Falls and health status in elderly women following second eye cataract surgery: a randomised controlled trial

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Abstract

Objective: first eye cataract surgery reduces the risk of falling. Most cataracts in elderly people are bilateral. Some binocular functions (e.g. stereopsis) are associated with falls. We aimed to determine if second eye cataract surgery reduces the risk of falling and to measure associated health gain.

Study design and setting: we randomised 239 women over 70, who had been referred to a hospital ophthalmology department, with one unoperated cataract, to expedited (approximately 4 weeks) or routine (12 months wait) surgery. Falls were ascertained by diary, with follow-up every 3 months for 12 months. We measured health status after 6 months.

Results: visual function (especially stereopsis) improved in the operated group. Over 12 months follow-up, 48 (40%) operated participants fell at least once, 22 (18%) fell more than once. Forty-one (34%) unoperated participants fell at least once, 22 (18%) fell more than once. Rate of falling was reduced by 32% in the operated group, but this was not statistically significant (rate ratio 0.68, 95% CI 0.39, 1.19, \(P = 0.18\)). Confidence, visual disability and handicap all improved in the operated compared with the control group.

Conclusion: second eye cataract surgery improves visual disability and general health status. The effect on rate of falling remains uncertain.

Keywords: cataract, elderly, falls, health status, outcome assessment, randomised controlled trial

Introduction

Falls among elderly people are a major clinical and public health concern because of associated injuries and hospital admissions, and loss of confidence, mobility and independence. Many risk factors for falling have been identified in epidemiological studies [1], including poor vision [2–9]. However, interventions to improve vision have been little studied in terms of their effects on falls. One trial of screening for visual problems showed little effect on rate of falling [10].

We recently demonstrated that first eye cataract surgery reduced the rate of falling in women over 70 by 34%. We demonstrated gains in visual acuity, contrast sensitivity and stereopsis, activity, anxiety, depression, confidence, visual disability and handicap in operated participants compared with unoperated controls, despite most participants having reasonable visual acuity at baseline [11].

Contrast sensitivity and stereopsis are probably more important than acuity in maintaining stability [12]. In people with two normal eyes, visual acuity, contrast sensitivity and stereopsis are quite closely correlated (coefficient about 0.6 [7, 13]), but this will not usually be the case in people with unilateral ocular pathology. The commonest cause of poor vision in elderly people is cataract, which is usually bilateral [14]. Current UK practice is to operate on each eye separately. Overall acuity will usually be good after first eye surgery. Binocular functions, such as stereopsis, should improve further with second eye surgery and might therefore lead to a further reduction in the rate of falling.

Second eye surgery has been shown to improve visual quality of life [15–20], but the extent of health gain from second eye surgery, and its cost-effectiveness, remain open to question [14, 21].
We aimed to see if second eye cataract surgery resulted in a reduction in the incidence of falls. We measured health gain associated with second eye surgery, using comparisons made with a ‘waiting list’ control group.

Methods

Participants
The study population was women over 70, following one successful cataract operation, who had a second operable cataract. About half were recruited from our first eye trial [11]. We excluded women who had complex cataracts (Fuchs corneal dystrophy, active intraocular inflammation, lens zonule dehiscence or lens instability); those with visual field defects, severe co-morbid eye disease affecting visual acuity and those with memory problems preventing the completion of the lengthy questionnaires or reliable recall of falls. All participants gave informed, written consent. Ethical committee approval for the study was granted.

Randomisation
Participants were randomised to either expedited surgery (target within a month) or routine surgery (a ‘waiting list’ control group, target surgery within 13 months or the routine waiting time when this became less than 13 months). Randomisation was from lists prepared (by R.H.) from random numbers, in variably sized, permuted blocks to maintain approximate equality in the size of the groups. Allocation was concealed in sequentially numbered, opaque, sealed envelopes that were opened after consent was obtained and baseline assessment made.

Surgery
Patients had small-incision cataract surgery and implantation of a folding silicone intraocular lens under local anaesthetic. There were minor differences between the surgical approaches of the three teams (see Appendix 1 on the website: http://www.ageing.oxfordjournals.org). All had refraction and assessment of their vision at 4 weeks.

Measurements
Baseline information was collected on history of falls, co-morbid diagnoses, drugs taken and social support [22]. A battery of health status measures was applied including: cognitive function (Mini-Mental State Examination); activity [23]; anxiety and depression (Hospital Anxiety and Depression Scale); confidence (falls efficacy scale [24]); activities of daily living (Barthel Index); visual disability (VF-14 [25]); handicap (London Handicap Scale, LHS, interview version [26]) and overall quality of life (Euroqol EQ-5D).

