



## Sökning i databaser för vetenskaplig evidens: Femtosekundlaser vid kataraktbehandling

### Frågeställning

Vilken dagsaktuell vetenskaplig evidens finns för rutinmässig användning av femtosekundlaser vid kataraktbehandling?

### Bakgrund

Traditionell manuell ultraljud- baserad kirurgisk behandling vid katarakt är väletablerad. Den grumliga naturliga linsen ersätts med konstgjord lins genom ett snitt. Femtosekundlaser är etablerad vid korrektion av brytningsfel, men har helt nyligen börjat användas för att öppna ögat för att byta ut en grumlig lins. CME märkta och FDA godkända femtosekundlaserutrustningar finns tillgängliga på marknaden sedan 2011 som datoriserar/automatiserar delar av kataraktkirurgin. Förhoppningen är att denna metod skall förkorta operationstiden och minska komplikationsfrekvensen genom att snittet för att öppna ögat blir mer precist, reproducerbart och minimerar skador på omgivande vävnader.

Sedan 2009 har 16 PubMed registrerade vetenskapliga publikationer utkommit i ämnet (sökning på "Femtosecond laser" och "cataract" i titeln) (Lee, Kim et al. 2009; Nagy, Takacs et al. 2009; Masket, Sarayba et al. 2010; Palanker, Blumenkranz et al. 2010; Ecsedy, Mihaltz et al. 2011; Feizi 2011; He, Sheehy et al. 2011; Mamalis 2011; Mihaltz, Knorz et al. 2011; Moshirfar, Churgin et al. 2011; Naranjo-Tackman 2011; Roberts, Sutton et al. 2011; Bali, Hodge et al. 2012; Takacs, Kovacs et al. 2012; Yeoh 2012; Yu and Yao 2012).

### Metodrådets sammanfattande bedömning

*Kliniska studier av femtosekundlaser för behandling av katarakt är i sin linda. Tillräckligt omfattande randomiserade och kontrollerade långtidsstudier saknas. Vetenskapligt stöd för införande av femtolaserbehandling vid rutinmässig kataraktkirurgi saknas i dagsläget.*

### Sökning i HTA (Health Technology Assessment) databaser (2012-05-21)

SBU - Kunskapscentrum för hälso- och sjukvården <http://www.sbu.se/sv/>

Ingen träff på "FS-laser" eller "kataraktkirurgi" eller "FS laser" eller "femtosekund"

Socialstyrelsen – nationella riktlinjer

<http://www.socialstyrelsen.se/riktlinjer/nationellariktlinjer>

Ingen träff på "FS laser" eller "FS-laser" eller "femtosekund"

TRIP databasen <http://www.tripdatabase.com/search/advanced>

7 träffar på "FS laser" and cataract. Ingen HTA granskning.

The Cochrane Library <http://www.thecochranelibrary.com/view/0/index.html>



20 träffar på "FS laser" men ingen på "FS laser cataract" och ingen op "femtosecond laser cataract". Ingen HTA granskning.

*Clinical Evidence* <http://www.clinicalevidence.com/x/index.html>

Inga träffar på "femtosecond laser"

*International Network of Agencies for Health Technology Assessment* <http://www.inahta.net/>

Två träffar på "femtosecond laser", men båda handlar om behandling av närsynthet.

*Nasjonalt kunnskapssenter for helsetjenesten, Norge* <http://www.kunnskapssenteret.no/>

Inga relevanta träffar på "FS-laser" eller "femtosekund" eller "katarakt"

För metodrådet i Sydöstra sjukvårdsregionen den 21 maj 2012

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### **Litteraturreferenser**

Bali, S. J., C. Hodge, et al. (2012). "Early experience with the femtosecond laser for cataract surgery." *Ophthalmology* **119**(5): 891-899.

