

## Extracapsular cataract extraction compared with small incision surgery by phacoemulsification: a randomised trial

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### Abstract

**Background**—Cataract extraction constitutes the largest surgical workload in ophthalmic units throughout the world. Extracapsular cataract extraction (ECCE), through a large incision, with insertion of an intraocular lens has been the most widely used method from 1982 until recently. Technological advances have led to the increasing use of phacoemulsification (Phako) to emulsify and remove the lens. The technique requires a smaller incision, but requires substantial capital investment in theatre equipment. In this randomised trial we assessed the clinical outcomes and carried out an economic evaluation of the two procedures.

**Methods**—In this two centre randomised trial, 232 patients with age related cataract received ECCE, and 244 received small incision surgery by Phako. The main comparative outcomes were visual acuity, refraction, and complication rates. Resource use was monitored in the two trial centres and in an independent comparator centre. Costs calculated included average cost per procedure, at each stage of follow up.

**Results**—Phako was found to be clinically superior. Surgical complications and capsule opacity within 1 year after surgery were significantly less frequent, and a higher proportion achieved an unaided visual acuity of 6/9 or better ( $<0.2$  log-MAR) in the Phako group. Postoperative astigmatism was more stable in Phako. The average cost of a cataract operation and postoperative care within the trial was similar for the two procedures. With the input of additional spectacles for corrected vision at 6 months after surgery, the average cost per procedure was £359.89 for Phako and £367.57 for ECCE. **Conclusion**—Phako is clinically superior to ECCE and is cost effective.

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Cataract extraction constitutes the largest workload in ophthalmic units throughout the world. In 1995-6, more than 156 000 cataract operations were performed within the National

Health Service in England and Wales.<sup>1</sup> New procedures have been adopted largely as a result of changes in fashion and anecdotal evidence, with little scientific assessment of clinical outcomes or economic evaluation.<sup>2</sup> Extracapsular cataract extraction (ECCE) with insertion of an intraocular lens has been the most widely used method from 1982 until recently. This requires a relatively large incision through which the lens is extracted and the new intraocular lens inserted. Technological advances have led to the increasing use of an ultrasonically driven oscillating needle to emulsify the lens (phacoemulsification) combined with an automated irrigation/aspiration system to remove the lens material from the eye. Although this newer technique (Phako) has been taken up widely in the UK since our study began in 1994, the most recent data available from a UK survey show that 20% of surgeons still use ECCE and that the use of the newer procedure (Phako) varied from 10% to 99% in different units.<sup>3</sup> Figures from Europe are not available. In the USA, where Phako is probably most widely used, the most recent annual survey of cataract specialists<sup>4</sup> shows that 11% of respondents are still performing ECCE. In developing countries, such as India, Phako is now being introduced in the major cities.

Phako requires a smaller incision, with the expected advantages of less post-surgical astigmatism, earlier stabilisation of refraction and of visual acuity, and earlier spectacle correction.<sup>5-10</sup> The newer technique, however, requires substantial capital investment in theatre equipment and additional "disposable" items.

Both procedures usually require most patients to wear spectacles for some activities. Both require follow up care in outpatients and some patients need laser treatment for posterior capsule opacity.

This randomised trial was conducted to compare the two surgical treatments for cataract: extracapsular cataract extraction (ECCE) and small incision surgery by phacoemulsification (Phako). The comparative outcomes studied were visual acuity and refraction, and complications. The economic analysis compared the costs to the NHS of achieving good visual outcomes at 6 weeks, 3, 6, and 12 months post-operatively by ECCE and Phako.

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## Methods

### PROTOCOL: (A) CLINICAL AND STATISTICAL ASPECTS

The clinical work was conducted in two centres: Moorfields Eye Hospital, London, and the Oxford Eye Hospital. Cataract patients attending the study centres or listed for cataract surgery at the centres formed the potential pool from which individuals were invited to participate in the trial. All consenting patients with age related cataract admitted for surgery were potentially eligible. The patients had to be residents within the region and willing and able to attend regular follow ups for 1 year. Patients were not recruited into the study if they were unsuitable for phacoemulsification ("hard" highly brunescant nuclear cataract), if they needed combined surgical procedures, if they had other eye disorders capable of compromising vision (for example, amblyopia,

glaucoma, diabetic retinopathy, macular degeneration), if the axial length of the eye was more than 26.5 mm (pathological high myopia), and if their mobility or social circumstances were thought likely to seriously hinder the required follow up visits. The lower age limit was 40 (initially set at 50 then relaxed by the steering committee).

The two planned treatments were: extracapsular cataract extraction (ECCE), and small incision surgery by phacoemulsification (Phako). In ECCE, a 12–14 mm corneoscleral section was made after raising a conjunctival flap, the lens capsule opened and the lens nucleus expressed or removed with a lens loop without fragmentation. A manual irrigation/aspiration system was then used to remove the remaining lens (cortical) material, a 7 mm all PMMA intraocular lens (IOL) was inserted into the capsular bag, and the incision closed with nylon sutures. In Phako, a self sealing 3.2 mm clear corneal incision was made on the steep axis of the corneal astigmatism. The lens was phacoemulsified via a capsulorhexis—a continuous curvilinear tear to create a round opening in the anterior capsule of the lens—and a three piece 6 mm folding silicone/Prolene lens inserted into the capsular bag. In both procedures, the viscoelastic used was Provisc (Alcon), a sodium hyaluronate. All the surgeons were experienced in both ECCE and Phako, and were required to have performed a minimum of 250 of each procedure before the trial. The surgical protocols for each technique were standardised to reflect best practice by experienced surgeons.

The four primary clinical outcome measures were as follows:

(1) Visual acuity (with best spectacle correction) and refraction. The proportion of patients who achieved a spectacle visual acuity of 6/9 or better ( $<0.2$  logMAR) and a refraction (spherical equivalent) within plus or minus 1 dioptre of the planned refraction were compared in the two treatment groups. Visual acuity was measured with the Baillie-Lovie log-MAR chart.

(2) Level of astigmatism and its course in the postoperative follow up period.

(3) Capsule rupture and/or vitreous loss as a complication during surgery.

(4) Incidence of capsule opacity during the 1 year follow up after surgery.

The visual acuity cut-off level of 6/9 was chosen to relate to the current requirement for driving in the UK. The severity of capsule opacity was graded clinically, and those requiring laser treatment were distinguished and recorded.

