Femtosecond laser-assisted cataract surgeries (FLACS) reported to the European Registry of Quality Outcomes for Cataract and Refractive Surgery (EUREQUO): baseline characteristics, surgical procedure, and outcomes.

Short running head: FLACS in EUREQUO

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Abstract

Purpose: To describe a large cohort of femtosecond laser-assisted cataract surgeries (FLACS) in terms of baseline characteristics and the related outcomes.

Setting: Eighteen cataract surgery clinics in nine European countries and Australia.

Design: Prospective multicentre cohort registry study.

Methods: Data about consecutive eyes undergoing FLACS in the participating clinics were entered into the European Registry of Quality Outcomes for Cataract and Refractive Surgery (EUREQUO). A specifically trained registry manager in each clinic was responsible for valid reporting to the EUREQUO. Data on demographics, preoperative corrected distance visual acuity (CDVA), risk factors, type of surgery, type of intraocular lens (IOL), visual outcome, refractive outcome, and complications were reported.

Results: Complete data were available for 3379 cases. The mean age was 64.4 (±10.9) years, and 57.8% (95%CI 56.1-59.5) of the patients were female. A surgical complication was reported in 2.9% (95% CI 2.4-3.5), of all cases (2.2% FLACS-related like laser incision: 0.8% and laser capsulotomy: 0.5% and in 0.7% ordinary phacoemulsification-related complications). The mean postoperative CDVA was LogMAR 0.04 (±0.15). A biometry prediction error (spherical equivalent) was within ±0.5D in 71.8% (95% CI 70.3-73.3) of all surgeries. Postoperative complications were reported in 3.3% (95% CI 2.7-4.0). Patients with good preoperative CDVA generally had the best visual and refractive outcome, patients with poor preoperative visual acuity had poorer outcomes.

Conclusions: The visual and refractive outcomes of FLACS were favourable compared to manual phacoemulsification. The outcome was highly influenced by the preoperative visual acuity, but all preoperative visual acuity groups showed an acceptable outcome.

Introduction

Femtosecond laser-assisted cataract surgery (FLACS) may represent a paradigm shift in cataract surgery, and has given rise to an increasing number of abstracts and publications. The main interest has focused on comparison with standard phacoemulsification, but attention has also been paid to the complications expected with this new technique.[1-4] The economics, surgical logistics, and influence on training and skills have raised questions about the benefit of FLACS in a healthcare setting. [5-6] Other questions of interest are whether FLACS works well for all kinds of eyes and settings, and when using different kinds of intraocular lenses. In this study, we explored a multi-national cohort of FLACS patients (the European Society of Cataract and Refractive Surgeons [ESCRS] FLACS Cohort Study) with reference to variation in outcomes versus preoperative conditions and type of implanted intraocular lens (IOL).

Methods

This prospective multinational multicentre registry study was designed to allow analyses of mandatory variables according to the web form guidelines for the European Registry of Quality Outcomes in Cataract and Refractive Surgery (EUREQUO). [7] Clinics performing FLACS were identified through international publications and abstracts, and invited to participate. One condition for joining the study was that each participating surgeon should have performed FLACS at least 50 times. The set of variables needed to capture the outcomes of this new technique were determined together with the surgeons, and registry parameters were updated accordingly. In each clinic, a registry manager was trained prior to the study to understand the coding guidelines of the registry and to report data to the database. Data were reported to EUREQUO using electronic case report forms. [8] Approval by the local ethics committee was obtained according to national requirements. Patients were assigned to FLACS according to the routines of each participating clinic. Per protocol, consecutive cases were reported to the database, and a follow-up examination was performed within 7-60 days after surgery. The study was carried out according to the tenets of the Declaration of Helsinki.

Statistical analysis

Statistical analyses were performed using version 22 of IBM SPSS Statistics (IBM SPSS, Chicago, IL, USA). Dichotomous variables were tested with logistic regression analysis, and continuous variables were tested with linear regression analysis. For all analyses, a p-value of 0.05 or less was considered significant.

