

# Outcomes in randomised controlled trials of multifocal lenses in cataract surgery: the case for development of a core outcome set

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## ABSTRACT

**Background/aims** To describe and summarise the outcomes reported in randomised controlled trials of multifocal versus monofocal intraocular lenses in cataract surgery.

**Methods** We identified all randomised controlled trials of multifocal versus monofocal lenses in a Cochrane review (last search date June 2016). We extracted and summarised data on all outcomes reported using the framework of domain, measurement, metric and method of aggregation.

**Results** All studies collected data on distance and near visual acuity but there was considerable variation in the measures used and whether these outcomes were unaided or best corrected. Most studies reported final value measurements, rather than change from baseline. Approximately half of the studies reported data as a continuous measure only, one-third reported both continuous and categorical measures and a minority reported categorical measures only. There was little consensus as to cut-points. Although a majority of studies included one or more patient-reported outcome measures, none of the studies reported patient involvement in the choice of outcomes.

**Conclusion** The collection and analysis of data on outcome measures in studies of multifocal intraocular lenses in cataract surgery are complicated. As a result, there is considerable heterogeneity in collection and reporting in the medical literature. This makes it difficult to synthesise such data to provide robust estimates of effect and is a potential source of research waste. Investigators in this field must produce a core outcome set that is informed by patients' views and we propose an initial set of outcomes on which these could be based.

## INTRODUCTION

An estimated 53 million people worldwide are visually impaired due to cataract.<sup>1</sup> Cataract surgery is one of the most commonly performed operations in the world, with around 330 000 cataract operations performed per year in England alone.<sup>2</sup>

The most frequently used replacement intraocular lens (IOL) usually has one focal length (monofocal), and usually corrects vision after cataract surgery for distance, for example, driving and viewing television, but not necessarily for near vision tasks, such as reading and seeing the computer. In order to achieve good near vision, an additional pair of spectacles after cataract surgery may be required.

Multifocal lenses can potentially overcome this difficulty by providing more than one focal distance; this may increase the chances of spectacle freedom following cataract surgery. However, multifocal lenses may be associated with more visual problems, for example, glare, starbursts and haloes (rings around lights).<sup>3</sup>

Randomised controlled trials can provide good quality evidence of risks and benefits of these IOLs. We have published an updated Cochrane systematic review comparing multifocal versus monofocal lenses.<sup>3</sup> As part of this review, we identified all the published randomised controlled trials of multifocal compared with monofocal lenses. Systematic reviews can provide more precise estimates of effect by pooling data from trials reporting the same outcome, thereby increasing the sample size and narrowing the CIs around the effect estimates. The usefulness of such a review is critically dependant on the included trials reporting the same outcomes.<sup>4</sup>

The Cochrane review included 20 relevant trials that enrolled 2230 people with data available on 2061 people (3194 eyes). The majority (18) of these trials compared multifocal lenses to monofocal lenses and two studies compared multifocal lenses to 'monovision' (monofocal lenses of different focal length in each eye). We extracted data based on prespecified outcomes for meta-analysis. The median number of studies reporting data on each prespecified outcome in the review was 4 (range 1–10). If all the studies had reported the same outcomes, in a similar format, each analysis would have had 18 trials contributing data (for the multifocal vs monofocal comparison, for example). The review, potentially, could have been more conclusive. We used Grading of Recommendations Assessment, Development and Evaluation to assess the certainty of the data<sup>5</sup> and downgraded much of the evidence due to imprecision. In addition, it was largely unclear if the data that were unreported were selectively omitted.<sup>6</sup>

The aim of the current paper is to describe all the outcomes published in these trials, not just the outcomes prespecified and reported in our Cochrane review, with a view to making suggestions for a set of core outcomes for this topic.<sup>7</sup> In particular, we were interested in the reporting and analysis of visual acuity and contrast sensitivity data. We also planned to assess whether the outcomes reported have changed over time.

