

Femtosecond laser-assisted cataract surgery (FLACS) for the treatment of age-related cataract

Abstract

Background.

Age-related cataract is the leading cause of visual impairment worldwide, and cataract surgery is the most commonly performed ophthalmic procedure. In higher income countries, standard cataract surgery requires manual formation of an opening in the anterior lens capsule. The size, shape and position of the anterior capsular opening are controlled by freehand pulling and tearing of the capsular tissue. The cataract is then emulsified and aspirated through an ultrasound probe (phacoemulsification).

Femtosecond laser assisted cataract surgery (FLACS) is an alternative technique where a computer-controlled system helps in creating incisions, performing capsulorhexis and fragmenting the lens. The procedure is then completed using conventional phacoemulsification equipment and techniques. Compared to standard phacoemulsification, FLACS is claimed to provide advantages in terms of effectiveness, safety and procedural time.

The objective of this rapid assessment was to evaluate the effectiveness, safety and procedural time of FLACS compared to the standard manual technique for cataract surgery in patients affected by age-related cataract.

Methods

International guidelines, UpToDate and relevant studies represented the main source for the "Health problem and current use" of FLACS domain. Manufacturers' brochures and information leaflets, manufacturers' manual for use, published articles and EUnetHTA manufacturer's submission template were sought for the Description and Technical Characteristic of the technology domain.

Patients' organizations were contacted to gather their perspectives and expectations on cataract surgery, on relevant outcomes and sub-populations to be considered within the assessment.

Outcomes of interest were rated as "critical" or "important" after a process involving authoring team and dedicated reviewers, using the GRADE methodology with the GRADE-pro software.

A systematic search of the scientific literature comparing effectiveness, safety and organizational impact of FLACS vs standard phacoemulsification in patients >18 years affected by cataract was carried out. As four recent systematic reviews were published in 2016, our search combined the search strategies of all four reviews and included randomised and non randomised controlled trials published from January 2016 to June 2018.

Four review authors independently screened and selected the eligible studies, and extracted data. Discrepancies were resolved through discussion among themselves and with a fifth author. Risk of bias at study and outcome level was assessed using the Cochrane risk of bias tool. Overall quality of evidence was graded using the GRADE methodology.

With eyes as unit of analysis, data were combined through metanalysis using odds ratios for binary outcomes and the mean difference for continuous outcomes.

Results.

The electronic search yielded 2473 references; 21 randomised controlled trials meeting the inclusion criteria were eventually analysed. These studies had recruited a total of 1633 patients, 76% of whom operated in Europe to one or both eyes. A total of 2118 eyes were randomised.

Seven parallel group RCTs and 3 within person paired-eye RCTs, recruiting a total of 648 patients and randomising 859 eyes, reported clinical effectiveness outcomes. All effectiveness outcomes assessed (Corrected Distance Visual Acuity - CDVA - and Uncorrected Distance Visual Acuity – UDVA - at 1 and 6 months, and refractive outcomes at 1 week and 1 month) were rated as “critical” by the panel. Overall quality of evidence for these outcomes was graded “low” for CDVA and refractive outcomes, and “very low” for UDVA. For all these outcomes, the pooled estimates showed no evidence of a difference between study groups.

Only one study reported data on patient-reported outcomes, showing no difference between study groups, while none of the retrieved studies reported results on health-related quality of life.

Fifteen small-sized RCTs assessed clinical safety outcomes, classified as intraoperative complications (anterior and posterior capsular tear, vitreous loss) and postoperative complications (cystoid macular oedema, infections, posterior capsule opacification, surgically induced astigmatism, endothelial cell loss at three months, elevated intraocular pressure, central corneal thickness). Overall, the 15 trials recruited a total of 1215 patients and randomised 1641 eyes. Except for surgically induced astigmatism, elevated intraocular pressure and central corneal thickness, all other safety outcomes were graded as “critical”. Overall quality of evidence for critical outcomes was judged as “low” for intraoperative complications. For postoperative complications rated as critical, overall quality of evidence was judged as “very low” for endothelial cell loss (at 3 and 6 months) and cystoid macular oedema, while it was graded as “low” for infections. Pooled analyses did not show differences between the two techniques in any of the above safety outcomes

No data were found on the following outcomes graded as critical: retinal detachment, visual acuity loss post-surgery, surgical re-intervention, secondary cataract, iridocyclitis..

Limited evidence is available on the impact of each technique on mean surgical time. One study showed a very limited reduction for this outcome with FLACS, without granting an improvement in productivity.

A late feed-back was obtained from a Spanish patient organization who underlined that, given the effectiveness and safety of standard treatment, more sophisticated technologies are not needed for cataract surgery. It was highlighted that resources should be invested in preventing cataracts, considering that preventive and non-surgical treatments represent an unmet need.

Despite several attempts to obtain information from the manufacturers, only one of the five identified responded and provided a complete EUnetHTA submission template.

Conclusion

The evidence retrieved, suggesting that FLACS does not lead to improvement in effectiveness and safety outcomes compared to standard cataract surgery, is of low or very low quality. Included studies did not report sufficient data on patient-reported outcomes. As for organizational impact and resource use, limited evidence is available on the effect of FLACS on mean surgical time, not showing a sufficient improvement in productivity.

Pending results from two large randomised studies could contribute to solving uncertainties. This report will be updated once the results from both studies will be available.