EXTENDED REPORT

Intraocular pressure following phacoemulsification in patients with and without exfoliation syndrome: a 2 year prospective study

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Br J Ophthalmol 2006;**90**:1014–1018. doi: 10.1136/bjo.2006.091447

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Accepted for publication 2 April 2006

Aim: To determine the long term intraocular pressure (IOP) response to phacoemulsification in patients with and without exfoliation syndrome (XFS).

Methods: Prospective, multicentre, cohort study with the following inclusion criteria: age over 50 years, open iridocorneal angle, and cataract. Two groups were enrolled: those with XFS and those without. The main outcome was mean IOP reduction 2 years after phacoemulsification cataract extraction (PCE). Univariate and multivariate analyses were performed.

Results: 183 patients were enrolled, 71 with and 112 without XFS. There were 29 patients with glaucoma in both groups. Mean baseline IOP was higher in XFS compared to control eyes (17.60 (SD 3.23) mm Hg *v* 16.08 (3.18) mm Hg, p = 0.002). Overall IOP reduction was significantly greater in the XFS group at the 2 year time point (−1.85 mm Hg *v* −0.62 mm Hg in the controls (p = 0.0037)). Multivariate analysis demonstrated that the IOP lowering effect in the XFS group may be related to irrigation volume at the time of surgery. In the subgroup analyses IOP lowering was significantly greater in the XFS and XFG patients than in controls without glaucoma, and POAG controls, respectively. The percentage of patients with a postoperative IOP spike was similar and relatively high in both XFS and control groups (34% *v* 25%; p = 0.54).

Conclusion: IOP decreases more in patients with XFS following PCE compared to control eyes without XFS. This effect is more pronounced in glaucoma patients and persists for at least 2 years.

Exfoliation syndrome (XFS) is an age related systemic disorder marked by the synthesis and progressive deposition of extracellular fibrillar material within the anterior segment.[1] It is, overall, the most common identifiable cause of glaucoma worldwide, and in some countries accounts for the majority of glaucoma.[2] The diagnosis of XFS is unusual before 50 years of age, and its prevalence tends to increase with age.[3]

XFS is associated with a number of ocular findings including increased intraocular pressure (IOP), open angle glaucoma (exfoliative glaucoma), increased prevalence of cataract, lens subluxation, blood-aqueous barrier breakdown, retinal vein occlusion, as well as others ophthalmic sequelae.[4] XFS has also been associated with increased intraoperative risks during extracapsular and phacoemulsification cataract extraction (PCE), including a higher incidence of vitreous loss and zonular/capsular tears.[5 6]

Elevated IOP with or without glaucomatous damage occurs in approximately 25% of people with XFS, or about 6–10 times the rate in eyes without XFS.[7–10] At the time of diagnosis, IOP is higher than in primary open angle glaucoma (POAG) and there is a higher frequency and severity of optic nerve damage, worse visual field damage, poorer response to medications, more rapid progression, more severe clinical course, and more frequent necessity for surgical intervention.[11–21] In light of this, careful monitoring and control of IOP is of great importance in this patient population. The common co-existence of cataract and glaucoma in XFS often poses management dilemmas as to the type of surgical approach. Determining the magnitude of IOP reduction response to cataract surgery in XFS or exfoliative glaucoma (XFG) would be useful in determining whether to do PCE alone or combine the surgery with trabeculectomy. Several studies have noted a decrease in IOP following PCE.[6 22] Our hypothesis was that patients with exfoliation would have a greater drop in IOP compared with those without because of a loss of iridolenticular friction—that is, there would be much less release of pigment from the iris, or exfoliation material from the lens and iris.

Our primary goal was to evaluate the effect of cataract surgery on IOP lowering, in patients with exfoliation, (with or without elevated IOP) and compare it to appropriate controls over a 2 year period. Our secondary goal was to evaluate IOP at other time points, between surgery and 2 years, to see if the IOP lowering correlated with any perioperative variables. In addition, we were interested in comparing the IOP drop in patients with XFG versus those with POAG.

METHODS

This multicentre, prospective cohort study included patients from the University of Ottawa Eye Institute, the university department of ophthalmology, Aristotle University (Thessaloniki, Greece), and the New York Eye and Ear Infirmary (New York City, USA). Surgery was conducted by six surgeons (KFD, AGPK, JML, GM, RR, NGZ) at these centres. Patients who met eligibility criteria were enrolled in one of two groups (only one eye of each patient was entered into the study): those with XFS and those without (controls).