**Table 1** Outcome domains reported

Domain	Number of studies reporting	Percentage of studies reporting
Distance visual acuity	20	100
Intermediate visual acuity	4	20
Near visual acuity	20	100
Contrast sensitivity	14	70
Patient-reported outcome measure (PROM)	16	80
Spectacle independence	12	60

## MATERIALS AND METHODS

### Included studies

We included randomised controlled trials comparing a multifocal IOL of any type with a monofocal IOL. Both unilateral and bilateral implantation trials were included. We also considered trials comparing multifocal IOLs with monovision.

### Search strategy

We searched CENTRAL (which contains the Cochrane Eyes and Vision Trials Register) (2016, Issue 5), Ovid MEDLINE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, Ovid MEDLINE Daily, Ovid OLDMEDLINE (January 1946 to June 2016), Embase (January 1980 to June 2016), the ISRCTN registry ([www.isrctn.com/editAdvancedSearch](http://www.isrctn.com/editAdvancedSearch)), ClinicalTrials.gov ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)) and the WHO International Clinical Trials Registry Platform (ICTRP) ([www.who.int/ictrp/search/en](http://www.who.int/ictrp/search/en)). We did not use any date or language restrictions in the electronic searches for trials. We last searched the electronic databases on 13 June 2016. The full search strategy is available here.<sup>3</sup> Two authors screened studies independently for relevant trials. We resolved disagreements by discussion.

### Data collection

We extracted the following information from the included trials onto an Excel spreadsheet. Data were extracted independently by two authors (pairs of JRE, MZ, KV and SdeS).

### Study-level data

- ▶ Study name.
- ▶ Date conducted.
- ▶ Location.
- ▶ Were patients involved in choice of outcomes?
- ▶ Parallel group/within-person study.
- ▶ Bilateral/unilateral surgery.

**Table 2** Measures of visual acuity and contrast sensitivity

Number of studies reporting	Distance (n=20)	Intermediate (n=4)	Near (n=20)	Contrast sensitivity (n=14)
Unaided	18	3	18	2
Best corrected (for distance)	14	2	9	1
Best corrected (for near)			7	
Best spectacle corrected	3			3
Presenting (with/without prescribed spectacles)	1		1	
Other	Corrected but not specified how (1 study)	-1.25 D addition (1 study)	Distance vision plus 2.75 reading additions Plus -2.5 D 'with near correction' Distance refraction with addition unspecified	Unclear or not reported (8 studies) Plus 2.75 D when testing near contrast sensitivity (1 study)

### Outcome-level data

We followed the terminology used by Zarin *et al*<sup>8</sup> to classify outcome data. This has been used previously in an assessment of Cochrane Eyes and Vision systematic reviews.<sup>9</sup>

- ▶ Domain (eg, distance visual acuity).
  - ▶ Specific measurement.
    - Chart (eg, ETDRS visual acuity chart).
    - Distance (eg, 4 m distance).
    - Lighting (eg, photopic conditions).
  - ▶ Specific metric (eg, change from baseline).
  - ▶ Method of aggregation (eg, mean).

We also collected data on:

- ▶ Timepoint (eg, 12 months).
- ▶ Eyes—monocular/binocular.

### Data analysis

We tabulated the collected data and provide a descriptive summary. We grouped the data on date conducted in 5-year bands.

## RESULTS

### Description of studies

We included 20 studies.<sup>10–29</sup> These studies took place over a 21-year period, largely in the European region (see online supplementary table 1). None of the studies reported patient involvement in the choice of outcomes. There was a mixture of unilateral surgery (40%) and bilateral surgery (50%) with 10% of studies reporting both. Follow-up duration varied from immediately postoperative (two studies, complications) to 18 months (one study) (see online supplementary table 2).

### Domains reported

All studies reported distance and near visual acuity (table 1). Very few studies reported intermediate visual acuity. Contrast sensitivity and patient-reported outcome measures (PROM), including spectacle independence, were reported by the majority, but not all, studies.

### Measures of visual acuity and contrast sensitivity

#### Distance visual acuity

Most studies (18/20) reported unaided distance visual acuity (table 2). Fourteen out of 20 studies reported best corrected visual acuity, five studies reported other corrections—either spectacle corrected (three studies), presenting (with/without spectacles), or unclearly reported.