Results

Baseline characteristics

Eighteen clinics in ten countries (Australia, Belgium, Czech Republic, Germany, Hungary, Italy, the Netherlands, Spain, Turkey, and the United Kingdom) reported a total of 3379 cataract extractions between 7 January 2013 and 16 April 2015. The mean number of cataract extractions per site was 187, with a median of 139 and range from 8 to 1068 operations. The mean age of the patients was 64.4 (±10.9) years, and 57.8% of them were female. Preoperative best corrected distance visual acuity (CDVA), measured as logarithm of the minimum angle of resolution (LogMAR), had a median of LogMAR 0.2 (range: -0.2 – 3.0), a mean of LogMAR 0.3 (±0.39), and a distribution as shown in Figure 1.

Between clinics, the median preoperative CDVA varied from LogMAR 0 (Snellen 6/6) to LogMAR 0.7 (Snellen 6/30). The percentage of eyes with a preoperative CDVA of LogMAR 0 (Snellen 6/6) or better varied from 0% to 58.1%. In order to study the outcome of different eyes, a visual acuity grouping was introduced. Preoperative CDVA distributed in these baseline groups is shown in Table 1. The groups represent: (1) very good vision; (2) good vision; (3) impaired vision, but good enough for driving and reading; (4) poor vision, good enough for reading but not for driving a car; and (5) low vision, not good enough for comfortable reading.

The preoperative refraction in the surgery eye was reported in all but 710 cases. The parameter preoperative refraction is optional. This means that it is possible to report and finalize a case without filling in this parameter. The reason for not reporting the parameter is not known. In some missing cases, the refraction was likely not examined or was unreliable because of poor preoperative visual acuity. Table 2 shows the preoperative spherical equivalent in groups.

As seen in Table 2, very good preoperative vision (LogMAR0.0 or better) was frequent (although not statistically significantly) in the spherical equivalent groups of -9.99D to -4.0D and 2.1D to 4.0D.

Risk factors

Preoperative risk factors were reported in terms of ocular comorbidity and pre-/intraoperative surgical difficulties (Table 3). A preoperative ocular comorbidity in the surgery eye was reported in 19.1% of all cases, comprising one or more of the following diagnoses: glaucoma (4.2%), age-related macular degeneration (4.9%), diabetic retinopathy (1.1%), amblyopia (4.0%) and "other vision-threatening co-existing eye disease" (7.5%). Pre- or intraoperative surgical difficulties were reported in 9.9% of all surgeries, comprising white/dense cataract (0.4%), pseudo-exfoliation (1.0%), corneal opacities (0.7%), small pupil (0.3%), and "other" difficulty (2.7%). Previous surgery to the eye was also included in this group of variables: previous corneal refractive surgery (4.9%) and previous vitrectomy (0.8%).

The average target refraction was -0.24D (±: 0.58), with visual acuity group variation of -0.11D (±: 0.36) – -0.42D (±: 0.82).

The femtosecond laser functions used for different surgical steps during the cataract extractions are shown in Table 4.

The combined use of the laser functions varied. The most common combination was using the femtosecond laser for both capsulotomy and nucleus fragmentation (n=3138, 94.1%).

The use of implanted intraocular lenses (IOL) is given in Table 5. As seen there, the choice of either a monofocal or a multifocal IOL was related to the patient's preoperative visual acuity.

Outcomes

The mean follow-up time was 34 ±26 days, quartiles: 19, 32, 42 days.