Abbreviations: BCVA, best corrected visual acuity; IOP, intraocular pressure; PCE, phacoemulsification cataract extraction; POAG, primary open angle glaucoma; XFG, exfoliative glaucoma; XFS, exfoliation syndrome

Inclusion criteria included age over 50 years, gonioscopically open angle, and visually significant cataract requiring phacoemulsification.

Consecutive XFS or XFG patients were selected based on clinical criteria of exfoliative material in a partial or complete central disc with or without a peripheral band in at least one eye, regardless of IOP. The control group consisted of either POAG patients, or normotensive patients with cataract only. The POAG control group included patients who had been previously diagnosed and met at least two of the following three eligibility criteria: IOP consistently greater than 21 mm Hg with a normal anterior chamber angle; visual field changes associated with glaucoma, or optic nerve changes consistent with glaucoma. The cataract only group required an IOP consistently less than 21 mm Hg with no signs of XFS, glaucoma, or other ocular pathology.

Exclusion criteria were advanced glaucoma (cup:disc ratio 0.85 and/or visual field defect within 10 degrees of fixation, or both), other types of pre-existing glaucoma (for example, secondary, normal tension, narrow angle), previous anterior segment surgery other than laser surgery (for example, trabeculectomy), other pre-existing ocular disease (for example, uveitis), use of steroid medications by any route for more than 2 weeks preoperatively, or patients with a corneal abnormality that precluded reliable applanation tonometry (for example, trauma, previous contact lens use, etc).

Patients underwent cataract extraction with intraocular lens implant using a standard phacoemulsification technique. If patients were on IOP lowering medication(s) preoperatively, these were continued postoperatively.

IOP, time IOP was taken, the number of medications, best corrected visual acuity (BCVA), and the presence or absence of anterior chamber cells were recorded 1 day, 1 week, and 1, 6, 12, and 24 months postoperatively. The main outcome was IOP change at 2 years versus preoperative IOP. Data were also collected on early postoperative IOP spikes (⩾6 mm Hg rise from baseline).

Standardised data collection forms documented initial examination, preoperative data, and postoperative follow up visits, and were sent from all sites to the coordinating centre at the University of Ottawa Eye Institute.

Sample size calculation

When comparing two means, sample size depends on (1) the minimum difference you wish to detect as significant, (2) the SD of each population (assume equal SDs), (3) probability of type I error. If there really is no difference, chance of randomly finding a ''significant'' difference, and (4) β probability of type II error, finding a ''non-significant'' difference when the true difference equals; power = 1 − β.

We assumed that patients with XFS will have a 3 mm Hg drop at 2 years following PCE, and those without will have a 1 mm Hg drop. The calculated crude sample size was 25 patients per arm. After we adjusted for an estimated 20% loss to follow up, and 90% power, the final sample size calculated was 41 patients per arm.

Statistical analysis

The primary outcome of this study is IOP reduction (difference taken between follow up time point and baseline measurement). The goal is to produce a multiple linear regression model that includes all factors that significantly contribute to the changes in IOP reduction, with the presence of exfoliation as the main predictor variable.

Normality was tested for each potential predictor variables before performance of bivariate comparisons by the XFS and non-XFS group. Unpaired *t* tests were used to compare continuous variables and χ^2 or Kruskal-Wallis test binary or categorical variables. Predictor variables displayed $p>0.10$ for the bivariate analyses were fitted in the regression model. Colinearity was checked before the final model was determined.

Data were analysed for the XFS and non-XFS groups as well as for subgroups (XFS without glaucoma, XFS with glaucoma—that is, XFG, cataract controls, and patients with POAG). All data analysis was performed using the Stata v.7 software.

RESULTS

A total of 183 patients were enrolled in the study, 71 with XFS and 112 without XFS (fig 1). There were 29 patients with glaucoma in both groups. Baseline variables were similar among the groups (tables 1 and 2), but the XFS group had a significantly higher mean baseline IOP compared to the control group (table 3).

IOP reduction was significantly greater in the exfoliation group at all time points out to 2 years (fig 2 and table 3). In the subgroup analyses (table 4), IOP lowering was −1.85 mm Hg at 2 years in the XFS patients versus −0.62 mm Hg in the controls ($p = 0.0037$). In patients with XFG, IOP lowering was more pronounced than those with POAG (−3.15 mm versus −1.54 mm Hg at 2 years, $p = 0.0336$).