#### Intermediate visual acuity

Three of the four studies that documented intermediate visual acuity reported unaided intermediate visual acuity; two of these

**Table 3** Method of measuring visual acuity and contrast sensitivity

Number of studies reporting	Distance (n=20)	Intermediate (n=4)	Near (n=20)	Contrast sensitivity (n=14)
Snellen	9	2		
LogMAR	7	2	4	
Regan 96% contrast chart	2			2
Jaeger reading chart			6	
Rosenbaum near acuity card			3	
Sloan letters near acuity chart			2	
Pelli-Robson contrast sensitivity chart				6
Vision Contrast Test System				4
Other			De Nederlanders (1 study) Salzburg reading desk (1 study)	CGT-1000 contrast sensitivity instrument (1 study) FACT chart/OPTEC 6500 (1 study)
Chart not specified or unclear specified	2		3	

FACT, Functional Acuity Contrast Test.

studies reported intermediate visual acuity with best distance correction.

### Near visual acuity

Most studies reported unaided near visual acuity. Nine studies reported near visual acuity with best distance correction, seven reported with best near correction, one study reported presenting near acuity (with or without prescribed spectacles) and three studies reported near acuity corrected for distance visual acuity but with a near addition.

### Contrast sensitivity

A total of 14 studies reported contrast sensitivity. In just over half of studies the correction was not specified or unclear (eight studies). Two studies stated that contrast sensitivity was tested unaided, one study that this was best corrected and three studies that this was best spectacle corrected.

### Testing conditions

#### Visual acuity test charts

The most commonly used visual acuity test chart was Snellen (nine studies), followed by logMAR (seven studies) (table 3). Two studies used the Regan 96% contrast chart, and in two studies the chart was not clearly specified. Intermediate visual acuity was measured using either Snellen (two studies) or logMAR charts (two studies). A wider variety of tests were used to measure near acuity including Jaeger charts (six studies), logMAR charts (four studies), Rosenbaum near acuity card (three studies), Sloan letters near acuity chart (two studies), and the De Nederlanders chart (one study) and Salzburg reading desk. Three studies did not specify the chart clearly. Pelli-Robson contrast sensitivity chart was the most commonly used method of measuring contrast sensitivity (six studies), followed by the Vision Contrast Test System (four studies), Regan 96% contrast chart (two studies), CGT-1000 contrast sensitivity instrument (one study) and Functional Acuity Contrast Test chart/OPTEC 6500 (1 study).

#### Distance at which visual acuity was measured

Most studies did not report the distance at which distance visual acuity was measured (nine studies), the most commonly reported distance was 4 m (five studies); two studies measured at 6 m, two at 5 m and one at 3 m. The four studies reporting intermediate visual acuity all reported at different distances—one study at 80 cm, one

study at 1 m, one study at three distances—70, 60 and 50 cm—and one study did not specify the distance. Distance was specified more commonly for near visual acuity but there was as wide variety of distances reported—33 cm (two studies), 35 cm (two studies), 35–46 cm (one study), 26 cm (one study), 40 cm (five studies). Nine studies did not report the distance, but of these nine studies, one used the patient's preferred reading distance (and corrected the score), one reported the preferred reading distance as an outcome and one reported '... the reading addition necessary to read J2 at 25 cm' as an outcome. Three studies measured contrast sensitivity at 1 m and one study normalised to a 10 ft test distance (probably measured at 8 and 10 ft). The remaining 10 studies did not report the distance at which contrast sensitivity was measured.

### Lighting

The lighting used to measure distance visual acuity was not described in most studies. Two studies reported they used photopic conditions (in one study this was stated to be approximately 85 candelas(cd)/m<sup>2</sup>). One study used the ACP-8 Auto Chart Projector. One study specified three light levels (three light levels 1–3 foot-candles (ft-c; night driving, no glare), 20–70 ft-c (normal indoor lighting) and full midday sunshine and glare (Brightness Acuity Tester (BAT) at medium)). In the four studies of intermediate visual acuity, lighting was not specified in two studies, was photopic (85 cd/m<sup>2</sup>) in one study and 6 cd/m<sup>2</sup> in one study. For near acuity, photopic conditions were used in three studies (not defined, 85 and 80 cd/m<sup>2</sup>) and mesopic conditions in two studies (5 and 6 cd/m<sup>2</sup>), one study used three levels of lighting (as for distance visual acuity), one study used a 40 W bulb with overhead lights off and one study used 500 lux (may apply to all visual acuity measurements). In 13 studies it was not clear what lighting was used.

