 and 90 respectively among the

Table 1 Uncorrected and corrected distance visual acuities: numbers of eyes (%) randomised to AC and PC IOLs achieving WHO categories of vision⁴ at final assessment

Uncorrected distance visual acuities						
AC IOL	PC IOL, uncorrected VA					
Uncorrected VA	Normal	VI	SVI	Blind	Unknown	Total
Normal (6/5 to 6/18)	24 (24)	12 (12)	2 (2)	0 (0)	0 (0)	38 (39)
Visual impairment (VI) (6/24 to 6/60)	16 (24)	27 (28)	1 (1)	2 (2)	0 (0)	46 (47)
Severely VI (SVI) (5/60 to 3/60)	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	4 (4)
Blind (worse than 3/60)	3 (3)	1 (1)	0 (0)	3 (3)	2 (2)	9 (9)
Unknown	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	1 (1)
Total	45 (46)	42 (43)	3 (3)	5 (5)	3 (3)	98 (100)

Corrected distance visual acuities						
AC IOL	PC IOL, corrected VA					
Corrected VA	Normal	VI	SVI	Blind	Unknown	Total
Normal (6/5 to 6/18)	72 (73)	5 (5)	1 (1)	1 (1)	1 (1)	80 (82)
Visual impairment (VI) (6/24 to 6/60)	4 (4)	2 (2)	0 (0)	1 (1)	0 (0)	7 (7)
Severely VI (SVI) (5/60 to 3/60)	2 (3)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Blind (worse than 3/60)	4 (4)	0 (0)	0 (0)	3 (3)	2 (2)	9 (9)
Unknown	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Total	82 (84)	7 (7)	1 (1)	5 (5)	3 (3)	98 (100)

Figure 1 Flow of participants through the study. *Nine eyes randomised to PC IOLs were converted intraoperatively to AC because of capsule rupture or zonule dehiscence. †One eye randomised to AC inadvertently received a PC lens.

number of patients followed up. Because some complications (for example, second surgical procedure) arose early and others during follow up, the denominators lie between these limits.

Based on the IOLs that were implanted, 12 eyes that received AC IOLs had second surgical procedures (11 of these had been randomised to AC IOL; one was converted to AC IOL after capsule rupture). Eight had partial or complete occlusion of the pupil with a post-inflammatory membrane causing marked diminution of vision (in six) or a restricted field but normal acuity (in two); all had immediate improvement in vision after avulsion of the membrane with a needle through the angle. Three had iris bombé (two with raised pressure), and were treated with repeat peripheral iridectomy, including trabeculectomy for one. The remaining case had a displaced lens, which was explanted and a smaller lens reimplanted.

Five eyes with PC lenses had second procedures. Three had occlusion of the pupil by a thickened flap of anterior capsule; they obtained immediate good vision after its removal. Two had residual cortical lens matter between the optic and capsule causing dense opacification. They were treated by closed capsulotomy; one failed and had an open capsulotomy.

Other complications occurred in five eyes with AC IOLs and three with PC IOLs. Three eyes with AC IOLs had iris bombé but did not have further surgery; two (in the same patient) had too little vision to warrant it, and the other had normal pressure and vision. One eye developed a large anterior chamber blood clot on the third postoperative day, which cleared spontaneously; however, at follow up she had a shallow chamber and high pressure with optic disc damage and nothing further was done. One eye developed a hypopyon on the third postoperative day and was treated with steroids and intravitreal antibiotic; it resolved rapidly but final vision was 3/60.

In two eyes with PC IOLs, posterior capsule thickening or wrinkling sufficient to cause significant (though minor) diminution of vision developed but both patients declined capsulotomy. One eye with a PC IOL developed a post-operative blood clot, which resulted in iris atrophy and diminished vision.

Final refraction

Table 2 summarises available objective refraction data for eyes that received AC and PC IOLs as randomised. For the within patient measure of anisometropia (spherical equivalent for eyes allocated to PC IOL minus spherical equivalent for eyes allocated to AC IOL eye; paired data for $n = 78$), the median was zero dioptres (interquartile range -0.5 to 1.0 ; range -3.0 to 3.25 ; sign rank test, $p = 0.23$).