Furthermore, multivariate analysis demonstrated that the IOP lowering effect in the XFS group was related to irrigation volume at the time of surgery. Results showed a significant correlation between greater volume of irrigation used and greater IOP reduction at 1 year ($r = 0.43$, $p = 0.005$) and 2 years ($r = 0.34$, $p = 0.023$) postoperatively, but not in the non-XFS group (1 year: $r = 0.10$; $p = 0.49$; 2 years: $5 = 0.13$; $p = 0.35$). The differences in irrigation volume between the XFG versus POAG controls and XFS versus cataract controls

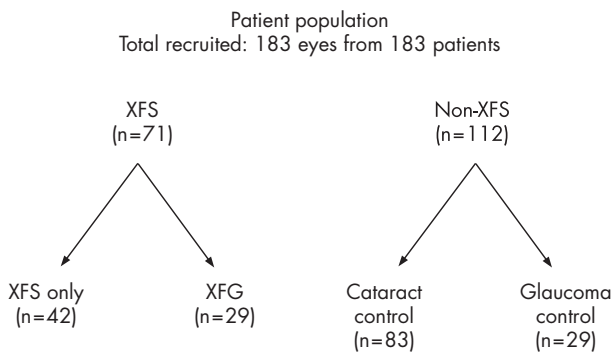

Figure 1 Patient population enrolled in the study (SD).

Table 1 Baseline variables

Covariate	XFS	Non-XFS
Mean patient age (years)	75.98 (6.74)	73.35 (10.59)
Men/women	20/51	38/74
Eye: R/L	35/36	41/71
Baseline IOP (mm Hg)	17.6 (3.24)	16.08 (3.18)
Mean phaco time (minutes)	2.65 (3.69)	0.74 (1.96)
Mean BCVA logMAR	0.68 (0.43)	0.48 (0.31)
Cataract: NS/PSC/cortical	60/21/6	98/27/16
Anaesthesia: peribulbar/topical/retrobulbar	21/33/17	11/74/26
Sutureless/suture	76/36	46/23
Mean vertical C:D ratio	0.46 (0.18)	0.43 (0.17)
Irrigation volume (ml)	345.8 (19.00)	220.9 (6.70)

BCVA, best corrected visual acuity.

Table 2 Baseline variables in subgroups

	XFS	Glaucoma control	Cataract control	XFG
Mean patient age (years)	78.40 (5.97)	73.99 (10.78)	73.13 (10.58)	72.49 (6.32)
Men/women	11/31	9/20	29/54	9/20
Baseline IOP (mm Hg)	16.07 (2.51)	18.52 (3.52)	15.23 (2.57)	19.81 (2.90)
Mean phaco time (minutes)	0.90 (1.35)	2.52 (3.75)	0.27 (0.52)	5.20 (4.50)
Mean preoperative BCVA logMAR	0.63 (0.43)	0.52 (0.31)	0.47 (0.31)	0.77 (0.43)
Cataract:				
NS/PSC/cortical	31/9/2	26/9/6	72/18/10	29/12/4
Anaesthesia:				
peribulbar/topical/retrobulbar	12/26/4	1/12/16	10/62/10	9/7/13
Sutureless/suture	34/8	13/16	63/20	13/16
Mean vertical C:D ratio	0.35 (0.14)	0.48 (0.20)	0.41 (0.15)	0.55 (0.17)
Irrigation volume (ml)	313 (143.50)	240.24 (76.43)	215.2 (50.83)	392.21 (136.12)

BCVA, best corrected visual acuity.

Table 3 IOP at various time points postoperatively

Postoperative time	IOPΔ XFS (SD) (n)	IOPΔ non-XFS (SD) (n)	p Value
1 day	3.42 (7.98) (71)	1.87 (7.18) (111)	0.1781
1 week	−1.23 (3.08) (31)	−0.61 (4.07) (66)	0.4539
3 weeks	−3.11 (2.96) (63)	−1.04 (3.76) (92)	0.0004
6 weeks	−2.14 (3.36) (29)	−1.70 (4.20) (53)	0.6289
6 months	−3.44 (3.25) (48)	−1.29 (3.71) (70)	0.0015
1 year	−2.64 (3.14) (52)	−1.07 (3.27) (72)	0.0073
2 years	−2.51 (3.70) (53)	−0.89 (3.51) (82)	0.0115

were also significant ($p = 0.0002$ and $p = 0.0000$, respectively).