### Metric and method of aggregation

Most studies reported final value for distance, intermediate, near visual acuity and contrast sensitivity (see online supplementary table 3). Only one study reported both final value and change from baseline. Most studies reported visual acuity measures as a continuous variable: for distance visual acuity 16/20 studies, for intermediate visual acuity 3/4 studies, for near visual acuity 13/20 studies and for contrast sensitivity all 14 studies reporting this outcome. All continuous variables were reported as means, one study reported both means and medians. There was a wide variety of categorical cut-points used.

**Table 4** Type of patient-reported outcome measure (PROM)

Name of PROM	Number of studies	Percentage
Able to manage activities of daily living without glasses	1	5
Cataract Symptom Score	2	10
Cataract TyPE Questionnaire	1	5
Modified Cataract TyPE Questionnaire	1	5
Modified V7 questionnaire	1	5
Rasch-scaled VF-11 (VF-11R) scores used after removing 3 questions from VF-14	1	5
Self-reported overall health (0–10)	1	5
Self-reported rating of vision	2	10
Self-reported satisfaction	10	50
Self-reported satisfaction with vision after surgery	1	5
Spectacle independence		
VF-14	2	10
VF-7	2	10
VQOL (vision-related quality of life)	1	5
Visual symptoms (glare, haloes, and so on)	14	70
Would patients choose the same IOL again?	1	5

IOL, intraocular lens.

Online supplementary table 4 shows how the included studies dealt with the analysis of eyes and people. None of the studies that reported by eye included an appropriate adjustment for within-person correlation. Approximately half of studies with a unilateral study design did not clearly state this in the report.

### Patient-reported outcome measures

A variety of PROMs were used (table 4). A number of studies used validated questionnaires (VF-7, VF-14, Cataract TyPE Questionnaire, Cataract Symptom Score), and modifications thereof, but each individual questionnaire was only used by one or two studies each. Although half of studies collected data on ‘self-reported satisfaction’ there was almost no agreement on how this should be collected. Most studies used some form of Likert scale with either 3, 5 or 10 categories. The wording associated with this Likert scale varied with different studies assessing different but related constructs: ‘satisfaction’ (eg, very dissatisfied to very or highly satisfied), ‘quality’ (eg, poor to excellent) or ‘impact’ (eg, incapacitating to excellent).

The majority of studies assessed visual symptoms such as glare/haloes. In most studies it was clear what ‘presence/absence’ was but some studies graded using a Likert scale and analysed as a quantitative measure (see online supplementary table 5). Some studies measured the effect of glare using the Brightness Acuity Tester, reporting visual acuity and contrast sensitivity with and without glare. There was inconsistency as to whether glare or glare disability was assessed. One study measured the effect of glare on a number of different activities.

Spectacle independence was assessed in most but not all studies. Again, there was considerable variability in how this was measured and reported (see online supplementary table 6).

### Other outcomes

A variety of other outcomes were reported (see online supplementary table 7).

## DISCUSSION

This study has documented considerable heterogeneity in data collection and reporting of outcomes when comparing multifocal

to monofocal lenses. This variability highlights the confusion evident as to what outcomes are important to study when conducting trials in this field. We have probably underestimated the variability for some domains: for example, the use of Jaeger charts for near vision testing is probably even more inconsistent than appears in this report because the J scale is not standardised and so differs between manufacturers.<sup>30</sup> It is also likely that lighting conditions, which were inconsistently documented in the studies, may also vary between studies.

It is notable that no patients were apparently consulted when doing these studies, especially since one of the main concerns regarding the use of multifocal lenses are subjective symptoms such as the presence of glare and haloes. Although we limited ourselves to randomised controlled trials identified in our Cochrane review for which the searches were done in 2016, an assessment of a selection of randomised controlled trials done after that time<sup>31–33</sup> (identified on PubMed) does not suggest that any improvement had occurred since, with little systematic consideration of how outcomes are selected and analysed and little evidence of patient involvement in the choice of outcomes.