**OBJECTIVE:** To describe the intraoperative complications and to evaluate the learning curve with femtosecond laser cataract surgery. **DESIGN:** Prospective, consecutive cohort study. **PARTICIPANTS:** The first 200 eyes undergoing femtosecond laser cataract surgery and refractive lens exchange in a single center. **METHODS:** The initial 200 eyes undergoing cataract surgery between April 2011 and June 2011 by 6 surgeons were included in the study. The cases underwent anterior capsulotomy, lens fragmentation, and corneal incisions with the femtosecond laser. The procedure was completed by phacoemulsification and insertion of an intraocular lens. Data were collected about patient demographics, preoperative investigations and intraoperative complications. The cases were divided into 4 groups-group 1 included the first 50 cases, group 2 included cases 51 through 100, group 3 included cases 101 through 150, and group 4 included cases 151 through 200-and were analyzed. **MAIN OUTCOME MEASURES:** Intraoperative complication rates. **RESULTS:** The mean age of patients included was 69.2+/-9.8 years. Of the 200 eyes, 74.5% underwent a complete procedure of laser capsulotomy, lens fragmentation, and corneal incisions. Five eyes had suction breaks during the laser procedure that led to the remainder of the laser procedure being aborted. Twenty-one (10.5%) eyes showed the presence of small anterior capsular tags. The number of eyes with free-floating capsulotomies was 35 (17.5%). The other complications during the study were anterior radial tears (n = 8; 4%), posterior capsular ruptures (n = 7; 3.5%), and dropped nucleus (n = 4; 2%). A significant difference was noted among the sequential groups with respect to the number of docking attempts (P<0.001), miosis after the laser procedure (P<0.001), and free-floating capsulotomies (P<0.001), suggesting an improving learning curve. The surgeons with prior experience with femtosecond lasers had fewer complications in the first 100 cases (P<0.001). No difference in complications was observed after the initial 100 cases. **CONCLUSIONS:** In this case series, there was a clear learning curve



associated with the use of femtosecond lasers for cataract surgery. Adjustment to surgical technique and prior experience with a femtosecond laser seemed to flatten the learning curve. FINANCIAL DISCLOSURE(S): Proprietary or commercial disclosure may be found after the references.

Ecsedy, M., K. Mihaltz, et al. (2011). "Effect of femtosecond laser cataract surgery on the macula." *J Refract Surg* **27**(10): 717-722.

**PURPOSE:** To compare the effect of conventional and femtosecond laser-assisted (Alcon LenSx Inc) phacoemulsification on the macula using optical coherence tomography (OCT). **METHODS:** Twenty eyes of 20 patients underwent uneventful cataract surgery in both study groups: femtosecond laser-assisted (laser group) and conventional phacoemulsification (control group). Macular thickness and volume were evaluated by OCT preoperatively and 1 week and 1 month postoperatively. Primary outcomes were OCT retinal thickness in 3 macular areas and total macular volume at 1 week and 1 month postoperative. Secondary outcomes were changes in retinal thickness at 1 week and 1 month postoperatively, with respect to preoperative retinal thickness values and effective phacoemulsification time. **RESULTS:** Multivariable modeling of the effect of surgery on postoperative macular thickness showed significantly lower macular thickness in the inner retinal ring in the laser group after adjusting for age and preoperative thickness across the time course ( $P=.002$ ). In the control group, the inner macular ring was significantly thicker at 1 week (mean: 21.68  $\mu\text{m}$ ; 95% confidence limit [CL]: 11.93-31.44  $\mu\text{m}$ ,  $P<.001$ ). After 1 month, this difference decreased to a mean of 17.56  $\mu\text{m}$  (95% CL: -3.21-38.32  $\mu\text{m}$ ,  $P=.09$ ) and became marginally significant. **CONCLUSIONS:** Results of this study suggest that femtosecond laser-assisted cataract extraction does not differ in postoperative macular thickness as compared with standard ultrasound phacoemulsification.

Feizi, S. (2011). "Femtosecond laser cataract surgery." *J Ophthalmic Vis Res* **6**(2): 151.

He, L., K. Sheehy, et al. (2011). "Femtosecond laser-assisted cataract surgery." *Curr Opin Ophthalmol* **22**(1): 43-52.

**PURPOSE OF REVIEW:** In 2010, the US Food and Drug Administration (FDA) cleared femtosecond laser systems for cataract surgery. Available in 2011, this technology has the potential to significantly impact cataract surgery. **RECENT FINDINGS:** Femtosecond lasers offer surgeons the ability to make very precise cuts in a targeted area without damaging the surrounding tissues. This technology has already dramatically changed refractive surgery and is poised to do the same for cataract surgery. Three companies, OptiMedica, LenSx (acquired by Alcon in September 2010), and LensAR, in different stages of FDA clearance, are developing femtosecond laser systems for cataract surgery. These systems will create the initial corneal incisions, capsulotomy, and also fragment the lens. **SUMMARY:** This article outlines the advantages of femtosecond laser cataract surgery and provides an initial



comparison of the LensAR, LenSx/Alcon, and OptiMedica systems and early clinical results.