The percentage of patients with a postoperative IOP spike (≥6 mm Hg) was similar and relatively high in both the XFS and non-XFS groups (34% *v* 25%; $p = 0.54$), but this had settled by 6 weeks.

DISCUSSION

To our knowledge, this is the first prospective study to demonstrate that IOP decreases significantly following PCE in eyes with XFS versus controls. This effect persisted throughout the 2 years of this study and closely correlated with the quantity of irrigation fluid used at the time of surgery. We also found that this IOP lowering is more pronounced in patients with XFG versus those with POAG.

We speculate that patients with XFS undergoing PCE experience a greater decrease in IOP postoperatively in comparison with patients without XFS as phacoemulsification eliminates iridolenticular friction and thus significantly reduces the release of pigment from the iris and exfoliation material from the lens and iris. The procedure may also remove loose exfoliation material and pigment from the clogged outflow system, and thus may lead to further IOP lowering in patients with exfoliation especially in those with XFG. It is relevant to note that recent work by Jacobi *et al*[23 24] supports this hypothesis and has advocated the use of anterior chamber irrigation with a trabecular aspiration device in XFG with a significant reduction in IOP over a 2 year follow up period. Other possibilities include the upregulation of matrix metalloproteinases or other physiological processes that alter trabecular or uveoscleral outflow.

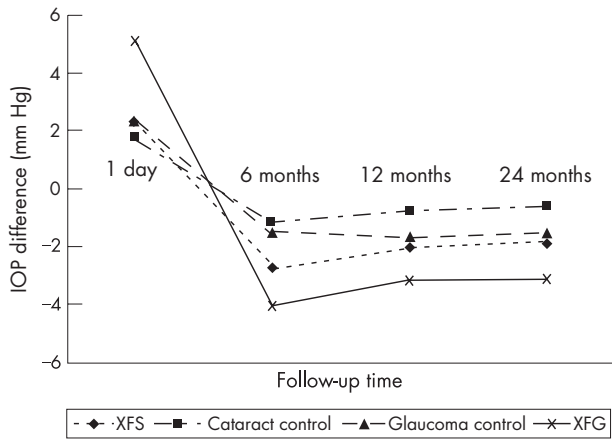

Figure 2 Group comparison of IOP reduction over time.

A number of retrospective studies have examined the effect of PCE on IOP levels in patents with and without XFS. Suzuki *et al*[25] and Wirbelauer *et al*[6] have reported a decrease in IOP after PCE and intraocular lens implantation in patients without preexisting disease. PCE patients with an increased preoperative IOP with or without glaucoma but no XFS also may exhibit meaningful postoperative drops.[22 25–28] Another study has reported that XFS patients with a normal preoperative IOP experienced a decrease in IOP postoperatively that was significantly greater than similarly matched controls without XFS.[29 30] These observations are consistent with our results.

The main predictors of post-PCE IOP reduction in our study after a 2 year follow up were the presence of exfoliation, baseline IOP, and irrigation volume. We also found that the decrease in IOP in patients with exfoliation is proportional to irrigation volume used at the time of surgery. We speculate that this may be because of one or more of the following factors: washing out of exfoliation material and pigment from the anterior segment, deepening of the anterior chamber angle, and low grade inflammation leading to enhanced aqueous outflow (that is, a laser trabeculoplasty-like effect).

Our study has some shortcomings. The number of patients with XFG was small and hence, it is difficult to draw

