Benefits and harms of femtosecond laser assisted cataract surgery: a systematic review


CRD summary
The authors of this well-conducted review concluded that conventional cataract surgery and femtosecond laser-assisted surgery had comparable outcomes (visual acuity, effective phacoemulsification time and adverse events). The authors' conclusions reflect the evidence presented and they appropriately highlighted the limited quality and generalisability of the evidence.

Authors' objectives
To examine the effectiveness and safety of femtosecond laser-assisted cataract surgery compared with conventional cataract surgery.

Searching
MEDLINE, CINAHL and The Cochrane Library were searched to May 2013; search strategies were reported. ClinicalTrials.gov, premarket notification 510(k) summaries, conference proceedings, reference lists of relevant studies and a number of topic-specific journals were searched and experts were consulted.

Study selection
Eligible studies were controlled and observational studies of adults undergoing cataract surgery using femtosecond laser technologies reporting short- and long-term visual acuity, quality of life measures, and intra- and post-operative complications. Case reports and case series were also eligible for the question of adverse events. In studies with a comparison group, the comparator (conventional cataract surgery) was defined as small incision, phacoemulsification with posterior chamber intraocular lenses implantation. Studies had to be in English.

Studies were conducted in Germany, Hungary and Australia. The mean age of participants ranged from 55 to 75 years. Cataract density scores, where reported, ranged from 2.13 to 3.7 (lens opacities classification system III). In most of the studies a single surgeon performed the procedure. Femtosecond laser-assisted surgery was performed using either Alcon LenSx or OptiMedica Catalys.

Two reviewers independently selected studies for inclusion; disagreements were resolved through discussion or referral to a third reviewer.

Assessment of study quality
The Cochrane risk of bias tool was used to assess the quality of randomised controlled trials and the Newcastle Ottawa tool was used to assess the quality of observational studies. The overall quality of evidence for outcomes was assessed using the GRADE framework.

Two reviewers independently assessed study quality with disagreements resolved through discussion.

Data extraction
Mean and standard deviations for continuous outcomes were extracted. Data were extracted by one reviewer and checked by a second reviewer.

Methods of synthesis
A narrative synthesis was presented following exploration of statistical heterogeneity using $I^2$ in a random-effects model. Sensitivity analysis excluding outlying studies did not account for the significant heterogeneity observed.

Results of the review
Fifteen studies were included (four randomised controlled trials (RCTs), nine cohort studies, one case control study and one case series). The strength of the evidence was graded as low for most outcomes.

There were no significant differences in visual acuity outcomes (495 patients; two RCTs, four observational studies)
between femtosecond laser-assisted surgery and conventional surgery. One RCT and three observational studies found no significant reduction in effective phacoemulsification time; however, two large observational studies reported significant reductions in favour of femtosecond laser-assisted surgery. No studies reported quality of life measures.

There was a low incidence of complications with femtosecond-assisted laser surgery, although increases in intraocular pressure were reported across studies (1,185 patients; six observational studies) and one cohort study reported significantly reduced endothelial loss associated with femtosecond laser-assisted surgery. Adverse events unique to femtosecond laser-assisted surgery were difficulties in laser docking. Greater surgical experience with femtosecond laser-assisted surgery was associated with fewer complications in two studies, although one study found no difference in outcomes between initial and subsequent groups of patients.

**Authors' conclusions**
Visual outcomes and effective phacoemulsification time were similar between femtosecond laser-assisted surgery and conventional surgery. Evidence for the relative benefit of femtosecond laser-assisted surgery was limited. Comparative adverse events in both types of surgery were found to be similar for intraocular lens positioning, corneal thickness, macular oedema and residual refractive error.

**CRD commentary**
The review question and inclusion criteria were clear. The authors searched a range of resources. The restriction to studies published in English may have excluded some relevant data. Efforts were made to minimise error and bias in the review process. A narrative synthesis was appropriate given the significant statistical heterogeneity. The quality of the evidence was generally low. As the authors noted, the review was limited by potential sources of bias in the included studies; many studies were observational, had small sample sizes with variable follow up, and the application of inclusion criteria was often unclear. The authors also noted that the highly selected patient populations (in a small number of centres) may limit the generalisability of the findings.

This was a well-conducted review. The authors' conclusions reflect the evidence presented and they appropriately highlighted the limited quality and generalisability of the evidence.

**Implications of the review for practice and research**
**Practice**: The authors did not state any implications for practice

**Research**: The authors stated that randomised controlled trials with large samples were needed to detect relative risks of rare events. Studies should be insulated from device manufacturers to eliminate potential bias. Studies of the costs and the suitability of femtosecond laser-assisted surgery for patients with commodities (dense cataracts, glaucoma, corneal pathology) are key to determining the feasibility of the procedure.

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.