Secondary outcomes considered were unaided visual acuity, frequency of the relatively common minor complications and difficulties encountered during surgery (for example, perioperative iris prolapse complicating surgery), serious rare complications such as choroidal haemorrhage at surgery or endophthalmitis following surgery, and the incidence of uncommon but vision impairing conditions (for example, cystoid macular oedema, previously

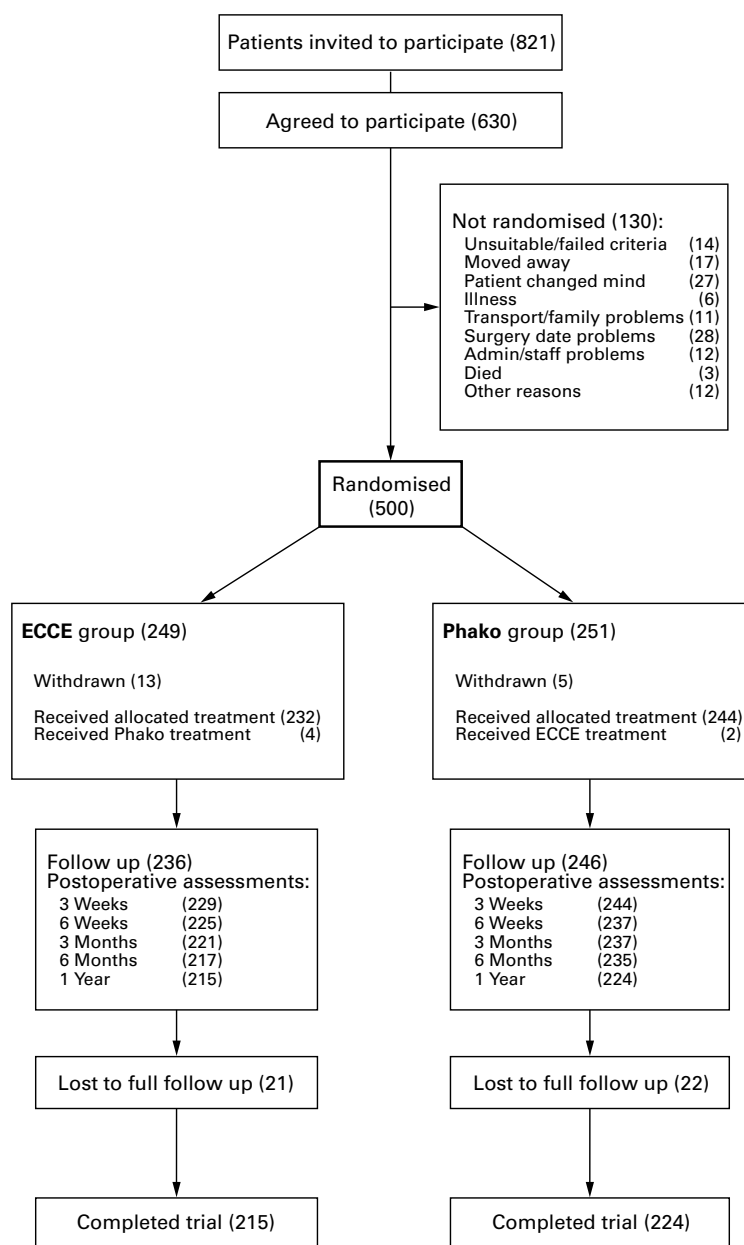


Figure 1 Recruitment, randomisation, and flow of patients through the various stages of the trial.

undetected macular degeneration, retinal detachment) in the postoperative follow up period. Loss of corneal endothelial cells (measured using a specular microscope SP1000 and the ImageNET 640 computerised analysis system) was also assessed before surgery and at each follow up visit. Time taken for surgery was recorded (from start of surgery to when the patient was taken off the table).

All the postoperative outcomes were assessed at 3 weeks, 6 weeks, 3 months, 6 months, and 1 year after surgery (Fig 1). Spectacles were given at 3 weeks postoperatively for the Phako cases and at 3 months for the ECCE patients (or earlier in case of need and then changed as necessary).

Assessments before surgery included grading of the brunescence of the lens (by the optometrist) using the Oxford Scale,<sup>11</sup> clinical examination to exclude other eye diseases, measurement of visual acuity and refraction, and corneal endothelial cell assessment.

Sample size estimation (assuming 1:1 randomisation) indicated 440 patients. This would give at least 90% power (and  $\alpha = 0.05$ ) to detect a difference between proportions of 15% or more (for example, 45% *v* 30%), and to detect a moderate difference between means (that is, standardised difference of 0.35 (the difference between the two expected means divided by the standard deviation)). The estimated sample size was adequate when considering the following outcome measures—visual acuity; astigmatism; capsule opacity; capsule rupture/vitreous loss; and corneal endothelial cell loss. Allowing for the expected losses to follow up, the study aimed to randomise 500 patients.

All the statistical analyses were completed on the intention to treat basis. For comparison of means, *t* tests or their non-parametric equivalent (Mann-Whitney) were used when appropriate, and for proportions,  $\chi^2$  based tests or their exact counterparts were used. Point estimates of the “treatment” effect were calculated as differences between means or as proportion ratios (for binomial outcomes) together with their 95% confidence limits. To adjust for possible confounding effect of prognostic factors such as age, multiple regression was used, including logistic regression for the binomial outcomes.

#### PROTOCOL: (B) ECONOMIC EVALUATION

The economic evaluation for the trial was part of an overall programme of health services research into the production and outcomes of cataract surgical services. This included a study of operating theatre capacity, outpatient health resource groups (HRGs), and patient related outcome studies (PORT). The work for

the trial was set up to take advantage of the methods of coding and data collection developed for the broader programme of work.

The perspective of the economic evaluation was that of ascertaining the direct costs of the treatment of cataract surgery to the National Health Service and including some direct costs to the patient. In order to allow a comparison of the costs and effectiveness of the new procedure, (Phako) with the more established one (ECCE); the likely resource inputs and outcome measures were identified.

The resource input categories for operating theatre/surgical episode, for outpatients, and for laser clinics are listed in Table 1.

Depreciation according to National Health Service agreement of 6% and discounting were incorporated into the calculations where relevant, such as those for theatre and equipment investment.

Calculation for the cost of outpatient care used a method that built up costs from measurements of time per patient in contact with staff and equipment.<sup>12</sup> In so far as was possible this method was also adopted for theatre costing.

Direct costs to patients (for example, spectacles) were measured and proxies for the costs of bus pass travel and accompaniment were ascertained from this study and an ongoing study of outcomes. Within the study, recruitment of patients for the trial and changes in clinic location for follow up, were such as to make the collection of travel cost data of doubtful use.

#### Outcome measures

The primary outcome measure used was the number of patients who achieved the clinical outcome of visual acuity of 6/9 or better, first without distance spectacles, and then after 6 months, with the additional input of distance spectacles where necessary. A successful outcome at each postoperative assessment (3 weeks, 6 weeks, 3, 6, and 12 months) was defined as visual acuity of 6/9 or better.