The impact of such variability is considerable research waste because it is difficult to compare the results of such studies and synthesise appropriately to provide an overall estimate of effect in a meta-analysis.<sup>3</sup> Chalmers and Glasziou have highlighted recently the huge avoidable waste in clinical research, estimated about \$100 billion annually.<sup>34</sup> It also means that, as systematic reviewers, we are unable to address effectively the extent to which selective reporting of outcomes occurs in this field.

The solution to this problem is conceptually simple but requires funding and collaboration. Prior to starting a new clinical trial, investigators need to consider carefully which outcomes should be collected and analysed. Ideally this would involve collaboration to develop a core outcome set and will include patients’ views.<sup>7</sup> There is considerable experience in how to develop core outcome sets<sup>35</sup> but ophthalmic researchers have been slow to adopt them. We are aware of one proposed minimum set of outcome measures for cataract surgery.<sup>36</sup> However, this was developed with healthcare professionals, rather than researchers, in mind. There were potentially some important omissions, for example, near visual acuity, spectacle independence and visual symptoms were not adequately addressed. The report also did not give any guidance on reporting of the outcomes, which can make a difference to the extent to which any trials’ findings may be incorporated in a systematic review.

Prespecification of a core outcome set and providing a strategy for analysis in a publicly available protocol would be an important step to eliminating problems of selective outcome reporting<sup>6</sup> which is common in medical research.<sup>37</sup> Importantly, it would allow a much more efficient use of the data collected and the resources (both health funding and patient time) involved.

Based on our analysis of the studies included in our Cochrane review, in which all studies reported distance and near visual acuity and most studies reported contrast sensitivity and PROMs, we propose an initial set of outcomes that could form the basis of the development of a core outcome set (table 5). We would suggest that these variables are measured at a postoperative visit between 6 and 18 months after surgery (metric: final value) and where possible binocular measures are also documented. This is a proposed minimum set of outcomes that would be measured and reported in every trial; this does not restrict trialists—they would be free to measure any number of additional outcomes. However, if all trials reported this minimum set, in this format, this would be an important step for future systematic reviews. This list is based on our experience of undertaking a Cochrane review and collecting data on the outcomes

**Table 5** Proposed outcomes to form the basis for a core outcome set for studies of multifocal lenses in cataract surgery

Domain	Specific measurement	Method of aggregation
Distance visual acuity	LogMAR chart, with and without usual spectacles	Mean
Near visual acuity	LogMAR chart, with and without usual spectacles	Mean
Contrast sensitivity	Pelli-Robson chart, with and without usual spectacles	Mean
Spectacle independence	Questionnaire, overall, distance and near separately	Proportion of people spectacle free, that is, do not need to use spectacles for any task
Quality of life	Questionnaire: ideally VF-7 or VF-14	Mean
Visual symptoms, for example, glare haloes	Questionnaire: glare, haloes and other visual symptoms	Proportion of people with visual symptoms, each symptom reported separately

used in these trials. The final choice of core outcomes should ideally be chosen by means of wider consultation, including trialists and patients, and using recognised method of establishing consensus, for example, using a Delphi survey.<sup>38</sup> Development of a core outcome set for cataract surgery will only be successful if there is genuine effort to achieve consensus with professional organisations, patient groups and key opinion leaders, in the choice, specification and dissemination of these outcomes.

**Contributors** JRE conceived the idea for this paper in discussion with all coauthors, coordinated the data collection and analysis and wrote the first draft of the paper. SdeS, MZ and KV collected the data. All authors revised the manuscript critically for important intellectual content and gave final approval of the manuscript.

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## Supplementary tables

*Supplementary table 1: Study characteristics*

	Number of studies	Percentage
<b>Date conducted (year recruitment ended)*</b>		
Before 1995	4	20%
1995 to 1999	4	20%
2000 to 2004	2	10%
2005 to 2009	7	35%
2010 to 2014	3	15%
2015 to present	0	0%
<b>Location (WHO regions)</b>		
Eastern Mediterranean	1	5%
European	14	70%
South-east Asia	1	5%
The Americas	1	5%
Western Pacific	3	15%
<b>PPI involvement in choice of outcomes</b>		
Yes	0	0%
No	20	100%
<b>Type of surgery</b>		
Unilateral	8	40%
Bilateral	10	50%
Unilateral and bilateral	2	10%

\* For 10 studies that did not report when they were conducted this was estimated as date of publication minus 3 years (based on analysis of 10 studies that did report recruitment dates).

