CLINICAL STUDY

Is anterior chamber lens implantation after intracapsular cataract extraction safe in rural black patients in Africa? A pilot study in KwaZulu-Natal, South Africa

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Abstract

Purpose **There are an estimated 16 million people blind from cataract world-wide. In many areas the routine operation is intracapsular cataract extraction (ICCE). The role of modern anterior chamber (AC) intraocular lenses (IOLs) is being explored, and they have been shown to be safe and successful in Asia. Are they equally safe in rural black African populations?**

Methods **One hundred black patients aged 50 years and over who attended Edendale Hospital were enrolled in a pilot study of insertion of AC IOLs after ICCE. They were followed up for 6 months.**

Results **With financial remuneration, the follow-up rate at 8 weeks increased from the usual 30% to 72%. At 6 months, 67% of eyes achieved a corrected visual acuity of 6/18 or better. Thirty per cent had persistent uveitis, 16% had peripheral anterior synechiae beyond the points of haptic contact, and 5% had an intraocular pressure greater than 21 mmHg.**

Conclusions **A randomised trial comparing ICCE with AC IOL and extracapsular cataract extraction with posterior chamber IOL is probably not justified at this time in this population. However, there may be wide variations in the reaction of the eyes of different African ethnic groups to IOLs. In view of the successful use of AC IOLs in Asian eyes, further pilot studies of AC IOLs may be warranted in other parts of Africa where ICCE is the routine procedure.**

Key words Anterior chamber, Cataract extraction, Lenses intraocular, Post-operative complications, South Africa, Zulus

Age-related cataract is the leading cause of blindness in the world, with an estimated 16 million people bilaterally blind as a result.[1] Most of these people live in rural areas in developing countries in Asia and Africa. Whereas 15 years ago intracapsular cataract extraction (ICCE) with spectacle correction of the aphakia was the only available treatment available for these patients, the development of improved surgical techniques presents a dilemma for ophthalmologists working in these parts of the world. It is estimated that at present only 1 in 10 patients in sub-Saharan Africa who are blind due to cataract are receiving surgery. Should patients continue to be offered ICCE, or should they be offered some form of extracapsular cataract extraction (ECCE)? Should the aphakia be corrected with spectacles, or with an intraocular lens (IOL)?

ICCE may offer advantages over ECCE in rural African patients. ICCE may be done under loupe magnification without the need for a microscope, and the majority of eye surgeons working in rural Africa have been trained in this technique. The risk of vitreoretinal complications following ICCE in black patients is low. There is no difference in the incidence of clinical cystoid macular oedema 1 year after ICCE and ECCE[2] and the incidence of rhegmatogenous retinal detachment following ICCE in blacks is reported as nil.[3,4] However, posterior capsule opacification is a significant complication following ECCE,[5,6] and it might be an important argument against the use of this technique in rural patients in developing countries, who have difficult access to ophthalmology services in referral hospitals for surgical or laser capsulotomy.

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The implantation of an IOL offers several advantages over aphakic spectacle correction. IOLs do not distort the vision, and cannot be lost or broken. Uncorrected aphakia is an important cause of blindness in both Africa[7] and Asia.[8] With the availability of good-quality, inexpensive IOLs there is a strong reason to offer IOL implantation in preference to aphakic spectacles. An anterior chamber IOL (AC IOL) can be implanted after ICCE. This would obviate the need for providing rural cataract surgeons in Africa with operating microscopes, YAG lasers and supplies of irrigating fluids, and would obviate the need for retraining in ECCE techniques. Whereas the older generations of AC IOLs have a poor reputation because of complications due to problems in design and manufacture,[9,10] modern multiflex open loop AC IOLs are safe.[11] The have been demonstrated to be safe and effective when used in rural patients in Asia, following ICCE under loupe magnification.[12,13]

This pilot study was undertaken to ascertain whether or not ICCE with AC IOL is a safe procedure in rural black patients, with a view to proceeding with a randomised trial comparing ICCE and AC IOL with ECCE and posterior chamber (PC) IOL in this population. It has been carried out at Edendale Hospital, where the surgeons are familiar with both techniques.