Additional costs relating to the secondary clinical outcomes were as follows:

- Additional visits to the ophthalmologist related to early postoperative complications.
- The number of patients considered to need laser treatment for capsule opacity within 1 year after surgery.
- The number of patients who at 6 months could achieve 6/9 visual acuity with the additional input of spectacles.

These applied to patients in both arms of the trial.

Resource use was monitored in the two trial centres. The sterilisation and purchasing policies at Moorfields, at the time of the trial, resulted in reduced costs for some equipment compared to other ophthalmic units and the potential for the introduction of bias in the costings. To avoid this, the equipment costs from a third independent comparator centre were substituted for Moorfields costs where these were atypically low. The cost of laser treatment and outpatient appointments were

Table 1 Resource input categories for the economic evaluation, for operating theatre/surgical episode, for outpatients, and for laser clinics

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Staffing, including “on costs” and grade allowances
Capital charges: an official shadow rent related to space in provider units
Overheads: lighting, heating, and administrative charges
Capital equipment: general and specific to the type of cataract procedure
Disposables and IOLs (for operating theatre/surgical episode only)
Drugs
Spectacles: costs to patients (for outpatients only)

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Table 2 Distribution of prognostic factors in the two treatment groups: extracapsular cataract extraction without phacoemulsification (ECCE, n=236) and with phacoemulsification (Phako, n=246). Percentages are of the total number in the treatment group

Characteristics at baseline (before surgery)	Treatment groups		Treatment groups	
	ECCE No (%)	Phako No (%)	ECCE Mean (SE)	Phako Mean (SE)
Age*			72.3 (0.6)	71.1 (0.6)
Sex:*				
Females	129 (55)	147 (60)		
Ethnic group:*				
White	213 (90)	237 (96)		
Asian	10 (4)	5 (2)		
African-Caribbean	4 (2)	13 (6)		
Previous cataract surgery in fellow eye	65 (28)	87 (35)		
Hypertension*	31 (13)	40 (16)		
Lens brunescence grade III-IV*	123 (52)	113 (46)		
Study centre:*				
Oxford	95 (40)	99 (40)		
London	141 (60)	147 (60)		
Surgeon:*				
A	95 (40)	99 (40)		
B	51 (22)	50 (20)		
C	41 (17)	47 (19)		
D	17 (7)	16 (7)		
E	14 (6)	16 (7)		
F	7 (3)	10 (4)		
G	6 (3)	5 (2)		
H	5 (2)	3 (1)		
Admission:				
Day case	174 (74)	195 (79)		
Inpatient	62 (26)	51 (21)		
Axial length of the eye (mm)			23.4 (0.1)	23.3 (0.1)
Corneal endothelia cell count (in 100s)			24.9 (2.5)	24.6 (2.6)
Corneal thickness (mm)			0.5 (0.003)	0.5 (0.003)
Unaided visual acuity (logMAR)			1.0 (0.03)	1.1 (0.03)

\*Factor adjusted for in multiple regression analyses, and assessed as possible "effect modifier."

verified against the findings of work in the comparator centre.

The "trial effect" (the effect of the trial on costs of treatment) was considered mainly by adjusting the costs of scheduled outpatient care to include two postoperative visits for each group (standard of care at the time study was started) and to exclude the additional trial monitoring visits. Salary calculations allowed for a range of "seniority" payments to consultant and nursing staff over a 3 year period and also included London weighting payments pro rata to the proportion of patients in the trial recruited in London. As some of the intraocular lenses were donated, proxy prices for ECCE and Phako lenses were calculated, allowing for the substantial change in relative market share over a 2 year period.

Analysis was as follows. In consultation with an external economist, the trial economists constructed a set of costing spreadsheets under the headings mentioned above. These were linked to the trial findings concerning data on resource usage in theatre time and follow up

Table 3 Complications at surgery in the two treatment groups: extracapsular cataract extraction without phacoemulsification (ECCE, n=236) and with phacoemulsification (Phako, n=246)

Complications at surgery	Treatment groups		Exact test: p value
	ECCE No (%)	Phako No (%)	
Choroidal haemorrhage	1 (0.4)	1 (0.4)	1.000
Capsule rupture and/or vitreous loss	9 (4)	8 (3)	0.808
Peroperative iris prolapse	17 (7)	0 (0)	<0.0001
Iris torn or emulsified	5 (2)	2 (1)	0.276
Other "minor" difficulties*	16 (7)	6 (2)	0.028
No surgical complications	188 (80)	229 (93)	<0.0001

\*Other 'minor' difficulties include: anterior chamber collapse or bleed, anterior capsule tear, and incomplete capsulorhexis.

for each patient in the trial. A further link was made to computer tables on the visual acuity outcome results at each point in the trial follow up for calculations of cost in relation to outcome and level of need for spectacles. A third combined set of spreadsheets incorporated the overall cost analysis and subsequent sensitivity analyses. This allowed the following to be calculated:

- Unit costs of inputs
  - Average cost per procedure including follow up and post-surgical laser treatment
  - Average costs per procedure with the input of additional spectacles for corrected vision.
- A sensitivity analysis took account of the variance in the most costly input.

#### ASSIGNMENT

The unit of randomisation was the individual patient, with only one eye considered for cataract surgery. The choice of eye in those with bilateral cataracts was as in routine clinical practice, and was independent of the allocated surgical treatment—that is, was made before randomisation. The randomisation was stratified by surgeon with blocks of size four and six. The allocation codes were sealed in sequentially numbered opaque envelopes, and placed in the care of the trial manager in each study centre. The participating surgeons were not involved in the care of or opening of the envelopes, and were informed of the treatment assignment in theatre immediately before surgery. The trial statistician who generated the allocation schedules was not involved in execution of the assignment.

#### MASKING

As in many surgical trials, complete masking was not possible. The patients and the optometrists in charge of the follow up outcome assessments were masked to the treatment allocation code. The optometrists examining the patient, however, could not be masked to the size and location of the surgical incision, which indicated the type of surgery.

#### Results

##### PARTICIPANT FLOW AND FOLLOW UP

Figure 1 shows the progress of the trial and flow of patients through the various stages. Of the 500 patients randomised, 473 (95%) had the week 3 assessment, 462 (92%) the week 6 assessment, 458 (92%) the month 3 assessment, 452 (90%) the month 6 assessment, and 439 (88%) the final 1 year assessment. Numbers lost to follow up were similar in the two treatment groups.

##### CLINICAL ASPECTS

###### General findings

A fairly even distribution of possible prognostic factors was achieved between the two treatment groups through the randomisation process. The details are shown in Table 2.