Lee, D., J. H. Kim, et al. (2009). "Femtosecond laser lamellar keratoplasty to aid visualization for cataract surgery." J Refract Surg **25**(10): 902-904.

**PURPOSE:** To describe a new surgical technique for a patient with cataract combined with corneal opacity. **METHODS:** This technique, femtosecond laser-assisted cataract surgery, was performed on a patient with a history of corneal opacity in both eyes from childhood. Because the patient had deep stromal corneal opacity, a corneal button 400- $\mu$ m thick was made for lamellar keratoplasty while cataract surgery was performed simultaneously. **RESULTS:** Lifting of the flap and removal of the corneal button before cataract surgery was successful without any intraoperative complications. **CONCLUSIONS:** Femtosecond laser-assisted cataract surgery is a promising surgical procedure for a cataract patient with stromal corneal opacity.

Mamalis, N. (2011). "Femtosecond laser: the future of cataract surgery?" J Cataract Refract Surg **37**(7): 1177-1178.

Masket, S., M. Sarayba, et al. (2010). "Femtosecond laser-assisted cataract incisions: architectural stability and reproducibility." J Cataract Refract Surg **36**(6): 1048-1049.

Mihaltz, K., M. C. Knorz, et al. (2011). "Internal aberrations and optical quality after femtosecond laser anterior capsulotomy in cataract surgery." J Refract Surg **27**(10): 711-716.

**PURPOSE:** To compare ocular and internal aberrations after femtosecond laser anterior capsulotomy and continuous curvilinear capsulorrhexis in cataract surgery. **METHODS:** In this prospective study, anterior capsulotomy was performed during cataract surgery with an intraocular femtosecond (FS) laser (Alcon LenSx Inc) in 48 eyes. As a control group, continuous curvilinear capsulorrhexis (CCC) was performed in 51 eyes. Wavefront aberrometry, corneal topography, and objective visual quality were measured using the OPD-Scan (NIDEK Co Ltd). Vertical and horizontal tilt, coma, and visual quality metrics were evaluated separately to determine whether the source of aberrations was ocular or internal. Main outcome measures included postoperative residual refraction, uncorrected and corrected visual acuities, ocular and internal aberrations, Strehl ratio, and modulation transfer function (MTF). **RESULTS:** No statistically significant differences were noted between the FS and CCC groups, respectively, in postoperative sphere ( $-0.60 \pm 1.50$  vs  $-0.50 \pm 1.40$  diopters [D]), postoperative cylinder ( $1.30 \pm 1.01$  vs  $1.10 \pm 1.10$  D), uncorrected distance visual acuity ( $0.86 \pm 0.15$  vs  $0.88 \pm 0.08$ ), or corrected distance visual acuity ( $0.97 \pm 0.08$  vs  $0.97 \pm 0.06$ ). The FS group had significantly lower values of intraocular vertical tilt ( $-0.05 \pm 0.36$  vs  $0.27 \pm 0.57$ ) and coma ( $-0.003 \pm 0.11$  vs  $0.1 \pm 0.15$ ), and significantly higher Strehl ratios ( $0.02 \pm 0.02$  vs  $0.01 \pm 0.01$ ) and MTF values at all measured cycles per degree, compared to the CCC group. **CONCLUSIONS:** Capsulotomy performed with an intraocular FS laser induced significantly less internal aberrations measured by the NIDEK OPD-Scan aberrometer compared to eyes that underwent CCC, which may result in better optical quality after the procedure.



Moshirfar, M., D. S. Churgin, et al. (2011). "Femtosecond laser-assisted cataract surgery: a current review." Middle East Afr J Ophthalmol **18**(4): 285-291.

To evaluate the safety, efficacy, advantages, and limitations of femtosecond laser-assisted cataract surgery through a review of the literature. A PubMed search was conducted using topic-appropriate keywords to screen and select articles. Initial research has shown appropriate safety and efficacy of femtosecond laser-assisted cataract surgery, with improvements in anterior capsulotomy, phacofragmentation, and corneal incision. Limitations of these studies include small sample size and short-term follow-up. Cost-benefit analysis has not yet been addressed. Preliminary data for femtosecond laser-assisted cataract surgery shows appropriate safety and efficacy, and possible advantage over conventional cataract surgery. Questions to eventually be answered include comparisons of long-term postoperative complication rates-including infection and visual outcomes-and analysis of contraindications and financial feasibility.