Methods

Black patients aged 50 years and over attending the eye clinic at Edendale Hospital were eligible if they had bilateral cataract reducing vision to 6/60 or less in both eyes. Most of the patients were Zulus, although a few were from Lesotho and Transkei. Exclusion criteria were diabetes mellitus, 'only eyes' (no light perception in one eye), glaucoma, uveitis, or keratopathy or other ocular pathology reducing vision. Patients provided written informed consent to participate in the study. One hundred patients were enrolled, and each had the surgery performed in one eye only.

Surgery was performed under local anaesthetic by two experienced ophthalmologists. The horizontal corneal diameter was measured at the start of the operation. Routine ICCE was performed, with removal of the lens with a cryoprobe. After constriction of the pupil with acetylcholine, an Allergan Ioptex AP961M open loop AC IOL of standard +17.50 dioptre power was inserted under hydroxypropylmethylcellulose. The lenses were all 13.0 mm in diameter. The corneoscleral section was closed with seven 10–0 nylon sutures, and a subconjunctival injection of gentamicin 20 mg, cefamandole 125 mg and betamethasone 4 mg was given.

Post-operatively, patients were given acetazolamide 250 mg 6 hourly for 1 day. They were instructed to instil chloramphenicol-dexamethasone combination drops 6 hourly for at least 8 weeks. Following discharge on day 2, they were reviewed after 1 week, 4 weeks, 8 weeks and 6 months. A repeat subconjunctival injection of betamethasone 4 mg was given on day 2, and on follow-up at week 1 and week 4. A financial remuneration was offered to encourage follow-up by compensating patients for fares, meals, and loss of earnings for their escorts. Patients who failed to reattend were sent a postcard reminding them of their appointment.

The primary outcome measures were:

1. Poor vision (best corrected visual acuity less than 6/60) at 6 months follow-up. Visual acuity was tested using a Snellen E chart. Vision was taken as the last line on which more than 50% of the optotypes were read correctly. Refraction was done at 8 weeks and 6 months with a Topcon RM-A6000 autorefractometer.
2. Persistent post-operative uveitis (aqueous cells and/or flare) at 8 weeks and 6 months follow-up. Uveitis was graded using the Tabbara scale.
3. Corneal oedema.
4. Elevated intraocular pressure at 8 weeks and 6 months follow-up.
5. Peripheral anterior synechiae beyond the points of the lens haptic contacts at 6 months follow-up. In all patients who returned at 6 months the operated eyes were examined by gonioscopy, using a Goldmann two-mirror lens. If present, the extent of peripheral anterior synechiae was estimated and was recorded in degrees of circumference.

All data were double-entered using EPI-INFO. Analyses were done using Statistical Analysis System (SAS; SAS Institute, Cary, NC).

Results

Characteristics of the study group

One hundred patients were entered into the study. The characteristics of the patients are shown in Table 1.

Surgery

The horizontal corneal diameters ranged from 11.0 mm to 12.0 mm, with a mean of 11.55 mm. Capsule rupture occurred in 17% of cases, and vitreous loss in 16%. There were no other complications of note.

Follow-up

At 1 week, 83 patients returned for a follow-up examination. Seventy-two patients returned at 8 weeks, and at 6 months 64 patients returned. The range of follow-up at '8 weeks' was 36–120 days (median 60), and at '6 months' the range was 102–376 days (median 183).

Table 1. *Characteristics of the patients (total number = 100)*

Age: mean (range), years	69 (55–94)
Gender: number female	71
Occupation: number pensioners	91
Literacy: number literate	27
Pre-operative visual acuity in operated eye: number <1/60	93
Pre-operative IOP in operated eye: mean (range), mmHg	15 (9–24)
Type of cataract: number of 'mature'	79
number 'hypermature'	15

Table 2. *Visual acuity in the operated eye at 6 months follow-up*

	Uncorrected		Corrected	
Visual acuity	*n*	%	*n*	%
6/6–6/18	23	35.9	37	67.3
6/24–6/60	34	53.1	18	32.7
5/60–3/60	6	9.4	0	–
<3/60	1	1.6	0	–
Total	64	100	55	100

Outcome

Visual acuity. Table 2 shows the uncorrected and corrected visual acuity at 6 months. There were 9 patients in whom an autorefractor reading could not be obtained. One of these had uncorrected vision <3/60 (count fingers at 0.5 m). Of the patients in whom an autorefractor reading could be obtained, none had a corrected visual acuity less than 6/60, and 67% had a corrected visual acuity of 6/18 or better.