Supplementary table 2: Follow-up time

Study name	At what follow-up times were outcomes reported			
	Less than 3 months	3 to less than 6 months	6 to less than 12 months	12 months or more
Cillino 2008				12 months
El-Maghraby 1992	2-4 weeks	2-4 months,		
Haaskjold 1998		5 to 6 months		
Harman 2008		3 months		18 months.
Javitt 2000		Clinical data: 3 months after surgery in the second eye QoL: 3 to 6 months after second eye surgery		
Ji 2013	7, 30 and 90 days			
Jusufovic 2011	6 weeks			
Kamlesh 2001		3 months		
Labiris 2015			6 months	
Leyland 2002	12 weeks	16-88 weeks	34-140 weeks	34-140 weeks
Nijkamp 2004		3 months after first eye surgery and 3 months after second eye surgery		
Palmer 2008	Outcomes measured at 1 and 3 months, unclear which time point reported outcomes are from	Outcomes measured at 1 and 3 months, unclear which time point reported outcomes are from		

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Peng 2012			6 months	
Percival 1993	operative/post op complications,	four to six months		
Rasp 2012	1 month		6 months	12 months
Rossetti 1994				12 months
Sen 2004	1 month			
Steinert 1992		Follow-up between 3 to 6 months, average 125 days i.e. approximately 4 months		
Wilkins 2013		4 months		
Zhao 2010	complications, 1 week, 1 month,		6 months	

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Supplementary table 3: Metric and method of aggregation for visual acuity and contrast sensitivity

Number of studies reporting	Distance (n=20)	Intermediate (n=4)	Near (n=20)	Contrast sensitivity (n=14)
<b>Metric</b>				
Final value only	19	4	20	14
Change from baseline only	0	0	0	0
Both final value and change from baseline	1	0	0	0
<b>Type of variable</b>				
Continuous only	10	3	10	12
Categorical only	4	1	7	0
Both continuous and categorical	6	0	3	2
<b>Method of aggregation for continuous variable</b>				
Mean only	15	3	12	14
Median only	0	0	0	0
Both mean and median	1	0	1	0
<b>Categorical cut-points</b>				
	20/20-25, 20/30-40, worse than 20/40	20/20 or better, 20/30, 20/40, 20/60, 20/80 or worse		% achieving 0.9, 1.05, 1.20, 1.35, 1.50, 1.65, 1.80 logunits
	0.5 or better, 1.0 or better, plus categories (0.10-0.25, 0.30-0.40, 0.50-0.60, 0.65-0.80, 1.00, 1.30- 1.60)		J1, J2, J3, J4-7, worse than J7	Percentage reading at higher than 1.35, 1.80 and 2.1
	20/40 or better		J3 or better, J1 or better, 20/40 or better and J3 or better, 20/20 or better and J1	

>=0.5	J4 or worse, J3 J2 J1
0.5; 0.6; 0.7; 0.8; 0.9; 1.0	?=0.3
> 6/9	J2 or better, J3, J5, J7 or worse
20/20 or better, 20/30, 20/40, 20/60, 20/80 or worse	More than or equal to N9
20/15. 20/20, 20/25, 20/30, 20/40, 20/50, 20/60, 20/80, 20/100, 20/200 and 20/30 or better, 20/40 or worse.	J1; J2; J3; J4; J5
20/20 or better, 20/25 or better, Improved by 1 lines or more, declined 1 line or more.	J1-2; J3-4; J5 or worse
20/12.5 to >20/71 (9 groups)	J6 or better, J2 or better

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J1 or  
better, j2  
or better,  
also  
categories  
J1+, J1, j2,  
J3, J5

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Supplementary table 4: Analysis approach to eyes / people