At the final assessment 1 year after surgery, more than 88% of patients (388/439) had spectacle visual acuity of 6/9 (<0.2 logMAR) or better, and 96% (420/439) had 6/12 (0.3 logMAR) or better vision (summarised from

**Table 4** Complications and events during the follow up period after cataract surgery, in the ECCE (n=232) and Phako (n=245) treatment groups. Of the 482 patients who had surgery, five were lost to all follow up. These are excluded from the table

Postoperative complications/events	Treatment groups		Exact test: p value
	ECCE No (%)	Phako No (%)	
Capsule opacity	68 (29)	48 (20)	0.014
Removal/cutting of sutures	85 (37)	8 (3)	<0.0001
Age related macular degeneration	4 (2)	2 (1)	0.439
Cystoid macular oedema	3 (1)	2 (1)	0.678
Retinal detachment	0 (0)	2 (1)	0.499
Endophthalmitis (with some of above)	1 (0.4)	3 (1)	0.624

data in Table 6). The main clinical outcomes were significantly more favourable in small incision surgery with phacoemulsification, as detailed below.

#### Complications during surgery

The frequencies of various complications during surgery in the two treatment groups are shown in Table 3. Peroperative iris prolapse complicating surgery occurred in 17/236 (7%) ECCE patients, and in none of the Phako group (exact  $p < 0.0001$ ). Other minor difficulties collectively were also significantly more common in the ECCE group.

**Table 5** Main outcome: visual acuity and refraction combined outcome in the two treatment groups during the 1 year follow up after surgery

Postop time	Treatment group	Achieved 6/9 or better vision and the planned refraction	Proportion ratio: Phako/ECCE (95% confidence limits)	p Value
		No (%)		
Week 3:	Phako	163/244 (67)	1.32 (1.13–1.54)	<0.001
	ECCE	116/229 (51)		
Week 6:	Phako	164/237 (69)	1.22 (1.06–1.40)	0.007
	ECCE	128/225 (57)		
Month 3:	Phako	164/237 (69)	1.15 (1.00–1.32)	0.050
	ECCE	133/221 (60)		
Month 6:	Phako	158/235 (67)	1.04 (0.91–1.19)	0.553
	ECCE	140/217 (65)		
Month 12:	Phako	155/224 (69)	1.07 (0.94–1.22)	0.361
	ECCE	139/215 (65)		

**Table 6** Visual Acuity outcome in the two treatment groups during the 1 year follow up after surgery

Postop time	Treatment group	Achieved 6/9 or better vision—ie, <0.2 logMAR	Proportion ratio: Phako/ECCE (95% confidence limits)	Fisher's exact test p value
		No (%)		
<b>Unaided visual acuity</b>				
Week 3	Phako	80/244 (33)	2.89 (1.93–4.33)	<0.001
	ECCE	26/229 (11)		
Week 6	Phako	85/237 (36)	2.37 (1.67–3.38)	<0.001
	ECCE	34/225 (15)		
Month 3	Phako	83/237 (35)	1.84 (1.33–2.55)	<0.001
	ECCE	42/221 (19)		
Month 6	Phako	89/235 (38)	1.83 (1.34–2.48)	<0.001
	ECCE	45/217 (21)		
Month 12	Phako	87/224 (39)	1.99 (1.45–2.73)	<0.001
	ECCE	42/215 (20)		
<b>With spectacle correction</b>				
Week 3	Phako	213/244 (87)	1.28 (1.16–1.42)	<0.001
	ECCE	156/229 (68)		
Week 6	Phako	213/237 (90)	1.15 (1.06–1.25)	0.001
	ECCE	176/225 (78)		
Month 3	Phako	220/237 (93)	1.16 (1.08–1.25)	<0.001
	ECCE	177/221 (80)		
Month 6	Phako	217/235 (92)	1.07 (1.00–1.14)	0.046
	ECCE	187/217 (86)		
Month 12	Phako	204/224 (91)	1.06 (0.99–1.14)	0.076
	ECCE	184/215 (86)		

#### Capsule opacity after surgery

The incidence of capsule opacity after cataract surgery was significantly higher in the ECCE group: risk ratio 1.5, 95% confidence limits 1.1 to 2.1, exact  $p = 0.014$  (derived from data in Table 4). The excess risk of capsule opacity in the ECCE group remained significant after further analysis by multiple logistic regression, making adjustments for possible confounding effects of age, sex, surgeon (or centre), and ethnic group (white, others). The odds ratio was 1.7 with 95% confidence limits of 1.1 to 2.7,  $p = 0.013$ , after adjustment for confounding. The higher risk in ECCE was consistently found in all the main subgroups defined by age, sex, study centres, and ethnic group. Laser capsulotomy rates during the 1 year postoperative follow up were 22/232 (9%) in ECCE and 12/245 (5%) in Phako, the adjusted odds ratio being 2.1 with 95% confidence limits of 1.0 to 4.5,  $p = 0.046$ .

#### Other events/complications after surgery (Table 4)

During the first 3 months of follow up, sutures had to be cut or removed in 85/232 (37%) in the ECCE group because of protrusion or to control astigmatism. Only 8/245 Phako patients required a corneal suture, to avoid a wound leak, and all of these eight sutures were removed (exact  $p < 0.0001$ ). Age related macular degeneration was found in four ECCE and in two Phako patients (exact  $p = 0.44$ ). Five patients developed clinical cystoid macular oedema (three in ECCE and two in Phako, exact  $p = 0.68$ ), and there were two retinal detachments, both in the Phako group. There were four cases of endophthalmitis, three of which occurred in the Phako group (exact  $p = 0.62$ ). Corneal endothelial cell loss 1 year after surgery was similar in the two treatment groups. The mean loss was in ECCE 224 per  $\text{mm}^2$  (–9%), and in Phako 259 per  $\text{mm}^2$  (–11%),  $p = 0.29$ .

The mean time taken for surgery per patient was 27.8 minutes for ECCE and 20.3 minutes for Phako (mean difference 7.5, 95% CL 5.8–9.3,  $p < 0.001$ ).

#### Visual acuity, refraction, and astigmatism after surgery

The combined outcome of visual acuity and refraction achieved after surgery in the two treatment groups is shown in Table 5. Up to 3 months after surgery, the proportion of patients achieving 6/9 or better (<0.2 logMAR) vision (with spectacle correction) and a refraction within plus or minus 1 dioptre of the planned refraction was significantly higher in the Phako group (for example 69% *v* 57% at week 6). Multiple logistic regression analyses showed that the significant differences, reported in Table 5, remained virtually unaltered after adjustments for the effects of other “prognostic” factors (such as age, sex, ethnic group, trial centre, and the preoperative lens brunescence grade). The two treatment groups had a similar distribution of target refraction (spherical equivalent), the 25th and 75th centiles being –0.58 and 0.0 in ECCE, and –0.59 and

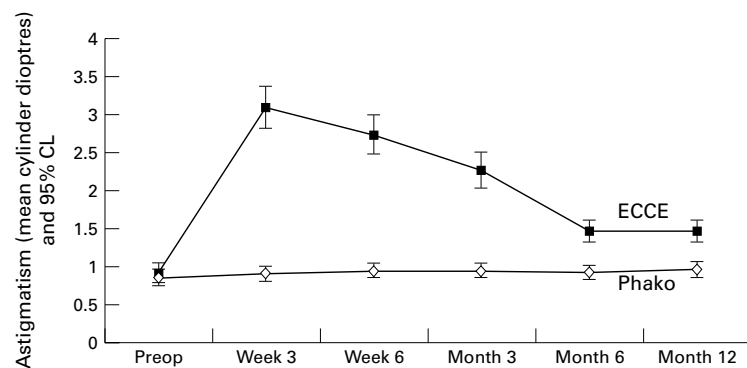


Figure 2 Astigmatism in the two treatment groups before surgery and in the follow up period after surgery. The higher figures (in the ECCE group) are undesirable as they result in poorer unaided vision and a greater requirement for spectacles.