Ophthalmic history included the use of glasses and presence of other ocular problems. Examination included visual acuity (unaided, with current spectacles and with pinhole, recorded as the logarithm of the minimum angle resolvable, log MAR, using an ETDRS-modified Bailey–Lovie chart; Precision Vision, Villa Park, II., USA); contrast sensitivity using a Pelli–Robson chart (Clement Clarke, Harlow, UK); stereopsis using the Frisy system and the Wirt Fly (Clement Clarke), which together measure down to 150 seconds of arc and full ocular examination.

A fall was defined as unintentionally coming to rest on the ground or at a lower level, with or without loss of consciousness. Participants were asked to record falls in a daily diary, and were telephoned at 3 and 9 months, and interviewed at 6 and 12 months, to record the dates of falls and fractures. Six months after randomisation, participants were interviewed to complete the anxiety, depression, activity, confidence, activities of daily living, visual disability, handicap and quality of life questionnaires. Ophthalmological examination was repeated 1 month after surgery, and 6 and 12 months after randomisation. Assessment (after baseline) was not masked to allocation.

Sample size
The expected prevalence of falls was 50%. A one-third reduction in participants falling, giving a difference of 16% between the two groups, was taken to be clinically significant. To have an 80% chance of detecting this at 95% confidence required 160 patients in each arm, giving a trial size of 320.

Statistical analysis
All analyses were by intention to treat. Our primary analysis was a comparison of the rate of falling (total number of falls/number of days in the trial). Falls are not statistically independent events (someone who falls is at increased risk of another); so mean number of falls cannot be compared directly. Therefore, we used negative binomial regression for statistical testing and to generate confidence intervals around the rate ratio. The trial observation time for routine surgery patients was up to a final assessment, scheduled about a week before surgery (including surgery performed before 12 months of follow-up was complete).

A more conservative analysis compares the proportions of participants falling (regardless of the number of falls they have), and we did this for both first and second falls using Cox proportional hazards regression analysis to estimate relative risk. Participants reaching the end of observation without experiencing a fall, and those withdrawing or having out-of-trial early surgery, were censored. We also compared the proportions of participants experiencing fractures.

Health gain was assessed by comparing changes in visual functions, activity, anxiety, depression, confidence, disability, handicap and quality of life measures between operated and control groups using linear regression to adjust for baseline imbalances. This yields a more precise comparison than crude scores, and corrects for regression to the mean. The relative size of differences in health status measures was compared using the effect size (mean change/initial standard deviation) [27].

Results
We randomised 120 participants to expedited surgery, and 119 to routine surgery, between 2000 and 2004. During this period, the waiting time for routine cataract surgery reduced from over a year to 6 months, and further recruitment
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became impossible. A total of 3 patients died, 16 (7%) withdrew or were lost and 7 (3%) had surgery outside the trial (Figure 1). Nine of these experienced a fall before being lost. Median time from randomisation to expedited surgery was 30 days (range 8–204, lower quartile 22 and upper quartile 45), and median time to routine surgery was 316 days (range 37–527, lower quartile 241 and upper quartile 344). Unintended delays were all due to ill health.

At baseline, the two groups were well matched (see Appendices 2 and 3 on the website: http://www.ageing.oxfordjournals.org). Participants with poor vision (Snellen acuity worse than 6/12) were 10 (8%) in the expedited group and 4 (3%) in the control group. Median acuity (log MAR 0.06 and 0.08, or about Snellen 6/7), and contrast sensitivity were similar between groups. About half reported falling in the previous 12 months.

Figure 1. Trial profile.
After surgery, refractive outcomes were satisfactory. The mean best sphere equivalent was −0.17DS (standard deviation 0.97), and mean astigmatism was 0.73DC (standard deviation 0.82). Complication rates were low (Appendix 1), with three anterior vitrectomies and no endophthalmitis. Median unaided acuity in the operated eye improved by 0.44 log MAR units (compared with deterioration of 0.02 units in the other eye).

Among 89 participants, 252 falls were recorded. Forty-eight (40%) operated patients fell compared with 41 (34%) control patients. Hazard ratio for first falls was 1.06 (95% CI 0.69, 1.61), log rank test 0.61, 1df, P = 0.80 (see survival curve in Appendix 4 on the website: http://www.ageing.oxfordjournals.org).

Second falls were reported by 44 participants. Twenty-two (18%) operated patients fell twice or more, as did 22 (18%) control patients. Hazard ratio was 0.85 (95% CI 0.49, 1.56), log rank test 0.26, 1df, P = 0.61.