Table 4 IOP change from baseline in subgroups

Mean group difference of IOP Δ from baseline	XFS	Cataract control	p Value*	POAG control	p Value**	XFG	p Value***	p Value****
Δ AT 1 week								
Mean	−1.0400	−0.3636	0.4265†	−1.8182	0.5568†	−2.0000	0.5029†	0.0003†
SE	0.540	0.514	0.0656‡	1.571	0.8328‡	1.880	0.0446‡	0.0152‡
No (eyes)	25	55		11		6		
Δ AT 3 weeks								
Mean	−2.6923	−0.6308	0.0020†	−2.0370	0.4693†	−3.7917	0.1535†	0.0317†
SE	0.459	0.421	0.0178‡	0.856	0.3159‡	0.620	0.0032‡	0.0494‡
No (eyes)	39	65		27		24		
Δ AT 6 weeks								
Mean	−2.5714	−1.3750	0.2120†	−2.6923	0.9359†	−1.0000	0.2674†	0.0292†
SE	0.692	0.582	0.0037‡	1.542	0.4056‡	1.336	0.7887‡	0.0328‡
No (eyes)	21	40		13		8		
Δ AT 6 months								
Mean	−2.7391	−1.1667	0.0548†	−1.5455	0.3525†	−4.0800	0.1560†	0.0735†
SE	0.722	0.437	0.0792‡	1.056	0.3020‡	0.594	0.0486‡	0.0215‡
No (eyes)	23	48		22		25		
Δ AT 12 months								
Mean	−2.0400	−0.8364	0.1089†	−1.6667	0.7060†	−3.2037	0.1848†	0.0287†
SE	0.601	0.419	0.0016‡	0.800	0.1329‡	0.619	0.0012‡	0.1124‡
No (eyes)	25	55		21		27		
Δ AT 24 months								
Mean	−1.8462	−0.6207	0.1080†	−1.5417	0.7742†	−3.1481	0.2031†	0.0180†
SE	0.632	0.418	0.0037‡	0.860	0.1554‡	0.782	0.0060‡	0.0336‡
No (eyes)	26	58		24		27		

No, number (of eyes); XFS, exfoliation syndrome; Cataract, cataract control patients; POAG, primary open angle glaucoma; XFG, exfoliation glaucoma.
*Multivariate analysis: comparing XFS and cataract control; **multivariate analysis: comparing XFS and glaucoma control; ***multivariate analysis: comparing XFS and XFG patients; ****multivariate analysis: comparing XFG and POAG control.
†Simple linear regression model.
‡Adjusted for highest preoperative IOP and irrigation volume.

definitive conclusions about this group of patients. Surgery was done at multiple sites resulting in slightly different techniques that may have influenced outcomes.

Our study has implications for management of patients who have XFG and a visually significant cataract. In this setting, the decision as to whether to proceed with simple cataract extraction or combine this procedure with a glaucoma procedure such as trabeculectomy can be a complex one. In patients with XFG and healthy, mild, or moderately damaged optic nerves with well controlled or borderline control of IOP, we recommend proceeding with clear cornea phacoemulsification cataract extraction and spending more time irrigating within the anterior chamber. This is because our study does suggest a margin of comfort for better IOP control in the medium term for these patients. How long the beneficial effect of cataract surgery on IOP lowering lasts is unknown, and merits further investigation. It is certainly possible that IOP control may worsen over time in patients with XFG, and hence we recommend following these patients diligently.[31] Proceeding through the cornea rather than sclera in these patients is preferred in our view, so as to preserve conjunctiva in case future filtration surgery is needed.

Although we did not study XFG patients with advanced damage who have inadequate 24 hour IOP control despite medical treatment, at present, we recommend proceeding with PCE combined with trabeculectomy in this group. We also recommend that combined cataract and glaucoma surgery be considered in patients with XFG and advanced optic nerve and/or visual field (for example, split fixation), regardless of IOP control. For both these groups of patients, a trabeculectomy generally ensures better quality of short and mid term IOP control, and thus less risk to the optic nerve than a cataract extraction done alone.

Our study has demonstrated that patients with XFS have a greater IOP lowering effect following PCE than those without XFS, and that this effect is correlated with the volume of irrigating fluid utilised at the time of surgery. Moreover, it appears that XFG patients have a greater IOP lowering post-PCE than POAG controls. Additional studies on patients with XFG and visually significant cataract are necessary in order to determine more definitely the optimal management of this challenging group of patients.

ACKNOWLEDGEMENTS

We thank the Lindberg Society members and Dr Anuj Bhargava for assistance with the protocol; Professor T Kivelä for assistance with sample size calculations; Sophia Chaudry, Hamidah Meghani, Yasmin Ladak, Dr Suleiman Sefau, and Amy Bovell for assistance in data collection and tabulation.

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Supported in part by the Joseph Cohen Research Fund of the New York Glaucoma Research Institute, New York, USA.

No financial interest.

Presented in part at the annual meeting of the Association for Research in Vision and Ophthalmology, Fort Lauderdale, FL, USA, April 2004.

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