<b>Number of studies reporting</b>	<b>Distance (n=20)</b>	<b>Intermediate (n=4)</b>	<b>Near (n=20)</b>	<b>Contrast sensitivity (n=14)</b>
<b>Bilateral surgery (n=12 studies)*</b>				
<b>Reported by person</b>				
Binocular acuity	6	2	6	5
Average of both eyes	1			
<b>Reported by eye</b>				
Data for both eyes reported, adjusted for within person correlation				
Data for both eyes reported, not adjusted for within person correlation	3	1	3	2
Right and left eye reported separately	1			1
Unclear how eyes / people managed in the analysis	2		3	
<b>Unilateral surgery (n=8 studies)</b>				
Clearly stated	5		5	3
Not clearly stated, inferred from report	3	1	3	3

2 studies had mixture of bilateral and unilateral surgery

Supplementary table 5: Measurement of glare and halos

Study name	Methods	Results
Cillino 2008	Quote: ".. the remaining 2 questions related to difficulty with night and daylight vision (presence or absence of halos and glare)."	Reported as proportion with glare and proportion with halos separately
Haaskjold 1998	Quote: "... and to indicate whether they had experienced ghost or double images, halos, glare, colour disturbances, distortion, blurring, or other visual complications at near or distance".	Quote: "Nine monofocal patients reported 14 phenomena (5 glare). In the bifocal group, 21 patients observed 40 phenomena (15 halos, 8 glare)." Unclear what the rest of the phenomena were.
Harman 2008	Quote: "Visual acuity and contrast sensitivity were measured with the BAT [Brightness Acuity Tester] at its brightest setting, and glare was calculated as the difference between the 2 scores." Quote: "Also at 18 months, patients were questioned about spectacle independence and presence or absence of glare symptoms using a validated questionnaire"	Results reported with and without BAT (Pelli-Robson Contrast Sensitivity). Subjective symptoms of glare reported as : none/some/severe.
Javitt 2000	Quote: "Patients were asked to rate glare disability on a scale of 0 to 4, where 0 was equated with "no" limitation resulting from glare" and 4 was equated with "extreme limitation resulting from glare," for the following activities: general daily activities, reading shiny paper, driving toward the sun, driving toward oncoming headlights, walking outside on sunny days, and reading signs in supermarkets"	
Kamlesh 2001	Quote: "Quality of vision was evaluated by patient questionnaire".	Quote "Do you have problems seeing in the dark?" No/Yes/Glare/Haloes
Labiris 2015	Quote: "Two direct 4-scale Likert-type questions (always, most of the times, sometimes, never) that pertained to the subjective perception of glare and unwanted shadows were included."	Glare and shadows reported as a mean score

Leyland 2002	Glare disability assessed as part of the TyPE questionnaire. Also used Brightness Acuity Tester.	Glare/halo related task difficulty (0-4) reported as median and range. Glare/halo degree of "bother" (0-4) reported as median and range.
Nijkamp 2004	Glare included as part of the Cataract Symptom Score	Not presented separately
Peng 2012	Glare and halos assessed by patient questionnaire, rated on scale of 0 to 7, with 0=no difficulty and 7=severe difficulty. .	Mean score presented
Percival 1993	Quote: "Patients were asked also asked [...] whether they were content with the optical quality"	Reported number of patients experiencing "ghosting from a second image" and "glare from oncoming headlights at night".
Rossetti 1994	Postoperative questionnaire on visual phenomena (glare, halos, blurred vision).	Reported proportion with glare and halos separately.
Sen 2004	Quote: "Severity of visual symptoms such as glare, halos, and cataract symptoms (CS-5). "	Glare and Halos reported as proportion in four categories: None/Very little/Moderate/Severe
Steinert 1992		Reported visual acuity with varied contrast and glare. Rated degree of difficulty with glare/flare, reported as mean score, but unclear what scale was used.
Wilkins 2013	Quote: "In addition to the standard VF-14 questions, patients answered 3 additional dysphotopsia questions: "Since your surgery have you noticed any (1) glare or dazzle, (2) unwanted images, or (3) unusual shadows?"	Reported as frequency: none/barely/annoying/debilitating
Zhao 2010	Not mentioned in methods.	Reported proportion with glare and halos separately.

