Clear lens extraction for the management of primary angle closure glaucoma: surgical technique and refractive outcomes in the EAGLE cohort

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Clear lens extraction for the management of primary angle closure glaucoma:

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Abstract

Background/Aims:

To describe the surgical technique and refractive outcomes following clear lens extraction (CLE) in the EAGLE trial.

Methods:

Review of prospectively collected data from a multicentre, randomised controlled trial. comparing CLE and laser peripheral iridotomy. Eligible participants were ≥50 years old, and newly diagnosed with (1) primary angle-closure (PAC) with intraocular pressure (IOP) above 30 mmHg, or (2) primary angle-closure glaucoma (PACG). We report the postoperative corrected distance visual acuity (CDVA), and refractive outcomes at 12 and 36 months postoperatively for those who underwent CLE.

Results:

Of the 419 participants, 208 were randomised to CLE. Two patients (2/208, 1.0%, 95% CI: 0.04 to 3.67%) had posterior capsule rupture requiring anterior vitrectomy and sulcus IOL placement. Mean baseline CDVA was 77.9 (SD 12.4) ETDRS letters and did not change significantly at 36 months, 79.9 (SD 10.9) letters. Mean preoperative spherical equivalent was +1.7 (SD 2.3) and +0.08 (SD 0.95) diopters (D) at 36 months. Fifty-nine percent and 85% eyes were within ±0.5D and ±1.0D of predicted refraction respectively at 36 months.

Conclusions:

Mean CDVA in patients undergoing clear lens extraction for angle-closure glaucoma appeared stable over the 3 year study period. Refractive error was significantly reduced with surgery but refractive predictability was sub-optimal.

Introduction

Refractive outcomes in patients with primary angle closure glaucoma (PACG) undergoing lens extraction can be unpredictable because of the anatomical features including shallow anterior chamber depth, thickened and anteriorly positioned lens, and short axial length. Large deviations from the target refraction have been reported.[1–3] The EAGLE (Effectiveness, in Angle-closure Glaucoma, of Lens Extraction) study recently reported that PACG and PAC patients with high intraocular pressure (IOP) who were treated with clear lens extraction (CLE) had better quality of life and IOP control and required fewer medications and surgeries to control their glaucoma than those undergoing laser peripheral iridotomy (PI).[4] Visual acuity outcomes were similar between the CLE and laser PI.

Given these positive results, the decision on whether or not to perform CLE in these patients as primary therapy depends largely on an individualised approach to the risks and benefits. The EAGLE trial reported low rates of surgical complications and irreversible vision loss in both groups. In this report, we describe the surgical details, visual outcomes and postoperative refractive error of participants undergoing CLE.

Materials and Methods

The EAGLE trial recruited 419 participants with either PAC with IOP of 30 mmHg or higher or non-severe PACG between January 2009 and December 2011.[4]   Full details of the treatments are specified in the published protocol.[5] Briefly, eligible patients underwent either laser peripheral iridotomy, or CLE by phacoemulsification with a monofocal intraocular lens (IOL) implantation within 60 days of randomisation. A total of 208 patients were randomised to lens extraction. Synechiolysis was allowed according to local practice.

Participating surgeons recorded operative details and intraoperative and post-operative complications at the time of surgery and at 6, 12, 24 and 36 months after randomisation using standardized forms.   Data were collected on the predicted refraction and IOL formula used. Laser biometry was used to estimate axial length and IOL power. The IOL formula and incision axis were selected by the local surgeon. Anti-glaucomatous treatment was allowed before surgery and selected according to local practice.   The most commonly used drug was prostaglandin (n=67, 54.0%) followed by beta-blocker (n=46 (37.1%)) and pilocarpine (n=41, 33.1%).