Rate of falling was 2.9 per 1000 patient-days in the operated group (range 0–31) and 4.3 per 1000 patient-days in the control group (range 0–120). The rate ratio was 0.68 (95% CI 0.39, 1.19, P = 0.18). There was no clear pattern of falls reduction, apart from very high falls rates (>35 per 1000 patient-days) in three participants in the control group being absent from the operated group (see distribution of fall rates in operated and control groups in Appendix 5 on the website: http://www.ageing.oxfordjournals.org).

Statistically adjusting the relative risk of falling for history of falls in the 1 and 12 months before randomisation; history of stroke; poor visual acuity; reported postural dizziness; and baseline visual disability and confidence, or, separately, for activity level at 6 months, had no effect on the results. Analysis restricted to the 111 participants who reported falling in the 12 months before randomisation gave a statistically uncertain 30% increase in first falls during the study period in the operated group (hazard ratio 1.30, 95% CI 0.8, 2.2, P = 0.35).

Six months after randomisation (median 181 days, range 121–217), the operated group reported statistically significant benefits in visual acuity, contrast sensitivity, stereopsis, confidence, visual disability and handicap compared with the control group (Tables 1 and 2). By six months, the number of patients with corrected binocular vision worse than 6/12 was two (2%) in the expedited group and nine (8%) in the control group. Effect sizes for the changes were 0.6 (moderate) for visual disability and pinhole visual acuity, 0.3–0.4 (small) for stereopsis, spectacle-aided visual acuity, contrast sensitivity, handicap and 0.2 (very small) for confidence.

Five participants (4%) in the operated group had five fractures (two hip, one pelvis, one wrist and one other arm), compared with three fractures in 2 (2%) control group participants (one non-hip leg, one neck of humerus and one other arm). Risk ratio was 2.5 (95% CI 0.5, 12.5, Fisher’s exact test, P = 0.45).

**Table 1. Changes in stereopsis**

<table>
<thead>
<tr>
<th>Stereopsis (seconds of arc)</th>
<th>Expedited</th>
<th>Routine</th>
</tr>
</thead>
<tbody>
<tr>
<td>150</td>
<td>76</td>
<td>63</td>
</tr>
<tr>
<td>300</td>
<td>22</td>
<td>18</td>
</tr>
<tr>
<td>600</td>
<td>11</td>
<td>9</td>
</tr>
<tr>
<td>&gt;600 wirt able</td>
<td>9</td>
<td>8</td>
</tr>
<tr>
<td>&gt;600 wirt unable</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>6 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>150</td>
<td>100</td>
<td>87</td>
</tr>
<tr>
<td>300</td>
<td>9</td>
<td>8</td>
</tr>
<tr>
<td>600</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>&gt;600 wirt able</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>&gt;600 wirt unable</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Discussion**

We demonstrated that second eye cataract surgery is associated with gains in visual function and confidence about falling and with reduced visual disability and handicap.

Our primary outcome measure was falls, and it was disappointing not to reach a more definite conclusion. The study was conceived against a background of waiting times in excess of 1 year, but when the waiting time dropped to less than 6 months, it was both impractical and unethical to continue. Consequently, it was under-powered.

We showed a moderately sized (32%) reduction in fall rate, which was statistically uncertain (i.e. no larger than may have occurred by chance through random variation) and imprecise (i.e. the size of any reduction may have been large or trivial). There was no reduction in the proportion of fallers. A few very frequent fallers (once a month or more) in the control group may have skewed the falls rate data. This compares with the effect of first eye surgery, where there was a reduction in falls for participants who fell more than once a year. We did not demonstrate increased physical activity after second eye surgery (unlike first eye surgery), although with increased confidence, risk-taking may have been greater. It may be that vision was simply too good at baseline to show any effect.

Binocular is superior to monocular vision for most functions. The visual field is larger, and stereopsis is possible. For acuity and contrast sensitivity, binocular vision with eyes of equal function will be about 40% better than that of either eye alone [28]. However, unilateral pathology can compromise this, and in some cases, binocular vision can be worse than vision in the better eye alone (due to binocular inhibition and rivalry [29, 30]).

In our study, second eye surgery was associated with improvements in acuity and contrast sensitivity, which were beyond those expected by chance but were quantitatively small. Median acuity gain in the operated eye was 0.44 log MAR units (the same as for first eye surgery). However, at baseline, almost all participants had at least reasonable corrected binocular acuity, so scope for further improvement was limited. Similarly, at baseline, contrast sensitivity was the best measurable value (1.65 dB) in 44%, and postoperative gains were small. Stereopsis improved more, and after second eye surgery almost all participants had good stereopsis (150 seconds of arc). However, first eye surgery improved...
each of these parameters considerably more than second eye surgery (0.32 versus 0.04 log MAR units for corrected visual acuity, 0.23 versus 0.09 dB for contrast sensitivity and 0.62 versus 0.45 ordinal scale units for stereopsis). In retrospect, this should not have been unexpected, although we initially assumed we might improve different visual parameters after operation on first and second eyes, thereby helping to determine which is most important for postural stability. The second eye was not completely blind, the cataract merely causing degraded vision, but sufficient to contribute to reasonable binocularity.