0.0 in Phako. The corresponding medians were  $-0.25$  in ECCE and  $-0.19$  in Phako.

The unaided visual acuity was significantly better following phacoemulsification throughout the postoperative follow up period, in terms of the mean logMAR acuity, and of the proportion of patients having 6/9 or better ( $<0.2$  logMAR) vision. This was particularly evident during the first 6 months after surgery (Table 6). Whereas the Phako group attained a good stable level of visual acuity quickly (by the third postoperative week), the vision in the ECCE group continued to improve for up to 6 months, but remained significantly poorer throughout the follow up. Further analysis by multiple regression modelling indicated that virtually all of the significantly poorer result in ECCE came about because of the higher levels of astigmatism after surgery (Fig 2). Adjustments for effect of other prognostic factors (such as age), did not materially alter the findings.

With spectacle correction (best corrected visual acuity), the differences in visual acuity between the two treatment groups were still evident but less marked, particularly at 6 months and 1 year after surgery (Table 6), reflecting the correction by spectacles of most but not all of the excess astigmatism in the EEC group.

Table 8 Average costs and outcomes for the two procedures

Treatment group	Cost	Successful outcome (VA 6/9 or better) proportion		
		6 weeks	6 months	12 months postop
Phako	£332.89	0.36		
ECCE	£335.07	0.15		
With additional input of spectacles (corrected vision):				
Phako	£359.89		0.92	0.91
ECCE	£367.57		0.86	0.86

#### ECONOMIC EVALUATION

Estimates of resource inputs and costs required for each procedure are shown in Table 7 as are the costs attached to these.

The following results allow for the level of follow up visits related to complications and also for those patients sent for laser treatment for capsule opacity. This included two follow up visits after surgery and not the additional visits for trial monitoring purposes required by the trial.

The table of outcomes and costs (Table 8) shows that the average cost of cataract extraction by phacoemulsification is similar to the average cost of an extracapsular extraction up to the 6 month follow up period (that is, £332.89 and £335.07 respectively). At all points up to 6 months Phako is more effective at achieving numbers of cases at the desired outcome of visual acuity of 6/9 or greater. After the 3 month follow up period the increased resources in the form of spectacles for distance are best evaluated for their effect on outcome; the related probability of the need for distance spectacles at this stage is 0.54 for Phako and 0.65 for ECCE. The increased overall cost to £359.89 for Phako patients is less than that for ECCE (£367.57). Phako is cheaper at the follow up points of 6 and 12 months and maintains some dominance in effectiveness (though less marked than earlier) with 92% of the patients achieving the required outcome with spectacles compared with 86% of those operated on by ECCE.

The sensitivity analysis considered the 95% confidence limits for the mean difference in "time taken for surgery." Under the assumption that the mean time difference was 5.8

Table 7 Estimates of amounts of inputs within resource groupings required for each procedure and the costs attached to these

	Phako			ECCE		
	Value of resource use	Average unit cost	Cost per procedure	Value of resource use	Average unit cost	Cost per procedure
<b>Surgery</b>			£174.82			£152.91
<b>Component:</b>						
All staffing inputs expressed in person hours	2.67	£14.55	£38.85	3.73	£14.57	£54.35
Capital and equipment in common	20 minutes		£13.40	28 minutes		£18.76
Overheads (heating and lighting)			£11.57			£16.20
Consumables of a type in common			£19.17			£22.69
Phako equipment and consumables	20 minutes		£38.99	N/A		0
Drugs			£2.84			£2.91
Intraocular lens implant	1	£50.00	£50.00	1	£38.00	£38.00
<b>Outpatient care</b>			£158.08			£182.16
<b>Component:</b>						
Scheduled outpatient visits (preop and postop)	3	£25.00	£75.00	3	£25.00	£75.00
Unscheduled visits (mean number per patient)	(0.51)	£25.64	£13.08	(0.70)	£25.33	£17.73
Laser capsulotomy (probability per patient)	(0.05)	£400	£20.00	(0.09)	£400	£36.00
Direct costs to patients (spectacles, etc)	1	£50.00	£50.00	1	£50.00	£50.00
<b>Surgery and outpatient care</b>			£332.89			£335.07
<b>Additional costs at 6 months</b>						
Spectacles (probability of requirement per patient)	(0.54)	£50.00	£27.00	(0.65)	£50.00	£32.50
<b>Total</b>			£359.89			£367.57

minutes (the lower limit), the difference in average costs per procedure (ECCE – Phako) was –£0.62 (in favour of ECCE). Assuming that the mean time difference was 9.3 minutes (the upper limit), the difference in average costs per procedure was £9.27 (in favour of Phako).

### Discussion

A possible source of bias in this study was the loss to follow up. This, however, was unlikely to have caused significant bias since similar numbers were lost in the two treatment groups, and the reasons for loss—mainly problems with attendance due to change of residence or death—were similar in the two groups.

Many factors have been identified as affecting the risk of postoperative capsule opacity including lens material, posterior convexity, and edge design<sup>13</sup> as well as intraoperative and postoperative drug regimens.<sup>14</sup> The type of IOL used in each arm of the trial, however, was part of the surgical procedure, reflecting best practice at the time, with no free choice of various lens materials or designs within each procedure. The implant used for ECCE in the trial is still considered the implant of choice for this procedure. Therefore, the type of IOL was not considered as a possible confounding factor separate from the type of surgical procedure.

It is also possible that ECCE using reduced or small incision may carry a lower risk of capsule opacification. There are no data on the type or size of ECCE incision favoured by any large group of cataract surgeons. We could find no data to support the view that conventional ECCE surgeons have changed to a smaller incision ECCE rather than convert to Phako. According to anecdotal information at the start of the trial, most surgeons who had not made the change to Phako had stayed with their tested conventional large incision ECCE.