DISCUSSION

Summary of main findings of the study

- There were no significant differences in corrected or uncorrected final distance VAs achieved with the two techniques
- Several complications occurred and some needed second surgical procedures. Those associated with AC lenses seem largely unavoidable. Complications with PC lenses could be avoided by meticulous surgery
- Significant late posterior capsule opacification after ECCE rarely occurred within the time span of the study
- The final refractive corrections after implanting standard power lenses were nearly all in the mildly myopic range; biometry would have made little difference.

Study population and follow up

In interpreting the results, the context is relevant. To make the study as representative as possible we excluded only people with obvious major co-morbidity. The participants were elderly with simple visual needs, and had advanced longstanding cataracts. The conditions for surgery were not ideal and, as high volume implant surgery in remote areas had only recently started, the team was still on its learning curve. When the patients went home, most were not seen again until visited at home, so complications were not treated promptly. These suboptimal conditions resemble those in cataract camps in India, which are considered to produce inferior results to those at base hospitals.⁵ However, this is the only way in which treatment will be provided to the target population and is typical of much of Africa, so the conclusions are widely applicable.

Near complete follow up was essential to obtain clear results, but the remoteness and the bad roads made follow up at home time consuming. Follow up was 89% complete with a minimum period of 1 year, and even for those lost, some information was obtained. Follow up was therefore better than other African studies.^{6,7} Vision testing in elderly illiterate people can be a problem. It can be difficult to persuade them that they really can read small letters and they often tire quickly. A few could not cooperate at all and were scored as vision unknown. There is also the cultural perception that one must not be well in the presence of the doctor, or else medicine will not be forthcoming! Therefore, VAs obtained were the minimum that participants could achieve. Some of the inexplicable poor outcomes might be spurious, though some might be caused by macular pathology such as oedema, which is difficult to exclude through an undilated pupil.

Overall outcome

Before considering the primary question, it is relevant to compare the overall results achieved in this study with other

Table 2 Final refractive correction (dioptres) of the eyes that received AC ($n = 79$) and PC IOLs ($n = 82$) as randomised

	Median	IQR*	Range
AC IOL			
Sphere	-1.00	-2.00 to 0.00	-4.50 to +1.50
Cylinder	-1.00	-1.50 to 0.00	-3.00 to +1.00
Spherical equivalent	-1.50	-2.50 to -0.25	-5.25 to +1.00
PC IOL			
Sphere	-0.75	-2.00 to 0.00	-4.00 to +2.50
Cylinder	-1.00	-1.50 to 0.00	-3.00 to 0.00
Spherical equivalent	-1.25	-2.25 to 0.00	-4.50 to +1.50

*IQR = interquartile range.

studies. The percentages achieving “normal” corrected vision (table 1) are acceptable (82% for AC and 84% for PC). Studies for comparison in Africa are few and their follow up times are shorter. One achieved 67% for AC lenses at 6 months⁶ and another achieved 83% for PC lenses at 2 months.⁸ The percentages are lower than in hospital based studies in Asia (in which over 90% of patients are classified as having normal VA after surgery), but higher than in population based studies there—that is, including patients having surgery in cataract camps.⁹ Excluding non-surgical problems slightly increased the percentages of eyes achieving “normal” corrected VA (to 86% and 91% respectively for AC and PC IOLs) and halved the number left blind. For uncorrected vision, the results are similar to hospital based African studies using PC lenses (all under 50% “normal”).^{7, 8} However, interpretation of uncorrected vision is confused by the issue of the test distance (discussed below).

The primary research question—*are AC or PC lenses better?*

At present in Africa, this is still a relevant question. Intention to treat analyses showed no differences in distance VA; although the study had less power than planned, there was no trend at all for VA to be better with one strategy than the other. However, taking the secondary outcomes into account, the situation is more complex. The strategies were still found to be similar using explanatory analyses but AC IOLs overall (including all eyes with AC IOLs, whether randomised or not) had more complications and second procedures. If increasing expertise could reduce the number of PC eyes needing conversion to AC IOL, and also minimise the complications of PC IOLs, it seems likely that they would be substantially better. The finding that significant posterior capsule opacification was rare (at least at the vision level required by trial participants in their usual, rural setting) removes the main objection to using PC IOLs in remote places.