Uveitis. Table 3 shows uveitis at 8 weeks and 6 months follow-up. Most of the uveitis was mild, with the majority of patients having uveitis of 2+ cells or less. Uveitis improved with length of follow-up. At 8 weeks 86% of patients had persistent uveitis, and at 6 months 33% had persistent uveitis.

Corneal oedema. At 6 months there was 1 patient with central corneal oedema and 1 patient with oedema of the superior cornea.

Intraocular pressure. Table 4 shows intraocular pressure at 8 weeks and 6 months follow-up. Eight per cent of patients had an intraocular pressure of greater than 21 mmHg at 8 weeks, and 5% at 6 months.

Peripheral anterior synechiae. The results of gonioscopy at 6 months are shown in Table 5. Seventy-eight per cent had some peripheral anterior synechiae. The majority was at the points of haptic contact only (63%).

Role of vitreous loss

Table 6 shows the results in patients according to whether or not they had vitreous loss during the operation. Patients with vitreous loss had a worse outcome, but excluding them from the analysis did not alter the clinical results dramatically. Of those patients who did not have vitreous loss, at 6 months 72% had a best corrected acuity of 6/18 or better, 26% had persistent uveitis, 6% had an intraocular pressure greater than 21 mmHg, and 78% had peripheral anterior synechiae.

Table 3. *Post-operative uveitis in the operated eye at 8 weeks and 6 months follow-up*

	8 weeks follow-up		6 months follow-up	
	n	%	*n*	%
No cells	10	13.9	43	67.2
1+ cells	40	55.6	13	20.3
2+ cells	20	27.8	5	7.8
3+ cells	2	2.8	1	1.6
Deposit on IOL	0	–	2	3.1
Total	72	100	64	100

Table 4. *Intraocular pressure in the operated eye (mmHg) at 8 weeks and 6 months follow-up*

Intraocular pressure	8 weeks follow-up		6 months follow-up	
(mmHg)	*n*	%	*n*	%
> 21 mmHg	6	8.3	3	4.7
< 21 mmHg	66	91.7	61	95.3
Total	72	100	64	100
Mean	15.6		15.8	
SD	± 4.2		± 4.5	
Minimum	6		8	
Maximum	32		35	

Discussion

Because of the success and safety of the use of AC IOLs after ICCE in Nepal[12] and in India, Bangladesh, and another area of Nepal,[13] a pilot study on the use of ICCE with AC IOLs in black African patients, mostly Zulus, was carried out in KwaZulu-Natal. This was with a view to a possible randomised clinical trial if the lenses proved satisfactory.

The follow-up rate was low. The difficulty of post-operative follow-up in this setting must be emphasised. Some patients come from up to 500 km away within KwaZulu-Natal. Others come from Transkei in the Eastern Cape or from the neighbouring country of Lesotho. The usual follow-up rate at 8 weeks after ECCE at this hospital is 30%. For the purposes of the study it was both impractical and unsafe for a doctor or ophthalmic nurse to travel to many of the rural districts to follow-up patients. The provision of financial remuneration allowed a substantial improvement in the follow-up rates to 72% at 8 weeks and 64% at 6 months.

Vitreous loss occurred in 16% of cases, which is high. It might be argued that, had the surgery been done by surgeons more experienced in ICCE techniques, this complication rate would have been lower and the outcome better. The 6 month follow-up analyses were therefore repeated, excluding patients with vitreous loss. Although patients with vitreous loss had a worse visual outcome than those without vitreous loss, excluding these patients from the analysis did not materially alter the results of the study.