Eight ophthalmic surgeons participated in the trial, some performing many more operations than others (Table 2). The main findings relating to the superiority of Phako, however, were highly consistent and there was no significant effect modification by “surgeon.” The trial simulated, as far as possible, real life hospital practice and had to be conducted with minimal disturbance to hospital routine. Accordingly, allocation of patients to surgeons was as per hospital routine practice. A separate randomisation schedule was prepared for each participating surgeon, so that regardless of the number of surgical cases, each surgeon would perform approximately equal numbers of Phako and ECCE, thus minimising any “confounding effects” by surgeon. Whereas the total number of operations was unbalanced between surgeons (as it is in real life), there was no such imbalance in the proportion Phako:ECCE.

There was no significant re-learning curve for the ECCE procedure—that is, no evidence that surgeons were regaining expertise in ECCE during the course of the trial. The rates of peroperative complications were similar in the first and second half of the trial (21.6% and 19.0% respectively), with mean astigmatism of 1.5 dioptres at 1 year postoperatively in both the first and second half of the trial.

The visual acuity outcomes in this trial are better than, but comparable with, those in a recent national survey of cataract surgery practice and outcomes including approximately 18 000 patients.<sup>3</sup> This large survey gives an indication of the visual outcome in patients with ocular co-morbidity (excluded from the trial). The proportions of these patients achieving a visual acuity of 6/9 or better at final refraction were 45% in ECCE and 65% in Phako.

The increased peroperative complication rate for ECCE may be related to the requirement for the eye to be “open” during surgery unlike Phako where the eye is “closed” with maintenance of higher mean IOP throughout.

The frequency of endophthalmitis in the trial of 4/477 (0.8%) was well in excess of the 0.1% national average,<sup>3</sup> which is also the expected rate at the trial centre hospitals. Possible reasons for the risk difference are being explored. A number of possible “causes” could be speculated, but we do not wish to give explanations without supporting data, as doing so may be misleading.

This study has shown that phacoemulsification leads to a better and more stable visual acuity after surgery, and that the use of phacoemulsification in cataract surgery may reduce the incidence of the relatively common complications and problems encountered during surgery and during the first postoperative year. Some of these complications, such as capsule opacity, require further clinical follow up and management.

One constraint of the economic evaluation was that patient recruitment logistics did not allow travel costs for patients to be reliably calculated or other indirect costs to be identified and documented. Because ECCE patients were more likely to suffer instability of vision postsurgically and made more follow up visits, the costs for ECCE may have been underestimated to a greater extent than those for Phako.

A similar underestimation could also arise in the use of the “comparator” centre in the costing methodology in that this device could have slightly overestimated the cost of “disposables” for Phako compared with ECCE.

For capsule opacity, the empirical data from cases were used to assign costs, because there was clear statistical evidence of a difference in risk between the two treatments. This type of cost assignment was not applied for endophthalmitis, since there was no such evidence for differential risk of endophthalmitis, nor was such evidence expected from a trial of this size.

The costs of Phako are similar to those for ECCE up to 6 weeks postoperatively, following which additional costs are incurred by ECCE in order to achieve a similar outcome (these included an increased requirement for unscheduled visits, spectacles, and laser treatment).

The economic evaluation has been carried out with the assumption of maximum efficiency in theatre throughput. Study of surgical throughput<sup>1</sup> indicates that this level of efficiency cannot be assumed because of the widespread custom of limiting the numbers of procedures in a theatre session to five cataract

cases. Where this custom is practised, the increased productivity, which might be gained from the lower theatre time required by Phako, cannot be maximised.

We know from the National Cataract Survey<sup>3</sup> and from Department of Health Statistics that Phako now covers more than 70% of the cataract workload in the UK but with wide variation between units. Given this, and given the favourable clinical and cost position of Phako, we can expect that a move towards maximising efficiency in the organisation of theatre throughput would also maximise the gains to be achieved in the use of this new procedure in place of the older one.

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We thank the Trial Steering Committee—Ralph Rosenthal (chairman), and the Data Monitoring and Ethics Committee—Richard Wormald (chairman). We thank the Allergan, Alcon, and Bausch & Lomb companies for donation of intraocular lenses and materials. We thank K Buckingham and J Roberts for advice on economic methods. We thank Isabel Moldon and Lynda Lindsell, the trial managers at the London and Oxford centres, and John Graham for reading the manuscript.

*Contributors:* PR, JD, PD, AR, and DM were involved in the conception, design, and writing up of this work; SK and NW were the optometrists involved in protocol preparation and the clinical measurements; MS was the assistant economist; epidemiological supervision and data analysis were the responsibility of DM; supervision of the clinical conduct of the trial in the two centres was the responsibility of JD and PR.

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#### Video Reports ([www.bjophthalmol.com](http://www.bjophthalmol.com))

Capsule staining and mature cataracts: a comparison of indocyanine green and trypan blue dyes. *D F Chang*

Pearls for implanting the Staar toric IOL. *D F Chang*

An intraocular steroid delivery system for cataract surgery. *D F Chang*

## LETTER TO THE EDITOR

### Analysis of publication trends in two internationally renowned ophthalmology journals

EDITOR.—International journals represent a forum for exchange of current information with contributions from all over the world. High standards are essential. In this report, we compared the publishing trends of two internationally renowned ophthalmology journals—the *British Journal of Ophthalmology* (*BJO*) and the *American Journal of Ophthalmology* (*AJO*).

#### METHOD AND RESULTS

Using the public Medline facility provided by the National Institutes of Health, the numbers of prospective studies and case reports published in the *AJO* and the *BJO* from January 1980 to December 1999 were determined. These were done using the following keyword searches: “prospective” and “case report.” The countries of origin of the articles were counted manually for the years 1990 and 1999, and were taken as the addresses of the corresponding author. Keyword searching was not possible owing to the non-uniformity of the way the addresses were registered.

The total number of publications remained fairly constant in the *AJO* over the two decades (Fig 1A). The percentage of prospective studies increased greatly from 1% to 12% (Fig 1B). Case reports, on the other hand, constituted 34–45% of the published articles (Fig 1C) with no obvious trend.