All patients underwent subjective refraction by a masked optometrist at 12 months and 36 months postoperative. Corrected distance visual acuity was measured with Early Treatment Diabetic Retinopathy Study (ETDRS) charts under standardized illumination.[6]

Mean biometry prediction errors were calculated by subtracting the postoperative spherical equivalent (SE) from the predicted spherical equivalent, allowing calculation of the mean prediction error (MPE, i.e., predicted SE minus postoperative SE).[7,8] A negative MPE indicates undercorrection (hyperopic outcome).[7,8] The mean absolute error (MAE) is the mean of the individual prediction errors without regard for sign. Visual acuity and refractive results are presented where possible in accordance with the standardized reporting guidelines for cataract and refractive surgery.[9,10] We used regression analysis to explore the possible influence of the following baseline variables on refractive error: axial length, anterior chamber depth, refraction, age, visual acuity, bilateral (one or both eyes fulfilling the inclusion criteria), gender, diagnosis (PAC or PACG), and ethnicity (Chinese versus non-chinese)"

Results:

 Most surgeries (181, 87%) were performed by senior consultant glaucoma specialists. Ninety-six percent cases were performed via a clear corneal incision, and 9% required a corneal suture to facilitate wound closure (see Table 1 for participant demographic and operative details). A monofocal IOL was used in all cases. The SRK/T formula was used for IOL power calculation in over 80% cases (Table 1).

Table 1. Demographic and operative details

	Lens extraction (n=208)
Age, years	67.1,(8.4)
Gender, M:F	86:122
Ethnicity (Chinese)	62 (29.8%)
N withdrawn intervention post randomisation but prior to surgery?	1 (0.5%)
Mean axial length, mm (SD)	22.5(0.9)
Mean preoperative anterior chamber depth, mm (SD)	2.5 (0.3)
Mean preoperative spherical equivalent, D (SD)	1.7(2.3)
Anaesthetic technique	65 (31.2%) topical and intracameral 116 (55.8%) sub-Tenon's 10 (4.8%) peribulbar 8 (3.8%) retrobulbar 9 (4.3%) general
Incision type (if reported)	200 (96.2%) corneal 1 (0.5%) scleral
Incision axis at 12 o'clock	55 (26.4%) 12 o'clock 145 (69.7%) other axis
Wound suture	18 (8.7%)
Intra-operative antibiotic	142 (68.3%) intracameral 40 (19.2%) subconjunctival

Visco-synechiolysis performed	18 (8.7%)
Grade of surgeon lens	181 (87.0%) Consultant
	16 (7.7%) Associate Specialist
	2 (1.0%) Fellow
	4 (1.9%) Other
IOL power used; diopters (SD)	23.8,(2.7)
Aimed refraction; diopters (SD)	-0.1,(0.6)
IOL formula used, total number	164
SRK-T	136 (82.4%)
Hoffer-Q	16 (9.1%)
Haigis	8 (4.8%)
Holladay	4 (2.4%)
Surgery time, minutes (SD)	22.9 (8.5)

Average baseline CDVA was 77.9 (12.4) ETDRS letters and did not differ significantly at 12 months or 36 months (see table 2). Almost 6% eyes lost 10 or more ETDRS letters of CDVA (equivalent to 2 line logMAR) at 12 months and 10% eyes lost 10 or more ETDRS letters at 36 months (see Figure 1). Two patients (2/208, 1.0%, 95% CI: 0.04 to 3.67%) had posterior capsule rupture requiring anterior vitrectomy and sulcus IOL placement, but these 2 eyes had satisfactory visual outcomes with no visual acuity loss of 10 or more ETDRS letters.

Postoperative target refraction and postoperative manifest refraction data was available for 154 eyes (154/208, 74%); of which, the IOL power formula used was available for 127 eyes (61%). The mean postoperative target refraction was -0.1D spherical equivalent (SD 0.6D). The overall mean prediction error (MPE) at 36 months was +0.16D (SD: 0.84). The mean absolute prediction error (MAE) at 36 months was +0.59D (SD = 0.61D). (see Table 2). Overall fifty-nine percent and 85% of eyes were within ±0.5D and ±1.0D of target refraction, respectively (see Table 3 including comparisons by IOL formula used, Figure 2). Table 4 shows the proportion eyes within ±0.25, ±0.50 and ±1.0D predicted refraction by axial length

(<22mm or ≥22mm). Eyes with axial length of <22mm were significantly more likely to have a postoperative refractive outcome >1D different from that predicted. Figure 3 shows the postoperative refractive cylinder at 36 months. Regression of attempted spherical equivalent correction vs achieved spherical equivalent correction is displayed in Figure 4.