Nagy, Z., A. Takacs, et al. (2009). "Initial clinical evaluation of an intraocular femtosecond laser in cataract surgery." J Refract Surg **25**(12): 1053-1060.

**PURPOSE:** To evaluate femtosecond laser lens fragmentation and anterior capsulotomy in cataract surgery. **METHODS:** Anterior capsulotomy and phacofragmentation procedures performed with an intraocular femtosecond laser (LenSx Lasers Inc) were initially evaluated in ex vivo porcine eyes. These procedures were then performed in an initial series of nine patients undergoing cataract surgery. In addition to standard intraoperative assessments (including capsulotomy diameter accuracy and reproducibility), optical coherence tomography was used to evaluate human procedures. **RESULTS:** For an intended 5-mm capsulorrhexis in porcine eyes, average achieved diameters were 5.88+/-0.73 mm using a standard manual technique and 5.02+/-0.04 mm using the femtosecond laser. Scanning electron microscopy revealed equally smooth cut edges of the capsulotomy with the femtosecond laser and manual technique. Compared to control porcine eyes, femtosecond laser phacofragmentation resulted in a 43% reduction in phacoemulsification power and a 51% decrease in phacoemulsification time. In a small series of human clinical procedures, femtosecond laser capsulotomies and phacofragmentation demonstrated similarly high levels of accuracy and effectiveness, with no operative complications. **CONCLUSIONS:** Initial results with an intraocular femtosecond laser demonstrate higher precision of capsulorrhexis and reduced phacoemulsification power in porcine and human eyes.

Naranjo-Tackman, R. (2011). "How a femtosecond laser increases safety and precision in cataract surgery?" Curr Opin Ophthalmol **22**(1): 53-57.

**PURPOSE OF REVIEW:** To look at the recent applications of femtosecond laser (FSL) technology for capsulotomy and nuclear fragmentation in cataract surgery, the potential advantages, such as more precise and adjustable capsulotomies and the use of less phaco energy with this technology. **RECENT FINDINGS:** The FSL can create incisions or spaces of different shapes, at a desired depth. This has started the application of the technology in the lens: after a clear image is taken of the lens through a previously dilated pupil, circular capsulotomy is done, with precision in shape and diameter, and in most cases, just needs to be grabbed, or requires very small





use of the with the forceps. Then photofragmentation of the nucleus is done, without the risk of damaging the posterior capsule, because it is well visualized, to achieve the aspiration of the nuclear material without applying phaco energy, in the soft or medium-hard nucleus, but eventually in almost all nucleus. SUMMARY: FSL is now used at the level of the lens, with the potentiality for very precise circular and adjustable diameter capsulotomies, and the fragmentation of the nuclear material, allowing the aspiration of the material and less emulsification especially in soft nucleus.

Palanker, D. V., M. S. Blumenkranz, et al. (2010). "Femtosecond laser-assisted cataract surgery with integrated optical coherence tomography." *Sci Transl Med* 2(58): 58ra85.

About one-third of people in the developed world will undergo cataract surgery in their lifetime. Although marked improvements in surgical technique have occurred since the development of the current approach to lens replacement in the late 1960s and early 1970s, some critical steps of the procedure can still only be executed with limited precision. Current practice requires manual formation of an opening in the anterior lens capsule, fragmentation and evacuation of the lens tissue with an ultrasound probe, and implantation of a plastic intraocular lens into the remaining capsular bag. The size, shape, and position of the anterior capsular opening (one of the most critical steps in the procedure) are controlled by freehand pulling and tearing of the capsular tissue. Here, we report a technique that improves the precision and reproducibility of cataract surgery by performing anterior capsulotomy, lens segmentation, and corneal incisions with a femtosecond laser. The placement of the cuts was determined by imaging the anterior segment of the eye with integrated optical coherence tomography. Femtosecond laser produced continuous anterior capsular incisions, which were twice as strong and more than five times as precise in size and shape than manual capsulorhexis. Lens segmentation and softening simplified its emulsification and removal, decreasing the perceived cataract hardness by two grades. Three-dimensional cutting of the cornea guided by diagnostic imaging creates multiplanar self-sealing incisions and allows exact placement of the limbal relaxing incisions, potentially increasing the safety and performance of cataract surgery.

