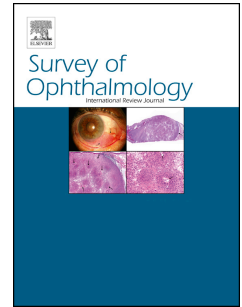


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Methodological challenges with randomized clinical trials for multifocal intraocular lenses

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We have read the article by Cao and coworkers,¹ and believe that some discussion is required. The authors compared the visual acuity, contrast sensitivity (CS) and adverse events in monofocal intraocular lenses and multifocal IOLs (MIOLs).

The aim of this review was to assess high-quality evidence based on only randomized controlled trials (RCTs).¹ The risk of bias was assessed in several aspects as recommended by the Cochrane Collaboration; however, some studies included in the final analysis cannot be considered as RCTs; this was meticulously described in the Cochrane review on the same topic.² Four studies included in the meta-analysis by Cao and coworkers¹ were excluded from the Cochrane review as they were retrospective (Shah and coworkers, 2010), the participants were not randomly allocated to the intervention (Puell and coworkers, 2015, Maxwell and coworkers, 2008) or because the Chinese-speaking Cochrane authors confirmed from the trialists that participants were not randomly allocated to the intervention (Ji and coworkers, 2011).² Of note, we believe that it is fairly difficult to perform a RCT in this area of research, as probably every patient would prefer to choose the IOL based on personal preferences, rather than to be randomized between monofocal or MIOL group.

Two out of 21 studies included in the final analysis, and seven out of 61 references were not in English; however, the methods section does not present which languages were included in the search strategy. Although there is no evidence on systemic bias from the use of English-language restrictions in systematic reviews and meta-analyses,³ the electronic search strategy of any review article should be repeatable. Moreover, English-language articles more commonly have larger sample sizes, better methodology, present adequate concealment of allocation, and are more commonly double blinded or assessor blinded.³

Finally, comparing CS outcomes in MIOLs is difficult due to the variation of tests used, different illumination levels and inconsistency in reported variables. We would like to ask which variables were used for this analysis? It is known that MIOLs might present worse performance in low illuminance conditions and higher spatial frequencies; did this review show similar results? Moreover, it is not stated at which time-point was CS analyzed, as CS in MIOLs has a tendency to improve over time. Finally, it should be clearly stated that to date none of the studies has presented an association between CS and the quality of vision.⁴

Methods of literature search

The search strategy was (“Lenses, Intraocular”[Mesh] AND “comparison”[ALL]); (“Multifocal Intraocular Lenses”[Mesh] AND “randomized”[ALL]); (“monofocal Intraocular lenses” AND “randomized”[ALL]); (“Multifocal Intraocular Lenses” [Mesh] AND “randomly”[ALL]); (“monofocal Intraocular lenses” AND “randomly” [ALL]) (“Multifocal Intraocular Lenses”[Mesh] AND “randomization”[ALL]); (“monofocal Intraocular lenses” AND “randomization” [ALL]); (“Intraocular lenses” AND “trial”[ALL]); (“bias” AND (“review” OR “meta-analysis”) [ALL]); (“quality of life” AND (“multifocal intraocular lenses”) [ALL])

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