The demographic and ocular variables explored were not associated with refractive predictability (p>0.05). Among participants with loss of vision one had irreversible and severe visual loss due to malignant glaucoma and uncontrolled IOP, but no specific complications were reported in other patients with decreased visual acuity. Decreased visual acuity was not considered to be permanent by the local clinician.

Table 2. Mean pre- and postoperative spherical equivalent refraction and visual acuity

Spherical equivalent, diopters	n	mean (SD)
Baseline	189	+1.7 (2.3)
12 months	176	+0.01 (0.97)
36 months	168	+0.08 (0.95)
ETDRS visual acuity, letters	n	mean (SD)
Baseline	207	77·9(12·4)
12 months	183	81.6(9.3)
36 months	176	79·9(10·9)

Table 3: Mean prediction errors, absolute prediction errors and proportion eyes within ±0.25, ±0.50 and ±1.0 diopters (D) predicted refraction.

IOL formula	n eyes	Mean prediction error at 36m, SD, range X-Y	Absolute prediction error at 36m, SD, range X-Y	% within±0.25D target	% within±0.50D target	% within±1.0D target
Hoffer Q	12	-0.37, SD: 1.71	1.11, SD: 1.32	25%	42%	67%
SRK/T	105	+0.28, SD: 0.76	0.61, SD: 0.53	32%	55%	84%
Haigis	6	+0.025, SD: 0.38	0.30, SD: 0.20	50%	83%	100%
All overall*	150	+0.16, SD: 0.84	0.59D, SD: 0.61,	35%	59%	85%

*Data for Holladay (n=4), and missing IOL power formula used (n=23), also included.

Table 4. Proportion eyes within ±0.25, ±0.50 and ±1.0 diopters (D) predicted refraction by axial length (<22mm or ≥22mm).

	% within ±0.25D target	% within ±0.50D target	% within ±1.0D target
Axial length <22mm [n=36]	**33%**	**50%**	**64%**
Axial length ≥22mm [n=112]	**35%**	**61%**	**92%**
All [n=148]	**34%**	**58%**	**85%**

Discussion:

In the EAGLE trial, 59% and 85% of eyes undergoing CLE were within ±0.5D and ±1.0D of predicted refraction, respectively. Refractive outcomes in patients with PACG undergoing lens extraction are typically believed to be unpredictable due to the anatomical features including shallow anterior chamber depth, thickened and anteriorly positioned lens, and short axial length. Overall our refractive outcomes were similar to previous large datasets of patients undergoing cataract surgery with values being 49-60% and 80-87% eyes within ±0.5D and ±1.0D of predicted refraction respectively using data from the UK;[11] and are in keeping with the previous refractive outcome benchmarking target set by the UK Royal College of Ophthalmologists of 85% within ±1.0D target.[12] The refractive accuracy is however less, than that reported in an analysis of 17 056 eyes undergoing cataract surgery in Sweden, where 71% were within ±0.5D and 93% within ±1.0D.[13] The EAGLE results compare favourably to previous studies of refractive outcomes in patients with PACG where 49-68% eyes (depending on the IOL power formula used) were reported to be within ±0.5D target a study of 63 eyes[14] and 77% eyes within 1.0D target refraction in study of 49 eyes with primary angle closure glaucoma.[15]

The mean prediction error varied by IOL formula used, being -0.4D for Hoffer Q and +0.3 for SRK/T, indicating undercorrection and overcorrection (myopic outcome) respectively for these IOL formulae. SRK/T was used in 83% cases and thus based on the data available, clinicians would typically experience a myopic overcorrection in patients with similar characteristics than those enrolled in EAGLE. Mean IOL formula prediction errors must be close to zero to minimize the systematic error from an incorrect IOL formula constant.[16,17] However this was not possible as keratometry data was not recorded as part of the EAGLE dataset. Simple comparison of the MAEs (with non-zero MPE values) between different

formulas used in EAGLE would be biased, and only six eyes used Haigis formula, but the MPE of 0.03 may suggest that the lens constants used with this formula were close to optimal. Interestingly a tendency towards myopic overcorrection in eyes with angle closure was reported by Kim et al.[15]; whilst Joo et al. reported a myopic overcorrection when using the Hoffer Q formula; and hyperopic undercorrection when using either SRK/T or the Haigis formulae.[18] The myopic overcorrection in eyes with PAC may be associated with a high lens vault (defined as the perpendicular distance between the anterior pole of the crystalline lens and a horizontal line connecting the two scleral spurs), and so an anteriorly positioned crystalline lens.[15] It is possible other factors may influence the refractive predictability such as the anterior chamber configuration and a large lens vault [19].