Roberts, T. V., G. Sutton, et al. (2011). "Capsular block syndrome associated with femtosecond laser-assisted cataract surgery." *J Cataract Refract Surg* 37(11): 2068-2070.

We report intraoperative capsular block syndrome occurring during the first 50 femtosecond laser-assisted cataract surgeries performed in our facility. Two patients had uneventful combined laser fragmentation, capsulotomy, and corneal incision procedures. In both cases, following transfer to the operating room and manual removal of the laser-cut capsulotomy, posterior capsule rupture was noted during hydrodissection, resulting in posterior dislocation of the lens. Pars plana vitrectomy, removal of the crystalline lens, and sulcus implantation of an intraocular lens were performed in both patients with good visual outcomes. Femtosecond laser-assisted cataract surgery changes the intraoperative environment with the generation of intracapsular gas and laser-induced changes in the cortex. With awareness of the changed intraocular environment following laser lens fragmentation and capsulotomy and a modification of the surgical technique, no additional cases of intraoperative CBS have been seen in more than 600 laser-assisted cataract surgery procedures performed



to date at our facility. FINANCIAL DISCLOSURE: No author has a financial or proprietary interest in any material or method mentioned. Additional disclosure is found in the footnotes.

Takacs, A. I., I. Kovacs, et al. (2012). "Central Corneal Volume and Endothelial Cell Count Following Femtosecond Laser-assisted Refractive Cataract Surgery Compared to Conventional Phacoemulsification." J Refract Surg: 1-6.

**PURPOSE:**To compare the effect of conventional phacoemulsification and femtosecond laser-assisted cataract surgery on the cornea using Scheimpflug imaging and noncontact specular microscopy. **METHODS:**In each group, 38 eyes (38 patients) underwent cataract surgery using either femtosecond laser-assisted (Alcon LenSx laser) (femtolaser group) or conventional phacoemulsification (phaco group). Central corneal thickness, 3-mm corneal volume, and Pentacam Nucleus Staging (PNS) were determined by a rotating Scheimpflug camera (Pentacam HR, Oculus Optikgerate GmbH), and the volume stress index was calculated at 1 day and 1 month postoperatively. Endothelial cell count was measured by noncontact specular microscopy preoperatively, 1 day, 1 week, and 1 month postoperatively.

**RESULTS:**Central corneal thickness was significantly higher in the phaco group (607+/-91  $\mu\text{m}$ ) than in the femtolaser group (580+/-42  $\mu\text{m}$ ) on day 1, but did not differ significantly preoperatively and at 1 week and 1 month. Volume stress index at day 1 was significantly lower in the femtolaser group than in the phaco group ( $P < .05$ ) but did not differ significantly at 1 month. Multivariate regression analysis showed that the type of surgery had a significant effect on central corneal thickness.

**CONCLUSIONS:**Femtosecond laser-assisted cataract surgery causes less corneal swelling in the early postoperative period and may cause less trauma to corneal endothelial cells than manual phacoemulsification.

Yeoh, R. (2012). "Hydrorrapture of the posterior capsule in femtosecond-laser cataract surgery." J Cataract Refract Surg **38**(4): 730; author reply 730.

Yu, Y. H. and K. Yao (2012). "New applications of femtosecond laser in cataract surgery." Yan Ke Xue Bao **27**(1): 50-56.

The high prevalence of blindness associated with cataract is an urgent public health issue. Femtosecond (FS) laser offers several advantages over conventional laser, such as high penetration, short pulse-duration and micro-precision. Since 2009, several types of FS laser systems have been applied to cataract surgery, offering novel approaches to the three steps of clear corneal incision (CCI) construction, anterior capsulotomy and lens fragmentation. Superior accuracy, predictability, reproducibility and safety have been achieved with use of this innovative technology. However, certain problems remain unresolved. More studies are needed to clarify the optimal utilization of FS in cataract surgery. The purpose of this review is to outline the features, applications, benefits and risks of FS in cataract surgery, and to discuss current scientific evidence and relevant commercial issues.