Surgical complications

The EUREQUO standard set of surgical complications were reported, along with any complications specific to FLACS. Any surgical complication was reported in 2.9% of all surgeries (visual acuity group variation: 0.7–7.7%, $p<0.001$, logistic regression). Of these complications, 2.2% were specific FLACS-related complications while the other 0.7% were traditional cataract surgical complications. The specific FLACS-related complications per visual acuity group are shown in Table 6. Of the traditional cataract surgery complications, 14 patients (0.4%) had a capsule complication, meaning a posterior capsular tear with (n=4) or without vitreous loss and with (n=3) or without a dropped nucleus. A specific FLACS complication was reported as related to the laser incision in 27 patients (0.8% of all cases, 2.39% of corneal laser incision cases). In 18 cases (0.5%) there was a complication related to the laser capsulotomy, and in 5 cases (0.1%) there was a complication related to the laser fragmentation of the nucleus. In 16 cases (0.5%) there were minor capsular tags, and in 3 cases (0.1%) there was an anterior capsular tear. In 3 cases, the femtosecond laser-assisted approach was abandoned due to loss of docking, loss of suction, and other reason, respectively.

Visual outcome

The mean postoperative CDVA was LogMAR 0.04 (±: 0.15) and the median postoperative CDVA was LogMAR 0 (Snellen 6/6). The distribution of postoperative visual acuity is shown in Figure 2. A postoperative CDVA of LogMAR 0.0 (Snellen 6/6) or better was achieved in 71.9% of cases and of LogMAR 0.3 (Snellen 6/12) or better in 96.2% of cases. In 52% of cases there was an improvement of more than 1 LogMAR notation unit, in 46.9% of cases the visual outcome was within ±1 LogMAR unit of the preoperative value, and in 1.1% of cases the visual outcome was more than 1 LogMAR unit worse compared with before surgery. Characteristics related to a worse outcome were existence of an ocular comorbidity and good preoperative visual acuity ($p<0.001$ and $p=0.012$, respectively, logistic regression).

Complications and change in visual acuity by surgery per baseline visual acuity group are shown in Table 6, refractive outcomes per baseline visual acuity group are shown in Table 7, and changes in visual acuity groups by surgery are shown in Table 8.

Refractive outcome

The absolute mean prediction error was 0.43D (±: 0.50) and the absolute median error was 0.30D. A biometry prediction error (spherical equivalent) within ±0.5D was achieved by 71.8% of all surgeries and an error within ±1.0D by 91.8%. Table 9 shows the parameters significantly related to a refractive outcome outside ±0.5D of error. A postoperative cylinder of 1.0D or less was achieved in 86.3% of all surgeries. In 2886 surgeries, the aim was to achieve emmetropia (spherical equivalent), and this was achieved in 2117 cases (73.4%). In 493 cases, target refraction differed from emmetropia. This aim was successfully achieved in

328 cases (66.5%).

Postoperative complications

Postoperative complications were reported in 113 cases: central corneal oedema (n=15, 0.4%), optic axis opacities (n=26, 0.8%), postoperative uveitis with need for medication (n=13, 0.4%), uncontrolled rise of intraocular pressure (IOP) (n=4, 0.1%), “other” sight-threatening postoperative complication (n= 58, 1.7%), and IOL explanted after surgery (n=3, 0.1%). Significantly related to postoperative complications were ocular co-morbidity and surgical difficulty ($p<0.001$, logistic regression). The number of eyes with diabetic retinopathy was low in this study, with only 36 cases (1.1%), and a postoperative complication (persistent corneal oedema) was reported for only one of these cases. The frequency of postoperative complications per preoperative visual acuity groups is shown in Table 6, and outcomes related to use of monofocal IOL versus multifocal IOL are shown in Table 10.