In the EAGLE trial visual acuity outcomes in the CLE group were similar to the laser PI group. There is limited data for comparison of visual outcomes as reported by reviews on refractive lens exchange.[20] A recent large dataset analysis on the results of cataract surgery in the UK reported visual acuity loss (defined as ≥0.30 logMAR loss) was 1.5% for the overall cohort and 6.9% for those with a preoperative visual acuity of 0.00 logMAR or better.[21]

Posterior capsule rupture (PCR) is associated with significantly higher risk of poor visual outcomes[22] and PCR has been reported to be the only potentially modifiable adverse risk indicator for visual loss following cataract surgery (OR=5.7),[22] but in the EAGLE trial the frequency of visual acuity loss was not different between the CLE and the laser PI groups. Overall PCR rates from large cataract outcome datasets are approximately 1.9 – 2.1%.[21,23,24]. In an analysis by Day et al. of 105 078 eyes undergoing cataract surgery, PCR rates showed little change with axial length except for an increase in eyes with axial length of <20.0mm (3.6% PCR rate vs 2.0% for those ≥20.0 mm axial length, OR 1.9).[25] In the EAGLE study two participants (2/208, 0.96%, 95% CI: 0.04 to 3.67%) had PCR. Based on the greater

than average complexity of surgery in eyes with PACG, the relatively low rate of PCR in EAGLE participants may reflect the experience of the operating surgeons or the fact that the relatively soft lens material could be easily removed.

EAGLE patients that underwent CLE had correction of their preoperative refractive error with emmetropia targeted in the vast majority of cases. Conversely EAGLE patients, that were randomized to laser peripheral iridotomy had a mean hyperopic error (+0.92D [SD 2.8D] at 36 months. Thus those that were randomized to CLE would have had unaided distance visual acuity improvement for both distance, intermediate and near, and refractive correction may have impacted the patient reported outcome questionnaires[26] with a change of almost 6% for EQ5D, 7% for the Glaucoma Utility Index, and 26% for the National Eye Institute VFQ-25 relative to those that underwent laser peripheral iridotomy.[4] The influence of refractive error on quality of life may deserve further analysis. Although refractive outcomes are important factors in determining the risk/benefit ratio of clear lens extraction as a first treatment for angle closure disease, possible long-term complications including the risk of retinal detachment after lens extraction should also be considered. The risk of pseudophakic retinal detachment is estimated to be 1.0% at 4 years.[27] This is particular important because randomised controlled trials are not useful to detect and quantify the frequency of uncommon complications.

As previously discussed, the main advantages of the EAGLE study are its prospective data collection, pragmatic design, large sample size, the involvement of centres in the UK and Asia and the masking of the clinical assessments in particular for visual acuity and refraction, which kept the potential risk of bias to a minimum.[4] There are also a number of limitations, these include that the CLE was not masked from participants and there were missing data issues

such as seen by the proportion of patients with complete biometric and refraction data. However there is no reason to suggest that missing data could have introduced bias.

In conclusion CLE for a subset of PAC or PACG patients is a suitable option, but an individualised decision on the risks and benefits of clear lens extraction versus laser peripheral iridotomy is warranted. This should include consideration of the potential error in refractive outcomes, particularly in eyes with short axial length.

Acknowledgement

Competing interests

None declared

Contributorship

AA-B and JB are chief investigators of the EAGLE trial. ACD and DC led the data analysis. AA-B and ACD led the drafting of the manuscript. All authors were actively involved in the interpretation of data and editing of the manuscript.

Legends:

Figure 1.

Change in logMAR lines of CDVA at 36 months;

Figure 2.

Postoperative spherical equivalent refraction at 36 months.

Figure 3.

Postoperative refractive cylinder at 36 months.

Figure 4.

Comparison of spherical equivalent attempted correction (preoperative minus predicted spherical equivalent) and achieved spherical equivalent correction (preoperative minus achieved spherical equivalent refraction) at 36 months.

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