Supplementary table 6: Spectacle independence

Study name	Question	Response categories	Spectacle use for distance or near vision
Cillino 2008	Quote "Postoperative spectacle independence was also evaluated." Question was not specified. In table, proportion with "Complete spectacle independence" reported.	Yes/No	Not reported
Haaskjold 1998	Quote: "At the 5 month vision, patients were asked if they used spectacles at any time and to estimate percentage of waking time that spectacles were needed for both distance and near tasks"	Yes/No and % time reported as a continuous measure	Distance and near vision separately
Harman 2008	Quote: "Also at 18 months, patients were questioned about spectacle independence and presence or absence of glare symptoms using a validated questionnaire". In text, reported proportion of patients who were "completely spectacle independent". In figure, reported "Spectacle use".	Yes/No	Not reported
Javitt 2000	Quote: "The primary endpoint of the study was spectacle dependence for daily tasks. "	Data not reported	Not reported
	Quote: "Patients were asked how often they wore glasses"	Always/Occasionally/Never	Probably either distance or near vision
	Quote: "Patients were asked how often they wore glasses for distance and near vision"	Never/Some of the time/Half of the time/Most of the time/All of the time.	Distance and near vision separately
Kamlesh 2001	Reported in results tables "Do you need additional glasses for near work? "	Yes/No	Not applicable
Labiris 2015	Quote: "The need for spectacles (ie, spectacle dependence) was evaluated for distance vision and near vision by 2 direct 4-scale Likert-type	Always/Most of the time/Sometimes/Never	Distance and near vision separately

	questions (always, most of the times, sometimes, never)."		
Leyland 2002	Quote: "Complete freedom from glasses..."	Yes/No	Not applicable
Nijkamp 2004	Quote: "Spectacle dependence was expressed by a frequency score varying from 1 (always) to 5 (never) for distance and near vision separately."	1 (always) to 5 (never) analysed as a continuous score	Distance and near vision separately
Palmer 2008	Quote: "At 3-month follow-up, patients were given a questionnaire regarding the presence of visual symptoms and their dependence on near correction." In the results, reported the "percentage of patients totally [spectacle] independent".	Yes/No	Probably near vision only
Peng 2012	Quote: "Overall spectacle independence, and spectacle independence for distance and near tasks were assessed."	Yes/No	Overall, distance and near
Percival 1993	Quote: "Patients were also asked whether they could manage their daily activities without glasses, whether reading glasses were used and why.."	Responses "sufficiently good to manage daily activities without glasses" and use of glasses "Sometimes/Always"	Distance and near vision separately
Rossetti 1994	"Spectacle use" but unclear how ascertained.	Yes/No	Distance or near vision
Steinert 1992	Quote (methods): "Patients also were asked to describe if and why they used spectacles for any task". Quote (results table): "What visual aid do you use to improve vision"	None/Spectacles for fellow eye/Spectacles used out of habit/Spectacles used for operative eye/Spectacles used for both eyes/Spectacles used-reason not provided.	Not reported
Wilkins 2013	Quote: "The primary outcome was spectacle independence" also described as "spectacle free" Quote (results): "When asked the question "How often do you wear glasses?"	Always/Sometimes/Never	Not reported
Zhao 2010	"Spectacle independent" unclear how assessed.	Yes/No	Not reported

Supplementary table 7: Other outcomes

Aberrations
Accommodation or accommodative amplitude
Astigmatism
Average near addition required for near vision N6
Binocular vision with Bagolini striped glasses
Complications (operative, post-operative)
Critical print size
Cylinder
Defocusing curves
Depth of focus (dioptries)
Deviation from target
Headache
IOL decentration
Keratometric cylinder
Light scatter
Light scatter analysis (glare),
Maximum reading speed Pupil size
Modulation transfer function
Posterior capsule opacification Refraction
Pseudoaccommodation
Pupil size
Range of distance vision
Range of near vision
Reading speed
Reading ability or fluency
Reading distance
Refractive cylinder
Refractive errors
Smallest print size
Sphere
Spherical equivalent
Spherical equivalent within 1.0 dioptries (%)
Spherical equivalent within target

Spherical error
Stereo vision
Straylight
Wavefront analysis