In comparison, there was a steady increase in the total number of articles (Fig 1A) in the

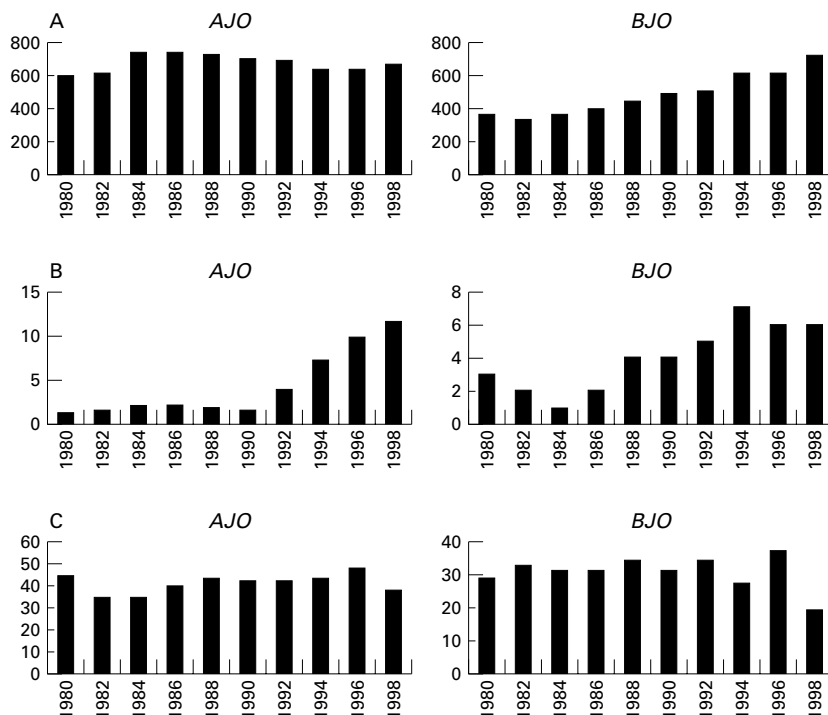


Figure 1 Histograms showing (A) the total number of articles (B) the percentage of prospective articles, and (C) the percentage of case reports in 2 yearly intervals in both journals.

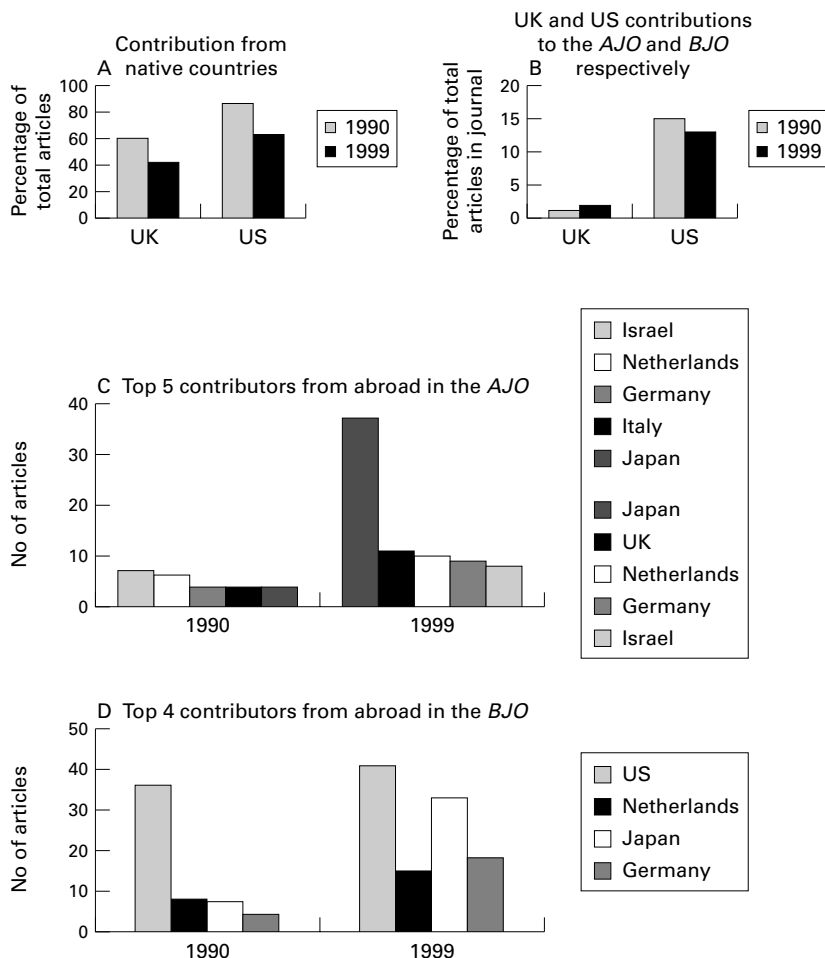


Figure 2 Histograms showing the contributions from native and foreign countries in the years 1990 and 1999 in the two journals.

*BJO*. The trends in the percentages of prospective studies and of case reports were similar to that in the *AJO* (Fig 1B and C).

The native countries (that is, the countries in which the journals are published) were the major contributors of articles for their respective journals (Fig 2A). The United States made a considerably larger contribution to the *BJO* than the United Kingdom did to the *AJO* (Fig 2B). Comparing 1990 with 1999, the contribution from foreign countries had risen significantly from 40% to 60% in the *BJO* and from 14% to 36% in the *AJO*. The top few foreign countries contributing to the respective journals are shown in Figures 2C and D.

#### COMMENT

In an ideal world, all studies will be randomised and controlled. In reality, however, this is often not the case for various reasons. In our present study, we arbitrarily and simplistically chose the prospective design as an indicator of a good quality publication. In both the *BJO* and the *AJO*, there had been an increasing percentage of prospective studies published (from 3% to 6% and from 1% to 12% respectively) over the past two decades. This is an encouraging sign but the percentages remain small, especially in the *BJO*, when compared with other types of publications. This is not necessarily the fault of the journals but merely a reflection of the research work done during that period.

Contributions from abroad appeared to be on the increase in both journals when comparing 1990 with 1999 with the *BJO*

being the more cosmopolitan of the two. This increasing trend of foreign contribution was also noted by Kaugars *et al* in the journal *Oral Surgery Oral Medicine Oral Pathology*.<sup>1</sup>

There are limitations to the present study. The *AJO* and the *BJO* may not be representative of the international ophthalmic journals from the United States and the United Kingdom respectively. Secondly, the total number of articles may be deceptive as the *BJO* and the *AJO* may have articles such as book reviews, editorials, letters, etc at different frequencies. Thirdly, there is the possibility of inadequate keyword classification of the publications in the journals. Finally, the address of the corresponding author may not always correspond to the country where the research was performed.

In conclusion, our study suggests that the standard of publications has improved in the *AJO* and the *BJO*, with an increasing international contribution over the past two decades.

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1 Kaugars GE, Riley WT, Grisius TM, *et al*. Comparison of articles published in *Oral Surgery Oral Medicine Oral Pathology* in 1972 and 1992. *Oral Surg Oral Med Oral Pathol* 1994;**78**:351-3.

## BOOK REVIEW

**Colour Atlas of the Eye in Systemic Disease.** Eds DH Gold, TA Weingeist. Pp 663; £115. Philadelphia: Lippincott Williams & Wilkins, 2001. ISBN 0-397-51525-1.