Second eye surgery also had less effect on health status outcomes than first eye surgery. One contributor to this was a ceiling effect of the measurement instruments. At baseline, 30% of scores on the LHS and 50% on the Falls Efficacy Scale and VF-14 visual disability scale were above 90% of the scale maximum, limiting scope for measuring further improvements.

This study confirms previous reports that second eye cataract surgery results in gains in visual function and reduced visual disability [15–21]. This suggests that aspects of visual quality other than acuity and contrast sensitivity are important. Stereopsis, absence of glare disability and motion misperception, and improved field of vision are possible explanations. The cataracts operated on in this study were less severe than those reported in the only comparable controlled study [15], in which similar small gains in acuity were reported, but with bigger gains in stereopsis and contrast sensitivity. Although that study reported gains in bespoke quality of life questions, no significant benefit was found in any of the eight dimensions of the SF-36, a generic quality of life measure. We demonstrated gains on both vision-directed and generic health status measures.

In conclusion, there is health gain from second cataract surgery, even when the vision in the overall vision is better than 6/12. However, the gain in vision and health status is less than with first eye cataract surgery. The impact on the overall rate of falling remains uncertain.

### Key points

- First eye cataract surgery reduces risk of falling in elderly women with bilateral cataracts, but some binocular functions, such as stereopsis, are also associated with risk of falling.
- Visual function, especially stereopsis, improved slightly after second eye cataract surgery, compared with unoperated controls.
- Rate of falling over 12 months was reduced by 32% in the operated group, but this was statistically uncertain (95% CI 61% reduction to 19% increase). Proportion of participants falling was unchanged.
- Visual disability, handicap and confidence about falling all significantly improved in the operated compared with the control group, indicating improved health status after surgery.

### Conflicts of interest

None

### Acknowledgements

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### Grant support

The Health Foundation and former Trent Regional Health Authority

### References


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Table 2. Comparison of changes in health status from baseline for participants completing 6 months assessments

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Expedited surgery first eye (n = 116)</th>
<th>Unoperated first eye (control) (n = 113)</th>
<th>Difference between expedited and control (adjusted for baseline values)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline mean</td>
<td>6 months mean</td>
<td>Baseline mean</td>
</tr>
<tr>
<td>Activity</td>
<td>7.4</td>
<td>7.6</td>
<td>8.1</td>
</tr>
<tr>
<td>Confidence</td>
<td>85.5</td>
<td>86.1</td>
<td>84.4</td>
</tr>
<tr>
<td>HADS—anxiety</td>
<td>6.4</td>
<td>6.6</td>
<td>6.8</td>
</tr>
<tr>
<td>HADS—depression</td>
<td>4.6</td>
<td>4.6</td>
<td>4.5</td>
</tr>
<tr>
<td>Barthel index</td>
<td>18.7</td>
<td>18.7</td>
<td>18.9</td>
</tr>
<tr>
<td>VF-14 visual disability</td>
<td>87.5</td>
<td>94.7</td>
<td>87.5</td>
</tr>
<tr>
<td>LHS</td>
<td>82.3</td>
<td>85.2</td>
<td>82.2</td>
</tr>
<tr>
<td>Euroqol</td>
<td>0.74</td>
<td>0.73</td>
<td>0.72</td>
</tr>
<tr>
<td>Unaided VA</td>
<td>0.22</td>
<td>0.15</td>
<td>0.26</td>
</tr>
<tr>
<td>Spectacles VA</td>
<td>0.09</td>
<td>0.04</td>
<td>0.11</td>
</tr>
<tr>
<td>Pinhole VA</td>
<td>0.10</td>
<td>0.04</td>
<td>0.09</td>
</tr>
<tr>
<td>Contrast sensitivity</td>
<td>1.45</td>
<td>1.60</td>
<td>1.42</td>
</tr>
<tr>
<td>Depth perception/5 point scale</td>
<td>1.66</td>
<td>1.36</td>
<td>1.85</td>
</tr>
</tbody>
</table>

HADS, Hospital Anxiety and Depression Scale; LHS, London Handicap Scale; VA, visual acuity in log MAR units.

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