Table 5. *Results of gonioscopy in the operated eye at 6 months follow-up*

Peripheral anterior synechiae	*n*	%
None	14	21.9
At points of haptic contact only	40	62.5
<90°	6	9.4
90° to <180°	3	4.7
180° to <270°	1	1.6
270° to 360°	0	–
Total	64	100

Table 6. *Outcome at 6 months in patients with and without vitreous loss*

	Without vitreous loss		With vitreous loss	
	n	%	*n*	%
Total followed up	51	100	13	100
Uncorrected acuity				
>6/18	21	41.2	2	15.4
6/24–6/60	27	52.9	7	53.8
5/60–3/60	3	5.9	3	23.1
<3/60	0	0.0	1	7.7
Corrected acuity[a]				
>6/18	34	72.3	3	37.5
6/24–6/60	13	27.7	5	62.5
5/60–3/60	0	–	0	–
<3/60	0	–	0	–
Corneal oedema				
None	50	98.0	12	92.3
Superior	0	–	1	7.7
Central	1	2.0	0	0.0
Uveitis				
No cells	38	74.5	5	38.5
1+ cells	9	17.6	4	30.8
2+ cells	4	7.8	4	30.8
Intraocular pressure				
>21 mmHg	3	6.0	0	–
Gonioscopy				
No PAS	11	21.6	3	23.1
PAS at haptic contact	34	66.7	6	46.2
PAS beyond haptic contact	6	11.8	4	30.8

PAS, peripheral anterior synechiae.
[a]Total with corrected acuity: 47 without vitreous loss, 8 with vitreous loss.

Intraocular lenses of standard power (+17.50 dioptres) and standard size (13 mm) were implanted in all patients. According to the manufacturer's instructions, the size of the IOL should be 1.0 mm larger than the horizontal white-to-white corneal diameter. Using excessively large or small lenses might cause complications, due either to stretching of the anterior segment or to movement of the IOL around the angle. The horizontal diameters ranged from 11.0 mm to 12.0 mm, with a mean of 11.55 mm. The IOL that was used is only available in a standard size of 13 mm. The lack of individual standardisation of the IOL size might contribute to post-operative complications in some of our patients.

It is often difficult to obtain a reliable subjective visual acuity from our elderly, mainly rural patients. The use of pinhole vision has been found to be impractical for many of them, and we have preferred to use an autorefractor reading. There were 9 eyes in which an autorefractor reading could not be obtained at 6 months. These eyes had persistent uveitis or corneal oedema precluding a reading. In those patients in whom a corrected visual acuity could be obtained at 6 months, there was none with a visual acuity less than 6/60 and only 67% reported a visual acuity of 6/18 or better.

Thirty-three per cent of the patients still had uveitis at 6 months follow-up, in spite of receiving repeated subconjunctival betamethasone injections and being instructed to continue instilling chloramphenicol-dexamethasone combination drops. This persistent uveitis in one-third of the patients supports anecdotal reports from other parts of Africa that the eyes of black African patients react more vigorously to routine cataract surgery with IOL implantation than the eyes of white patients. Sixteen per cent of the patients had peripheral anterior synechiae beyond the points of haptic contact, and 5% had an intraocular pressure greater than 21 mmHg at 6 months.

Because of the small sample size and the low follow-up rate, we need to interpret the results of this pilot study with caution. We believe it would be inappropriate for us to proceed to a randomised clinical trail comparing ICCE and AC IOL with ECCE and PC IOL in our patients. However, there are wide variations in the biological characteristics of different African populations. For example, Pretorius[14] has reported successful routine use of ICCE and AC IOLs in black patients in the Johannesburg region. It is recommended that AC IOLs should be used with caution in black African patients, and that they should be tested further for safety in different populations before being widely used in Africa.

Conclusion

Poor visual outcome, persistent uveitis, peripheral anterior synechiae and elevated intraocular pressure may all be significant complications following ICCE and AC IOL in our black patients. A randomised clinical trial

comparing ICCE and AC IOL with ECCE and PC IOL is not justified in our population. In view of the successful results of ICCE and AC IOL in Nepalese, Indian and Bangladeshi patients, further pilot studies of AC IOLs and possible trials may be warranted in other parts of Africa where ICCE is the standard technique and facilities for ECCE and PC IOL are not at present available.

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