This is a large reference multiauthored, well illustrated text on a multitude of systemic conditions that have ophthalmic manifestations. It certainly is an enjoyable book to "flick through," with some excellent photographs ranging from retinal disorders associated with infection and systemic disease to genetic disorders, including a multitude of pictures on dysmorphic syndrome. There are chapters on relatively rare conditions such as ocular pharyngeal muscular dystrophy, periodic paralysis and myopathies, and encephalopathies associated with vitamin disorders. The list goes on and indeed the book is a useful reference, with illustrations and bullet points on the manifestations seen in these diseases. But, without prior knowledge or other texts to read the book is not easy to use. However, with an impressive 159 chapters every library should have this book on the shelf. It would offer residents and students from all disciplines the opportunity to appreciate how many diseases have ocular manifestations. What a great subject we are involved with!

A D DICK

## NOTICES

### Onchocerciasis

The latest issue of *Community Eye Health* (No 38) discusses onchocerciasis and the impact of interventions, with an editorial by Bjorn Thylfors, former director of the Programme for the Prevention of Blindness and Deafness, WHO. For further information please contact *Community Eye Health*, International Centre for Eye Health, Institute of Ophthalmology, 11-43 Bath Street, London EC1V 9EL. (tel: (+44) (0) 20-7608 6909/6910/6923; fax: (+44) (0) 7250 3207; email: [eyesource@ucl.ac.uk](mailto:eyesource@ucl.ac.uk)) Annual subscription £25. Free to workers in developing countries.

### International Centre for Eye Health

The International Centre for Eye Health has published a new edition of the *Standard List of Medicines, Equipment, Instruments and Optical Supplies* (2001) for eye care services in developing countries. It is compiled by the Task Force of the International Agency for the Prevention of Blindness. Further details: Sue Stevens, International Centre for Eye Health, 11-43 Bath Street, London EC1V 9EL, UK (tel: (+44) (0) 20-7608 6910; email: [eyesource@ucl.ac.uk](mailto:eyesource@ucl.ac.uk)).

### Second Sight

Second Sight, a UK based charity whose aims are to eliminate the backlog of cataract blind in India by the year 2020 and to establish strong links between Indian and British ophthalmologists, is regularly sending volunteer surgeons to India. Details can be found at the charity website ([www.secondsight.org.uk](http://www.secondsight.org.uk)) or by contacting Dr Lucy Mathen ([lucymathen@yahoo.com](mailto:lucymathen@yahoo.com)).

### Specific Eye ConditionS (SPECS)

SPECS is a not for profit organisation acting as an umbrella organisation for support groups of any conditions or syndrome with an integral eye disorder. The SPECS website ([www.eyeconditions.org.uk](http://www.eyeconditions.org.uk)) acts as a portal to support groups, and is a valuable resource for professionals and may also be of interest to people with a visual impairment or who are blind. Further details: Kay Parkinson, SPECS development officer. (tel: +44 01803 524 238; email: [k@eyeconditions.org.uk](mailto:k@eyeconditions.org.uk)).

### 41st St Andrew's Day Festival Symposium on Therapeutics

The 41st St Andrew's Day Festival Symposium on Therapeutics will be held on 6-7 December 2001 at the Royal College of Physicians of Edinburgh. Further details: Ms Eileen Strawn, Symposium Co-ordinator (tel: 0131 225 7324; fax: 0131 220 4393; email: [e.strawn@rcpe.ac.uk](mailto:e.strawn@rcpe.ac.uk); website: [www.rcpe.ac.uk](http://www.rcpe.ac.uk)).

### 4th International Conference on the Adjuvant Therapy of Malignant Melanoma

The 4th International Conference on the adjuvant therapy of malignant melanoma will

be held at The Royal College of Physicians, London on 15-16 March 2002. Further details: Conference Secretariat, CCI Ltd, 2 Palmerston Court, Palmerston Way, London SW8 4AJ, UK (tel: + 44 (0) 20 7720 0600; fax: + 44 (0) 20 7720 7177; email: [melanoma@confcomm.co.uk](mailto:melanoma@confcomm.co.uk); website: [www.confcomm.co.uk/Melanoma](http://www.confcomm.co.uk/Melanoma)).

### EUPO 2002 Course Retina

A course on retina will be held on 15-17 March 2002 at Erlangen, Germany, where European professors will teach European residents. Further details: Priv Doz Dr Ulrich Schonherr, Friedrich-Alexander-University of Erlangen-Nuemberg, Department of Ophthalmology, Schwabachanlage 6 (Kopfklinikum), D-91054 Erlangen, Germany (tel: +49 9131-853-4379; fax: +49 9131-853-4332; email: [ulrich-schoenherr@augen.imed.uni-erlangen.de](mailto:ulrich-schoenherr@augen.imed.uni-erlangen.de)).

### XXIXth International Congress of Ophthalmology

The XXIXth International Congress of Ophthalmology will be held on 21-25 April 2002 in Sydney, Australia. Further details: Congress Secretariat, C/- ICMS Australia Pty Ltd, GPO Box 2609, Sydney, NSW 2001, Australia (tel: +61 2 9241 1478; fax: +61 2 9251 3552; email: [ophthal@icmaust.com.au](mailto:ophthal@icmaust.com.au); website: [www.opthalmology.aust.com](http://www.opthalmology.aust.com)).

### International Society for Behçet's Disease

The 10th International Congress on Behçet's Disease will be held in Berlin 27-29 June 2002. Further details: Professor Ch Zouboulis (email: [zoubbere@zedat.fu-berlin.de](mailto:zoubbere@zedat.fu-berlin.de)).

### Singapore National Eye Centre 5th International meeting

3-5 August 2002, Singapore. Further details: Ms Amy Lim, Organising Secretariat, Singapore National Eye Center, Third Hospital Avenue, Singapore 168751 (tel: +65 322 8374; fax: +65 227 7290; email: [amy\\_lim@snecc.com.sg](mailto:amy_lim@snecc.com.sg)).

## CORRECTIONS

In a paper published by Minassian *et al* in the July issue of the *BJO* (2001;**85**:822-9) two authors who made significant contributions to the project were omitted. They are Sunny Kaushal, research optometrist, Oxford Eye Hospital, and Nicholas Wingate, research optometrist, Moorfields Eye Hospital. We apologise for this omission.

A translation error occurred in the article by Demailly *et al* which appeared in the August issue of the *BJO* (2001;**85**:921-4). In the abstract (p 921 line 16) and the text (p 922, line 8) the dose for carteolol alginate was given as "four times daily" when it should be once daily. We apologise for this error.



## Extracapsular cataract extraction compared with small incision surgery by phacoemulsification: a randomised trial

D C Minassian, P Rosen, J K G Dart, et al.

*Br J Ophthalmol* 2001 85: 822-829

doi: 10.1136/bjo.85.7.822

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