The answer to the primary research question is therefore debatable. With only average expertise (as with this team at the time of the study), outcome is similar with both strategies because the results with PC IOLs were compromised by the need to convert some to AC IOLs. With increased expertise, it seems likely that the PC technique would be better, unless this also resulted in fewer complications with AC lenses, which seems less likely.

The AC strategy is sometimes inevitable. In African patients, cataracts are usually longstanding and degenerate, and this may result in inadequate support for a PC IOL. In this study about 9% needed converting from PC to AC, similar to other studies.^{7, 8} The number decreases with experience (as has since happened with this team) but never becomes zero. Many aphakic people also need secondary AC IOL implantation; therefore, surgeons should be trained in both techniques. It is often stated in favour of AC IOLs that it is easy to add them to the familiar ICCE procedure. This statement underestimates the problems in the setting of this study and in the reference population. It can require exceptional skill to insert them without contamination by the lashes, or snagging the vitreous and iris with the haptic foot. The difficulty is often worsened by the sunken eyes of undernourished old people, by distortion of the lids and contraction of the conjunctival sac from trachoma, and by reduced corneal clarity from solar damage, trichiasis, or trauma. It can be eased by using a lens glide, but this needs control of two objects in the eye at once. In contrast, insertion of a PC lens into the capsular bag is usually easier (although it does need the skill of preparing the bag).

Complications and second procedures

The need for second operations is unacceptable, as very few patients return spontaneously. The visual results achieved would have been worse had patients not been followed up for the study. The complications of PC IOLs (redundant anterior capsule and retained lens matter) should be avoidable by meticulous surgery. Pressure of time must not be allowed to compromise details like this. The complications of AC IOLs are more common and also seem harder to avoid. The occluded pupils presumably followed a low grade but prolonged iritis, which accords with the South African experience.⁶ The frequency of iris bombé is puzzling, as the patency of iridectomies was checked, and the large Nepal study does not report it (they used two iridectomies).¹⁰ Presumably the mechanism is blockage of the iridectomy by vitreous, and two iridectomies might be safer. Perhaps the problem arose from the technique of lens extraction used and might not apply to other teams. However, it is also possible that it is commoner in Africa than previously thought and could be a major disadvantage of AC IOLs. The stability of AC IOLs was not studied, but it was noted at follow up that many were not vertical; therefore, they seem prone to rotation despite being measured to fit. In two eyes a foot had rotated into the iridectomy, and in one this contributed to corneal decompensation.

To find if these complications also apply to the work of other surgeons, it would be ideal to repeat the study at other sites in Africa, despite careful follow up being labour intensive. Since further testing of AC IOLs against PC IOLs may be unacceptable, the long term outcome of AC IOLs in places where PC IOLs are not available should be audited.

Refractive correction to obtain best vision

Since biometry in remote places was impracticable, standard lens powers were used. In rural African settings, this practice will need to continue. The final refractive state is therefore an important secondary outcome measure, especially in evaluating the acceptability of the uncorrected vision. The main cause of subnormal uncorrected vision was refractive error; the numbers with normal vision doubled when corrected (see table 1). Yet, since few participants wanted spectacles, uncorrected vision is what they actually use. Most eyes were mildly myopic (median spherical equivalent $-1D$; table 2). A few eyes were emmetropic or mildly hyperopic, and a few were over $-3D$ myopic, but none was far outside an acceptable range and, without correction, most eyes were focused for nearer tasks. Participants appreciated the good working vision that this mild myopia gave them. Therefore, the practice of testing vision at 6 metres and categorising this as “functional” and “best” is flawed. It would be more meaningful for these people to assess acuities at 1 or 2 metres. This would also simplify the test, since it would be easier to hold their attention at this distance.

Conclusions

Accepting that this is not a large study and needs confirmation (it did not achieve the target sample size and involved only one surgeon), we conclude that:

- where both techniques are available, the PC strategy should be preferred because of fewer complications, unless AC IOL surgery is specifically indicated
- where introduction of the PC strategy is not immediately feasible and would result in undue delay in implementing universal implantation, the AC the strategy using a microscope is acceptable but not as easy as sometimes stated
- the longer term goal should be development of skills and equipment so as to offer the PC technique as first choice

for all, unless contraindicated, but this should not be hurried for doctrinaire reasons, and training must be adequate to ensure good standards.

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