Discussion

This large cohort of patients undergoing cataract extractions with FLACS is among the largest numbers of cases reported so far. A strength of this study is the multinational and multiclinic participation. The average patient was a 64-year old woman with a preoperative visual acuity of LogMAR 0.2 and without any ocular comorbidity or surgical difficulty. However, there was a large variation in baseline visual acuity and mean age. The gender distribution in our cohort is comparable with two previously published FLACS studies (57.8% female vs 56% and 56%, respectively), while the mean age is somewhat lower (mean age 64.4 vs 71.6 and 73.5, respectively).[2, 3] A lower mean age may be explained by a variation in indications for cataract surgery,[9] and the same reason likely underlies the large variation in preoperative visual acuity in our study. One aim of our study was to analyse FLACS outcomes for different types of eyes, and so cases were grouped on the basis of baseline visual acuity. In this article, we introduce a novel scale/method of analysing a cohort of patients' cataract surgery outcomes related to visual acuity. As shown in Tables 3 and 6, age, risk factors, surgical complications, and visual outcomes were closely related to preoperative visual acuity. A certain proportion of the patients had a large ametropia before surgery combined with good preoperative visual acuity, which may indicate a predominantly refractive indication for surgery. This means that the FLACS technique was used to correct ametropia in some cases with mild cataract. Consequently, some of these surgeries have been performed in the grey zone between refractive lens exchange and cataract extraction. A weakness in our study is the lack of information on axial length, which means that it is not possible to fully interpret the causes of a preoperative ametropia.

On average, risk factors in terms of ocular comorbidity were few compared with two previous published cohorts undergoing phacoemulsification cataract surgery (19.1% vs 37.5% and 39.7%, respectively).[10,11] This may have been caused by unwillingness to use this new techniques in risky cases, which means that this cohort could comprise a selection of good cases compared to ordinary phacoemulsification cataract surgery. The significant relation between risk factors and baseline visual acuity group is shown in Table 3.

We did not collect data on brands in this study. The use of certain laser features (such as those for making the corneal incision) might be related to the specific laser machine used and the surgeon's preference. The use of laser for the corneal incision was only reported in 33.9% of the surgeries (Table 4). Seven surgeons did not report any such procedure and for the rest of surgeons a laser corneal incision was used for a reduced number of cases (data not shown). It has been reported that the laser corneal incision takes significantly longer time than a manual corneal incision and this may contribute to a lower usage of the laser for corneal incisions. [12]

Correction of astigmatism was not used to any great extent; less than 10% of the eyes were treated for astigmatism. The impact of this treatment as well as use of toric IOLs will be described elsewhere.

The rate of traditional surgical complications (complications engaging the posterior capsule) was low in our study compared to previous publications,[13] while the rate of FLACS-associated complications was higher. One reason for this is of course the fact that even insignificant and harmless complications were registered in order to get a full picture. However, a more interesting result is that the femtosecond approach had to be abandoned in only three cases (0.1%). This is a low number, and probably reflects the inclusion criterion that participating surgeons should have performed at least 50 femtosecond laser-assisted cataract surgeries before entering the study. Suction loss could be a sign of unfamiliarity with this technique.[14]

The use of a toric IOL was evenly distributed among the visual acuity groups, while the opposite was true for the use of a monofocal or multifocal IOL. The groups representing good preoperative visual acuity (groups 1 and 2, which also had lower age and fewer risk factors) were often given a multifocal IOL, while the groups representing poor preoperative visual acuity (groups 4 and 5, which also had higher age and more risk factors) were given a monofocal IOL in most cases.

The visual outcome of FLACS was very good in our study, and better than in previous reports from the EUREQUO database. [10, 15] We created baseline visual acuity groups in order to reflect the outcomes for various functional groups of eyes. Grouping eyes based on visual acuity also meant a grouping in terms of risk factors (Table 3). As can be seen from Table 8, the impact of FLACS meant an improvement to better functional groups, and this was specifically evident for eyes belonging to groups with poor preoperative visual acuity. As shown in Table 8, 94.6% of the eyes in group 4 and 82.7% of the eyes in group 5 achieved a final CDVA of LogMAR 0.3 (6/12; 0.5) or better. In the evidence-based guidelines cited above 94.4% of all eyes achieved this visual outcome after ordinary manual phacoemulsification. [10] The visual outcome for all patients in our study was comparable with a previous reported FLACS study. [1] Thus, we can conclude that this new technique works well for eyes with poor preoperative visual acuity. On the other hand, 5.9% of the cases belonging to the best preoperative visual acuity group were made worse by surgery, moving into a poorer visual acuity group (Table 6). Operating eyes with very good preoperative visual acuity means a risk for poorer postoperative visual acuity, [15] and it seems that the femtosecond laser technique does not prevent this. In our study, the visual outcome was strongly related to the preoperative visual acuity and thereby to indications for surgery (Tables 6 and 8). In the multifocal IOL group 1.2% had a worse visual outcome (Table 10). Most of these cases (10 out of 16) reported postoperative complications in terms of “Other” postoperative complication (data not shown). This could be caused by multifocal-related problems and not the FLACS procedure itself.

The refractive outcome of the FLACS was well within the limits suggested by the guidelines based on EUREQUO data (absolute mean prediction error of 0.6D or less and 87% or more within ±1.0D).[10] The absolute mean error was in the upper region compared with the results described in a meta-analysis of FLACS,[13] while the percentage of cases within ±0.5D error was similar to a previous report.[16] As for the refractive error versus preoperative visual acuity group, it is obvious that very good preoperative visual acuity (group 1) gave the best outcome while a poor preoperative visual acuity (group 5) gave the poorest refractive outcome.

The postoperative complications in our study must be interpreted against the follow-up time; this was only 7-60 days (mean 34±26), which means that we could not analyse the true long-term complications such as posterior capsule opacification, retinal detachment, late endophthalmitis, and long-standing central macular oedema. The reported number of postoperative complications was higher than expected. In 26 cases (0.8%), early optic axis opacities were reported. Previous studies have suggested that the incidence of posterior capsular opacification should be low after FLACS,[17] and that the incidence of central macular oedema should not be higher after FLACS compared with phacoemulsification cataract surgery.[18] We cannot explain the occurrence of postoperative uveitis with need for medication (13 cases) or high intraocular pressure (4 cases). The question of whether these complications are related to an increased inflammation caused by the FLACS can only be answered by more detailed future studies. It has been reported that FLACS is related to a high prostaglandin concentration in the aqueous humor.[19] On the other hand, lower aqueous flare has been reported in FLACS compared with conventional cataract surgery.[20]

Conclusions

In this cohort study of femtosecond laser-assisted cataract surgery performed by 18 clinics in 10 different countries, the visual and refractive outcome of surgery was favourable compared to manual phacoemulsification. However, the outcome and the choice of IOL were both strongly influenced by the preoperative visual acuity. A very good preoperative visual acuity (group 1) was related to few complications, good visual and refractive outcomes, and a choice of multifocal IOL, while a poor preoperative visual acuity (group 5) was related to more complications, poorer visual and refractive outcomes, and a choice of monofocal IOL. Poor preoperative visual acuity was associated with better improvement, while good preoperative visual acuity was associated with better outcome. However, all visual acuity groups showed an acceptable outcome. The rate of postoperative complications was higher than expected, and demands further studies. Even with a perfect clinical outcome the lack of evidence for cost-effectiveness remains as a big obstacle for FLACS. [5] It is therefore strongly recommended that patient-reported outcomes and economic aspects should be added to the clinical outcomes in future studies.

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WHAT WAS KNOWN

- FLACS is a new technique with some reported advantages compared with traditional phacoemulsification surgery. These advantages include less energy into the eye during emulsification and a more standardized capsulorhexis technique.
- FLACS does not produce better outcomes than traditional phacoemulsification.

WHAT THIS PAPER ADDS

- FLACS performs well in eyes with different preoperative visual acuity levels.
- The outcome of FLACS is strongly related to the preoperative characteristics.

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Legends

Figure 1. Histogram showing the distribution of preoperative corrected distance visual acuity (CDVA) in LogMAR units in the eye to be operated on. N=3379. Number of eyes on the Y-axis.

Figure 2. Histogram showing the distribution of postoperative corrected distance visual acuity (CDVA) in LogMAR units in the operated eye. Number of eyes on the Y-axis.